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****(INCLUDE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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****(USE IN ALL SOLICITATIONS, CONTRACTS AND ORDERS INVOLVING HUMAN SUBJECTS.)****

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015)

- The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.
- The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.
- Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).
- If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of

suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

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****(USE BELOW, WHEN RESEARCH INVOLVING HUMAN SUBJECTS IS NOT TO BE CONDUCTED UNDER THE CONTRACT. **Note:** *There is no legal objection to the restriction imposed by the phrase "..., or any subsequent modification of such material,..." contained in this provision. However, inclusion of this phrase is NOT a requirement. Therefore, this language may be modified based on negotiations and/or Contracting Officer's discretion* .)****

ARTICLE H.2. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

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****(THE FOLLOWING MAY BE USED FOR CLINICAL TRIALS OR SIMILAR STUDIES WHERE PROTOCOLS WILL BE PERFORMED AFTER 1st PHASE OF THE STUDY/CONTRACT. **Note for Contracts** *: This should be used only for Contractors who have a multiple project assurance or already received the single project assurance from OHRP. Single Project Assurances which have not yet obtained prior approval from OHRP before contract award will require the use of restricted language contained in the NEXT Item* .)****

ARTICLE H.3. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by _____ (INSERT IC), written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other

performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

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****(USE BELOW IN CONTRACTS AND ORDERS IF THE CONTRACTORS HAS AN APPROVED FWA OF COMPLIANCE IN PLACE, BUT CANOT CERTIFY PRIOR TO AWARD THAT AN IRB REGISTERED WITH OHRP REVIEWED AND APPROVED THE RESEARCH. See HHSAR 370.304(b) for more information.)****

ARTICLE H.4. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-6 (December 2015)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR RESEARCH INVOLVING HUMAN SUBJECTS. **Note:** *It is anticipated that this NIH Policy will be superseded by DHHS ORI's institutional assurance once this requirement has been incorporated* .)****

ARTICLE H.5. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html .

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are

responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

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****(USE BELOW FOR CLINICAL TRIALS.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Last (4th) Paragraph:**
  - **For Contracts:** Select the appropriate wording from the Drop Down List. Note: Phase III Clinical Trials generally require both a DSMB and a Plan. Phase I and Phase II Clinical Trials generally require only a Plan.
  - **For RFPs:** Select "Board and/or Plan" from the Drop Down List.)****

ARTICLE H.6. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.
Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.
The Data and Safety Monitoring [Board/Plan/Board and Plan/Board and/or Plan] shall be established and approved prior to beginning the conduct of the clinical trial.

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****(FOR NHLBI: USE IN CONTRACTS AND RFPs WHEN THE NHLBI WILL ESTABLISH A DSMB OR AN OSMB)****

ARTICLE H.7. DATA AND SAFETY MONITORING IN CLINICAL TRIALS AND EPIDEMIOLOGICAL STUDIES

For informational purposes, the Contractor is directed to the full text of the NHLBI policies regarding Data and Safety Monitoring Boards and Observational Study Monitoring Boards, which may be found at:
https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-data-and-safety-monitoring-extramural-clinical-studies

- Establishing Data and Safety Monitoring Boards and Observational Study Monitoring Boards
- Data Quality Assurance in Clinical Trials and Observational Studies-Guidelines
- Responsibilities of DSMBs Appointed by the NHLBI
- Responsibilities of OSMBs Appointed by the NHLBI

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE NIH-FUNDED CLINICAL TRIALS.)
NIH Policy on "Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trails" can be found at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

ARTICLE H.8. GOOD CLINICAL PRACTICE TRAINING FOR NIH AWARDEES INVOLVED IN NIH-FUNDED CLINICAL TRIALS

All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2). GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. GCP training should be refreshed at least every three years to remain current with regulations, standards and guidelines. The Contractor shall provide completion of training documentation to the Contracting Officer's Representative (COR).

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical Trial Staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE WHOLLY OR PARTIALLY NIH-FUNDED CLINICAL TRIALS)
A clinical trial that uses NIH-supported infrastructure but **does not** receive NIH funds to support its conduct is not subject to the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information.

ARTICLE H.9. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION

The Contractor conducting clinical trials, funded wholly or partially through the NIH extramural and intramural programs, shall ensure that its NIH-funded clinical trials are registered at, and summary results information is submitted to, www.clinicaltrials.gov for public posting. See NIH Guide Notice NOT-OD-16-149 dated September 16, 2016.
All NIH-funded clinical trials shall be registered and results information submitted to www.clinicaltrials.gov regardless of study phase, type of intervention, or whether they are subject to the regulation 42 CFR Part 11. Clinical trials subject to the regulation are called "applicable clinical trials."
The Contractor must submit a plan with its proposal to meet the regulatory requirements of the dissemination of information of NIH-funded Clinical Trials. The Contractor and investigators are required to comply with all terms and conditions of award, including following their acceptable plan for the dissemination of NIH-funded clinical trial information.
The Contractor must register all NIH-funded clinical trials in www.clinicaltrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought. The Contractor shall include the trial registration number (NCT number) in the Technical Progress Report covering the period in which registration occurred, and as a standalone notification to the Contracting Officer within ten (10) calendar days of the registration. Each NIH-funded clinical trial must have only one entry in ClinicalTrials.gov that contains its registration and results information
The Contractor shall include a specific statement in all informed consent documents relating to posting of clinical trials information to www.clinicaltrials.gov . The responsibilities of the Contractor will fall within one of the following three categories:

- If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the Contractor is the responsible party, the Contractor will ensure that all regulatory requirements are met.
- If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the Contractor is not the responsible party, the Contractor will coordinate with the responsible party to ensure that all regulatory requirements are met.

- If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the Contractor will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Failure to comply with the terms and conditions of the award may provide a basis for enforcement actions. Identifying clinical trial record as non-compliant in ClinicalTrials.gov may lead to termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

The Contracting Officer may take one or more of the following enforcement actions, if the Contractor fails to provide evidence of compliance within 30 days.

- Temporary withhold payments pending correction of the deficiency;
- Disallow all or part of the cost of the activity or action not in compliance;
- Wholly or partly suspend or terminate the contract award;
- Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding regulations at 2 CFR part 376;
- Withhold further awards for the project and program;
- Take other remedies that may be legally available.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE WHOLLY OR PARTIALLY FUNDED NIH-FUNDED CLINICAL TRIALS)
Note:
Contractor submits clinical trial information dissemination plan in the proposal.

- If plan is not acceptable, CO work with the Contractor to obtain an acceptable plan.
- If Contractor cannot provide an acceptable plan, the award cannot be made.

Once accepted, the plan is incorporated as a term and condition of award.

ARTICLE H.10. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION PLAN

The special terms and conditions in the Contract Award that include a clinical trial:

- The clinical trial(s) supported by this award is subject to the plan dated [DATE] submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan must state that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant. The plan also must state that primary summary results shall be reported in ClinicalTrials.gov, including adverse event information, not later than one

year after the primary completion date of the trial. The reporting of summary results is required by this term of award.

- This award is subject to reporting requirements with each submission of the annual report. Contractor shall agree to the following annual certification. By affirming this annual certification:

The Contractor hereby certifies that all investigators conducting NIH-funded clinical trials under the NIH contract number _____ are in compliance with the Contractor's plan addressing compliance with the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded wholly or partially under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Primary summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the primary completion date of the trial.

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****(USE INSTRUCTIONS BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE BIOMEDICAL, BEHAVIORAL, CLINICAL OR OTHER RESEARCH IN WHICH IDENTIFIABLE, SENSITIVE INFORMATION IS COLLECTED OR USED (INCLUDING RESEARCH ON MENTAL HEALTH AND RESEARCH ON THE USE AND EFFECT OF ALCOHOL AND OTHER PSYCHOACTIVE DRUGS).

ARTICLE H.11. CERTIFICATE OF CONFIDENTIALITY

Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions governing the authority of the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act.

Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the NIH Policy for Issuing Certificate of Confidentiality (CoC) NOT-OD-17-109, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act as a term and condition of the contract. The certificate will not be issued as a separate document.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO minimum ten (10) calendar days prior to disclosure.

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In accordance with 45 CFR Part 75.303(a), the Contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

The recipient of CoCs shall ensure that any company/institution/individual not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate is subject to the requirements of subsection 301(d) of the Public Health Service Act. The

Contractor shall ensure that Subcontractors who receive funds to carry out part of the Federal award are subject to subsection 301(d) of the Public Health Service Act and the NIH Policy for Issuing CoC.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH) SEE NIH NOTICE- NOT-OD-16-094 .

NOTES- Types of awards typically will follow one of the examples below.

- Award to a Single Contractor with Multiple Sites participating as subcontractors; sIRB may be a separate subcontractor or a part of one of the existing sites
- Awards to Multiple Sites. A Central IRB (CIRB) or sIRB, either as part of a lead Contractor, or under a separate contract
- Award to a lead Contractor as set forth in the RFP, e.g., a Data Coordinating Center. The sIRB will be a part of the DCC, or as a separate IRB Contractor

ARTICLE H.12. SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For Institutional Review Board (IRB), the Contractor shall use the single Institutional Review Board (sIRB) of record for multi-site research. All domestic sites participating in multi-site studies involving a non-exempt human subjects research funded wholly or partially by the National Institutes of Health (NIH) shall use a sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46 and the NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research . Any IRB serving as the sIRB of record for NIH funded research shall be registered with the HHS Office for Human Research Protections (OHRP) and shall have membership sufficient to adequately review the proposed study.

The Contractor shall provide to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 certifying IRB review and approval of the research that encompasses all sites of performance.

This paragraph applies only if the Government provided a sIRB through a separate entity as stated in section- C . When the Government provided sIRB through a separate entity, the Contractor agrees to use of the sIRB. The Contractor shall provide to the Contracting Officer sIRB information and data in a timely manner as necessary to meet the policy and/or regulatory requirements of the Protection of Human Subjects at 45 CFR Part 46.

Exceptions to the NIH Single IRB Policy

The Contractor may request an exception in the following instances:

- Sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions);
- *Other exceptions*, to be determined by NIH if there is a compelling justification; and

- Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy.

Policy-based exceptions and time limited exceptions are automatically granted when identified in the sIRB Plan.

Other exceptions must be reviewed by NIH sIRB Exceptions Review Committee (ERC) and are expected to be granted rarely. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification-

- Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
- Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
- Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).

  - For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.

- Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception.* The Offerors should not assume that an *other exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their Contracting Officer (CO). For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions* , the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an Other Exception to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO. For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals in the competitive range. The decision of NIH ERC is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and

condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.
The award budget may need to be adjusted if an exception is granted.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH) SEE NIH NOTICE- NOT-OD-16-094.

ARTICLE H.13. PLAN FOR SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For this multi-site study, the _____ (Contractor/each Contractor) agrees to adhere to the NIH sIRB policy, and the _____ (IRB Name) IRB shall serve as the single IRB of record. All participating sites have agreed to rely on the _____ (IRB Name) IRB, and a written authorization/reliance agreement shall be developed. Any additional sites added after contract award shall also agree to rely on this study's single IRB of record. Communication plans for interactions between the sIRB and participating sites shall be described in the authorization/reliance agreement. All participating sites shall, prior to initiating the study, sign the authorization/reliance agreement that shall clarify the roles and responsibilities of the sIRB and participating sites. The _____ (Contractor Name/Name of the Coordinating Center or Contract Research Organization (CRO)/Names of Contractor's Lead Person and Alternate Person) shall maintain records of the authorization/reliance agreements, including the communication plans. The approved sIRB plan will be incorporated as a term and condition of the award. Any updates/changes to the plan shall be provided to the Contracting Officer's Representative with a copy submitted to the Contracting Officer within 30 calendar days.

Exceptions to the Single IRB Plan

The Contractor may request an exception to the sIRB plan under the following instances:

- Sites for which federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions)

*Review by a single IRB of record will not be possible for (**sites)** because of federal/state/tribal law, regulation, or policy (**provide specific citation(s))***

- *Other exceptions* , to be determined by NIH if there is a compelling justification

*Review by a single IRB of record will not be possible for (**this Contractor)** because of (**provide compelling justification and rationale why local IRB is uniquely qualified to be the reviewing IRB for the specific site(s**)).*

- Time Limited Exceptions: New multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy.

*Review by a single IRB of record will not be possible for (**sites)** because of ongoing multi-site parent study (**provide parent contract number)** .*

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS).

ARTICLE H.14. INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm .

The Contractor must submit the results of valid analyses by sex/gender and race/ethnicity to Clinicaltrials.gov for all NIH-conducted or supported applicable NIH-defined Phase III clinical trials. This requirement does not apply to NIH-defined Phase III trials not considered to applicable clinical trials under 42 CFR Part 11. The Contractor must report applicable NIH-defined Phase III clinical trials involving research subjects of all ages, including foreign awards and domestic awards with a foreign component. The Contractor must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

Note: Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information, including the results of the valid analyses by sex/gender and race/ethnicity, from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of new use is being sought.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS).

ARTICLE H.15. INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The Contractor must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Contractor must provide a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the Contractor must provide acceptable justification for the exclusion.

The Contractor must submit cumulative data as prescribed in the Age Enrollment Report template on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS).

ARTICLE H.16. POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's

(NIH's) clinical trials registry and results database ClinicalTrials.gov . Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to Regulations.gov . The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit. The Contracting Officer (CO) and/or Contracting Officer's Representative (COR) may permit or require redactions as appropriate.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR APPLICABLE CLINICAL TRIALS.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- For information about how to determine "applicable clinical trials" see Step 1 of the following link: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm#whatsteps
- For information about how the "Sponsor" role is determined, see the flowchart at: http://grants.nih.gov/ClinicalTrials_fdaaa/docs/registration_flow_chart.pdf

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- CLINICAL TRIALS CONDUCTED UNDER INVESTIGATIONAL NEW DRUG/INVESTIGATIONAL DEVICE EXEMPTION (IND/IDE) REQUIREMENTS:
  - INCLUDE this Article in all contracts as follows:
    - When the Contractor is the IND/IDE holder (Sponsor) select the words: "Contractor is the Sponsor, therefore the" from the drop down box.
    - When the Government is the IND/IDE holder (Sponsor) **AND** the Government will delegate the role of "Responsible Party" to the Principal Investigator, select the words: "Government is the Sponsor and delegates the Contractor's Principal Investigator as" from the drop down box.
    - When the Government is the IND/IDE holder (Sponsor) **AND** will not delegate a PI as "Responsible Party," select the words: "Government is the Sponsor, therefore" from the drop down box.
    - If neither the Government nor the Contractor is the IND/IDE holder, consult with the Project Officer to determine how to address this situation. Note: If none of the choices in the drop down box apply in this situation, you can delete the drop down box and insert the appropriate Sponsor information.
- SINGLE CENTER TRIALS (not conducted under IND/IDE requirements):
  - INCLUDE this Article in all contracts as follows:
    - When the Government will not delegate the PI as "Responsible Party," select the words, "Government is the Sponsor, therefore" from the drop-down box.
    - When Government will delegate the PI as the "Responsible Party," select the words: "Government is the Sponsor and delegates the Contractor's Principal Investigator as" from the drop down box.
    - If neither the Government nor the Contractor has initiated the trial (neither is the "Sponsor"), consult with the Project Officer to determine how to address this situation. Note: If none of the choices in the drop down box apply in this situation, you can delete the drop down box and insert the appropriate Sponsor information.

- MULTICENTER TRIALS (not conducted under IND/IDE requirements):
  - INCLUDE this Article in the contract as follows:
    - When the Government will not delegate a PI as "Responsible Party," select the words, "Government is the Sponsor, therefore" from the drop-down box **AND** include this Article in all of the multi-center trial contracts.
    - When Government will delegate a PI as "Responsible Party," select the words: "The Government is the Sponsor and delegates the Contractor's Principal Investigator as" from the drop down box **AND** include this Article in only the contract that has been delegated "Responsible Party" (generally the designated lead clinical site) *Note: Contractors involved in the Multi-Center trial, but not designated "Responsible Party, will require the clause in the next item (Below)* .

Note: *The Contracting Officer should consult with the Project Officer/Contracting Officer's Representative (COR) to assist in making this determination*)****

ARTICLE H.17. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf , Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand-alone notification.

The [Contractor is the Sponsor, therefore/Government is the Sponsor and delegates the Contractor's Principal Investigator as/Government is the Sponsor, therefore] the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

Additional information is available at: http://prsinfo.clinicaltrials.gov .

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****(USE BELOW IN EACH CONTRACT PARTICIPATING IN A MULTI-CENTER "APPLICABLE CLINICAL TRIAL," **EXCEPT** DO NOT USE IF THE CONTRACTOR IS DESIGNATED AS THE "RESPONSIBLE PARTY." **Note** *: The Contractor that is designated as the "Responsible Party" will use the previous Article, above* .

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Second paragraph:** Insert the Name of the Individual (and Contractor) designated as the "Responsible Party" of the Multi-Center Trial.

Note: *The Contracting Officer should consult with the Project Officer/Contracting Officer's Representative (COR) to assist in making this determination* .)****

ARTICLE H.18. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA), at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf , Title VIII, expands National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

_____ is the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of the applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

The Contractor shall provide the "Responsible Party" with all essential data for timely compliance with ClinicalTrials.gov reporting requirements.

Additional information is available at: http://prsinfo.clinicaltrials.gov .

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR HIV ANTIRETROVIRAL TREATMENT TRIALS THAT WILL TAKE PLACE IN WHOLE OR IN PART IN DEVELOPING COUNTRIES - DEFINED AS THE LOW- AND MIDDLE-INCOME ECONOMIES, USING WORLD BANK CLASSIFICATIONS - AND THE OFFEROR PLANNED TO DEVELOP SOURCES TO PROVIDE TREATMENT OF TRIAL PARTICIPANTS AFTER THEIR COMPLETION OF THE TRIAL.)****

ARTICLE H.19. HIV ANTIRETROVIRAL TREATMENT TRIALS

The Contractor shall work with the host countries' authorities and other stakeholders in accordance with the approved plan to develop sources to provide HIV antiretroviral treatment to participants of the trials contracted for under this contract after the participants' completion of the trial.

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****(USE BELOW IN ALL COVID -19 SOLICITATIONS, CONTRACTS, LETTER CONTRACTS, MODIFICATIONS, AND EXERCISING OPTIONS.

Contracting Officers (CO) shall include the following language in all COVID–19 solicitations, contracts, letter contracts, modifications, and exercising options that involves recovery efforts necessary to address the 2019 Novel Coronavirus (COVID–19).

Note: The CO shall incorporate the following language by bilateral modification in contracts that requires a modification to include the COVID–19 recovery efforts.)****

ARTICLE H.20. COVID–19 RECOVERY EFFORTS

"HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System."

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****(USE BELOW, WHEN HUMAN MATERIALS WILL BE ACQUIRED AND/OR GENERATED UNDER THE CONTRACT.)****

ARTICLE H.21. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

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****(USE BELOW, WHEN THE CONTRACTOR WILL BE RECEIVING HUMAN MATERIALS FROM AN OUTSIDE SOURCE, ANOTHER CONTRACT OR FROM A SUBCONTRACTOR.)****

ARTICLE H.22. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING HUMAN FETAL TISSUE.)****

ARTICLE H.23. RESEARCH INVOLVING HUMAN FETAL TISSUE

Research involving Human Fetal Tissue (HFT) must be conducted in accordance with applicable Federal, State and local laws, regulations, and policies. Selected Federal statutes, regulations, and policies are provided below:

42 U.S.C. 289g-1 and 289g-2 set forth specific requirements and prohibitions on research involving human fetal tissue. For example, among other prohibitions, 42 U.S.C. 289g-2 provides:

"Prohibitions regarding human fetal tissue

a. Purchase of tissue- It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

The full text of 42 U.S.C. 289g-1 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-1.htm

The full text of 42 U.S.C. 289g-2 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-2.htm

Research involving HFT is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B). The following provisions may be specifically relevant:
§46.204 Research involving pregnant women or fetuses.
~ (a) - (g)

h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
j. Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

a. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
b. If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

The full text of the HHS Regulations for the Protection of Human Subjects is available at:
http://www.hhs.gov/ohrp/policy/ohrpregulations.pdf .
Furthermore, per NOT-OD-16-033, when obtaining primary HFT for research purposes, The Contractor shall maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

Human Fetal Tissue Obtained from Elective Abortions

The Contractor shall adhere to NIH Policy NOT-OD-19-128 on all contracts that involves the use of HFT obtained from elective abortions. The HFT is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following (the definition implements the statute (42 U.S.C. Chapter 6A, Subchapter III, Part H, Sec. 289):

- human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
- animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.
- derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.
- any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

The definition of research involving HFT **does not** include the following:

- human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion.
- already-established (as of June 5, 2019) human fetal cell lines (e.g. induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).
- derivative products from human fetal tissue or cells (e.g. DNA, RNA, protein) **if not derived** from elective abortion.
- human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi **if not derived** from elective abortion.
- human fetal cells present in maternal blood or other maternal sources
- embryonic stem cells or embryonic cell lines.
- research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research).

To assure compliance with all applicable laws and HHS/NIH policies concerning the acquisition and use of HFT obtained from elective abortions, the Contractor shall submit detailed information addressing the use of HFT to Contracting Officer's Representative (COR) in monthly progress reports.

The Contractor shall comply with the following terms and conditions:

a) The Contractor shall comply with all HHS/NIH policies specific to HFT.
b) The Contractor shall justify the continued use of HFT obtained from elective abortions in their monthly progress reports by describing the ongoing scientific necessity for the use of HFT.
c) Informed consents for use of HFT in research, containing certain statements/representations that acknowledges informed consent for donation of HFT

was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and the informed consent will be signed by both the woman and the person who obtains the informed consent.

d) The Contractor shall maintain documentation from the HFT donating organization assuring adherence to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration. The Contractor will acquire this assurance for each year of the award HFT research is conducted for the life of the award and maintain this documentation in accordance with the NIH Record Retention and Access policy.
e) HFT was not obtained or acquired for valuable consideration, as such term is defined in 42 USC § 289g-2.
f) The treatment of HFT, and the disposal of HFT when research is complete, shall be consistent with the plans outlined in the HFT proposal justification.

Requests to Add New or Additional Human Fetal Tissue from Elective Abortions after Contract Award

The Contractor shall submit a justification request to the Contracting Officer and COR to modify the contract to add either new or additional sources of HFT obtained from elective abortions. The Contractor shall include the information identified below in their justification request which will undergo review by the Ethics Advisory Board. The Government will not execute a modification to the contract without the recommendation of the Ethics Advisory Board to fund the proposed HFT obtained from elective abortions.

The Contractor shall include the following information in the justification package:

- Use the specific heading: "Human Fetal Tissue Obtained from Elective Abortions Justification". The justification should be in detail for review by the Ethics Advisory Board.
- The Contractor must include the following in the justification:
  - Indicate why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion, animal models, and *in vitro* models that are not developed from HFT, and computational models).

- Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments).
- Conduct and describe results from a literature review used to provide justifications.
- Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
- Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.
- Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the acquisition of HFT or indicate the cost is $0 if using donated or existing HFT.
- HFT Compliance Assurance: The Contractor shall provide a letter signed by the PD/PI assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.

Research using HFT shall be in compliance with all applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), NOT-OD-16-033, and NOT-OD-19-128.

As applicable, the Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING RECOMBINANT DNA OR SYNTHETIC NUCLEIC ACID MOLECULES (INCLUDING HUMAN GENE TRANSFER RESEARCH)****

ARTICLE H.24. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) available at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines* .

The *NIH Guidelines* stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the *NIH Guidelines* as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines* .

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with the NIH Office of Science Policy that complies with the requirements of the *NIH Guidelines* . Further information about compliance with the *NIH Guidelines* can be found on the NIH Office of Science Policy website available at: http://osp.od.nih.gov /.

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****(USE BELOW IN SOLICITATIONS THAT INVOLVE HUMAN STEM CELL RESEARCH.)****

ARTICLE H.25. HUMAN STEM CELL RESEARCH

All research conducted under this contract shall be in accordance with NIH Guidelines on Human Stem Cell Research (https://stemcells.nih.gov/research/newcell_qa.htm) and shall involve the use of approved human embryonic stem cells (hESCs) or derivatives that are listed on the NIH Human Embryonic Stem Cell Registry (http://grants.nih.gov/stem_cells/registry/current.htm).

- Sections II and III of the National Institutes of Health Guidelines for Research Using Human Stem Cells (https://stemcells.nih.gov/research/newcell_qa.htm) apply specifically to human embryonic stem cells (hESCs).
    - Section II details the eligibility criteria used by NIH to determine if specific hESC lines are eligible for use in NIH-funded research.
    - Section III explains the responsibility of NIH-funding recipients to assure that hESCs used in NIH-funded research are approved by NIH.
- Section IV sets limits on certain animal studies using all types of human pluripotent stem cells, including, but not limited to, those developed by methods such as the expression of genes involved in establishing pluripotency (e.g. the "Yamanaka factors") and the culturing of embryonic germ cells from primordial germ cells. Prohibited experiments include those in which the cells are introduced into non-human primate blastocysts and the breeding of animals in which the cells may contribute to the germ line.
- Section V details other types of research not eligible for NIH funding: the derivation of stem cells from human embryos and research using hESCs derived from sources other than human embryos created using in vitro fertilization for reproductive purposes.

  Research involving the use of human embryonic stem cells, or derivatives, that are not listed on the NIH Registry may not be conducted with Federal funding. Derivatives include, but are not limited to, subclones of hESC lines, modified hESC lines (such as a line expressing green fluorescent protein), differentiated cells developed from hESC lines (such as muscle progenitor cells), and cellular materials (such as DNA, RNA, and proteins). Thus, no federal funds may be used for the generation of new data from unapproved hESC lines or derivatives. However publicly accessible data from unapproved lines or derivatives are not considered "derivative" and therefore not subject to this prohibition. Such publicly accessible data can be used and analyzed with federal funds.

USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE THE SALE OF RESEARCH SUBSTANCES AND/OR LIVING ORGANISMS.

NOTES:

- Carefully read the OALM/OAMP/DAPE Guidance on the REIMBURSEMENT FOR RESEARCH SUBSTANCES AND LIVING ORGANISMS before including this Article in solicitations/contracts.
- Include the following attachments in solicitations/contracts when using this Article: Monthly Summary of Sales; Sample Recipient Invoice; NIH Pay.gov User Guide; and price list (optional for solicitation).
- The contract shall describe any relevant standards for the safety and use of the research substances and/or living organisms. This information must also be furnished to eventual recipients of such research materials before they are physically transferred. Where appropriate, recipients shall be required to execute an assurance certificate whereby they agree not to use the research substances and/or living organisms in any unauthorized or unsafe manner. Such assurances shall be obtained by the Contractor before the research substances and/or living organisms are shipped/transferred to the recipient and shall be forwarded to the Government and retained as part of the contract file.
- The Program Office shall perform an assessment of the nature of the research substances and/or living organisms to be made available to potential recipients to determine whether the contract should include a requirement to obtain a release and indemnification agreement from recipients (whether payment is requested or the substances/organisms are provided free of charge). If the Program Office determines that there is potential risk (e.g., risk of property damage or personal injury resulting from use of the research substances and/or living organisms), consultation with the General Law Division, Office of General Counsel, HHS, is recommended and language similar to that provided in Section F.4. of the Guidance should be incorporated into any resultant contract.

ARTICLE H.26. REMITTANCE PROCEDURES FOR SALE OF RESEARCH SUBSTANCES AND LIVING ORGANISMS

- The Contractor shall make available to individuals and entities, for biomedical and behavioral research, research substances and/or living organisms under the terms and conditions specified below and in Section C, Description/Specifications/Statement of Work, of this contract.
- The Contractor shall bill recipients directly for the research substances and/or living organisms provided, including any shipping and handling costs, which shall be itemized separately on the recipient's invoice. The prices charged for research substances and/or living organisms shall be as specified in the price list, which is included as an attachment in Section J of this contract. Under no circumstances shall the Contractor bill prices other than those included in the price list unless directed to do so by the Contracting Officer or his/her designated representative. The Government, without the concurrence

of the Contractor, may revise the price of the research substances and/or living organisms being made available. The Contracting Officer or his/her designated representative may direct the Contractor to make the research substances and/or living organisms available free of charge to recipients, including any shipping and handling costs.

- The Contractor shall include with each shipment/transfer of research substances and/or living organisms to recipients an invoice substantially the same as the Sample Recipient Invoice, which is included as an attachment in Section J of this contract, and instruct the recipients how and when to make payments.
- The Contractor shall assign a unique invoice number to each invoice and instruct recipients to remit payment to the Contractor in U.S. dollars by check or other method acceptable to the Contractor within 15 calendar days from the date of the invoice. All payments shall be made payable to the Contractor.
- The Contractor shall inform the recipients of the research substances and/or living organisms prior to shipment/transfer that: 1) such research materials are not returnable and the costs associated with providing them, including shipping and handling, are not refundable; and 2) failure to pay an invoice may result in future purchase requests being denied. The Contractor shall contact the Contracting Officer and his/her designated representative immediately if there are any issues with the research substances and/or living organisms provided to the recipients.
- Shipping and handling costs are defined as follows: 1) shipping costs are costs charged for delivering the research substances and/or living organisms to the recipient, including insurance, if required; and 2) handling costs are the costs charged for preparing the research substances and/or living organisms for shipment/transfer, including labor, packaging, and invoicing. Excessive shipping and handling charges are to be avoided. Establishment of flat rate shipping and handling charges is encouraged; however, such charges must be approved in advance by the Contracting Officer or his/her designated representative.
- The Contractor shall keep an accurate account of all sales of research substances and/or living organisms on a calendar month basis and report the following information to the Government: 1) recipient's name, address, and contact information; 2) quantity; 3) item shipped/transferred; 4) unit price; 5) shipping and handling charges; 6) total charges; 7) shipment/transfer date; 8) invoice number; and 9) payment due date. This information shall be reported on the form, Monthly Summary of Sales, which is included as an attachment in Section J of this contract, and submitted to the Government in accordance with the delivery schedule in Section F of this contract. **[Identify designated staff in Section F, Deliveries, to receive a copy of the Monthly Summary of Sales, which will be used to enter accounts receivables in the NIH Business System (NBS), as well as for contract administration purposes. The delivery date for the Monthly Summary of Sales should not extend beyond 10 business days from the close of the reporting period, i.e., the end of each calendar month.]**
- Upon receipt by the Government of the Monthly Summary of Sales, the Government will provide the Contractor with an invoice number needed to process payments

through the U.S. Department of Treasury's government-wide collection portal, Pay.gov. Within 30 calendar days of receipt of the invoice number from the Government, the Contractor shall submit payment to the Government through Pay.gov for the research substances and/or living organisms associated with the invoice number received from the Government. Before submitting payment through Pay.gov, the Contractor shall reconcile the sales of research substances and/or living organisms reported on the Monthly Summary of Sales with the payment to be submitted to the Government.
[NIH staff responsible for providing the invoice number to the Contractor shall clearly identify the contract/order number and calendar month of sales to which it applies.]
For assistance with Pay.gov, reference the NIH Pay.gov User Guide included as an attachment in Section J of this contract. For further assistance, contact _____

- Examination of costs and transaction records related to the sale of research substances and/or living organisms shall be subject to the terms and conditions of this contract, including FAR Clause 52.215-2, Audit and Records-Negotiation, and its applicable Alternates.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR R&D REQUIREMENTS INCLUDING SBIRs.)****

ARTICLE H.27. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103 , "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102 , "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research , whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm , including FAQs and a General Policy Overview.

251

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING NIH-FUNDED RESEARCH THAT GENERATES LARGE-SCALE HUMAN OR NON-HUMAN GENOMIC DATA ON OR AFTER JANUARY 25, 2015.)****

ARTICLE H.28. DATA SHARING IN LARGE-SCALE HUMAN OR NON-HUMAN GENOMIC DATA

The Contractor shall comply with the NIH "Genomic Data Sharing Policy" located at: https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf . The Contractor shall submit and certify data obtained in the genomic data study to the data repository in accordance with the policy. The Contractor shall also submit the data to the Contracting Officer and Contracting Officer's Representative.
Large-scale data include genome-wide association studies, single nucleotide polymorphisms arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism.

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****FOR USE IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE HeLa CELL WHOLE GENOME SEQUENCE DATA****

ARTICLE H.29. SHARING HeLa CELL WHOLE GENOME SEQUENCE DATA AND FAMILY ACKNOWLEDGEMENT

All research using HeLa Cell Whole Genome Sequence data shall be conducted in accordance with NIH notice NOT-OD-13-099, entitled, "Notice of NIH Guidance on the Family Acknowledgement and Use of HeLa Cell Whole Genome Sequence Data" located at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-099.html . The Contractor shall submit HeLa Whole Genome Sequence Data generated under this contract to the database of Genotypes and Phenotypes (dbGaP) available at: http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640.v1.p1, in accordance with the HeLa Genome Data Use Agreement available at: https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?view_pdf&stacc=phs000640.v1.p1.

The following acknowledgment, or a variation of it that has been reviewed by the HeLa Genome Data Access Working Group, shall be made in any dissemination of research findings:

"The genome sequence described/used in this research was derived from a HeLa cell line (URL to dbGaP). Henrietta Lacks, and the HeLa cell line that was established from her tumor cells without her knowledge or consent in 1951, have made significant contributions to scientific progress and advances in human health. We are grateful to Henrietta Lacks, now deceased, and to her surviving family members for their contributions to biomedical research. This study was reviewed by the NIH HeLa Genome Data Access Working Group."

Contact helagenome@nih.gov for acknowledgement variation requests.

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****(INCLUDE THE FOLLOWING IN ALL SOLICITATIONS AND CONTRACTS FOR R&D REQUIREMENTS.)****

ARTICLE H.30. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov .
Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov .

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE MAY INVOLVE AN AGENT OR TOXIN THAT IS LISTED IN THE UNITED STATES GOVERNMENT POLICY FOR OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (DURC).

ADDITIONAL INFORMATION ABOUT THIS ITEM:

• For a list of applicable agents or toxins, refer to Section 6 of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf .)****

ARTICLE H.31. DUAL USE RESEARCH OF CONCERN

The Contractor shall comply with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or "DURC policy". The responsibilities of the Contractor include but are not limited to:

- Establishing internal policies and practices that provide for the identification and effective oversight of DURC;
- Establishing an institutional review entity (IRE);
- Ensuring that laboratory personnel conducting research have received education and training;
- Maintaining records of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract, for the term of the contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation;
- Promptly providing records upon request by the U.S. Government, of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract;

- Obtaining pre-approval from the Contracting Officer's Representative for all communications with third-parties, involving DURC funded by this contract, and;
- Obtaining pre-approval from the Contracting Officer for subcontracts, subgrants, consultant agreements, or any other subaward involving research subject to the DURC policy and funded by this contract. The Contractor shall ensure that the substantive requirements of this article are included in any such agreements.

Non-compliance with the DURC policy or with this article may result in suspension, debarment or termination for default.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING HUMAN SUBJECTS.)****

ARTICLE H.32. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

(End of clause)

256

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ARTICLE H.33. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

257

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR INVOLVING HUMAN SUBJECTS.)****

ARTICLE H.34. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

- The Contractor shall not use any funds obligated under this contract for any abortion.
- The Contractor shall not use any funds obligated under this contract for the following:

a. The creation of a human embryo or embryos for research purposes; or
b. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

- The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
- The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause)

258

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT IS EXPECTED TO INVOLVE THE USE OF DRUGS OR OTHER SUBSTANCES INCLUDED IN SCHEDULE I OF THE SCHEDULES OF CONTROLLED SUBSTANCES ESTABLISHED BY SECTION 202 OF THE CONTROLLED SUBSTANCES ACT (21 U.S.C. 812.)****

ARTICLE H.35. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

259

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT REQUIRE THE DISSEMINATION OF INFORMATION.)****

ARTICLE H.36. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

260

****(USE BELOW WHEN THE SOLICITATION OR CONTRACT HAS BEEN SELECTED TO INCLUDE THE OPTION FOR PROPOSING MULTIPLE PRINCIPAL INVESTIGATORS UNDER THE CONTRACT.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Second Paragraph:**
  - Complete the date of the Leadership Plan.
  - Select the appropriate location for the Leadership Plan from the Drop Down List.)****

ARTICLE H.37. MULTIPLE PRINCIPAL INVESTIGATORS

The NIH awarded this contract as a multiple Principal Investigators project. The Key Personnel Article in SECTION G of this contract designates the Contact Principal Investigator and all other Principal Investigators.

Contracts designating multiple Principal Investigators require a current Leadership Plan with updates as needed. The Contractor's Leadership Plan, dated _____, (and as modified thereafter, in accordance with the Reporting Requirements Article in SECTION C of this contract), is hereby [incorporated by reference./included as an Attachment in SECTION J of this contract.]

261

****(USE BELOW, IN SOLICITATIONS, CONTRACTS AND ORDERS THAT REQUIRE THE DESIGN, DEVELOPMENT, OR OPERATION OF A SYSTEM OF RECORDS TO NOTIFY THE CONTRACTOR THAT IT AND ITS EMPLOYEES ARE SUBJECT TO CRIMINAL PENALTIES FOR VIOLATIONS OF THE PRIVACY ACT (5 U.S.C. 552A(I) TO THE SAME EXTENT AS HHS EMPLOYEES. *See HHSAR 324.105(a) for more information* .)****

ARTICLE H.38. PRIVACY ACT, HHSAR 352.224-70 (December 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor

awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement:
(a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and
(b) specifies the disposition to be made of such records upon completion of contract performance.

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****(USE BELOW WHEN THE CONTRACT IS FUNDED WITH 1% SET-ASIDE EVALUATION FUNDS.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **2nd Paragraph:** Insert the NIH Evaluation Project Number and Contract Number.)****

ARTICLE H.39. EVALUATION PROJECTS

All publications including reports, compilations of data, articles and the like resulting from this contract shall contain the statement below. It shall be located on the cover, inside cover, or title page.

> This project, _____ received support from the evaluation set-aside Section 513, Public Health Service Act.

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****(USE IN ALL SOLICITATIONS, CONTRACTS AND ORDERS INVOLVING LIVE VERTEBRATE ANIMALS.)****

ARTICLE H.40. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

- Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
- The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.
- The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq.

and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

- If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c)above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of
  suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with Animal Welfare Assurances.

Note : The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov ; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

(End of clause)

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING LIVE VERTEBRATE ANIMALS.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Second paragraph:** Insert the date of the Contractor's Vertebrate Animal Section (VAS) from the technical proposal, as applicable. For additional information about the VAS, see NIH Notice NOT-OD-16-006 available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html .)****

ARTICLE H.41. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the Contractor's

technical proposal, as modified in the Final Proposal Revision (FPR), dated _____ , which is incorporated by reference.

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****(USE BELOW AS REQUIRED.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- **First sentence:** Insert the appropriate I/C and contract number in each text box.
- **Fifth sentence:** Insert the appropriate I/C in the text box.)****

ARTICLE H.42. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, __ environment (NIH) directly, or through collaborative research or holding facilities under contract to __ except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, __ environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

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****(FOR NIEHS USE ONLY, AS REQUIRED.)****

ARTICLE H.43. INTRODUCTION OF RODENTS AND RODENT PRODUCTS - NIEHS

No rodent or rodent product shall be delivered to NIEHS directly or through collaborative research or holding facilities under contract to NIEHS except by prior approval by the Comparative Medicine Branch, NIEHS. The approval form, Application to Introduce Rodents and Rodent Products into NIEHS, is available by contacting the Comparative Medicine Branch, Quality Assurance Laboratory at 919-541-3239. Approval must be obtained by the Contractor prior to shipment to NIEHS of the rodents and/or rodent products. The Contractor must be sure that this approval exists and is current before transferring rodents or rodent products into the NIEHS. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Requests for approval should be submitted within 30 days of the shipping date to: NIEHS, Comparative Medicine Branch, Quality Assurance Laboratory, PO Box 12233, MD C1-06, Building 101, Room C128, Research Triangle Park, NC, 27709. United States Department of Agriculture permits are required for the importation of monoclonal antibodies, hybridoma cell lines, cell cultures, and other biologic materials that have been in contact with material of animal origin. USDA permit forms and information are available online (

http://www.aphis.usda.gov/permits/). A copy of the completed permit form should be submitted to the Comparative Medicine Branch.

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****(USE BELOW, WHEN THE CONTRACT WILL INCLUDE RESEARCH INVOLVING NON HUMAN PRIMATES.)****

ARTICLE H.44. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

http://oma.od1.nih.gov/manualchapters/intramural/3044-2/

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****(USE BELOW ONLY IF OER, OLAW HAS GRANTED APPROVAL TO AWARD TO A CONTRACTOR NOT CURRENTLY COVERED BY AN APPROPRIATE ANIMAL WELFARE ASSURANCE AND VALID INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) APPROVAL. THE FOLLOWING **MUST** BE INCLUDED IN ANY CONTRACT RECEIVING THIS CONDITIONAL PREAWARD APPROVAL FROM OLAW.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- Select and/or remove the approval required from the choices in the brackets, as appropriate.)****

ARTICLE H.45. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

Under Governing Policy, Federal Funds administered by the Public Health Service (PHS) shall not be expended for research involving live vertebrate animals without prior approval by the Office of Laboratory Animal Welfare (OLAW), of [**An Animal Welfare Assurance that Complies with the PHS Policy on Humane Care and Use of Laboratory Animals and/or a valid Institutional Animal Care and Use Committee (IACUC) Approval**]. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES (e.g. COLLABORATING INSTITUTIONS, SUBCONTRACTORS, SUBGRANTEES) WITHOUT OLAW-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.

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****(USE BELOW, AS NECESSARY.)****

ARTICLE H.46. OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS)****

ARTICLE H.47. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS)****

ARTICLE H.48. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

272

****(USE BELOW, WHEN THE CONTRACT WILL CONTAIN OPTIONS. COMPLETE ACCORDING TO TIME PERIODS NEGOTIATED. INCLUDE APPROPRIATE CLAUSE IN SECTION I.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- Select the applicable Option Clause from the Drop Down List.
- Select the appropriate information within the brackets. Delete the information that does not apply.)****

ARTICLE H.49. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to [FAR Clause 52.217-6, Option for Increased Quantity/FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item/FAR Clause 52.217-8, Option to Extend Services/FAR Clause 52.217-9, Option to Extend the Term of the Contract] set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the [**Use for Cost-Reimbursement Contracts:** estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE]/ **Use for Fixed-Price Contracts:** price of the contract will be increased as set forth in the OPTION PRICES] Article in SECTION B of this contract.

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****(USE BELOW WHEN THE CONTRACT WILL BE PERFORMANCE-BASED AND OUTSTANDING PERFORMANCE IS REWARDED BY AN EXTENSION OF THE CONTRACT PERIOD (AWARD TERM). ***Notes:*** *(1) This "award term" incentive differs from the "award option" incentive in the next Article in that this item is a contractual entitlement earned by the Contractor and, once earned, should be awarded contingent only upon lack of funds availability or continued need for the supplies/services; and, (2) When awarding a Performance Based Acquisition using an "Award Term" incentive, make sure to include the cost/price information for the Award Term(s) in the appropriate Article in Section B. of your contract.*

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Paragraph a:** When no FEE, remove [ ] language in paragraph, below. If FEE, keep the language and remove the brackets.
- **Paragraph b.1:** Fill in the information as appropriate. Make sure to delete any sentences that do not apply.
- **Subparagraph b.3.a:** Insert the date of the "Contractor Assessment Report/Performance Indicators and Standards."
- **Subparagraph b.3.b.(1) & (2):** IMPORTANT NOTE: The language contained within the brackets in subparagraphs (1) and (2), is suggested only. It is set for a Five year base with two Award Term years. If this is not appropriate for your project, modify the paragraphs to be consistent with your requirement.)****

ARTICLE H.50. AWARD TERM

- Award Term Contract

  This contract contains Award Term incentive(s). Award Terms will be awarded based on the criteria set forth in paragraph b. below. The final decision whether the Award Term has been earned will be made annually and is at the sole discretion of the Contracting Officer.

  Award Terms that have been earned, but not yet awarded are contingent on the availability of funds and/or the continuing need of the items or services set forth in the Statement of Work. As the determination not to award the Award Term is not considered a termination, no equitable adjustments to the contract price will be made. There is no guarantee the Government will continue Performance beyond the base performance period.

  If the Contracting Officer determines that the Award Term has been earned and the Government's need for the items or services still exists and funds are available, the estimated cost [plus fixed fee] will be increased as set forth in the ESTIMATED COST, [FIXED FEE] AND AWARD TERM Article in SECTION B of this contract.

- Award Term Provisions

a. This contract has a base performance period of _ years _____ [insert dates]. The Contractor will have the opportunity to earn _ additional years of work _____ [insert dates here] using the evaluation process described herein. These additional years of work are called Award Terms. The total duration of this contract, including all Award Terms, shall not exceed a period of _ years _____ [insert dates].

b. A unilateral contract modification to add the Award Term will be issued when scoring meets or exceeds that set forth in the contract. The Government shall issue this modification at least 60 days prior to contract expiration. The Award Term determination and the methodology for determining the award term are unilateral decisions made solely by the Government and are not subject to dispute.

c. <u>Quality Assurance Surveillance Plan (QASP)</u>

    a. The Contractor's performance under this contract will be observed and evaluated continuously by the Government. The Contractor Assessment Report will be used to assess Contractor performance and determine whether the Contractor will receive Award Term(s). The Contractor Assessment Report includes Performance Indicators and Standards which identify the indicators to be evaluated and the associated standards for each indicator. A copy of the "Contractor Assessment Report/Performance Indicators and Standards," dated _____ is included as an attachment in SECTION J of this contract.
    b. The "Contractor Assessment Report/Performance Indicators and Standards" will be prepared by the Government, resulting in an overall rating which will be disseminated to the Contractor annually. The Award Term earned will be determined based upon review of the Contractor's performance against the performance indicators and standards as follows:
        a. [*Using the 0-5 point score in the Plan, the Contractor must receive an average of 3.5 or better for the first three years of Contractor performance. In years four and five, the Contractor must receive an average of 3.8 or better in each year to earn the Award Term.]* These goals are intended to be a stretch for the Contractor, but achievable.
        b. [*At the conclusion of year four, in addition to the year four "Contractor Assessment Report/Performance Indicators and Standards," the Government will prepare a summary report which will set forth the average rating for the first three years' of performance and the year four rating. This summary report will be*

used to determine if the Award Term for year six has been earned. Likewise, at the conclusion of year five, the Government will prepare a "Contractor Assessment Report/Performance Indicators and Standards" and a summary report of year five to determine if the Award Term for year seven has been earned.]

The advance evaluation of performance is required to allow adequate time for recompetition of the requirement in the event that Contractor performance does not meet the Award Term requirements. If the Contractor does not earn the first Award Term, there will be no opportunity to earn subsequent Award Term(s) and the contract expiration date will remain unchanged.

c. The "Contractor Assessment Report/Performance Indicators and Standards" described herein contains rating criteria used solely to assess whether the Contractor has earned the award term specified in this contract. This report differs from the Contractor Performance Report described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract, which uses a standard rating criteria established for the Federal Contractor Performance System to evaluate overall contract performance. For this reason, the Contractor's performance scores for determining authorization of the award term(s) may differ from the Contractor's performance scores for overall contract performance.

d. <u>Changes to the Contractor Assessment Report/Performance Indicators and Standards</u>

Unilateral changes to the Contractor Assessment Report/Performance Indicators and Standards may be made if the Contractor is provided written notification by the Contracting Officer at least 30 days before the start of the upcoming evaluation period. Changes affecting the current evaluation period must be by mutual agreement of both parties.

e. <u>Contractor Performance Assessment</u>

The Contracting Officer's Representative (COR), and other Government personnel as appropriate, will use the "Contractor Assessment Report/Performance Indicators and Standards" and the associated performance elements and standards to score contract performance for the Award Term determination. The Contracting Officer is responsible for making the final decision on the Contractor's score and for determining whether the Contractor has earned the Award Term.

f. Contractor Performance Evaluation

The COR and Contracting Officer will prepare reports required by FAR 42.15 and described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract to determine the Contractor's overall contract performance. Unless specifically identified as a rating criterion in the "Contractor Assessment Report/Performance Indicators and Standards," this evaluation report will not be used in the Award Term determination.

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****(USE BELOW WHEN THE CONTRACT WILL BE PERFORMANCE-BASED, WITH THE INCENTIVE OF AN AWARD OPTION FOR EXCELLENT PERFORMANCE. THIS ITEM SHOULD BE USED WHEN THE CONTRACTING OFFICER HAS DETERMINED THAT IT IS IN THE BEST INTEREST OF THE GOVERNMENT TO HAVE THE AWARD TERM EVALUATION SERVE AS THE PRECURSOR TO THE DECISION TO EXERCISE THE AWARD OPTION. **Note:** *This item may be more appropriate in high dollar and/or highly complex contracts.*

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Subparagraph a (last paragraph):** When no FEE, remove [ ] language in paragraph, below. If FEE, keep the language and remove the brackets.
- **Subparagraph b.1:** Fill in the information as appropriate. Make sure to delete any sentences that do not apply.
- **Subparagraph b.3.a:** Insert the date of the "Contractor Assessment Report/Performance Indicators and Standards."
- **Subparagraph b.3.b.(1) & (2):** IMPORTANT NOTE: The language contained within the brackets in subparagraphs (1) and (2), is suggested only. It is set for a Five year base with two Award Term years. If this is not appropriate for your project, modify the paragraphs to be consistent with your requirement.)****

ARTICLE H.51. AWARD OPTION

- Award Option Contract

This Contract contains Award Option(s). The Contractor is not entitled to the exercise of any Award Options solely by meeting the criteria of the Quality Assurance Surveillance Plan (QASP). The Award Option evaluation serves as a precursor to the Government exercising its unilateral rights in accordance with FAR Part 17.2. A successful Award Option evaluation precedes the Government's review and determination to exercise or not to exercise the Award Option, in accordance with FAR Part 17.2. There is no guarantee the Government will continue Performance beyond the base performance period.

Award Option(s) will be exercised based on the criteria set forth below, and the final decision whether to exercise the Award Option(s) will be made annually and is at the sole discretion of the Contracting Officer. If the Contracting Officer determines that the

standards for the Award Option have been met, and the Government exercises its option, the estimated cost [plus fixed fee] will be increased as set forth in the ESTIMATED COST, [FIXED FEE] AND AWARD TERM Article in SECTION B of this contract.

- Award Option Provisions
  a. This contract has a base performance period of _ years _____ . The Contractor will have the opportunity to earn additional _ years of work _____ using the evaluation process described herein. These additional years of work are called Award Option(s). The total duration of this contract, including all Award Option(s), shall not exceed a period of _ years _____ .

  b. A unilateral contract modification to add the Award Option may be issued when scoring meets or exceeds that set forth in the contract. The Award Option determination and the methodology for determining the award option are unilateral decisions made solely by the Government and are not subject to dispute.

  c. Quality Assurance Surveillance Plan (QASP)

     a. The Contractor's performance under this contract will be observed and evaluated continuously by the Government. The Contractor Assessment Report will be used to assess Contractor performance and determine whether the Contractor will receive Award Option(s). The Contractor Assessment Report includes Performance Indicators and Standards which identify the indicators to be evaluated and the associated standards for each indicator. A copy of the "Contractor Assessment Report/Performance Indicators and Standards," dated _____ is included as an attachment in SECTION J of this contract.

     b. The "Contractor Assessment Report/Performance Indicators and Standards" will be prepared by the Government, resulting in an overall rating which will be disseminated to the Contractor annually. The Award Option earned will be determined based upon review of the Contractor's performance against the performance indicators and standards as follows:

        a. [Using the 0-5 point score in the Plan, the Contractor must receive an average of 3.5 or better for the first three years of Contractor performance. In years four and five, the Contractor must receive an average of 3.8 or better in each year to earn the Award Option.] These goals are intended to be a stretch for the

Contractor, but achievable.

b. [At the conclusion of year four, in addition to the year four "Contractor Assessment Report/Performance Indicators and Standards," the Government will prepare a summary report which will set forth the average rating for the first three years' of performance and the year four rating. This summary report will be used to determine if the Award Option for year six has been earned. Likewise, at the conclusion of year five, the Government will prepare a "Contractor Assessment Report/Performance Indicators and Standards" and a summary report of year five to determine if the Award Option for year seven has been earned.]

The advance evaluation of performance is required to allow adequate time for recompetition of the requirement in the event that Contractor performance does not meet the Award Option requirements. If the Contractor does not earn the first Award Option, there will be no opportunity to earn subsequent Award Option(s) and the contract expiration date will remain unchanged.

c. The "Contractor Assessment Report/Performance Indicators and Standards" described herein contains rating criteria used solely to assess whether the Contractor has earned the Award Option specified in this contract. This report differs from the Contractor Performance Report described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract, which uses a standard rating criteria established for the Federal Contractor Performance System to evaluate overall contract performance. For this reason, the Contractor's performance scores for determining authorization of the Award Option(s) may differ from the Contractor's performance scores for overall contract performance.

d. <u>Changes to the Contractor Assessment Report/Performance Indicators and Standards</u>

Unilateral changes to the Contractor Assessment Report/Performance Indicators and Standards may be made if the Contractor is provided written notification by the Contracting Officer at least 30 days before the start of the upcoming evaluation period. Changes affecting the current evaluation period must be by mutual agreement of both parties.

e. <u>Contractor Performance Assessment</u>

The Contracting Officer's Representative (COR), and other Government

personnel as appropriate, will use the "Contractor Assessment Report/Performance Indicators and Standards" and the associated performance elements and standards to score contract performance for the Award Option determination. The Contracting Officer is responsible for making the final decision on the Contractor's score and for determining whether the Contractor has earned the Award Option.

f. Contractor Performance Evaluation

The COR, and Contracting Officer will prepare reports required by FAR 42.15 and described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract to determine the Contractor's overall contract performance. Unless specifically identified as a rating criterion in the "Contractor Assessment Report/Performance Indicators and Standards," this evaluation report will not be used in the Award Option determination.

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****(USE BELOW WHEN CONTRACT REQUIRES A SUBCONTRACTING PLAN (All Contracts OVER $700,000 - OR $1.5 million for construction of Public Facilities) EXCEPT SMALL BUSINESS CONTRACTS.)

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Last Paragraph:** Select appropriate contact from bracketed information within the paragraph; Insert e-mail address for the Government contact; and Select the appropriate title for the Government contact from the bracketed information.)****

ARTICLE H.52. SUBCONTRACTING PROVISIONS

- **Small Business Subcontracting Plan**
  a. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.
  b. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

- **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov .

a. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30th
October 30th
Expiration Date of Contract

b. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the [Contracting Officer/Contract Specialist/title of alternate designee] shall be included as a contact for notification purposes at the following e-mail address:

_____
[Contracting Officer/Contract Specialist]

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****(USE BELOW IN ALL SBIR CONTRACTS.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **For SBIR Phase I Contracts** : Select "two thirds" from the drop down box.
- **For SBIR Phase II Contracts** : Select "one half" from the drop down box.
- Choose the applicable language within the brackets and delete the language that is not appropriate. Awards made by the FY 2014 SBIR solicitation PHS 2014-1 should use "total labor hours." Awards made by the FY 2015 SBIR solicitation PHS 2015-1 should use "total contract costs less profit/fee." Prior to FY 2014, see the applicable SBIR solicitation for guidance.)****

ARTICLE H.53. LIMITATIONS ON SUBCONTRACTING - SBIR

The Contractor shall perform a minimum of [two-thirds/one-half] of the research and/or analytical effort [total labor hours/total contract costs less profit/fee] conducted under this contract. Any deviation from this requirement must be approved in writing by the Contracting Officer.

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****(The security and privacy requirements set forth herein apply to all new and existing information and IT solicitations and contracts, irrespective of dollar amount.) To determine the applicable language for each solicitation and contract, the requiring activity representative must confer with NIH Information System Security Officer (ISSO)/Chief Information Security Officer (CISO) and Privacy Officer/Senior Official for Privacy (SOP) to complete the "Information Security & Privacy Certification Checklists.****

ARTICLE H.54. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

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****(USE BELOW HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS, IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENTS REQUIRING INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY.
NOTE:
A procurement requires security if, as a result of the procurement, any Contractor (and/or any subcontractor) employee:

- will develop, have the ability to access, use, or host and/or maintain government information and/or government information system(s), including instances of remote access to or physical removal of such information beyond agency premises or control; or
- will have regular or prolonged physical access to a "federally-controlled facility," as defined in FAR Subpart 2.1.

Physical and Logical Access refers to when Contractor personnel (and/or any subcontractor) are expected to have (1) routine physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to government information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3) as per the HHSAR Subpart 304.13 - Personal Identity Verification and OMB M-05-24, Implementation of Homeland Security Presidential Directive (HSPD) 12 - Policy for a Common Identification Standard for Federal Employees and Contractors.

Additional guidance is located in Table 2, Position Sensitivity Designations for Individuals Accessing Agency Information at:
https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Pages/table2.aspx
General Resource Information for this Article:

- For more information, see HHS OCIO Policies at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/information-security-privacy-program/index.html
- The Contract Specialist, Project Officer, I/C Information Systems Security Officer (ISSO), and/or Privacy Officer can assist the acquisition staff in tailoring the language in the below Article. If additional guidance is needed, contact NIH Office of the Chief Information Officer (OCIO) at nihisaopolicy@mail.nih.gov
****

ARTICLE H.54.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

- **Applicability-** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

- Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
- Operate a Federal System Containing Information: A Contractor (and/or any subcontractor)will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

- **Safeguarding Information and Information Systems-** In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

- Protect government information and information systems in order to ensure:
- **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
- **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
- **Availability**, which means ensuring timely and reliable access to and use of information.
- Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or Contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less** , bring the situation to the attention of the other party.
- Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov .
- Comply with the Privacy Act requirements.

- **Information Security Categorization-** In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Contractor Non-Disclosure Agreement and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality:	[ ] Low	[ ] Moderate	[ ] High
Integrity:	[ ] Low	[ ] Moderate	[ ] High
Availability:	[ ] Low	[ ] Moderate	[ ] High
Overall Risk Level:	[ ] Low	[ ] Moderate	[ ] High

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [ ] Yes PII

Personally Identifiable Information (PII). Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [ ] Low [ ] Moderate [ ] High

- **Controlled Unclassified Information (CUI)-** CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling" refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

- Marked appropriately;
- Disclosed to authorized personnel on a Need-To-Know basis;
- Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and

- Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

- **Protection of Sensitive Information-** For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.
- **Confidentiality and Nondisclosure of Information-** Any information provided to the Contractor (and/or any subcontractor) by HHS or collected by the Contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/NIH sanction policies and/or governed by the following laws and regulations:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
- 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at:
https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf
A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

- **Internet Protocol Version 6 (IPv6)-** All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6).
- **Government Websites-** All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that

attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

- **Contract Documentation-** The Contractor shall use provided templates, policies, forms and other agency documents provided by the Contracting Officer and the Contracting Officer's Representative to comply with contract deliverables as appropriate.
- **Standard for Encryption-** The Contractor (and/or any subcontractor) shall:

- Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.
- Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.
- Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
- Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative within ***15 days*** of the validation .
- Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to the COR upon request and at the conclusion of the contract.

- **Contractor Non-Disclosure Agreement (NDA)-** Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the NIH non-disclosure agreement https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf , as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.
- **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)-** The Contractor shall assist the NIH Office of the Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed. The NIH PIA guide is located at https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/NIH%20PIA%20Guide.pdf .

- If the results of the PTA show that a full PIA is needed, the Contractor shall assist the OpDiv SOP or designee with completing a PIA for the system or information within ***60 days*** after completion of the PTA and in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.
- The Contractor shall assist the NIH Office of the SOP or designee in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

B. **TRAINING**

- **Mandatory Training for All Contractor Staff-** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/NIH Contractor Information Security Awareness, Privacy, and Records Management training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.

1. **Role-based Training-** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum. Read further guidance about the NIH Role-based Training Role-based Training https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html

- **Training Records-** The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and ***annually*** thereafter or upon request.

C. **RULES OF BEHAVIOR**

- The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and comply with the NIH Information Technology General Rules of Behavior https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html , which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov .
- All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or

networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual NIH Information Security Awareness Training. If the training is provided by the Contractor, the signed Rules of Behavior must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

D. **INCIDENT RESPONSE**

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII" .

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

- Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
- DO NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals in accordance with https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines
- Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at IRT@mail.nih.gov , COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and

guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

- cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
- not include any sensitive information in the subject or body of any reporting e-mail; and
- encrypt sensitive information in attachments to email, media, etc.

- Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
- Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to Contractor facilities during a breach/incident investigation within an hour of discovery.

E. POSITION SENSITIVITY DESIGNATIONS

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[ ] Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[ ] Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

F. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification

(PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12)

Roster-

- The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx .
- If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.
- Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.
- The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.
- All Contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.
- Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's

discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

- The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
- Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

G. **CONTRACT INITIATION AND EXPIRATION**

- **General Security Requirements-** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the Contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Guide (2012).

  HHS EA requirements may be located here:
  https://www.hhs.gov/sites/default/files/ocio/eplc-lifecycle-framework.pdf

- **System Documentation-** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.
- **Sanitization of Government Files and Information-** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.
- **Notification-** The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO within ***fifteen days*** before an employee stops working under this contract.
- **Contractor Responsibilities Upon Physical Completion of the Contract-** The Contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup

systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.

- The Contractor (and/or any subcontractor) shall perform and document the actions identified in the NIH Contractor Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

H. RECORDS MANAGEMENT AND RETENTION

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/NIH policies and shall not dispose of any records unless authorized by HHS/NIH.
In the event that a Contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/NIH policies.

****(USE BELOW HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS, IN SOLICITATIONS, CONTRACTS AND ORDERS THAT REQUIRE THE DESIGN, DEVELOPMENT, OR OPERATION OF A SYSTEM OF RECORDS TO NOTIFY THE CONTRACTOR THAT IT AND ITS EMPLOYEES ARE SUBJECT TO CRIMINAL PENALTIES FOR VIOLATIONS OF THE PRIVACY ACT (5 U.S.C. 552A(I) TO THE SAME EXTENT AS HHS EMPLOYEES. See HHSAR 324.105(a) for more information .)****

NOTE:

This language does not alleviate the requirement to properly incorporate the three FAR and HHSAR clauses identified below in the applicable solicitation and resultant contract. The following definitions and clauses are relevant to this section:

1. FAR Subpart 24.101- Definitions. Consult the definitions of "agency," "individual," "maintain," "operation of a system of records," "record," and "system of records on individuals" to determine if the Privacy Act applies. If the Privacy Act applies, the following three clauses must be incorporated.
2. FAR Clause 52.224-1 Privacy Act Notification.
3. FAR Clause 52.224-2 Privacy Act.
4. HHSAR Clause 352.224-70 Privacy Act. NOTE: This clause requires inclusion of Language specifying the applicable system(s) of records or proposed system(s) of records, the design, development, or operation work the Contractor is to perform, and the records disposition instructions to be followed by the Contractor upon completion of contract performance.

ARTICLE H.54.2. PRIVACY ACT

It has been determined that this contract is subject to the Privacy Act of 1974, because this contract provides for the design, development, or operation of a system of records on individuals.

The System of Records Notice (SORN) that is applicable to this contract is: _____ [*Insert SORN number if one exists. If there is no SORN, indicate that a SORN will be developed*].

The design, development, or operation work the Contractor is to perform is: _____ [*Insert description of design, development, and/or operation work; see definitions in the FAR at 24.101 - Definitions*].

The Contractor and any Subcontractor must follow disposition to be made of the Privacy Act records upon completion of contract performance shall be in accordance with Section C of the contract, and by direction of the Contracting Officer/Contracting Officer's representative.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS. In addition to definitions and clauses specified in clause "Procurement Requiring Information Security and/or Physical Access Security" and applicable definitions and clauses in "Requirements for Procurements Involving Privacy Act Records.")****

The following FAR references are relevant to this section:

1. FAR Part 52 including clauses 52.239-1 and 52.204-21 (Section 4.A.)
2. FAR Subpart 39.101(c) (Section 4.5)b.)

ARTICLE H.54.3. GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS

A. SECURITY REQUIREMENTS FOR GOVERNMENT-OWNED/CONTRACTOR-OPERATED (GOCO) AND CONTRACTOR-OWNED/CONTRACTOR-OPERATED (COCO) RESOURCES

- **Federal Policies-** The Contractor (and/or any subcontractor) shall comply with applicable federal laws that include, but are not limited to, the HHS Information Security and Privacy Policy (IS2P), Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101); National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Security and Privacy Controls for Federal Information Systems and Organizations; Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource; and other applicable federal laws, regulations, NIST guidance, and Departmental policies.
- **Security Assessment and Authorization (SA&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.

NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

- **<u>SA&A Package Deliverables -</u>** The Contractor (and/or any subcontractor) shall provide an SA&A package within 30 days of contract award to the CO and/or COR. The following SA&A deliverables are required to complete the SA&A package.
- **System Security Plan (SSP) -** due within 30 days after contract award. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal

Information Systems, the Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.

- **Security Assessment Plan/Report (SAP/SAR) -** due 30 days after the contract award. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by Contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below.

Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

- **Independent Assessment -** due 90 days after the contract award. The Contractor (and/or subcontractor) shall have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M).
- **POA&M -** due 30 days after contract award. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All high-risk weaknesses must be mitigated within 30 days and all medium weaknesses must be mitigated within 60 days from the date the weaknesses are formally identified and documented. The NIH will determine the risk rating of vulnerabilities.
  Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.

- **Contingency Plan and Contingency Plan Test -** due 60 days after contract award. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.
- **E-Authentication Questionnaire -** The Contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, *Electronic Authentication Guidelines.*

Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

- **Information Security Continuous Monitoring-** Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, *Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations* , and HHS IS2P. The following are the minimum requirements for ISCM:
- **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's Representative.
- **Asset Management -** Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The Contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration

compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.

- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The Contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least within 30 days of the contract award.
- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.
- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

- **Government Access for Security Assessment**. In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) shall afford the Government access to the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

- At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours Contractor local time, to access Contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.

- The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.

- At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the Contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.
- Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.
- Cooperate with inspections, audits, investigations, and reviews.

2. **End of Life Compliance.** The Contractor (and/or any subcontractor) must use Commercial off the Shelf (COTS) software or other software that is supported by the manufacturer. In addition, the COTS/other software need to be within one major version of the current version; deviation from this requirement will only be allowed via the HHS waiver process (approved by HHS CISO). The Contractor shall retire and/or upgrade all software/systems that have reached end-of-life in accordance with HHS End-of-Life Operating Systems, Software, and Applications Policy.

3. **Desktops, Laptops, and Other Computing Devices Required for Use by the Contractor.** The Contractor (and/or any subcontractor) shall ensure that all IT equipment (e.g., laptops, desktops, servers, routers, mobile devices, peripheral devices, etc.) used to process information on behalf of HHS are deployed and operated in accordance with approved security configurations and meet the following minimum requirements:

- Encrypt equipment and sensitive information stored and/or processed by such equipment in accordance with HHS and FIPS 140-2 encryption standards.
- Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline (USGCB), and HHS Minimum Security Configuration Standards;
- Maintain the latest operating system patch release and anti-virus software definitions within 15 days.
- Validate the configuration settings after hardware and software installation, operation, maintenance, update, and patching and ensure changes in hardware and software do not alter the approved configuration settings; and
- Automate configuration settings and configuration management in accordance with HHS security policies, including but not limited to:
- Configuring its systems to allow for periodic HHS vulnerability and security configuration assessment scanning; and
- Using Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capabilities to scan its systems at least on a monthly basis and report the results of these scans to the CO and/or COR, Project Officer, and any other applicable designated POC.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING CLOUD SERVICES
In addition to the standard baseline language in Section "Procurement Requiring Information Security and/or Physical Access Security" and applicable language from clause "Requirements for Procurements Involving Privacy Act Records." and section for "Government Information Processed on GOCO/COCO Systems." These include: Infrastructure as a Service (IaaS), Platform as a Service (PaaS), Software as a Service (SaaS), and information systems moving to a cloud environment. The requiring activity representative must confer with the NIH's System Owner, ISSO or CISO, and the NIH Office of SOP to determine any additional security and privacy requirements applicable to the solicitation/contract that need to be included)****

ARTICLE H.54.4. CLOUD SERVICES

A. **HHS FedRAMP Privacy and Security Requirements**

The Contractor (and/or any subcontractor) shall be responsible for the following privacy and security requirements:

- **FedRAMP Compliant ATO.** Comply with FedRAMP Security Assessment and Authorization (SA&A) requirements and ensure the information system/service under this contract has a valid FedRAMP compliant (approved) authority to operate (ATO) in accordance with Federal Information Processing Standard (FIPS) Publication 199 defined security categorization. If a FedRAMP compliant ATO has not been granted, the Contractor shall submit a plan to obtain a FedRAMP compliant ATO by 30 days of the contract award.
- A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.

- **Data Jurisdiction-** The Contractor shall store all information within the security authorization boundary, data at rest or data backup, within the continental United States (CONUS) if so required as stated in section C.
- **Service Level Agreements-** Add when applicable/Mark as Not Applicable _____ The Contractor shall understand the terms of the service agreements that define the legal relationships between cloud customers and cloud providers and work with NIH to develop and maintain an SLA.
- **Interconnection Agreements/Memorandum of Agreements-** Add when applicable/Mark as Not Applicable _____ The Contractor shall establish and maintain Interconnection Agreements and or Memorandum of Agreements/Understanding in accordance with HHS/NIH policies.

B. **Protection of Information in a Cloud Environment**

- If Contractor (and/or any subcontractor) personnel must remove any information from the primary work area, they shall protect it to the same extent they would the proprietary data and/or company trade secrets and in accordance with HHS/NIH policies.
- HHS will retain unrestricted rights to federal data handled under this contract. Specifically, HHS retains ownership of any user created/loaded data and applications collected, maintained, used, or operated on behalf of HHS and hosted on Contractor's infrastructure, as well as maintains the right to request full copies of these at any time. If requested, data must be available to HHS within one (1) business day from request date or within the timeframe specified otherwise. In addition, the data shall be provided at no additional cost to HHS.
- The Contractor (and/or any subcontractor) shall ensure that the facilities that house the network infrastructure are physically and logically secure in accordance with FedRAMP requirements and HHS policies.
- The Contractor shall support a system of records in accordance with NARA-approved records schedule(s) and protection requirements for federal agencies to manage their electronic records in accordance with 36 CFR § 1236.20 & 1236.22 (ref. a), including but not limited to the following:

- Maintenance of links between records and metadata, and
- Categorization of records to manage retention and disposal, either through transfer of permanent records to NARA or deletion of temporary records in accordance with NARA-approved retention schedules.
- The disposition of all HHS data shall be at the written direction of HHS/NIH. This may include documents returned to HHS control; destroyed; or held as specified until otherwise directed. Items returned to the Government shall be hand carried or sent by certified mail to the COR.
- If the system involves the design, development, or operation of a system of records on individuals, the Contractor shall comply with the Privacy Act requirements.

C. **Security Assessment and Authorization (SA&A) Process**

- The Contractor (and/or any subcontractor) shall comply with HHS and FedRAMP requirements as mandated by federal laws, regulations, and HHS policies, including making available any documentation, physical access, and logical access needed to support the SA&A requirement. The level of effort for the SA&A is based on the system's FIPS 199 security categorization and HHS/NIH security policies.

- In addition to the FedRAMP compliant ATO, the Contractor shall complete and maintain an agency SA&A package to obtain agency ATO prior to system deployment/service

implementation. The agency ATO must be approved by the NIH authorizing official (AO) prior to implementation of system and/or service being acquired.

- CSP systems categorized as Federal Information Processing Standards (FIPS) 199 high must leverage a FedRAMP accredited third-party assessment organization (3PAO); moderate impact CSP systems must make a best effort to use a FedRAMP accredited 3PAO. CSP systems categorized as FIPS 199 low impact may leverage a non-accredited, independent assessor.
- For all acquired cloud services, the SA&A package must contain the following documentation: SSP, SAR, POA&M, Authorization Letter, CP and CPT report, E-Authorization (if applicable), PTA/PIA (if applicable), Interconnection/Data Use Agreements (if applicable), Authorization Letter, Configuration Management Plan (if applicable), Configuration Baseline, Following the initial ATO, the Contractor must review and maintain the ATO in accordance with HHS/NIH policies.
- HHS reserves the right to perform penetration testing (pen testing) on all systems operated on behalf of agency. If HHS exercises this right, the Contractor (and/or any subcontractor) shall allow HHS employees (and/or designated third parties) to conduct Security Assessment activities to include control reviews in accordance with HHS requirements. Review activities include, but are not limited to, scanning operating systems, web applications, wireless scanning; network device scanning to include routers, switches, and firewall, and IDS/IPS; databases and other applicable systems, including general support structure, that support the processing, transportation, storage, or security of Government information for vulnerabilities.
- The Contractor must identify any gaps between required FedRAMP Security Control Baseline/Continuous Monitoring controls and the Contractor's implementation status as documented in the Security Assessment Report and related Continuous Monitoring artifacts. In addition, all gaps shall be documented and tracked by the Contractor for mitigation in a Plan of Action and Milestones (POA&M) document. Depending on the severity of the risks, HHS may require remediation at the Contractor's expense, before HHS issues an ATO.
- The Contractor (and/or any subcontractor) shall mitigate security risks for which they are responsible, including those identified during SA&A and continuous monitoring activities. All vulnerabilities and other risk findings shall be remediated by the prescribed timelines from discovery: (1) critical vulnerabilities no later than thirty (30) days and (2) high, medium and low vulnerabilities no later than sixty (60) days. In the event a vulnerability or other risk finding cannot be mitigated within the prescribed timelines above, they shall be added to the designated POA&M and mitigated within the newly designated timelines 30 days. HHS will determine the risk rating of vulnerabilities using FedRAMP baselines.
- Revocation of a Cloud Service. HHS/NIH staff division have the right to take action in response to the CSP's lack of compliance and/or increased level of risk. In the event the CSP fails to meet HHS and FedRAMP security and privacy requirements and/or there is an incident involving sensitive information, HHS and/or NIH may suspend or revoke an existing agency ATO (either in part or in whole) and/or cease operations. If an ATO is

suspended or revoked in accordance with this provision, the CO and/or COR may direct the CSP to take additional security measures to secure sensitive information. These measures may include restricting access to sensitive information on the Contractor information system under this contract. Restricting access may include disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls.

D. **Reporting and Continuous Monitoring**

- Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.
- **Information Security Continuous Monitoring-** Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations, and HHS IS2P. The following are the minimum requirements for ISCM:
- **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's Representative.
- **Asset Management -** Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The Contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration

baselines at least within 60 days. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.

- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The Contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least within 30 days of the contract award.
- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.
- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).
- A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.
- At a minimum, the Contractor must provide the following artifacts/deliverables on a monthly basis as directed by the Contracting Officer/Contracting Officer's Representative.

    - Operating system, database, Web application, and network vulnerability scan results;
    - Updated POA&Ms;
    - Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the NIH System Owner or AO; and
    - Any configuration changes to the system and/or system components or CSP's cloud environment, that may impact HHS/NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

E. **Configuration Baseline**

- The Contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS-identified configuration baseline. The standard installation, operation, maintenance, updates, and/or patching of software shall not alter the configuration settings from the approved HHS/NIH.
- The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH , and the National Institute of Standards and Technology (NIST). NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)
- The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://ocio.nih.gov/ITGovPolicy/Pages/spec_policy.aspx .
- The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capability to ensure its products operate correctly with USGCB configurations and do not alter USCGB settings - (See: http://scap.nist.gov/validation) . The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest USGCB major version and subsequent major versions.
- The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (See: http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

- The Contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

F. **Incident Reporting**

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative. FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.
A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII" .
In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

- Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
- NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals within ***5 business days*** of the incident.
- Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) IRT@nih.gov **,** COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

- Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
- Not include any sensitive information in the subject or body of any reporting e-mail; and
- Encrypt sensitive information in attachments to email, media, etc.
- Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
- Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to Contractor facilities during a breach/incident investigation.
- The Contractor (and/or any subcontractor) shall provide an Incident and Breach Response Plan (IRP) in accordance with HHS/NIH, OMB, and US-CERT requirements and obtain approval from the NIH. In addition, the Contractor must follow the incident response and US-CERT reporting guidance contained in the FedRAMP Incident Communications.
- The Contractor (and/or any subcontractor) must implement a program of inspection to safeguard against threats and hazards to the security, confidentiality, integrity, and availability of federal data, afford HHS access to its facilities, installations, technical capabilities, operations, documentation, records, and databases within 72 hours of notification. The program of inspection shall include, but is not limited to:

- Conduct authenticated and unauthenticated operating system/network/database/Web application vulnerability scans. Automated scans can be performed by HHS/NIH personnel, or agents acting on behalf of HHS/NIH, using agency-operated equipment and/or specified tools. The Contractor may choose to run its own automated scans or audits, provided the scanning tools and configuration settings are compliant with NIST Security Content Automation Protocol (SCAP) standards and have been approved by the agency. The agency may request the Contractor's scanning results and, at the agency discretion, accept those in lieu of agency performed vulnerability scans.
- In the event an incident involving sensitive information occurs, cooperate on all required activities determined by the agency to ensure an effective incident or breach response and provide all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. In addition, the Contractor must follow the agency reporting procedures and document the steps it takes to contain and eradicate the incident, recover from the incident, and provide a post-incident report that includes at a minimum the following:
- Company and point of contact name;
- Contract information;

- Impact classifications/threat vector;
- Type of information compromised;
- A summary of lessons learned; and
- Explanation of the mitigation steps of exploited vulnerabilities to prevent similar incidents in the future.

G. **Media Transport**

- The Contractor and its employees shall be accountable and document all activities associated with the transport of government information, devices, and media transported outside controlled areas and/or facilities. These include information stored on digital and non-digital media (e.g., CD-ROM, tapes, etc.), mobile/portable devices (e.g., USB flash drives, external hard drives, and SD cards).
- All information, devices and media must be encrypted with HHS-approved encryption mechanisms to protect the confidentiality, integrity, and availability of all government information transported outside of controlled facilities.

H. **Boundary Protection: Trusted Internet Connections (TIC)**

- The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities using cloud services is inspected by Trusted Internet Connection (TIC) processes.
- The Contractor shall route all external connections through a TIC.
- **Non-Repudiation-** The Contractor shall provide a system that implements FIPS 140-2 validated encryption that provides for origin authentication, data integrity, and signer non-repudiation.

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****The following acquisition types are categories that are not covered by other clauses. These include hardware procurements, non-commercial/open source software procurements and procurements involving information technology (IT) design, development and support.
The Contracting Officer's shall adhere to OMB M-16-20 Category Management Policy 16-3: Improving the Acquisition and Management of Common Information Technology: Mobile Devices and Services when acquiring mobile devices.****

ARTICLE H.54.5. OTHER IT PROCUREMENTS

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING HARDWARE)****

NOTE: The Contracting Officer should confer with the System Owner, Information System Security Office (ISSO) and/or OpDiv Office of the Chief Information Security Officer (OCISO) when developing a contract involving other types of IT procurements to make sure all applicable security and privacy language is included.

The following clauses apply to this section:

- FAR Part 12 (Section 6.A.1.)
- FAR Subpart 4.13 (Section 6.A.1.)

ARTICLE H.54.5.1. HARDWARE PROCUREMENTS

- **Card Readers-** The Contractor (and/or any subcontractor) shall include Federal Information Processing Standard (FIPS) 201-compliant smart card readers (referred to as LACS Transparent Readers) with the purchase of servers, printers, desktops, and laptops.
- **Mobile Devices-** The Contractor shall follow NIST 800-124, Rev. 1, Guidelines for Managing the Security of Mobile Devices in the Enterprise when using mobile devices that process or store HHS data.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING NON-COMMERCIAL AND OPEN SOURCE COMPUTER SOFTWARE)****

The use of non-commercial and open source computer software is in accordance with the HHS Guidance for Purchasing Noncommercial Computer Software and "Open Source" Licenses (2012),25 and OMB M-04-16, Software Acquisition26.

If HHS wants to be able to use or distribute the computer software, it is imperative that the computer software, including the source code if it is required by the procuring program, be included as a deliverable.

Noncommercial computer software means software that does not qualify as commercial in nature (e.g., commercial items and commercial off the shelf (COTS) items as defined in FAR 2.101). The following language should be used as appropriate in noncommercial computer software contracts. Each section includes an instruction providing where the information should be included in the contract.

(NOTE: If this procurement involves handling of sensitive information, include language from clause "Procurements Requiring Information Security and/or Physical Access Security)

ARTICLE H.54.5.2. NON-COMMERCIAL AND OPEN SOURCE COMPUTER SOFTWARE

The Contractor (and/or any subcontractor) shall follow secure coding best practice requirements, as directed by the United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP) that will limit system software vulnerability exploits.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING INFORMATION TECHNOLOGY APPLICATION DESIGN, DEVELOPMENT, OR SUPPORT)****

This section refers to procurements including application design, development, or support. For the purposes of this document, "Computer software" means:

- Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and
- Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

"Computer software" does not include computer databases or computer software documentation.

ARTICLE H.54.5.3. INFORMATION TECHNOLOGY APPLICATION DESIGN, DEVELOPMENT, OR SUPPORT

- The Contractor (and/or any subcontractor) shall ensure IT applications designed and developed for end users (including mobile applications and software licenses) run in the standard user context without requiring elevated administrative privileges.
- The Contractor (and/or any subcontractor) shall follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- The Contractor (and/or any subcontractor) shall ensure that computer software developed on behalf of HHS or tailored from an open-source product, is fully functional and operates correctly on systems configured in accordance with government policy and federal configuration standards. The Contractor shall test applicable products and versions with all relevant and current updates and patches updated prior to installing in the HHS environment. No sensitive data shall be used during software testing.
- The Contractor (and/or any subcontractor) shall protect information that is deemed sensitive from unauthorized disclosure to persons, organizations or subcontractors who do not have a need to know the information. Information which, either alone or when compared with other reasonably-available information, is deemed sensitive or proprietary by HHS shall be protected as instructed in accordance with the magnitude of the loss or harm that could result from inadvertent or deliberate disclosure, alteration,

or destruction of the data. This language also applies to all subcontractors that are performing under this contract.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING PHYSICAL ACCESS TO GOVERNMENT CONTROLLED FACILITIES)****
(NOTE: For procurements involving physical access to government facilities, selected language from "Procurement Requiring Information Security and/or Physical Access Security" may apply. This includes, but not limited to security awareness, incident response, and HSPD-12. Consult with the NIH Information Systems Security Officer (ISSO), the NIH Office of Senior Official for Privacy (SOP) and other relevant stakeholders to select applicable language.)

ARTICLE H.54.5.4. PHYSICAL ACCESS TO GOVERNMENT CONTROLLED FACILITIES

Refer to Section H clause- Government Information and Physical Access Security.

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****(USE BELOW IN ALL CONTRACTS AND ORDERS)****

ARTICLE H.55. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015)

- Pursuant to Section 508 of the Rehabilitation Act of 1973(29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards'' set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board'') in 36 CFR part 1194. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards .
- The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The Contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- The Section 508 accessibility standards applicable to this contract are: (Contract staff must list applicable standards)

- In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the Contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (http://www.hhs.gov/web/508). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
- If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://www.hhs.gov/web/508 . If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

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****(USE IN ALL SOLICITATIONS)****

ARTICLE H.56. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE HHSAR 352.239-73 (December 2015)

- Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are

not individuals with disabilities, unless an undue burden would be imposed on the agency.

- Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and standards/communications-and-it/about-the-section-508-standards .
- The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508 . In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
- Respondents to this solicitation must identify any exception to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

  The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

(End of clause)

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**** (USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE THE DEVELOPMENT, MAINTENANCE, AND/OR DISTRIBUTION OF NIH SPONSORED COMMUNICATION MATERIALS AND/OR SERVICES. THESE INCLUDE WEBSITES, PRINTED PRODUCTS, CAMPAIGN MATERIALS, AND PRODUCTS BEARING FEDERAL MARKS, TRADEMARKS, AND LOGOS.

Note to Contracting Officer and Contract Specialist: *Additional information about NIH Office of Communications and Public Liaison policy and procedures are contained in NIH Manual Chapters, which can be accessed at the following address: (* http://oma.od.nih.gov/public/MS/manualchapters/Pages/default.aspx *)*

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

• **Second paragraph** : Select all that contract requirements that apply.)****

ARTICLE H.57. COMMUNICATIONS MATERIALS AND SERVICES

To build and maintain public trust; promote credibility and consistency; minimize consistency and frustration; and contribute to efforts aimed at leveraging reduced resources and eliminating waste in Government, the Contractor shall ensure that all materials generated and/or services provided under this contract, comply with all applicable NIH policy and procedures published by the NIH Office of Management Assessment in conjunction with the NIH Office of Communications and Public Liaison as set forth below.

This acquisition requires the Contractor to:

[ ] Prepare, review, and/or distribute NIH Publications and Audiovisuals.

NIH Policy Manual Chapter 1183, "NIH Publications & Audiovisuals: Preparation, Review, Approval & Distribution," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/1183/ .

[ ] Use the NIH name and logo.

NIH Policy Manual Chapter 1186, "Use of NIH Names and Logos," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/1186/ .

[ ] Create and/or Manage a Public Website which includes NIH hosted social media site(s), Web application(s) and mobile Web Site(s).

NIH Policy Manual Chapter 2804, "Public-Facing Web Management," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2804/ .

[ ] Create and/or Manage an NIH Website that maintains and disseminates personal information.

NIH Policy Manual Chapter 2805, "NIH Web Privacy Policy," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2805/ .

[ ] Create and/or Manage an NIH hosted and/or funded social media site(s), Web application(s) and mobile Web site(s).

NIH Policy Manual Chapter 2809, "NIH Social and New Media Policy," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2809/ .

Additional Standards applicable to this contract are identified in the Statement of Work. If it is determined by the Government that products, services, and deliverables provided by the Contractor do not conform to standards described in these directives, remediation to an acceptable level of conformance shall be the responsibility of the Contractor at its own expense.

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****(USE BELOW, WHEN THE CONTRACTOR WILL GENERATE MATERIALS UNDER THE CONTRACT FOR WHICH COMMERCIAL RECORDS STORAGE WILL BE REQUIRED. **Note:** *This requirement may not be known at the time of initial award. If this is the case, this Article should be included in the contract, by modification, as soon as practicable, once the requirement need for commercial records storage has been determined* .)****

ARTICLE H.58. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

The Contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the Contractor shall provide a copy of the "Facility Standards for Records Storage Facilities Inspection Checklist," self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=b5a00a361423743ff1a062faafcfdd89&rgn=div5&view=text&node=36:3.0.10.2.23&idno=36

Sixty (60) days prior to contract end date, the Contractor shall submit to the Contracting Officer's Representative (COR) and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

Additional information about Records Storage Facility Standards can be found at: http://www.archives.gov/records-mgmt/storage-standards-toolkit/

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****(USE BELOW FOR SOLICITATIONS AND CONTRACTS WHERE THE POSSIBILITY EXISTS THAT THE CONTRACTOR WILL HAVE ACCESS TO NIH E-MAIL.)****

ARTICLE H.59. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as Contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital

Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

e. BE EITHER COST-REIMBURSEMENT OR FIXED-PRICE-INCENTIVE (Where the incentive is based on cost);
f. HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $25 MILLION; AND,
g. REQUIRE A CONTRACTOR TO USE FULL EVMS (See HHSAR 334.201)
h. EVM IS APPLICABLE TO SOLICITATIONS AND CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS.
Note: *Funds used to develop, Plan, Modernize, or Enhance an IT System are considered DME. DME does not include maintenance of existing IT systems (including technology refreshment hardware and software* .

For more information about EARNED VALUE MANAGEMENT (EVM) See: HHSAR 334.2.)****

ARTICLE H.60. FULL EARNED VALUE MANAGEMENT SYSTEM

- The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been validated and accepted by the CFA at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

- If, at the time of award, the Contractor's EVM system has not been validated and accepted by the CFA as complying with EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

    a. Apply the current system to the contract; and
    b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

- HHS requires the Contractor to obtain validation and acceptance of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress

payments, or a reduction in fee.

- HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

- Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

- The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

- The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

i. BE EITHER COST-REIMBURSEMENT OR FIXED-PRICE-INCENTIVE (Where the incentive is based on cost);
j. HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $10 MILLION BUT LESS THAN $25 MILLION; AND,
k. REQUIRE A CONTRACTOR TO USE FULL EVMS (See HHSAR 334.201)
l. EVM IS APPLICABLE TO SOLICITATIONS AND CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS. **Note:** *Funds used to develop, Plan, Modernize, or Enhance an IT System are considered DME. DME does not include maintenance of existing IT systems (including technology refreshment hardware and software* .

For more information about EARNED VALUE MANAGEMENT (EVM) See: HHSAR 334.2.)
****

ARTICLE H.61. FULL EARNED VALUE MANAGEMENT SYSTEM

- The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in

accordance with the requirements of this contract.

- If, at the time of award, the Contractor's EVM system is not in compliance with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

    a. Apply the current system to the contract; and
    b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

- HHS will not formally validate or accept the Contractor's EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

- HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

- -Not Applicable-

- The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

- The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

m. BE EITHER FIRM-FIXED-PRICE, TIME AND MATERIALS, LABOR-HOURS OR TERM FORM CONTRACTS;
n. HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $25 MILLION; AND,
o. REQUIRE A CONTRACTOR TO USE PARTIAL EVMS (See HHSAR 334.201.)****

ARTICLE H.62. PARTIAL EARNED VALUE MANAGEMENT SYSTEM

- The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been validated and accepted by the CFA at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

- If, at the time of award, the Contractor's EVM system has not been validated and accepted by the CFA as complying with the schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

    a. Apply the current system to the contract; and
    b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

- HHS requires the Contractor to obtain validation and acceptance of the schedule-related portions of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

- HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

- Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of

proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

- The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

- The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

p. BE EITHER FIRM-FIXED-PRICE, TIME AND MATERIALS, LABOR-HOURS OR TERM FORM CONTRACTS;
q. HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $10 MILLION BUT LESS THAN $25 MILLION; AND,
r. REQUIRE A CONTRACTOR TO USE PARTIAL EVMS (See HHSAR 334.201.)****

ARTICLE H.63. PARTIAL EARNED VALUE MANAGEMENT SYSTEM

- The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

- If, at the time of award, the Contractor's schedule-related EVM system is not in compliance with the schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), or the Contractor does not have an existing schedule control system that is compliant with such guidelines, the Contractor shall:

    a. Apply the current system to the contract; and
    b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

- HHS will not formally validate or accept the Contractor's schedule-related EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted

during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction.

- HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

- -Not Applicable-

- The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

- The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN THE CONTRACTOR WILL HAVE ACCESS TO LIBRARY RESOURCES AT NIH, e.g. when a Contractor is added to the NIH Enterprise Directory (NED) with the same privileges as NIH staff.)****

ARTICLE H.64. CONTRACTOR'S USE OF LIBRARY RESOURCES AT NIH

The Contractor is authorized to use library resources at NIH in the same manner as NIH staff. The Contractor's approved use of these resources is limited to performing the requirements of this contract. The Contractor shall not use library resources at NIH in a manner that exceeds the Fair Use limitations codified in 17 U.S.C. sec. 107 of the Copyright Act. Contractors shall not share access to library resources at NIH with, perform searches for, or provide results to, non-NIH users, i.e. collaborators at other universities or research centers.

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**** (THE FOLLOWING IS OPTIONAL. USE ONLY FOR PROPRIETARY INFORMATION, PERSONAL INFORMATION, OR INFORMATION WHICH MAY REQUIRE SPECIAL CONSIDERATION WITH REGARD TO THE TIMING OF DISCLOSURE. THE GOVERNMENT MUST IDENTIFY THE SPECIFIC INFORMATION TO BE COVERED BY THIS ARTICLE. **Note:** *Before using this Article, the Contract Specialist/CO should review the Advance Understandings to determine if "Confidential Treatment of Sensitive Information" is more appropriate.*

ADDTIONAL INFORMATION TO COMPLETE THIS ARTICLE:

s. Insert the specific information applicable to this Article.)****

ARTICLE H.65. CONFIDENTIALITY OF INFORMATION

- Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

- The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

- If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

- Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

- Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

- Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

- The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR R&D EXCEPT PHASE I SBIR/STTR AND CONTRACTS WITH FEDERAL AGENCIES.)****

ARTICLE H.66. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

As required by 45 CFR Part 94, the Institution shall, at a minimum:

- Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    a. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;
    b. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve

months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

c. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

a. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
b. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

- Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

- Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

- Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

- Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s),

reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

- Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

- Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

- Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

- Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

- Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.
The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests.. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.
If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been

designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

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****(USE BELOW, IN ALL R&D AND R&D SUPPORT SOLICITATIONS AND CONTRACTS. THIS MAY ALSO BE USED IN OTHER CONTRACTS AT THE DISCRETION OF THE CONTRACTING OFFICER.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

t. **Second Paragraph (acknowledgment**): Insert the appropriate Institute/Center (I/C) and contract number in their respective text boxes.)****

ARTICLE H.67. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the _____ , National Institutes of Health, Department of Health and Human Services, under Contract No. _____ "

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****(FOR NIAID: INSERT BELOW IN ALL CONTRACTS THAT READS SUBSTANTIALLY AS FOLLOWS)****

- **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall ensure that the Contracting Officer's Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

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****(NCI ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

- **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any

medium, excluding peer-reviewed scientific publications. The Contractor shall not publish a press release related to this contract without receiving prior concurrence from the Contracting Officer. The Contractor shall submit an advance copy of the press release to the Contracting Officer and Contracting Officer's Representative (COR). Upon acknowledgment of receipt, the Contracting Officer will have five (5) working days to respond with concurrence or comments. In the event that the Contracting Officer does not communicate concurrence or comments to the Contractor within five (5) working days following acknowledgement of receipt of the press release advance copy, concurrence may be presumed.

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****(NHLBI: USE BELOW IN ALL NHLBI SOLICITATIONS AND CONTRACTS.)****

ARTICLE H.68. REVIEW OF MANUSCRIPTS

In order to balance the oversight responsibility of the National Heart, Lung, and Blood Institute (NHLBI) with the authorization provided the Contractor by the Rights in Data clause of this contract, the NHLBI has established a process to review manuscripts produced under this contract. Please note that the NHLBI does not require Contractors to seek the Institute's approval of manuscripts.

In order to have sufficient time to conduct a meaningful review, please provide to the Institute's Contracting Officer's Representative (COR) and Contracting Officer advance notice of intent to submit a manuscript for publication at least 45 days prior to submission to the publisher. The advance notice should briefly describe the plans for publication of the manuscript. Concurrently or as soon as possible following this notice, provide a copy of the manuscript to the COR.

Any comments from the NHLBI will be provided in writing within 15 days after receipt of the manuscript by the COR. Comments expressed by the NHLBI about the manuscript shall not be a cause for action under the Disputes clause of the contract by either NHLBI or the Contractor, since the NHLBI does not approve manuscripts and draft manuscripts are not contract deliverables.

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****(NHLBI: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN THERE IS A REQUIREMENT FOR THE DELIVERY OF A DATA SET.)****

ARTICLE H.69. NHLBI DATA REPOSITORY OF EPIDEMIOLOGY AND CLINICAL TRIALS

The National Heart, Lung, and Blood Institute (NHLBI) has supported data collection from participants in numerous clinical trials and epidemiologic studies. These data from well-characterized population samples constitute an important scientific resource. It is the view of the NHLBI that their full value can only be realized if they are made available, under appropriate terms and conditions consistent with the informed consent provided by

individual participants, in a timely manner to the largest possible number of qualified investigators.

Data sets distributed under this policy include only data with personal identifiers and other variables that might enable individual participants to be identified, such as outliers, dates, and study sites, removed or otherwise modified. Because it may still be possible to combine the data with other publicly available data and thereby determine with reasonable certainty the identity of individual participants, these data sets are not truly anonymous. They are, therefore, only provided to investigators who agree in advance to adhere to established policies for distribution.

Investigators shall provide data sets in accordance with the NHLBI Data Set policy at https://biolincc.nhlbi.nih.gov/home/ . All changes to the policy are hereby incorporated by reference without further amendment to the contract. Data sets are a deliverable under this contract for this trial or study, as described in Section C. Description/Specification/Work Statement and/or Section F. Deliveries or Performance of the contract.

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****(USE BELOW, FOR MULTIPLE AWARD TASK ORDER OR DELIVERY ORDER CONTRACTS.

ADDITIONAL INFORMATION FOR COMPLETING THIS ARTICLE:

- Select the appropriate individual based on the type of contract awarded (e.g. R&D vs Non R&D).
- Include the complete address if multiple awards will be made (See FAR 16.504(a)(4)(v).
- Delete the name and address of the non-applicable individual.)****

ARTICLE H.70. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with FAR 16.505(b)(5), the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

Dr. Sherry Mills	**OR**	Dr. Richard G. Wyatt
NIH Competition Advocate for R&D Contracts		NIH Competition Advocate for Non R&D Contracts
6705 Rockledge Drive, Suite 305		1 Center Drive, 160, MSC 0151
Bethesda, MD 20892		Bethesda, MD 20892-0151
Phone: 301-435-2729		Phone: (301) 496-4920
E-mail: sherry.mills@nih.gov		E mail: WyattRG@mail.nih.gov

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****(USE BELOW, IN ALL SOLICITATIONS AND CONTRACTS.)****

ARTICLE H.71. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: https://oig.hhs.gov/fraud/report-fraud/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR A/E, CQM SERVICES, CONSTRUCTION, DESIGN-BUILD AND FACILITIES SERVICES.)****

ARTICLE H.72. INSURANCE

- The Contractor shall, at his own expense, procure and maintain, during the entire performance period of this contract, insurance of at least the kinds and amounts set forth below:

    a. Worker's Compensation and Employer's Liability

    Contractors are required to comply with applicable Federal and State worker's compensation and occupational disease statutes. Employer's liability coverage of at least $100,000 shall be required except in states with exclusive or monopolistic funds that do not permit workers' compensation to be written by private carriers.

    b. General Liability

    Contractors are required to have bodily injury liability insurance coverage written on the comprehensive form of policy of at least $2,000,000 per occurrence.

    c. Automobile Liability

    The Contractor is required to have automobile liability insurance written on the comprehensive form of policy. The policy shall provide for bodily injury and property damage liability covering the operation of all automobiles used in

connection with performing the contract. Policies covering automobiles operated in the United States shall provide coverage of at least $200,000 per person and $500,000 per occurrence for bodily injury and $20,000 per occurrence for property damage. The amount of liability coverage on other policies shall be commensurate with any legal requirements of the locality and sufficient to meet normal and customary claims.

- At all times during performance, the Contractor shall maintain with the Contracting Officer a current Certificate of Insurance showing at least the insurance required by the Schedule, and providing for thirty (30) days written notice to the Contracting Officer by the insurance company prior to cancellation or material change in policy coverage.

- The Contractor shall also require all first-tier subcontractors who will perform work on a Government installation to procure and maintain the insurance required by the Schedule during the entire period of their performance. The Contractor shall furnish (or assure that there has been furnished) to the Contracting Officer a current Certificate of Insurance meeting the requirements of 1. above for each such first-tier subcontractors, at least five (5) days prior to entry of each subcontractor's personnel on the Government installation.

- Current certificates of insurance shall be furnished by the Contractor and first tier subcontractor(s) to the Contracting Officer before starting work under the contract.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, DESIGN-BUILD AND FACILITIES SERVICES.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

u. **Last (4th) Paragraph:**

a. **For Contracts:** Select the first sentence from the drop-down box.

b. **For Solicitations:** Select the second sentence from the drop-down box.)****

ARTICLE H.73. HEALTH AND SAFETY PLAN

The Contractor is responsible for safety at the construction or work site. The Contractor is also responsible for preparation of a safety plan and for carrying out the safety plan. The Contractor staff shall maintain conformance to the health and safety plan throughout the course of construction.

Contractor inspectors shall consider safety a key element of their daily inspections.

The Contractor is required to cooperate with officials of other agencies (Federal and/or state) who are vested with authority to enforce requirements of the Occupational Safety and Health Act. If required, the Contractor will assist the Government in preparing accident

and fire reports.

[The Contractor shall comply with the following NIH Health and Safety Requirements./The resultant contract will require the Contractor to comply with the following NIH Health and Safety Requirements.]

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, DESIGN-BUILD AND FACILITIES SERVICES.)****

ARTICLE H.73.1. CONTRACTOR REQUIREMENTS

- At a minimum, the Contractor shall comply with applicable Occupational Safety and Health Administration (OSHA) Regulations. Construction, renovation, alteration and maintenance services must adhere to the provisions of the US Army Corps of Engineers Safety and Health Manual 385-1-1 (EM 385-1-1). If there is a conflict between the two, the more strict regulation or provision will be adhered to.
- Each contract employee is responsible for complying with applicable safety and occupational health requirements, wearing prescribed safety and health equipment, reporting unsafe conditions/activities, and avoiding actions and conditions that may result in an accident.
- The Contractor will not commence services authorized under this contract without first submitting for review each deliverable specified in section "DELIVERABLES". Copies of each deliverable must be provided to the NIH Contracting Officer, NIH Contracting Officer's Representative, and the Division of Occupational Health and Safety (DOHS) Safety Officer (safety@nih.gov).
- Prior to commencing contract services, the Contractor's Project Manager, NIH Contracting Officer's Representative, and DOHS Safety Officer shall meet to review and discuss the safety requirements of this contract. The Contractor's Project Manager is responsible for scheduling the meeting arrangement. The purpose of the meeting is to verify that project hazards have been identified and appropriately controlled.
- The Contractor is responsible for ensuring that all of its subcontractors are compliant with all of the Contractor requirements outlined in this section.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, DESIGN-BUILD AND FACILITIES SERVICES **UNLESS** A WAIVER HAS BEEN GRANTED.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

Subparagraph b:

v. **When No Waiver has been granted:** Include this subparagraph b. as is.

w. **When a Waiver has been granted by the ORF Health & Safety Officer:** Delete this subparagraph b. and **ADD** a state that a waiver has been granted and the date granted.)****

ARTICLE H.73.2. WAIVER FROM NIH IMPOSED CONTRACTOR HEALTH AND SAFETY REQUIREMENTS

- The Contractor may request a waiver from the requirements contained in the Contractor Health and Safety Requirements section. The waiver does not release the Contractor, subcontractor, or any party associated with this contract from federal, state, and local health and safety requirements.

- The following must be addressed used when requesting a waiver or a variance:

  a. The request must state the specific Contractor Health and Safety Requirement to be waived. State the period of time the requested waiver will cover.
  b. Details as to why it is not possible or practical to comply with the requirement.
  c. The request must explain the impact on the Contractor operations and services if this waiver is not approved.
  d. Statement as to whether a waiver (total elimination of the requirement) or a variance (retaining the basic requirement, but doing it differently) is being sought;
  e. Explanation of the method the Contractor suggests to use in lieu of the existing requirement and how it provides protection equal to or greater than the requirement under waiver review. The burden of proof rests with the requesting Contractor.
  f. The waiver request must be submitted to the NIH Contracting Officer, the NIH Contracting Officer's Representative and DOHS Safety Officer (safety@nih.gov) prior to commencing services.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, DESIGN-BUILD AND FACILITIES SERVICES.)****

ARTICLE H.73.3. NIH REQUIRED SAFETY TRAINING MANDATE

- As a minimum all Contractor and subcontractor personnel working at NIH shall be certified as having successfully completed the OSHA 10-hour General Industry Outreach

class or OSHA 10-hour Construction Industry Outreach class. The OSHA 30-hour course can be substituted for the 10-hour course.

- Proof of completion may be demonstrated through either: 1) the presentation of a bona fide student course completion card issued by the federal OSHA Training Institute; 2) or the presentation of documentation provided to an employee by a trainer certified by the Institute pending the actual issuance of the completion card.

- Any card with an issuance date more than three (3) years shall not constitute proof of compliance with this requirement.

- Any employee required to complete the safety and health course required under this section who has not completed the course shall be subject to removal from the worksite if the employee does not provide documentation of having completed such course by the fifteenth day after the date the employee is found to be in noncompliance.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, DESIGN-BUILD AND F/ACILITIES SERVICES.)****

ARTICLE H.73.4. NIH SAFETY PROFICIENCY REQUIREMENTS

- Contractor Safety Program Assessment: The NIH is committed to providing a safe environment for its employees, guests, and patients. Safety, as demonstrated during previous contracts, may be used in the past performance evaluation of a Contractor. Contractors are required to enroll in the Contractor Safety Assessment Program (CSAP). The prime Contractor is responsible for ensuring that all subcontractors have completed the CSAP prior to beginning work at NIH. This program is used to assess Contractor's commitment to safety through a review of lagging and leading indicators. Contractors with a low assessment scores will be required to address program deficiencies prior to performing work. The assessment process requires the following items:

- Company Information
- Insurance Experience Modification Rate (EMR)
- General Liability Claims
- OSHA Citation History (previous three years)
- Safety Program Elements

To enroll in CSAP: create an account at https://www.constructsecure.com/nih and enter the requested information. There is no fee to complete the assessment. Upon completion of the assessment a certification will be available to download. The certificate must be provided to the NIH Contracting Officer's Representative and NIH Contracting Officer.

- As a minimum requirement, all Contractor and subcontractor personnel working at NIH owned or leased property shall be certified as having successfully completed the OSHA

10-hour General Industry Outreach course or OSHA 10-hour Construction Industry Outreach course. The OSHA 510 Occupational Safety and Health Standards for Construction or the OSHA 511 Occupational Safety and Health Standards for General Industry course can be substituted for the 10-hour OSHA class.

x. Proof of completion may be demonstrated through either: 1) the presentation of a bona fide student course completion card issued by an approved federal OSHA training provider; or 2) the presentation of documentation provided to an employee by a certified OSHA Outreach Instructor pending the actual issuance of the completion card.
y. Employees shall be prepared to provide proof of training upon request.
z. Any card with an issuance date more than 3 years shall not constitute proof of compliance with this requirement.
aa. Any employee required to complete the safety and health course required under this section who has not completed the course shall be removed from the worksite until the required training is completed.

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ARTICLE H.73.5. CONTRACTOR SUPERVISOR ORIENTATION

- Prior to commencing work, ensure that all Contractor and subcontractor site supervisors, at any tier, have completed the NIH Contractor Supervisor Orientation. The time expended and any associated costs to attend the orientation (such as travel time, parking, and other expenses) are to be borne by the Contractor.
- It is the responsibility of the Contractor and subcontractor to contact the DOHS Safety Officer to register each supervisor for orientation. Orientation must be completed prior to commencing contract services or the date that the supervisor is assigned to NIH. Contact the ORF Safety Officer (safety@nih.gov) or by phone (301) 496-2960 for the orientation schedule.

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ARTICLE H.73.6. DELIVERABLES

- The deliverables below must be affirmed and provided to the NIH Contracting Officer, NIH Contracting Officer Representative and DOHS Safety Officer (safety@nih.gov). All deliverables shall be submitted by email prior to the commencement of work activities. The deliverables must be in either MS Word or Adobe Acrobat format. Deliverables include:

- The submission of a site specific accident prevention plan completed in accordance with the Army Corps of Engineers Safety Manual Appendix A, EM 385-1-1 (including activity hazard analysis worksheets).
- The submission of the Contractor Safety Assessment Program certification (https://www.constructsecure.com/nih) for the Contractor and each sub-contractor.
- The submission of the curriculum vitae (a.k.a. resume) of the Contractors' assigned site safety and health officer to oversee the contract operations.
- Verification of OSHA 10-hour training certification (i.e. general industry or construction) requirements for on-site personnel and other appropriate training (i.e. 1st Aid/CPR, etc.).
- The completed and submitted "Affirmation of NIH Contractor Safety Deliverables" form.

- The DOHS Safety Officer will notify the Contractor once the deliverables have been accepted. Acceptance of the deliverables by the NIH indicates only that the Government has received the item. Acceptance of a deliverable does not waive or lessen any contract requirements or the Contractor's obligation to meet all contract requirements and correct any later discovered deficiencies. Nor does acceptable by the Government imply that the deliverables or material contained within are adequate to prevent injury or illness.
- Delays caused by failure to timely submit the required documentation shall not be considered a reason for extension of contract time or increase in costs to the Government.

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ARTICLE H.73.7. SITE SPECIFIC ACCIDENT PREVENTION PLAN

The Contractor shall submit a Site Specific Accident Prevention Plan, to the NIH Contracting Officer's Representative and the DOHS Safety Officer at safety@nih.gov, one week prior to the commencement of work for NIH's review and comment. The submittal shall contain the "Contract Number" and "Project Name" in the subject line.

For construction, renovation, alteration, and maintenance services the contents of the Contractor's Site Specific Accident Prevention Plan will be in accordance with Appendix A, EM 385-1-1. See https://www.publications.usace.army.mil/Portals/76/Publications/EngineerManuals/EM_385-1-1.pdf

Activity Hazard Analysis (AHA) shall be prepared for all field, laboratory, industrial, and maintenance activities. As outlined in Appendix A, EM 385-1-1, an AHA shall be completed

for each major phase of work or service and included in the Site Specific Accident Prevention Plan.

Note: For LIMITED-SCOPE SERVICE, SUPPLY, AND R&D CONTRACTS, (e.g. painting, janitorial service), the DOHS Safety Officer may allow an Abbreviated Accident Prevention Plan (see EM 385-1-1) and waive the more stringent elements of the comprehensive plan. The Contractor must make a written request to the DOHS Safety Officer safety@nih.gov and provide copy to the NIH Contracting Officer's Representative.

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ARTICLE H.73.8. CONTRACTOR FULLY RESPONSIBLE FOR SITE SAFETY

- The Contractor assumes full and sole responsibility for ensuring the safety of its personnel and sub-contractors.

The Contractor shall comply with all laws, regulations ordinances, and governmental orders pertaining to employee worksite safety in the performance of this contract. Nothing the NIH may do, or fail to do, with respect to safety in the performance of the scope of work shall relieve the Contractor of this responsibility.

- The Contractor shall be responsible for employing appropriate safety measures and taking all other actions reasonably necessary to protect the life, health, and safety of the public and to protect adjacent and NIH-owned property in connection with the performance of the scope of work. Personal protective equipment shall be selected for anticipated hazards and provided to the employee. Employees shall be instructed on the proper wear, maintenance, and limitations of the PPE.

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ARTICLE H.73.9. SELECTION OF CONTRACTOR SITE SAFETY AND HEALTH OFFICER

- When the number of personnel on any shift is under 40 (including subcontractor employees), the Contractor's safety representative meeting the definition of "Collateral Duty Safety Officer" as defined in Section titled "SITE SAFETY AND HEALTH OFFICER" paragraph a) 2) CONTRACTOR SITE SAFETY AND HEALTH OFFICER shall be present on the project site.
- For Contractors with a total of 40 or more personnel (including subcontractor employees) on any shift, a Full-time Safety Professional as defined in Section titled "SITE SAFETY AND HEALTH OFFICER" paragraph a) 1) CONTRACTOR SITE SAFETY AND HEALTH OFFICER shall be present on the project site.

- At the discretion of the NIH Contracting Officer's Representative or DOHS Safety Officer, the requirements for the Contractor Safety and Health Officer can be reviewed and action taken to decrease or increase the number of onsite Contractor safety representatives. However, the need for a Contractor Safety and Health Officer is required and will not be waived.

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ARTICLE H.73.10. CONTRACTOR SITE SAFETY AND HEALTH OFFICER RESPONSIBILITIES

- The responsibility for safety lies with the Contractor. Each Contractor shall appoint an individual(s) responsible for contract personnel safety. This individual(s) must be employed in a supervisory position, empowered by their employer to take corrective action; be present on the project while work is being performed; and spend the amount of time necessary to ensure the Contractor's compliance with safety requirements.
- The Contractor Site Safety and Health Officer shall be primarily responsible for ensuring the safe work performed under this contract. Without limiting the generality of the foregoing, the Contractor Site Safety and Health Officer shall:
  - Review all subcontractor and sub-tier Contractor's Site Specific Accident Prevention Plan and Activity Hazard Analysis for compliance with applicable safety standards.
  - Perform or ensure that all Contractor, subcontractors and sub-tier Contractors' employees have received a site specific safety orientation prior to beginning work. Training will include discussion of the Site Specific Accident Prevention Plan and Activity Hazard Analysis worksheets. This site specific orientation is in addition to the NIH's Contractor Supervisor Safety Orientation course.
  - Regularly perform and document worksite inspections, assess hazards, and immediately correct any safety deficiencies, including those of any subcontractor. The Contractor shall specifically respond in writing to any substandard safety conditions or practices identified by the NIH. Inspection records shall be maintained at the project site and be made available upon request by the NIH Contracting Officer's Representative or DOHS Safety Officer.
  - Immediately report all personnel injuries, vehicle accidents, near miss incidents, and property damage within 24-hours to both the NIH Contracting Officer's Representative and DOHS Safety Officer (safety@nih.gov). Undertake a complete investigation of all accidents, injuries, illnesses, and near-misses (in the opinion of either the Contractor or NIH representatives) and implement corrective actions to prevent recurrence. Upon request, written findings shall be provided to NIH representatives.
  - Ensure appropriate safety meetings are held for all onsite employees, to include subcontractors. Safety meetings shall be conducted to review past activities, plan for new or changed operations, review pertinent aspects of appropriate Activity Hazard

Analyses, establish safe working procedures for anticipated hazards, and provide pertinent safety and health training and motivation.

i. Meetings shall be conducted at least once weekly for all workers.

ii. Meetings shall be documented, including the date, persons in attendance, subjects discussed, and names of individual(s) who conducted the meeting. Documentation shall be maintained and copies furnished to the NIH on request.

- Be responsible for the control, availability, and use of necessary safety equipment, including personal protective equipment and apparel for the employees.

- A Contractor Site Safety and Health Officer not performing his/her duties in accordance with the contract clauses, shall be replaced by the Contractor, or at the NIH's discretion.

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ARTICLE H.73.11. SITE SAFETY AND HEALTH OFFICER DEFINITIONS

- ORF SAFETY OFFICER

  An employee of the NIH, or designated representative who is responsible for management of the Office of Research Facilities Development and Operations (ORF) Safety Program.

- NIH CONTRACTING OFFICER REPRESENTATIVE (COR)

  An employee of the NIH or designated representative who conducts and monitors jobsite inspections and verifies Contractor compliance with identified corrective actions.

- CONTRACTOR

  The General Contractor contracted with NIH.

- CONTRACTOR SITE SAFETY AND HEALTH OFFICER

  The Contractor Site Safety and Health Officer(s) will be categorized as either a Full-time Safety Professional or a Collateral Duty Safety Officer based on the scope and size of the project.

  a. Full-time Safety Professional qualifications include:

     i. He/She shall have no other duties.

ii. An individual possessing a minimum of five years progressive experience managing safety programs on large projects comparable to this contract in scope and complexity.
iii. Be knowledgeable concerning all federal, state, and local regulations applicable to construction and industrial safety.
iv. Possess "Competent Person" certification in safety disciplines related to the work performed and possess verifiable training. This individual shall also be responsible for identifying "Competent Persons" required by state and federal safety standards for which they are not certified.
v. Have successfully completed the OSHA 500 Trainer Course in OSHA Standards for Construction or OSHA 501 Trainer Course in OSHA Standards for General Industry. This requirement may be waived in lieu of an accredited safety and health degree or professional safety or industrial hygiene certification (i.e. CSP or CIH).
vi. Be trained in, and possess current certification for CPR and First Aid.
vii. Be capable of performing accident investigations and developing a concise written report.
viii. Is proficient in the development and presentation of "tool box" meetings and safety training.

b. Collateral Duty Safety Officer qualifications include:

i. An individual assigned to perform safety functions on any contract not requiring a Full-time Safety Professional. This can be a collateral duty position held by a supervisor.
ii. Possess a minimum 5 years progressive experience in their trade.
iii. Be knowledgeable concerning all federal, state, and local regulations applicable to safety.
iv. Have successfully completed the OSHA 30-Hour Course in OSHA Standards for Construction or OSHA 30-Hour Course in OSHA Standards for General Industry.
v. Possess "Competent Person" certification in safety disciplines related to the work performed and possess verifiable training. This individual shall also be responsible for identifying "Competent Persons" required by state and federal safety standards for which they are not certified.
vi. Be trained in, and possess current certification for CPR and First Aid.
vii. Possess verifiable training and be capable of performing accident investigations and developing a concise written report.

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ARTICLE H.73.12. CONTRACTOR SAFETY AND HEALTH OFFICER QUALIFICATIONS

Prior to commencing services or assignment to the contract, the Contractor shall submit a resume to the NIH Contracting Officer's Representative and the DOHS Safety Officer (Safety@nih.gov) identifying the experience and qualifications for the proposed Contractor Safety and Health Officer(s). The NIH Contracting Officer's Representative or DOHS Safety Officer may reject individuals deemed "Not Qualified" if the proposed personnel does not meet the qualifications outlined in Section titled "SITE SAFETY AND HEALTH OFFICER".

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ARTICLE H.73.13. GENERAL OBLIGATIONS

The Contractor is responsible for accident prevention and worksite safety. This responsibility cannot be delegated to subcontractors, suppliers, the NIH, or other persons. To this end, the Contractor shall:

- Promote a safe and healthy work environment.
- Provide a Site Specific Accident Prevention Program.
- Ensure subcontractors and employees are adequately trained in occupational safety and health topics relevant to the activities to be performed under this contract. This includes, but not limited communication and training of anticipated hazards (e.g. chemical, physical, biological, etc.). Maintain documentation of the employee training, to include the date and subject taught and be prepared to present upon request.
- Instruct all employees of safe work methods and practices when assigning work.
- Ensure that employees have, use, and understand the limitations of the proper protective equipment and equipment for the services performed under the contract.
- Ensure that all heavy equipment operators (i.e. lasers, heavy equipment, etc.) are properly qualified and trained on the specific piece of equipment in use. Such verification shall be readily available upon request.
- Cooperate fully with the NIH and its representatives in connection with all matters pertaining to safety.
- Conduct a documented orientation training session for new employees that includes at a minimum, a review of:
    a. The Site Specific Accident Prevention Plan
    b. Potential hazards in assigned work areas
    c. Proper wear of required personal protective equipment
    d. Methods to mitigate anticipated hazards
    e. Emergency response procedures

- Ensure that all of its subcontractors, suppliers delivering materials or services to the worksite, etc., are provided with a copy of this specification and are informed of their

obligations regarding worksite safety under this requirement. Ensure that provisions are documented and available upon request.

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ARTICLE H.73.14. ACCIDENT PREVENTION

- The Contractor shall be responsible for correcting hazardous conditions and practices.
- If it is determined there is an immediate threat of harm to anybody, the Contractor shall:
    a. Take immediate action to remove/safeguard personnel from the hazard and stabilize or stop work until corrective actions can be implemented to eliminate the hazard.
    b. Immediately notify the NIH Contracting Officer's Representative and the DOHS Safety Officer via (safety@nih.gov) or by phone (301) 496-2960.

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ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Subparagraph a:** Check to make sure contact information below is current and update as may be required.)****

ARTICLE H.73.15. CONTRACTOR INJURIES AND ILLNESSES

- Injury or illness resulting from work under this contract shall be reported to the NIH Contracting Officer's Representative and DOHS Safety Officer (safety@nih.gov) within 24-hours of the incident.
- For work conducted at remote locations where emergency medical service personnel are not capable of responding within 4-minutes, at least two persons shall be available at the work site at all times to render first aid and CPR. These personnel must have a valid certificate in first-aid and CPR from the U.S. Bureau of Mines, the American Red Cross, or equivalent verifiable training program. A minimum ratio of one such qualified person for every 25 employees shall be maintained throughout the project, but no less than 2 qualified persons at any time.
- The Contractor is required to have and maintain at the worksite a first-aid treatment kit adequate for the anticipated hazards and number of personnel.

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ARTICLE H.73.16. NIH RIGHTS

- INSPECTIONS/INVESTIGATIONS
    a. The NIH Contracting Officer's Representative may, in any reasonable manner, observe and inspect the Contractor's safety and accident prevention procedures for all activities and personnel. This specifically includes, but is not limited to, the right to attend all safety meetings.
    b. Upon request, the NIH Contracting Officer's Representative shall receive copies of any safety inspection reports completed by the Contractor or anyone performing work for, on behalf of, or under the Contractor.
    c. The NIH Contracting Officer's Representative may, in any reasonable manner, observe or participate in any accident investigation conducted by the Contractor or anyone performing work for, on behalf of or under the Contractor. The NIH may also, at its sole discretion and in any reasonable manner, undertake its own accident investigation.

- CORRECTIVE ACTIONS/STOP-WORK
    a. The NIH Contracting Officer's Representative shall have the right to direct the Contractor to correct unsafe working conditions, including taking corrective action when unsafe working conditions are observed (i.e. lack of good housekeeping practices, use of equipment in obviously poor condition, failure to adhere to statutory OSHA regulations, etc.).
    b. The NIH Contracting Officer's Representative shall have the right to require the removal, from the project, any person, property, or equipment that, in the NIH's opinion, is deemed unsafe.
    c. The NIH Contracting Officer's Representative shall have the right to instruct the Contractor to immediately cease any action and/or stop work (or any action thereof) when any conditions exist that, in the NIH's opinion, constitutes an imminent danger or could result in serious harm.
    d. The NIH Contracting Officer's Representative shall have the right to suspend the work pending the completion of any accident/incident investigation, whether undertaken by the Contractor, the NIH, or other parties of interest.
    e. The Contractor is responsible for costs, expenses, and other obligations paid or incurred, as a result of the Contractor or subcontractor's noncompliance with federal, state, or local safety regulations; or failure to comply with terms and conditions of this contract.

- NIH'S ACTION/INACTION DOES NOT RELIEVE CONTRACTOR

  Nothing the NIH may do, or fail to do, with respect to safety in the performance of the work shall relieve the Contractor of its responsibility to comply strictly with this Contract and all standards referenced in this document.

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ARTICLE H.73.17. SPECIFIC SAFETY PROVISIONS

In addition to federal, state, and local regulations pertaining to operations and safety, the Contractor shall adhere to the following NIH mandated safety requirements:

- Asbestos: Many of NIH's buildings have asbestos-containing materials. It is the Contractor's responsibility to coordinate with the NIH Contracting Officer's Representative to ensure that a survey for asbestos is conducted prior to commencing work. The Contractor shall ensure that all personnel who may disturb building materials have received and documented initial and annual Asbestos Awareness training prior to the start of work.
- Entry into Confined Spaces: The Contractor shall provide the NIH Contracting Officer's Representative a copy of its Confined Space Entry Program as part of the Site Specific Accident Prevention Plan.
    a. Should the Contractor employ subcontractors to work in confined spaces, it shall be the Contractor's responsibility to submit the required documentation for each subcontractor.
    b. Work shall not start in a confined space until the required submittals have been made and appropriate safety precautions have been taken by the Contractor or its subcontractors. In the event the Contractor does not comply with these regulations; ACCESS WILL BE DENIED.
    c. Personnel working in confined spaces must be trained in accordance with OSHA regulations.
- Entry into mechanical spaces requires proper wear of head, eye, and hearing protection.
- Wood and metal ladders are prohibited for personnel use. Fiberglass or ladders formed from non-conductive materials are appropriate.
- Electrical - Safe Clearance Procedures:
    a. Entry into High Voltage Areas: Work under this contract may require entry into High Voltage Areas.
    b. In the event entry is required, the Contractor is obligated to identify any High Voltage areas that may be involved in work under this contract. Before entry into a High Voltage work area, the Contractor shall notify the NIH Contracting Officer's Representative.
    c. To prevent employee exposure or damage to electrical systems the Contractor shall exhaust all options and means to de-energize live electrical parts in accordance with OSHA lock-out/tag-out requirements. Work around energized components requires appropriate safety training and PPE.
- Fire Prevention: The Contractor shall ensure that the fire prevention measures on-site are in accordance with OSHA, NIH Division of Fire Protection policies, and the National

Fire Protection Association standards.
Approved safety cans (approved or listed by a nationally recognized testing laboratory) shall be used for flammable and combustible liquids. Fire extinguishers shall be provided by the Contractor where required.

a. Open Flame Devices: Prohibit the use of unapproved fuel-burning types of lanterns, torches, flares or other open-flame devices on NIH property.
b. Hot Work Permit: Open flame welding and spark producing equipment and tasks require the Contractor to secure a "Hot Work Permit" from the NIH Fire Department. This can be obtained by calling the NIH Fire Marshall at (301) 496-0414.

- Excavating and Trenching:
    a. Excavations and trenches shall be evaluated for confined spaces before entry.
    b. Ensure a Competent Person inspects the excavation or trench before work begins and as needed during the shift. When the Competent Person finds evidence of a hazardous condition, exposed employees shall be removed from the hazardous areas until the necessary precautions have been taken to ensure their safety.
    c. All excavations, regardless of depth, shall be barricaded or covered. If barricades are utilized and are left overnight they shall be equipped with appropriate lights or reflectors.
    d. Walkways shall be provided where employees or equipment are required or permitted to cross over excavations. When walkways are utilized, a guardrail system shall be in place.
- Activities that pose a potential risk of exposure to hazardous materials during remediation activities shall be supervised by personnel who have a current 40-hour Hazardous Waste Supervisor's certification and available upon request. These individuals shall be able to identify the potential need for upgrading the level of health and safety protection. All personnel working in direct contact with hazardous materials shall have a current 40-hour Hazardous Waste Operations certification and medical monitoring, in accordance with OSHA regulations. The Contractor is responsible for personnel monitoring to determine hazards and exposures to their employees.
- Cranes and Hoisting Operations:
  A written lift plan shall be submitted for all crane operations. The written lift plan will include as a minimum:
    a. Make and model of the crane
    b. Name of the crane operator, documentation of training and competent person responsible for the execution of the lift plan.
    c. A copy of the crane's most recent certificate of annual inspection.
    d. A copy of the cranes maximum loads at various boom angles and radii.
    e. Utilizing the crane boom angle and radius information identify all loads that will exceed 75% of the crane capability.
    f. Identify if two or more cranes are required.

g. Provide a sketch or drawing of the anticipated boom angle, radius, center of gravity and crane placement.
h. Provide a sketch or drawing of anticipated rigging methods to include:
    i. Number of slings
    ii. Type of configuration
    iii. Size and length of slings
    iv. Rated capacity of slings
    v. Sling angle
    vi. Size, number and rated capacity of shackles
i. Identify number of ground handlers and location of ground handlers
j. Communication method between ground handlers and crane operator
k. Location of material staging area
l. Method of managing vehicle and pedestrian traffic

- Chemical Exposure Plan: The Contractor shall submit a Chemical Exposure Plan for any products containing isocyanates, methylene chloride, lead, silica, hydrofluoric acid and processes involving floor sealers, traffic coatings, terrazzo sealers, specialty paints or any other chemical which can produce nuisance odors. The plan shall include employee exposure control methods, isolation methods to prevent spread of chemicals and odors outside the work area and safeguarding of the NIH employees and public. Safety Data Sheets for each chemical must be maintained on site and available upon request.
- Protection of the Public: The Contractor shall submit a plan for the protection of the public on or adjacent to construction and demolition operations.

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ARTICLE H.73.18. SAFETY PERFORMANCE

- If the Contractor experiences repeated safety violations or fails to abate violations in a timely manner, the Contractor shall be subject to any of the following actions, at the Contracting Officer's Representative or Contracting Officer's discretion:
    a. Removal and replacement of management personnel.
    b. Submitting a written safety recovery plan detailing what changes will be made to their safety program and a timeline as to when the changes will be implemented.
    c. Hiring an independent health and safety consultant who shall audit the Contractor's procedures and operations. The consultant shall compile a plan detailing what changes the Contractor shall implement. This report shall be submitted to the NIH Contracting Officer's Representative.
    d. Conduct a "Safety Stand Down" (suspend all work or any action thereof).
    e. Issue a cure notice notifying that the Contractor has failed to comply with a contract requirement and directing that the deficiency be "cured" within a

specified time period.

- Costs incurred by the Contractor to abate hazards or to respond to actions noted in this Safety Performance Section shall not be considered a reason for extension of contract time or increase in costs to the Government.

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ARTICLE H.73.19. HEALTH AND SAFETY REQUIREMENTS

The Contractor is responsible for safety at the construction or work site. The Contractor is also responsible for preparation of a safety plan and for carrying out the safety plan. The Contractor staff shall maintain conformance to the health and safety plan throughout the course of construction.

Contractor inspectors shall consider safety a key element of their daily inspections.

The Contractor is required to cooperate with officials of other agencies (Federal and/or state) who are vested with authority to enforce requirements of the Occupational Safety and Health Act. If required, the Contractor will assist the Government in preparing accident and fire reports.

The Contractor shall comply with the following NIH Health and Safety Requirements:

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ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Subparagraph C:** Select the Contracting Officer or the Contracting Officer Representative (COR) from the drop-down box as appropriate. Note: If another individual will be designated for notification, delete the drop-down box and enter the Name and/or Title of the appropriate individual.)****

ARTICLE H.74. SECURITY

GENERAL

- The Contractor and all subcontractor's personnel will observe and adhere to all National Institutes of Health (NIH) security regulations and requirements when using or providing services on the NIH property. The Contractor shall be responsible for subcontractor compliance and include specific provisions in all subcontracts that these regulations be accepted.

- The Contractor shall be accountable for compliance with the provisions of this Section by all individuals and entities employed by or under contract to the Contractor.

- Notification: Notify the [Contracting Officer (CO)/Contracting Officer Representative (COR)] or a designated representative, not less than 48 hours prior to performing work in a restricted-access area as defined by the NIH. Include the following:
    a. Companies: Name of each company performing the work.
    b. Personnel: Name, social security number, date and place of birth, citizenship and, where applicable, visa status of each individual who is to work.
    c. Time: The exact time, date, and hours of work.
    d. Areas: Specific areas of the building in which work is to be performed.

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ARTICLE H.74.1. CONTRACTOR RESPONSIBILITY

- Contractors shall be responsible for security of their property and material from theft and vandalism.

- The Government does not accept responsibility for loss or damage to any property or work it has not accepted.

- Contractors shall be responsible for excluding all but authorized persons from their work sites.

- Contractors and their employees shall immediately report any known violations of law or regulations, or the discovery of unaccountable property, either private or Government-owned, to the Contracting Officer Representative (COR).

- Conduct on Federal Property: Contractors are advised that operating a motor vehicle when entering upon or while on NIH property by a person under the influence of alcoholic beverages, narcotic drugs, including hallucinogens, marijuana, barbiturates or amphetamines, is prohibited. Entering upon the property, or while on the property, under the influence of, or using, or possessing any narcotic drug is prohibited. Such prohibition shall not apply in cases where the drug has been prescribed by a physician. Entering upon the property, or being on the property, under the influence of alcoholic beverages is prohibited. The use or possession of alcoholic beverages on NIH property is prohibited unless, upon occasions and at specific locations which the Director, NIH, or his delegated official has for appropriate official uses, granted an exemption in writing.

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ARTICLE H.74.2. CONTRACTOR SECURITY PLAN

- Upon award of contract for this requirement, the Contractor shall develop and submit for approval a Contract specific Contractor Security Plan. The Contractor Security Plan shall encompass all administrative, physical, and operational security requirements noted in this specification section for all persons and subcontractors under this Contract.

- The Contractor shall, within 10 days receive Contractor Security Plans from each subcontractor or other entity to be engaged under the Contract, and shall furnish evidence satisfactory to the Contracting Officer Representative (COR) that this has been done.

- All persons employed within the boundaries of the property or restricted-access areas therein, and all persons permitted to enter such property and areas shall comply with the security regulations and procedures that have been established for this Contract.

- The Contractor Security Plan shall include provisions to address various Security Alert Levels as determined by the Department of Homeland Security.

- The Contractor Security Plan shall include provisions to address an approach to overall security that is consistent with the goals contained in existing NIH Security Policies, Guidelines and Regulations.

  The Contract specific Contractor Security Plan seeks to achieve the following security goals:

  a. Screen Contractor workforce consistent with NIH policies and procedures.
  b. Safeguard NIH employees and assets from events or persons who could cause harm.
  c. Limit project information distribution and ensure compliance with the National Institutes of Health Confidentiality Non-Disclosure Certification, a copy of which is included as an attachment to authorized persons and entities to the greatest extent that is practical, and as directed by the Associate Director for Security and Emergency Response (ADSER).

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ARTICLE H.74.3. CONTRACTOR PERSONNEL

- Upon award of Contract the following security procedures will apply:

    a. The Contractor shall provide information about all Contractor and subcontractor personnel and others who require continued access to the site, before access is required and when access ceases.
    b. No interviews of prospective Contractor employees shall be conducted on the project site or NIH property. The Contractor and subcontractors will be required to maintain a field office, outside the project site or NIH property, for all public contacts. Applicants for employment and other persons not entitled to access to the project site shall be required to contact the Contractor or subcontractor at these offices.
    c. Within 10 calendar days after the award of the Contract, the Contractor shall submit a list of all employees, subcontractors and their employees, and others who will perform work or otherwise require access to the site. Personnel shall be listed in alphabetical order by company. The list shall include the full name, social security number, date and place of birth, citizenship and, where applicable, visa status for each individual.
    d. Name of any employee added later to the original list shall be submitted with the same information on the Contractor's letterhead at least 8 calendar days in advance of the date of access by the employee.
    e. The Contractor shall notify the Government in writing when personnel are no longer employed by the Contractor or a subcontractor. The written notification all include the individual's name, social security number and date and place of birth, citizenship, visa status and the company who employed the individual, if applicable.
    f. Each company or entity with personnel assigned to this Project shall ensure that all personnel undergo a personnel security screening to determine their suitability for access to NIH facilities, information and data.
        a. The Contractor Security Plan establishes two levels of Contractor personnel involvement: those involved in sensitive duties; and those not involved in sensitive duties. The NIH will provide two different screening processes accordingly.
        b. Completion of a background questionnaire and assorted forms (Standard Form 85P - "Long Form Screening") as well as a credit check is required for the following sensitive duties:

            a. Contractor personnel with direct senior level management responsibilities on the Contract.
            b. Contractor personnel with direct management responsibilities on the Contract and requiring access to "Law Enforcement Sensitive" or other NIH-designated sensitive information.

c. Contractor personnel with direct in-depth knowledge or installation responsibilities of access control systems, closed circuit television (CCTV), and/or intrusion, motion or other detection devices on the Contract and requiring access to "Law Enforcement Sensitive" or other NIH-designated sensitive information.

c. A police check provided by the NIH Police through the National Crime Information Center (NCIC) (NCIC "Short Form" screening) is required for all other Contractor personnel working on the project involving non-sensitive duties.
d. In addition to other disqualifying factors as determined by the NIH, the following shall apply:

a. Conviction for tax evasion may disqualify Contractor personnel being considered for sensitive positions.
b. A history of acts of violence, arrests for firearms or explosives violations, illegal alien status, or any felony convictions will disqualify Contractor personnel from working on this Contract.

g. The Contractor shall notify the NIH Division of Police through the Contracting Officer, or a designated representative, of any change in personnel assigned to the project site, including changes in employee status such as terminations of employment, civil or criminal charges, visa status, if applicable.
h. The NIH reserves the right to require the removal of any Contractor employee from the project site if the employee is deemed a security risk by the ADSER.
i. In order to permit the NIH Division of Police to supply NIH ID Badges for on-site personnel, the Contractor shall cause each individual to complete a personnel identification form. These forms will be provided by the NIH to the Contractor at the pre-construction conference. Processing of the forms and issuance of NIH ID Badges will be performed by the NIH at NIH expense.
j. At a time designated by the Contracting Officer or when an individual reports to the site for work the first time, a period of at least 2 hours will be required for security processing, including review of identification forms and fabrication of a permanent badge. Personnel will then be permitted to go to work without further processing of identification forms by the Government, but at least 15 minutes should be allowed each day for signing in with security to obtain access to the site.
k. The permanent NIH ID Badge furnished by the NIH to each Contractor employee or other person granted access to the site will serve to authorize the wearer to enter and leave the project area. The NIH ID Badge must be worn so as to be clearly visible at all times when at the work site.

l. Access to other parts of the NIH property will be subject to the screening procedures applicable to visitors under the Alert Level in effect as determined by the Department of Homeland Security.
m. The NIH ID Badge will be retained by the individual as long as continued admittance to the site is required. The Contractor will arrange for immediate return of the badge to NIH when such need ceases. Temporary or visitor ID Badges will be provided for persons who are identified as having an infrequent or temporary legitimate business need for access to the site.

- Security Manager

  a. A Security Manager (SM) shall be designated by the Contractor for the duration of the project. The SM must report directly to an officer of the firm and not to the site superintendent and must be provided the authority in writing to implement the designated security plan, policies, procedures and directives for the project as provided by the NIH Division of Police.
  b. The individual must be familiar with the requirements of the Department of Homeland Security threat levels. NIH Division of Police will define the NIH responses to the various threat levels to the successful Contractor.
  c. The individual must be fluent in speaking and writing English.
  d. The individual must undergo and pass a U.S. Government Background Investigation prior to receiving security sensitive information from the NIH Police.
  e. The individual must be capable of understanding potential security problems, exploring issues and developing efficient and effective solutions.
  f. The individual must possess good interpersonal skills and be capable of working with a variety of organizations, including the NIH, other federal agencies, local law enforcement, and the private sector.
  g. In addition to implementing and managing the construction security program for the project, the construction security manager may perform other management-level duties within the firm.
  h. The only duties and responsibilities of the construction security manager are to manage and implement the construction security program on this contract.

- All personnel engaged on the Contract will be required to execute a National Institutes of Health Confidentiality Non-Disclosure Certification. (See Section J - List of Attachments.)

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ARTICLE H.74.4. SECURITY PROCEDURES

Upon commencement of the work under this contract, the following security procedures shall apply to the Contractor and all subcontractors.

- Contractor personnel shall not enter the NIH campus without appropriate NIH ID Badge.

- For work outside "normal work hours" as defined in the Contract, the Contractor shall give the Contracting Officer or his designated representative at least three (3) calendar days notice. This notice is required so that security arrangements may be provided and is separate and distinct from any notices required for utility shutdown or other outages.

- The NIH reserves the right to restrict photography of the project or other areas of the NIH premises.
    a. Cameras are not permitted without written permission from the Contracting Officer or his designated representative. If approved, permission will be granted in writing and will provide additional guidelines.

- Personnel may be subject to inspection of their personal effects when entering and leaving the project site. In addition, unscheduled inspections of personnel may be made while on site.

- The NIH reserves the right to alter security procedures based on the Security Alert Level in effect as determined by the Department of Homeland Security, for as long as the Security Alert Level change exists.

- The NIH reserves the right to close down the project site and order Contractor personnel off the premises in the event of a national emergency or a shut-down, for as long as the national emergency or shut down exists. The Contractor may only return to the site with written approval from the Contracting Officer or authorized representative.

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ARTICLE H.75. OTHER ON-SITE

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ARTICLE H.75.1. NON-INTERRUPTION OF GOVERNMENT ACTIVITIES

All work areas must be separated from the remainder of the building with smoke tight partitions constructed with non-combustible or fire retardant materials. Barriers must be in place prior to and during all stages of renovation work.

Interruption or interference with the conduct of government business in other building areas outside the contract area, or damage to existing equipment within the contract area, will not be permitted. To protect government property and to isolate his work, the Contractor shall provide, at no additional expense to the government, drop cloths, plastic film draping, taping, barriers, weatherproof closures and/or coverings, and temporary dust-proof enclosures and partitions, etc. Temporary dust-proof enclosures and partitions shall be provided wherever demolition or construction operations will produce dust or dirt subject to spreading via tracking or air currents beyond the immediate area of work. Such enclosures shall be erected structurally sound, and shall be maintained dust proof so as to keep surrounding areas clean and free of dust. Where practical, dust-producing activities shall be kept dampened with water, so as to reduce the generation of dust.

Temporary dust-proof enclosures will always be required to separate sterile or germ-free areas from the Contractor's work area. Materials shall be conveyed inside buildings in and on rubber-tired vehicles provided by the Contractor. Use of NIH equipment is prohibited. The use of equipment which produces substantial noise or vibration in buildings, such as pneumatic hammers, etc., is prohibited except in those cases where it is approved by the Contracting Officer Representative (COR) because no other method is available. If use of such equipment is approved, work will be restricted to non-NIH work hours, 6:00 P.M. through 6:00 A.M. Monday through Friday or weekends.

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ARTICLE H.75.2. UTILITY SHUTDOWNS

All outages or modifications to the fire protection systems must be scheduled and approved by the Contracting Officer or his/her representative(s). Contractors shall not cut, disconnect, switch, open, or alter position of valves, or otherwise interrupt any utility systems, piping systems, electric services, etc. without prior approval of the Contracting Officer Representative (COR). Shutdown of any utility service which will affect service to any areas other than those in the contract area, must be requested in writing a minimum of fifteen (15) working days in advance, and requires written confirmation/approval prior to service interruption. This work shall be accomplished outside normal NIH working hours, at no additional cost to the Government.

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ARTICLE H.75.3. USE OF GOVERNMENT BUILDING FACILITIES

General

Where the term "NIH Reservation" appears herein, it shall be defined as also including all "off reservation" facilities.

- Contractors (including subcontractors), their officials, employees, and all other persons visiting or conducting business on the NIH Reservation, NIH Animal Center, Federal Building and future construction sites pertaining to NIH facilities in connection with contract work shall conform to these requirements.

  The Contractor shall be responsible for the enforcement of these requirements by his subcontractors.

- Before work is started, the Contractor shall furnish to the NIH Contracting Officer Representative (COR), the name of the principle responsible official for the contract plus at least one alternate, with their home addresses and phone numbers, who may be contacted in case of emergencies occurring outside the regular hours of work. Similar information shall be furnished concerning all subcontractors.

- The COR shall act as the liaison between the Contractor and NIH activities to provide or obtain:

  a. Truck routes for delivery of supplies and equipment.
  b. Storage areas for Contractor's materials and equipment (generally limited to the Contractor's site).
  c. Staging areas for Contractor's trucks, cranes, etc., within limits of space available as outlined in Section H, Motor Vehicles and Parking Regulations.
  d. Approvals, clearances, permits, and inspections by NIH activities.
  e. Notification to affected NIH activities regarding interruptions of services and blasting operations.
  f. Compliance of the Contractor with general and specific requirements listed here.

- Contractors shall comply with all orders and directives of NIH Police and Fireman or local jurisdiction for off "reservation" projects.

  Building freight elevators may be used by the Contractor to transport materials only at times when such use does not interfere with normal NIH operations. Elevator use shall be arranged through the COR. The Contractor is responsible for protecting elevator cab interiors from damage. Construction Contractors and subcontractors working at NIH

facilities shall not use NIH toilet facilities. The Contractor shall make arrangements for portable toilet facilities.

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ARTICLE H.75.4. MATERIAL DELIVERY, STORAGE AREAS AND DEBRIS REMOVAL

- Material Delivery -- Contractors shall arrange for the deliveries of supplies or material and equipment to the work site or designated storage areas via previously approved routes. Wherever practicable, deliveries shall be made during the regular NIH working hours and only when the Contractor's representative is available to receive them. If a Contractor's representative cannot be located, the NIH Police Force has standing instructions not to allow the material to be unloaded at the construction site. When deliveries are to be made outside normal NIH work hours, they must be scheduled for a pre-designated time in advance through the Contracting Officer Representative (COR) or Construction Manager so that the NIH Police can arrange to open (and secure) doors to the building and area. This requirement is necessary to maintain building security.

- Storage of Materials -- There is no space available in NIH buildings for the storage of materials and equipment. The Contractor shall be responsible for storing all of the long-lead-time materials and equipment, as designated within the project's specifications and drawings. Corridors and other public areas must be kept clear at all times. Materials stored at locations not authorized by the COR or Construction Manager are subject to being hauled away by the government or having the Contractor's progress payments delayed.

  Contractor shall provide and maintain proper storage for all hazardous materials and/or wastes, and maintain copies of all relevant Material Safety Data Sheets (MSDS) paperwork on-site for NIH review.

- Debris Removal -- Removed materials, which are designated in the specifications or drawings as Contractor's property, or debris shall be promptly removed from the job site and the NIH Reservation. Storage and/or collection of debris inside or outside buildings will not be permitted. Contractors shall remove all debris and other material from the job site and Reservation with their own carts, containers, and/or refuse disposal facilities. Government facilities may not be used for this purpose. All interior areas of existing buildings shall be left clean on a daily basis. When debris must be removed from buildings outside normal NIH work hours, it must be scheduled for a designated time in advance (the same as for material deliveries).
  Projects in Building 10 shall dispose of construction debris and trash in the B-2 level loading dock dumpsters. Dispose of debris and trash in the appropriate dumpsters

according to the type of refuse.

- Combustible debris and trash must be removed from the work site daily.

- No corridor or stairwell can be locked, blocked, closed or used for storage without the written permission of the COR.

- Keep passage through all corridors clear and without obstructions at all times. Do not block the emergency egress with construction supplies, equipment or debris. Written permission must be obtained from the COR for temporary storage of supplies.

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ARTICLE H.75.5. CONSTRUCTION DEBRIS

The ORF Division of Environmental Protection (DEP) provides construction dumpsters for all construction and renovation projects on the Bethesda Campus at no cost. The dumpster rental, transportation, and disposal costs of all collected materials are covered by DEP. Before the dumpster will be delivered, the Contracting Officer Representative (COR) must submit a Site Selection Request and obtain approval. For additional information, view the DEP Construction Dumpster Program, the COR's Guide, and Construction Debris Waste Management and Recycling Plan at the DEP section of the ORF website. Contact DEP staff at 301-496-7990 with questions about this service.

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ARTICLE H.75.6. FIRE PREVENTION

- Contractors shall instruct their employees to immediately report any fire to the NIH Fire Department, (dial 116 if the phone is on an NIH exchange or 496-9913 if the phone is not on an NIH exchange) even if it has been extinguished. In addition, the NIH Fire Department shall be immediately notified on any hazardous material spill, ambulance or rescue emergency.

- Contractors are responsible for promptly replacing/recharging any self-owned fire extinguisher that has been discharged. If the fire extinguisher is NIH owned, the NIH Fire Department shall be promptly notified for a replacement (dial 496-2372). Portable NIH-owned fire protection equipment shall not be moved unless approved by the NIH Fire

Department.

- All construction trailers shall not be moved into place or erected on the NIH reservation without prior approval by the NIH Fire Prevention Section as to location, type and method of heating and lighting. They must be located within the Contractor's assigned area and are generally restricted by a minimum separation distance of 40 feet to an adjacent trailer or an occupied building. In cases where this separation distance is not feasible, additional fire protection features will be required dependent on the maximum separation distance which can be attained. The Fire Prevention Section shall be consulted to determine the additional fire protection features which must be incorporated.

- The installation of aboveground tanks for fueling the Contractor's equipment must be approved by the NIH Fire Prevention Section. Contractor shall provide secondary containment equipment for all fuel and/or chemical storage containers/tanks that meets Maryland Department of the Environment regulatory requirements.

- Contractor shall not use water from fire hydrants to standpipe risers without prior approval from the NIH Fire Department. In the event of actual emergencies, the fire department may discontinue the use of water from fire hydrants and or standpipe risers without advance notice.

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ARTICLE H.75.7. RECYCLING OF CONSTRUCTION MATERIALS

The only construction debris material that should not be placed into debris dumpsters is ceiling titles. Contractors are to separate and stack these on the loading docks. The DEP recycling Contractor will collect them for consolidation and recycling. Ceiling titles must be palletized on the loading dock to allow for removal. Broken ceiling titles will not be accepted. Cardboard generated from any projects should also not be placed in the dumpsters. Cardboard is to be flattened and left on the loading document for collection by the DEP on-site Contractor collects loading dock cardboard at each dock in the mornings and afternoons.

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ARTICLE H.75.8. ENVIRONMENTAL

- The Contractor shall strictly follow all the conditions and requirements in the Maryland Department of the Environment (MDE)-approved drawings.

- Inspect all the erosion and sediment control measures daily and perform necessary repairs.

- Maintain a log of the site erosion control measures' condition. At the minimum, the log shall contain information such as date and time of the inspection, weather, deficiencies found, and any corrective measures (repairs, in/out side of the site cleaning) performed.

- Make the above inspection log available upon request by NIH-Division of Environmental Protection (DEP) representative and/or MDE inspector.

- Completely cover any dirt/stock piles with plastic tarp at the end of every business day regardless of the weather condition.

- Clean/sweep the road as well as adjacent areas of the site of any debris that may have expelled from the site. The debris includes dirt, sand, gravel, and any other material related to the construction project.

- Notify NIH-DEP of any utility line (pipes, plumbing, etc.) cleaning, flushing and/or testing at least one week in advance. The Contractor's procedure must be prepared and provided to NIH-DEP for approval.

- Notify NIH-DEP as the project nears its completion and coordinate for a final site inspection by MDE. The Contractor shall be responsible for the site condition and the contract shall not be closed however until the site is inspected and approved by NIH-DEP.

- The address for NIH-DEP is NIH, Division of Environmental Protection, 9000 Rockville Pike, Bldg. 13, Room 2S11, MSC 5746, Bethesda, Maryland 20892-5746. The phone number is (301) 496-7775.

- As-built drawings of the stormwater management features shall be provided to DEP upon completion.

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ARTICLE H.75.9. INTERIM LIFE SAFETY MEASURES (ILSM)

- Interim Life Safety Measures (ILSM)

  The Contractor shall comply with the ILSM established by the NIH Division of the Fire Marshal or the Clinical Center. These measures shall be implemented for all construction, renovation and alteration work and periods when the work compromises the fire protection systems such that the facility does not meet applicable provisions of the Life Safety Code®.

  a. All contract employees shall abide by the no smoking policy when working in or around the perimeter of the facility.
  b. All corridors and stairs required for emergency egress shall remain clear and unobstructed at all times.
  c. Access to emergency services and for fire, police, and other emergency forces shall remain free and unobstructed at all times.
  d. When normal access or exiting paths need to be changed or modified in any way, this action shall be done only with prior written approval by the authority having jurisdiction (AHJ). The AHJ will keep the NIH Fire Department and relevant occupants notified of all route changes.
  e. Existing fire alarm, detection, and suppression systems shall remain in good working order. All modifications or planned shutdowns of the fire protection systems must be scheduled and approved by Maintenance Engineering. It is the responsibility of Maintenance Engineering to notify the AHJ and the NIH Fire Department of all modifications in these systems and to ensure that temporary, but equivalent, fire safety measures are in place when the operation of any fire system is impaired. Temporary and equivalent systems must be tested monthly.
  f. All work areas will be separated from the remaining portion of the building with smoke-tight partitions constructed with noncombustible or fire-retardant materials. All barriers shall have clean, smooth surfaces and provide a contiguous seal to minimize the migration of construction dust as well as smoke.
  g. Because the building's air pressure is negative relative to the outdoors, work that involves a break in an exterior wall shall be protected with two parallel noncombustible or fire-retardant partitions to minimize energy loss, property damage, and occupants' discomfort or exposure to chemical vapors and bioaerosols.
  h. Penetrations in fire and smoke walls contiguous with occupied areas will be properly sealed at the end of each work shift.
  i. All individuals must obtain a NIH Hazardous Work Permit from the NIH Division of the Fire Marshal by calling 301-496-0414 prior to the start of any welding, cutting, or use of an open flame.
  j. Fire safety measures as required by the NIH Hazardous Work Permit shall be conspicuously posted at the work site and accessible at all times. Measures may

include fire extinguishers, blankets, and other suppression methods designated by the AHJ or NIH Fire Department.

k. Commensurate with the fire hazard potential, the NIH Fire Department may provide employees and Contractors who perform work requiring an NIH Hazardous Work Permit training in the use of portable fire extinguishers.
l. Prior to use, the Contracting Officer Representative (COR), with the CC safety officer and CC Office of Facility Management will assess the risks associated with the flammables, oxidizers, irritants, and other potentially hazardous chemicals proposed for use in the work area.
m. The Contractor will provide the Material Safety Data Sheets (MSDS) for chemicals used on the site in accordance with provisions of the OSHA Hazard Communication Act. The Contractor must keep a binder containing all MSDS for chemicals approved for use at the worksite---where it is readily available for employees and emergency responders at NIH.
n. Flammable and oxidizing chemicals on the jobsite shall be limited to a one-day supply. Additional supplies shall not be stored in a building unless an approved storage area is designated by the AHJ.
o. Flammable compressed gas cylinders shall be limited to a one-day supply. Additional cylinders shall not be stored in a building unless an approved storage area is designated by the AHJ.
p. Compressed gas cylinders shall be securely stored in an approved cart.
q. Wastes shall be removed from the worksite at the end of each work shift or as needed.
r. Until completion of the construction project, all combustible storage on the jobsite shall be kept at the minimum level acceptable to the AHJ for daily operations.
s. The NIH Division of the Fire Marshal [the fire safety "authority having jurisdiction" (AHJ)], as well as the CORs will monitor renovation and construction areas for compliance with the ILSM.
t. The NIH AHJ shall approve all completed work for compliance with provisions of the National Fire Codes prior to acceptance and beneficial occupancy of the space.
u. Daily Inspections:

    a. The Contractor's Project Manager or Superintendent shall monitor compliance with the ILSM on a daily basis.
    b. Contractor shall address ILSM requirements in their daily report that shall be provided to the COR.
    c. Noncompliance with checklist is sufficient cause for a "Stop Work Order".

- Building 10 Complex - Construction Risk Assessment (CRA).

The Contractor shall comply with Construction Risk Measures that identify and address

hazards that could potentially compromise patient care, treatment, and services in occupied areas of the Building 10 complex (i.e., Buildings 10, 10B (ACRF), CRC, and NMR imaging center). Hazards include air quality requirements, infection control measures, utility requirements, noise, vibration and emergency procedures. Construction Risk Measures must be implemented prior to the project execution phase and be maintained through demolition, construction or renovation till the completion of the project. The Contractor shall complete the Construction Risk Assessment (CRA) to identify, develop and implement control measures required for the TYPE, GROUP and CLASS of area in which work will be performed (using the Patient Risk Group Drawings) and for adjacent areas that may be affected by the work. The Contractor shall complete the information included in the CRA procedure, distribute this information to the COR and other persons designated by the COR and receive approval from the government prior to starting work. This construction risk assessment process shall be repeated each time when the location or character of work changes. Construction risk measures include scheduled times and thresholds for vibration and noise; barriers to contain particulates including sticky carpet mats, smoke-tight wall boards, air pressure differentials, and filtration devices; redundant or comparable safeguards to maintain effective odor removal, air conditioning, humidification, heating, critical air quality and clinical parameters required for patient care and the safety of all occupants, and emergency procedures. The TYPE, GROUP and LOCATION of the work determines when and to what extent construction risk measures applies to the work performed by the Contractor.

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ARTICLE H.75.10. MOTOR VEHICLE AND PARKING REGULATIONS

- All persons driving motor vehicles on the NIH Reservation in connection with Contractor business, including the driving of employees' personal vehicles, shall abide by the Conduct of Persons and Traffic on Certain Federal Enclaves, dated July 21, 1980, as a condition of being permitted to enter the Reservation and as part of the contract.

- When Contractor trucks are to be parked for loading or unloading materials for a period longer than just a routine delivery, approval must be obtained from the Contracting Officer Representative (COR) who will notify the NIH Police Section. During the course of a construction job, as space needed for truck parking changes, the Contractor shall inform the COR who will clear the need through the NIH Police Section.

- Vehicles operated over reservation roads in connection with contract work shall be loaded so as to minimize spillage of dirt, gravel, and other debris. The Contractor shall remove inadvertent spillage of nails, construction materials, scrap, etc., immediately. Dirt and gravel spillages or accumulations shall be removed as soon as practicable and as satisfactory to the COR, but in every case it shall be removed no later than the end of

each workday.

- The driver of any vehicle involved in an accident on the NIH Reservation shall stop and render aid as required. The accident shall be reported as soon as possible in person or by telephone to the NIH Police Section. Drivers of the vehicles involved shall remain until released, and shall furnish such reports of the accident as required.

- When closing of roads or lots is necessary for a Contractor to perform work, notify the COR at least fourteen (14) calendar days in advance, so that the action may be cleared through the NIH Police Section. Once approval is granted, Contractors shall provide their own barricades and cones and block off the area.

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ARTICLE H.75.11. PARKING REGULATIONS

Parking Policy for Construction Personnel and Miscellaneous Contract Service Vehicles at the National Institutes of Health (NIH) Bethesda, Maryland Campus.

The purpose of this clause is to establish clear directives for parking of Construction/Contract service vehicles and their personnel.
Construction/Contract service categories have been established to identify policies specific to individual user groups.

Category 1 - General Labor
All Category 1 parking will be located off-site
The NIH shall require that Contractors for projects in excess of $10 million (construction contract award amount) provide off-site parking and shuttle service for their workers for the duration of their project. This cost shall be borne by the Contractor.
Construction workers are strictly prohibited from parking their personal vehicles on the NIH campus including visitor parking areas between the hours of 7:00 a.m. and 7:00 p.m.
Construction workers may park in the general employee parking: i) outside this time period, ii) during federal holidays, and iii) on weekends.

Category 2 - Specialty Contractors
Includes smaller job Contractors who work out of their vehicles for projects of short duration and no staging area is provided. (This would include elevator Contractors, plumbing Contractors, etc.).
Specialty Contractors shall use paid visitor lots. This cost shall be borne by the Contractor.
When it is essential that the specialty Contractor's vehicle be in close proximity to the work area, the Contractor may request special exception through the Contracting Officer

Representative (COR). The COR will notify the Division of Public Safety for specific instructions.

Category 3 - Contractors with Approved Staging Areas

Includes Contractors with approved staging areas. This would include general Contractors as well as their subcontractors.

Properly marked company vehicles and equipment required in the performance of their project shall be permitted to park within their approved staging areas. Personal vehicles are prohibited from parking within the staging areas.

Category 4 - Full Time CQM/A&E/Consultants for Design and Construction Activity

Properly marked company vehicles required as part of their work shall be permitted to park within their approved staging areas. Personal vehicles are prohibited from parking within the staging areas.

Personnel in a continuing role on construction sites may be provided parking permits in accordance with NIH parking policies by request through their COR.

Off-site CQM/consultant personnel shall use paid visitor parking areas.

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ARTICLE H.75.12. PARKING MITIGATION PLAN

PROJECT TRAFFIC / PARKING REQUIREMENTS

PART 1 - GENERAL

1.1 RELATED DOCUMENTS

A. Drawings and general provisions of the Contract, including General and Supplementary Conditions and other Division 1 Specification Sections, apply to this Section.

1.2 SUMMARY

A. This Section defines parking requirements and responsibilities for all parties involved in the performance of the work, and includes the following types of provisions:
    a. On Campus parking
    b. Project Site parking
    c. Satellite parking
    d. Shuttle service to the NIH campus
    e. Parking monitoring/enforcement

B. This Section includes the requirements for providing the following documentation as part of the Project Traffic / Parking Mitigation Plan:

a. List of all management personnel working full time on site for the Prime Contractor.
b. Site Plan identifying available parking on the Project Site and staging areas for construction vehicles and materials.
c. Number of workers requiring parking; not including personnel identified in item B.1.
d. Identification of Satellite Parking facilities.
e. Identification of means to transport workers to project site.
f. Identification of enforcement procedures.

C. Related Sections: This specification section is related to any and all specification sections with explicit or implicit reference to construction progress documentation. Specific submittal requirements of these related specification sections are not included in this section. Related sections include but are not limited to the following specification sections:
    a. Section 00700 General Conditions - AIA document A201-1997
    b. Section 00800 Supplemental Conditions
    c. Division 1 Section "Submittal Procedures"
    d. Division 1 Section "Reference Standards and Definitions"
    e. Division 1 Section "Temporary Facilities and Controls"

1.3 DEFINITIONS

A. NIH Campus: NIH main campus in Bethesda, Maryland (boundaries to be determined, is it applicable to other campuses…Poolesville, RML, etc.)

B. NIH Parking Policy: All full time, management staff of the Prime Contractor shall be provided either On Campus Parking or Project Site Parking at no cost to the Prime Contractor. All Subcontractors must park in Satellite Parking facilities as provided by the Prime Contractor. Costs for providing the Satellite Parking, shuttle service, enforcement, management and evaluation of the parking plan shall be included in cost of the work.

C. On Campus Parking; Parking located on the NIH Campus, either in NIH parking lots/structured parking facilities or on the Project Site.

D. Owner: Either the NIH and/or NIH's Contractor (General Contractor, Construction Quality Manager, Architect/Engineer, etc.).

E. Prime Contractor: The entity that has executed the contract with the owner.

F. Project Site Parking: Parking located within the Limits of Disturbance as defined by the approved Site Plan or MDE Soil Erosion, Sediment Control Plan.

G. Satellite Parking: Parking not located within the NIH Campus or in neighborhoods adjoining the NIH Campus.

H. Shuttle Service: Transportation service provided by responsible Contractor from Satellite Parking to the Project Site. Examples include bus service and public transportation.

I. Public Transportation: Any mode of transportation service offered by local and state authorities. (Examples: WMATA, Montgomery County Bus Service)

J. Subcontractor: Any Contractor that is not a Prime Contractor.

PART 2 - PRODUCTS

2.1 PROJECT TRAFFIC / PARKING MITIGATION PLAN

A. Prime Contractor shall prepare and submit to the Contracting Officer Representative (COR) for approval a Parking Plan showing the measures to control and manage parking of its personnel including but not limited to management personnel, construction labor and subcontractor personnel during the performance of the work. The Parking Plan shall contain the information and be presented in the format shown in Attachment 1 at the end of this section.
    a. Be in the form of a written report.
    b. Identify all management personnel working full time on site for the Prime Contractor.
    c. Identify the number of subcontractor vehicles requiring parking. The description shall provide the maximum number of parking spaces required for each six month period for the project duration.
    d. Identify Satellite parking locations, their distance from the NIH Campus and time required to travel to the NIH Campus.
    e. Identify if the Satellite parking facility requires additional fees for parking after hours, weekends or holidays. Such costs shall be included in cost of the work.
    f. Identify the Shuttle service to be used along with the means to transport subcontractors to their vehicles in the case of weekend/holiday work, personal emergencies, a project emergency or unscheduled overtime to maintain project schedule and project quality. The Plan shall also include the time frames the shuttle service will be regularly operating as well as for atypical occurrences.
    g. Identify the means the Prime Contractor shall use to monitor/enforce the Subcontractors commitment to utilizing Satellite Parking.
    h. Identify the number of subcontractors utilizing public transportation.
    i. Provide a means for evaluating the Plan at the end of each project. Such evaluation shall be provided to the NIH with the Project Close-out documents.
    j. Identify means to communicate the Plan to Subcontractors: Contracts, training, handouts, etc.
    k. Identify total cost of parking for the contract duration.

PART 3 - EXECUTION

3.1 PROJECT TRAFFIC / PARKING MITIGATION PLAN

A. Parking Officer: Designated member of Prime Contractors team that will be responsible for writing and implementing Parking Plan.
    a. Submission of the plan: The plan shall be submitted and approved prior to site mobilization. On campus parking permits will not be provided until plan is approved in its entirety.
    b. Meetings: The Parking Officer shall provide a parking update at the regularly scheduled Project Meeting.

B. Contractor's Parking Plan update: At six month intervals, Prime Contractor shall update Parking Plan to reflect the actual number of subcontractors using satellite parking, public transportation as well as report occurrences of parking not consistent with the Parking Plan.

C. Distribution: Distribute copies of the Parking Plan to (to be determined)
    a. When revisions are made, distribute updated plans to the same parties.

3.2 COORDINATION

A. Coordinate Project Traffic / Parking Mitigation Plan with information provided by Owner.

B. Coordinate Project Traffic / Parking Mitigation Plan with the project Site logistics plan and the project Site Selection Plan.

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ARTICLE H.75.13. DESIGNATED CONSTRUCTION TRAFFIC ROUTE

The designated construction traffic truck route for this contract will be determined on a task order basis.

The requirement for truck inspection stations will be addressed on a task order basis.

The NIH will provide the truck inspection security guards.

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ARTICLE H.75.14. SANITATION AND FOOD SERVICES

- Contractors shall maintain their working areas free from food debris and wrappers. Contractors shall provide covered trash containers in the number and type approved by the NIH Sanitarian, and shall be responsible for the sanitary collection and prompt removal of trash in these containers from the NIH grounds.

- All temporary toilets used by the Contractor must be approved as to number, location, and construction by the NIH Sanitarian. The Contractor will make arrangements to secure this approval with the Contracting Officer Representative (COR).

- The NIH Sanitarian will periodically inspect the site for the presence of insects and rodents. If a significant problem related to Contractor activities is found, NIH authorities will institute action to eradicate the infestation, back charging the Contractor for this service.

- No food or drinks are allowed within the building.

- Contractor's food service facilities must meet all local food service ordinances and be approved by the NIH Sanitarian before operating. The facilities must be open for inspection by the NIH Sanitarian at all times. The Contractor shall arrange for approval through the COR.

- The government will provide catered food services under a separate contract. General Contractor is to coordinate locations and time schedules.

- The project construction site will not permit construction Contractor personnel overall access to the campus, but to the assigned work area only. The construction Contractor personnel assigned to this project will not be permitted access to NIH cafeterias.

  The Office of Research Services, Division of Amenities and Transportation Services (DATS), will provide the name and associated contact information regarding the qualified mobile food vendor that will be permitted access to the construction site that can be used by the Construction Management Contractor (CMc) or General Contractor to provide mobile food vending to the project site.

The construction Contractor is not permitted to use the mobile food services of any other company other than that provided to DATS by the Maryland Business Enterprise Program for the Blind (MBEPB) as a result of the associated requirements within the Randolph-Sheppard Act as promulgated.
The Contractor shall establish the times that the mobile food vendor is to be on-site and coordinate and provide the locations on site; directly with the vendor from MBEPB.

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ARTICLE H.75.15. DOCUMENT CONTROL

The Contractor shall assume responsibility for and maintain records of distribution of all drawings, specifications and other project information. Such information shall be distributed only to those specifically with a need for them to accomplish the Work.

Certain documents may be marked as "Sensitive Unclassified - For Official Use Only" or "Law Enforcement Sensitive", hereinafter called "sensitive" information which may include drawings, sketches, digital photographs, exposed negatives, video, written descriptions of work requirements, and similar information. Return such information promptly to Contracting Officer Representative (COR) upon request, including any copies.

Store all Project Information in file cabinets locked during non-business hours. Store "Sensitive" documents in separate containers with access restricted to those with a specific need for use of the information.

Reproduction of documents shall be kept at the minimum needed to accomplish the Work, and all copies shall be numbered and recipients recorded. "Sensitive" documents shall be returned to the NIH COR when no longer needed, and the NIH will arrange for their proper disposal.

Limit dissemination of sensitive information on need-to-know basis.

Any proposed deviations from these requirements must be submitted to the COR for review. Approval may or may not be granted. Do not allow removal/transmission of such information from Project Site without prior written approval by COR.

"Sensitive" documents shall be transmitted using U.S. Postal Service or any commercial services that permit delivery only after receiving signature.

All paper waste and electronic media such as diskettes and CDS of "Sensitive" documents shall be shredded or otherwise destroyed in a manner acceptable to the NIH.

Notification and Reporting: Notify both the COR and the Construction Security Manager immediately when known or suspected loss/compromise of "sensitive" information or other documents, notes, drawings, sketches, reports, photographs, exposed films, or similar information has occurred which may affect the security interests of the NIH. Extend this requirement to employees and other personnel working on behalf of Contractor, and expand the responsibility to include prompt reporting of security issues, including observed efforts by unauthorized persons to gain access to sensitive information.

The Contractor and each sub-contractor or other entity involved in the Contract shall submit an electronic security memorandum describing the approach to meeting the above goals and maintaining confidentiality of Contract files The memorandum shall describe security within the Project, including any intrusion prevention and detection methodology.

The Contractor shall not proceed without NIH's written approval of the memorandum. Any requests for exceptions from these requirements shall be submitted in writing to the COR for review. No entity or person shall proceed with such exception without written approval by the NIH.

Electronic Document Security

All Electronic files shall be stored in specified location following NIH standards and procedures using an Engineering Document Management Software (EDMS).
Each Project shall have a registry file, listing the project team with their contact information, drawing list, and Revision index stored in the same location of the other project documents.
Security, access and maintenance of all project engineering drawings and related documents, both scanned and electronic, shall be performed and tracked through the EDMS system.
All documents shall be distributed among team members, including A/E, DM, CM, and their sub-contractors with approval and knowledge of the NIH COR.
Three principles shall always be followed in providing information:

- Only give the information to those that have a need to know
- Keep records of who received the information
- Safeguard the information during use.

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ARTICLE H.75.16. COMMUNICATIONS

Use of telephone or facsimile for communications will not be restricted except that these means shall not be used for "Sensitive" information.
"Sensitive" information, including drawings and other documents may be attached to electronic mail. However, the commercially available encryption software must be approved in advance for use by the NIH and must be compatible with Microsoft Outlook.
If computer area networks are used for performing administrative or technical work, electronic partitions must be installed to limit access by unauthorized personnel Contract to electronic files. Electronic files shall be organized to allow complete purging of Contract files at the conclusion of the Work.

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ARTICLE H.76. WORK BY THE GOVERNMENT

- The Government reserves the right to undertake performance by Government forces or other Contractors, the same type or similar work as contracted for herein, as the Government deems necessary or desirable, and to do so will not breach or otherwise violate this contract.
    a. General. The Government has awarded and will award other contracts for specialized work, which is outside the scope of this contract or outside the scope of awarded options. These contracts will involve additional work at or near the site of the work under this contract. The Contractor shall carefully adapt its schedule and performance of work under this contract to accommodate the work of the Other Government Contractors (OGC's), and shall take coordinating direction from the Contracting Officer. The OGCs will be placed under similar contracting conditions regarding coordination. The Contractor shall make every reasonable effort to avoid interference with the performance of work by the OGCs, as scheduled by the OGCs or by the Government.

    b. Critical Path Method (CPM) Schedule Inclusion. The Contractor's CPM Schedule shall include all OGC activities as indicated by the Contracting Officer.

    c. Notification of Defective Work. If any part of the Contractor's work is dependent upon the completion of work by OGCs, the Contractor shall inspect such work and promptly report to the Contracting Officer in writing any apparent defects or deficiencies in such work that would render it unacceptable or prevent the Contractor from fulfilling his requirements to deliver a quality product in compliance with the Contractor's CPM schedule. Failure to perform such inspection of dependent OGC work, prior to Contractor commencement or continuance of Contractor follow upon work would constitute an acceptance by the Contractor of work by other Contractors, as being fit and proper for integration with work under this contract, except for those defects and deficiencies in the work by other Contractors which are latent or otherwise were not discoverable by reasonable inspection.

    d. Notification of Obstructive conditions. If any part of the Contractor's work is impeded by unscheduled occupation or obstruction of Contractor work areas by OGCs, the Contractor shall promptly report such conditions in writing to the Contracting Officer.

    e. Preparation of and access to OGC Worksites. The Contractor shall be responsible to make ready applicable areas to allow for scheduled activities by each of the OGCs in accordance with the project schedule.

f. Notification of Scheduling Conflicts. If the Contractor becomes aware of potential scheduling conflicts with activities by OGCs, the Contractor shall promptly notify the Contracting Officer in writing.

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ARTICLE H.76.1. SUPPORT OF NIH REPLACED, RENOVATED, IMPROVED EQUIPMENT OR FACILITIES

Within the term of this contract, NIH may replace, renovate, or improve equipment, systems, facilities, components, and fixtures by means not associated with this contract. The Contractor shall provide Task Order maintenance support for replaced, renovated, improved, and repaired systems facilities, components, and fixtures in the same manner as would be performed for existing systems, facilities, components, and fixtures.

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ARTICLE H.76.2. EQUIPMENT DEVIATIONS

Equipment deviations of greater or larger power, dimensions, capacity, and ratings may be furnished provided such proposed equipment is approved in writing by the Contracting Officer Representative (COR); and, feeders, circuit breakers, conduit, motors, bases, structural support, and equipment spaces are increased by the Contractor and other adjustments required to accommodate proper installment and use are made by the Contractor at no additional cost to the Government.

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ARTICLE H.77. PERFORMANCE REQUIREMENTS

Personnel operating heavy equipment shall have appropriate training and experience with the specific equipment they operate, and shall operate the equipment in a proper and safe manner. Personnel shall be certificated and/or licensed for equipment operation where required by Maryland State Statutes.

Every Contractor employee entering the NIHAC Poolesville Monkey Field Habitat shall have a TB Certificate indicating a TB test with a negative result was conducted on the individual within the previous twelve (12) months. No Contractor employee shall enter the Monkey Habitat without an active certificate or with an expired certificate.

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ARTICLE H.77.1. EQUIPMENT AND FIXTURE REPLACEMENT REQUIREMENT

When the Contractor completes work on a facility, system, or piece of equipment, that facility, or equipment shall be free of missing components or defects that would prevent it from functioning as originally intended and/or designed.

Corrective or repair and/or replacement work shall include operational checks and cleanup of the job site. When equipment and/or fixtures are replaced or repaired the Contractor shall perform specific inspections, procedures, and preservation required by the manufacturer and shall verify all systems and components are operating as designed. Except where approved by the Contracting Officer Representative (COR), replacements shall match the existing in dimensions, finish, color, and design.

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ARTICLE H.77.2. COMPLYING WITH STANDARDS

The Contractor shall meet workmanship standards specified herein and shall perform work in accordance with approved and accepted industry standards; equipment manufacturers' standards; local, state, and federal standards; and applicable building and safety standards. The Contractor shall perform work in a neat and workmanlike manner readily and easily accessible for operation, maintenance, and repair. The Contractor shall perform work and install equipment in accordance with manufacturer's instructions and recommendations. The Contractor shall provide necessary access panels in walls and ceilings for access to equipment.

Applicable standards include, but not limited to:

- American Institutes of Architects (AIA)
- American National Standards Institute (ANSI)
- American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE)
- American Society of Mechanical Engineers (ASME)
- American Society of Safety Engineers (ASSE)
- American Society for Testing and Materials (ASTM)
- American Water Works Association (AWWA)
- Americans with Disabilities Act (ADA)
- Association for Assessment and Accreditation of Laboratory Animal Care (AALAC)

- Illumination Engineering Society (IES)
- Institute of Electrical and Electronic Engineers (IEEE)
- International Electrical Testing Association (NETA)
- Joint Commission for the Accreditation of Healthcare Organizations (JCAHO)
- National Electrical Manufacturers Association

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ARTICLE H.78. CONTRACTOR FURNISHED ITEMS

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ARTICLE H.78.1. CONTRACTOR MACHINERY AND STORAGE

- The Contractor shall have sufficient (quantity and type) machinery, and tools to perform the work specified herein. All machinery, equipment, and tools shall be in good, safe, and efficient working order.
- Any equipment allowed by the Contracting Officer Representative (COR) to be stored or to remain overnight on NIH property shall be kept only in designated areas and shall be the Contractor's total responsibility. The Government will not accept responsibility for loss or damage to any property of the Contractor.

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ARTICLE H.78.2. VEHICLES

All Contractor and Sub-contractor vehicles including but not limited to trucks, tractors, and trailers shall be well maintained, and shall clearly display the company name, address, telephone number.

- Motor vehicles and trailers shall have and display valid license plates.
- There are no fueling facilities on either campus. Bulk gasoline storage containers over five (5) gallons are not permitted.
- Under no circumstances shall Contractor employees work, service, or clean their private or work vehicles on either the NIH or NIHAC campuses.

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ARTICLE H.78.3. FURNISHED PARTS AND INDUSTRIAL CODES

The Contractor shall provide new or factory reconditioned parts and components when providing maintenance, repair, and alteration services as described herein. Lack of availability of parts, material, or equipment will not relieve the Contractor from the requirement to complete work within the time limits and quality standards stated herein. All replacement units, parts, components and materials to be used in the maintenance, repair, and alteration of facilities and equipment shall be compatible with the existing equipment on which it is to be used, shall be of equal or better quality than original equipment specifications, shall comply with all applicable Government, commercial, or industrial standards and regulations.

All parts shall be used in accordance with original design and manufacture intent, and shall be of acceptable industrial grade and quality. If the original manufacturer has updated the quality of parts for current production, parts supplied under this contract shall equal to or exceed the updated quality.

The Contractor shall provide copies of all applicable manufacturer operation and maintenance (O&M) manuals, pamphlets, and any other documentation related to the products provided.

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ARTICLE H.78.4. CARE AND PROTECTION OF MATERIALS AND EQUIPMENT

The Contractor shall protect and store material and equipment in such a manner as to effectively prevent damage from climatic and work conditions. The Contractor shall cover the ends of all ducts and pipes during work. The Contractor shall coordinate storage locations with the Contracting Officer Representative (COR).

If the Contractor is unsure as to the disposition of any portion of the materials, with regards to the Task Order, the Contractor must request clarification from the COR prior to removal. In the event that the Contractor removes material and equipment not intended for removal, the Contractor shall replace those materials and equipment in a similar condition prior to removal at no cost to NIH.

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ARTICLE H.79. PARTNERING

- The NIH encourages a partnering relationship with the Contractor and its Subcontractors. This relationship will draw on the strengths of each organization to identify and achieve common goals and objectives of efficient and effective contract performance and to facilitate on-time, within budget completion of projects in accordance with contract plans and specifications.

  The guiding principles of partnering are:

  Identification and Elimination of Barriers
  Continuous Process Improvement
  Mutual Respect
  Open Communications

  An integral part of the partnering concept is resolution of disputes in a timely, professional and non-adversarial manner. Alternative Dispute Resolution (ADR) methodologies are encouraged in place of more formal dispute resolution procedures.
- In order to effectively accomplish this project, a partnering provision is included for implementation with the selected Contractor. Partnering is a concept of contract execution and management, which strives to draw on the strengths of both the NIH and the Contractor in an effort to achieve:
  a. A quality project done right the first time.
  b. Budget control and on-time scheduling in accordance with plans and specifications.

     The NIH intends that its relationship with the Contractor will be one of mutual cooperation and benefit. To implement this partnership initiative, the Contractor's key project staff and NIH representatives will attend a one to two-day partnership development and team-building workshop within thirty calendar days after the Contractor has mobilized its workforce on site at NIH. The Contractor and the NIH will hold follow-up workshops periodically throughout the duration of the contract as agreed upon.

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ADDITIONAL INFORMATION ABOUT THIS ITEM:

- Replace or Edit this item IF other quality control systems are required other than what is indicated below.)****

ARTICLE H.80. CONTRACTOR QUALITY CONTROL (CQC) PROGRAM

- The Contractor shall establish and maintain a CQC Program that supports the intent of the ISO 9001 standards and the ORF/AECCB Quality System Manual. The Contractor will incorporate these quality system components in its CQC Program to the maximum extent possible to ensure that annual audits of ORF/AECCB Quality Systems by ISO9001 auditors result in re-certification status.

- A general description of the Contractor's CQC Program shall be available for NIH review during the pre-award survey. Two copies of the complete CQC Program shall be provided to the Contracting Officer for review and approval within thirty days after award of master contract and as changes are made thereafter. The program shall include:

    a. A quality control inspection system covering all contract services. It must specify areas to be inspected on either a scheduled or unscheduled basis and how inspections are to be conducted.
    b. The name(s) and qualifications of the individual(s) tasked to perform the quality control inspections, and the extent of their authority.
    c. A method for identifying deficiencies in the quality of services performed and taking corrective action before the level of performance becomes mandatory.

- A file of all Quality Control Inspections, Inspection results, and corrective actions required, shall be maintained by the Contractor throughout the term of this contract. This file shall be the property of the NIH and shall be made available to the Contracting Officer within one hour of request. The file shall be turned over to the Contracting Officer within five days after completion and prior to final payment.

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ARTICLE H.81. DESIGN BUILD CONTRACT - ORDER OF PRECEDENCE

- The contract includes the standard contract clauses and schedules current at the time of award. It also entails: (1) the solicitation in its entirety, including all drawings, cuts and illustrations, and any amendments during proposal evaluation and selection, and (2) the

successful Offeror's accepted proposal. The contract constitutes and defines the entire agreement between the Contractor and the Government. No documentation shall be omitted which in any ways bears upon the terms of that agreement.

- In the event of conflict or inconsistency between any of the provisions of the various portions of this contract, precedence shall be given in the following order:
    a. Betterments: Any portions of the Offeror's proposal which both meet and exceed the provisions of the solicitation.
    b. The provisions of the solicitation. (See also FAR Clause 52.236-21, Specifications and Drawings for Construction.)
    c. All other provisions of the accepted proposal.
    d. Any design products, including but not limited to plans, specifications, engineering studies and analyses, shop drawings, equipment installation drawings, etc. These are "deliverables" under the contract and are not part of the contract itself. Design products must conform to all provisions of the contract, in the order of precedence herein.

RESPONSIBILITY OF THE CONTRACTOR FOR DESIGN

- The Contractor shall be responsible for the professional quality, technical accuracy, and the coordination of all designs, drawings, specifications, and other non-construction services furnished by the Contractor under this contract. The Contractor shall, without additional compensation, correct or revise any errors or deficiency in its designs, drawings, specifications, and other non-construction services and perform any necessary rework or modifications, including any damage to real or personal property, resulting
from the design error or omission.

- Neither the Government's review, approval or acceptance of, nor payment for, the services required under this contract shall be construed to operate as a waiver of any rights under this contract or of any cause of action arising out of the performance of this contract. The Contractor shall be and remain liable to the Government in accordance with applicable law for all damages to the Government caused by the Contractor's negligent performance of any of these services furnished under this contract.

- The rights and remedies of the Government provided for under this contract are in addition to any other rights and remedies provided by law.

- If the Contractor is comprised of more than one legal entity shall be jointly and severally liable there under.

SEQUENCE OF DESIGN-CONSTRUCTION

- After receipt of the Contract Award the Contractor shall initiate design, comply with all design submission requirements and obtain Government review of each submission. No

construction may be started, until the Government reviews the Final Design submission and determines it satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

- If the Government allows the Contractor to proceed with limited construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any in-place construction related to the pending revisions until they are completed, resubmitted and are satisfactory to the Government.

- No payment will be made for any in-place construction until all required submittals have been made, reviewed and are satisfactory to the Government.

SEQUENCE OF DESIGN - CONSTRUCTION (FAST TRACK)

- After receipt of the Contract Award the Contractor shall initiate design, comply with all design submissions requirements and obtain Government review of each submission. The Contractor may begin construction on portions of the work for which the Government has reviewed the final design submission and has determined satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

- If the Government allows the Contractor to proceed with the construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any in-place construction related to the pending revisions until they are completed, resubmitted and are satisfactory to the Government.

- No payment will be made for any in-place construction until all required submittals have been made, reviewed and are satisfactory to the Government.

CONSTRUCTOR'S ROLE DURING DESIGN

The Contractor's construction management key personnel shall be actively involved during the design process to effectively integrate the design and construction requirements of this contract. In addition to the typical required construction activities, the constructor's involvement includes, but is not limited to actions such as: integrating the design schedule into the Master Schedule to maximize the effectiveness of fast-tracking design and construction (within the limits allowed in the contract), ensuring constructability and economy of the design, integrating the shop drawing and installation drawing process into the design, executing the material and equipment acquisition programs to meet critical

schedules, effectively interfacing the construction QC program with the design QC program, and maintaining and providing the design team with accurate, up-to-date redline and as-built documentation. The Contractor shall require and manage the active involvement of key trade subcontractors in the above activities.

PRECONSTRUCTION CONFERENCE . (FAR 36.305)

- A preconstruction conference will be arranged by the contracting officer after award of contract and before commencement of work. The contracting officer or designated representative will notify the Contractor of the time and date set for the meeting. At this conference, the Contractor shall be oriented with respect to Government procedures and line of authority, contractual, administrative, and construction matters.

- The Contractor shall bring to this conference, in completed form, a Certificate of Insurance, plus the following items in either completed or draft form:

  Accident Prevention Plan (5 copies)
  Quality Control Plan (5 copies)
  Letter Appointing Superintendent
  Transmittal Register
  Power of Attorney and Certified Copy of Resolution
  Network Analysis System, when applicable
  List of Subcontractors

- A letter of record will be written documenting all items discussed at the conference, and a copy will be furnished by the contracting officer to all in attendance.

PAYMENT FOR DESIGN UNDER FIXED-PRICE DESIGN-BUILD CONTRACTS

- The contracting Officer may approve progress payments for work performed during the project design phase up to the maximum amount of four (4) percent of the contract price.

- Contractor invoices for payment must be accompanied by satisfactory documentation supporting the amounts for which payments are requested. Progress payments approved by the contracting officer during the project design phase in no way constitute an acceptance of functional and aesthetic design elements nor acceptance of a final settlement amount in the event of a buy-out nor a waiver of any contractual requirements.

UNSCHEDULED JOBSITE SHUTDOWNS

Due to security reasons during the life of this contract the government may on an unscheduled basis ask the Contractor to shut down their jobsite for 2 days per year.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR INDEFINITE DELIVERY/INDEFINITE QUANTITY (IDIQ) REQUIREMENTS ONLY.)****

ARTICLE H.82. EMERGENCY TASK ORDER PROCEDURES

Emergency work is defined as work of such an unusual or compelling nature that the NIH would suffer serious or irreparable damage if the work is not completed immediately. The Government reserves the right to award an emergency Task Order to any IDIQ contract holder related to this IDIQ.

Emergency work is received by the Government Call Center through the MS2000 system. The Contracting Officer Representative (COR) notifies the Contractor telephonically of the nature and the location of the emergency; and, the Contractor, upon receipt of a Contracting Officer's verbal or written Notice to Proceed (NTP) shall mobilize without delay in response to such calls be on-site and ready to commence work at the designated time arranged by the COR.

Where the Contract is specifically directed to perform designated emergency work, the Contractor shall be entitled to add a surcharge to his standard (non-premium time) labor rates when work is performed outside of regular work hours. For emergency work outside normal work hours, the Contractor shall use the fixed labor rates for Evening/Weekend work as identified in the Fixed Labor Rate tables in Section B of the contract.

The COR will accompany the Contractor to inspect finished emergency Task Order work upon notification by the Contractor that work is complete before the Contractor is released.

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**** (NCI APPROVED PROVISION: USE TO PROTECT INTELLECTUAL PROPERTY FOR ALL SOLICITATIONS AND CONTRACTS INVOLVING THE RAPID ACCESS TO INTERVENTION DEVELOPMENT (RAID) PROGRAM. **Note:** *This must be in place prior to filing an IND* .) ****

ARTICLE H.83. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR

NCI may collaborate with an outside investigator who has proprietary rights to compounds which may be assigned under this contract. This collaborator will be identified by the Contracting Officer's Representative (COR) at the time of assignment and in this case, the following option regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NCI and "Collaborator" in writing of any inventions, discoveries or innovations made by the Contractor's principal investigator or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Agent (hereinafter "Contractor Inventions").

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (2) a time-limited first option to negotiate an exclusive world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Contractor Inventions on terms to be negotiated in good faith by Collaborator and Contractor. Collaborator shall notify Contractor, in writing, of its interest in obtaining an exclusive license to any Contractor Invention within six (6) months of Collaborator's receipt of notice of such Contractor Invention(s). In the event that Collaborator fails to so notify Contractor or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Contractor Invention, and Contractor will be free to dispose of its interests in such Contractor Invention in accordance with its own policies. If Contractor and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter, Contractor shall not offer to license the Contractor Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Contractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 U.S.C. 201(e),* arising out of any unauthorized use of the Collaborator's Study Agent shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Contractor will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all right, title and interest in an to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Contractor may also be conducting other more basic research using Study Agent under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

*35 U.S.C. 201(e): The term "subject invention" means any invention of the Contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d)(FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

Protection of Proprietary Data

Data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI and the Collaborator. The Contractor retains the right to publish research results subject to the terms of this contract.

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****(USE BELOW IN R&D AND NON-R&D SOLICITATIONS AND CONTRACTS THAT INVOLVE BIOMEDICAL RESOURCES SUCH AS A REPOSITORY, STORAGE FACILITY OF MATERIALS, OR TRANSFER OF HUMAN MATERIALS.)****

ARTICLE H.84. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf is intended to help Contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy. Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

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****(ADD THE FOLLOWING PARAGRAPH BELOW FOR CONTRACTS THAT INVOLVE BIOMEDICAL RESEARCH OF MODEL ORGANISMS.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- Select the sentence to be used in the contract within the brackets below. Make sure to delete the sentence you will not be using.)****

- Sharing of Model Organisms for Biomedical Research

  [The plan for sharing model organisms submitted by the Contractor is acceptable/The Contractor's plan for sharing model organisms, dated _____ , is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

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****(FOR NCI USE: ADD THE FOLLOWING PARAGRAPH, BELOW, FOR CONTRACTS THAT INVOLVE THE TRANSFER OF HUMAN MATERIALS FROM INTRAMURAL LABORATORIES FOR RESEARCH.)****

- Transfer of Human Materials

  All human materials transferred to the Contractor under this contract for the purposes of research shall be accomplished in accordance with the Policy entitled, "Policy for the Transfer of Materials from NIH Intramural Laboratories," located at: http://www.ott.nih.gov/mta-policy .

The Contractor shall coordinate with the **NCI Technology Transfer Center** (see http://ttc.nci.nih.gov) [or the contracting officer will insert name and contact information of the appropriate TDC] to determine the specific terms and conditions for the human materials to be transferred. Generally, the Government and Contractor will enter into Material Transfer Agreement which stipulates the specific terms and conditions relating to the materials being transferred.

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****(USE BELOW FOR CONTRACTS THAT REQUIRE A "DATA SHARING PLAN" FOR SHARING OF FINAL RESEARCH DATA.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **First Paragraph:** Select the appropriate sentence within the brackets below. Make sure to delete the sentence you will not be using.)****

ARTICLE H.85. SHARING RESEARCH DATA

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated _____ is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

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****(USE BELOW WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS. **Note:** *At this time, may only be applicable to NIAID projects* .)****

ARTICLE H.86. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The work being conducted under this contract may involve the possession, use, or transfer of a select agent or toxin. The Contractor shall not conduct work involving a Select Agent or Toxin under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer a Select Agent or Toxin under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.selectagents.gov/Regulations.html) as required, before using NIH funds for work involving a *Select Agent or Toxin* . **No NIH funds can be used for research involving a *Select Agent or Toxin* at a domestic institution without a valid registration certificate.**

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin* , before using NIH funds for any work directly involving a *Select Agent or Toxin* , the foreign institution must provide information satisfactory to the NIAID that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agent or Toxin and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents or Toxins under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. Site visits to foreign laboratories are conducted every three years after the initial review. **No NIH funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Prior to conducting a restricted experiment with a Select Agent or Toxin under this contract or any associated subcontract, the Contractor must discuss the experiment with the Contracting Officer's Representative (COR) and request and obtain written approval from the Contracting Officer. **Domestic institutions** must submit to the Contracting Officer written approval from the CDC to perform the proposed restricted experiment. **Foreign institutions** require review by a NIAID representative. The prime Contractor must contact the COR and the NIAID Office of International Extramural Activities (OIEA) at

mailto:niaidforeignawards@niaid.nih.gov for guidance on the process used by NIAID to review proposed restricted experiments. The NIAID website provides an overview of the review process at http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/saconproc.aspx . The Contracting Officer will notify the prime Contractor when the process is complete. **No NIH funds can be used for a restricted experiment with a Select Agent or Toxin at either a domestic or foreign institution without written approval from the Contracting Officer.**

Listings of HHS and USDA select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.selectagents.gov/ and http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html .

For foreign institutions, see the NIAID Select Agent Award information: (http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/default.aspx).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF A HIGHLY PATHOGENIC AGENT. **Note:** *At this time, may only be applicable to NIAID projects* .)****

ARTICLE H.87. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a *Highly Pathogenic Agent (HPA).* The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

- The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http://www.cdc.gov/biosafety/publications/index.htm under "Publications);
- The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
- The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS IN WHICH THE POSSIBILITY OF A FEDERALLY FUNDED, IN WHOLE OR IN PART, MEETING, CONVENTION, CONFERENCE OR TRAINING SEMINAR EXISTS.)****

ARTICLE H.88. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or

that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.
Public accommodations that meet the requirements can be accessed at: http://apps.usfa.fema.gov/hotel/ .

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****(USE BELOW, IN ALL SOLICITATIONS AND CONTRACTS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS. **Note:** *At this time, may only be applicable to NIAID projects* .)****

ARTICLE H.89. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

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****(THE FOLLOWING ITEM IS FOR NIEHS USE ONLY. TO BE USED AT THE CONTRACTING OFFICER'S DISCRETION. **Note** *: The purpose of this clause is to adequately define the Government's level of control over records and data that are produced by the Contractor under the contract, but are defined as a deliverable under the terms of the contract, or are not yet in the Government's physical possession as defined as a deliverable under the terms of the contract* .)****

ARTICLE H.90. GOVERNMENT CONTROL OVER UNDELIVERED AND/OR UNPUBLISHED RECORDS AND DATA

- As used in this clause, "records and data" means: (1) any handwritten, typed, or printed documents (including, but not limited to, memoranda, letters, writings, books, brochures, transcripts, minutes, electronic transmissions, study findings, laboratory note books, chromatograms, spectra, and maps); (2) documentary material in other forms (such as punch cards, magnetic or paper tapes, instrumentation cards, computer discs, electronically stored information, audio or video recordings, motion pictures, photographs, slides, microfilm, and microfiche); and, (3) biological samples and pathology materials (pathology slides, paraffin blocks, and wet tissues). Records and data may or may not constitute a specific deliverable defined under the terms of the contract.
- The purpose of this clause is to define the Government's control over records and data that are produced by the Contractor under this contract, but are not defined as a

deliverable under the terms of the contract, or are not yet in the Government's physical possession if a deliverable under the terms of the contract. This clause is designed to serve public policy by limiting the disclosure of certain records and data if disclosure is made at a time when such records and data remain unvalidated and unreliable (i.e. may not have undergone a quality control nor subsequent audit and inspection as part of a quality assurance process) and could thereby lead to erroneous conclusions which might threaten public health or safety.

- The Government shall be deemed as having no control over, or direct ownership of records and data created or produced by the Contractor in the performance of this contract until such time as the records and data have been: (1) subjected to an acceptable method of quality control and quality assurance; (2) delivered to the Government or obtained by the Government under the terms of this contract; (3) published in accordance with the terms of this contract; or (4) used by the Federal Government in developing an agency action that has the force and effect of law.
- In the event of a contract termination, this clause does not relieve the Contractor of its obligations set forth elsewhere in this contract to transfer title and deliver to the Government work in process, completed work, supplies, and other material produced or acquired for the work terminated, or, the completed or partially completed plans, drawings, information, and other property that, if the contract had been completed, would be required to be furnished to the Government.
- This clause shall have no effect on the Government's rights during the performance of the contract as specified elsewhere herein, including the Governments rights and abilities to request access to or be provided with such records and data for the purpose of conducting any inspections, examinations or audits as set forth in the contract.

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**** (USE BELOW IN ALL RFPs & CONTRACTS WITH EDUCATIONAL INSTITUTIONS.) ****

ARTICLE H.91. CONSTITUTION DAY

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

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****(INCLUDE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE LOGISTICAL SUPPORT SERVICES; OR ANY CONTRACT THAT INCLUDES THE CONDUCT OF A CONFERENCE OR MEETING, EVEN IF INCIDENTAL TO THE PERFORMANCE OF THE CONTRACT.

IMPORTANT INFORMATION ABOUT THIS ARTICLE:

- The Contracting Officer shall not authorize the Contractor to conduct any conferences or meetings until the appropriate conference approval/waiver has been approved by the IC EO, NIH Director or HHS Deputy Secretary as applicable in accordance with the NIH Policy Memorandum Implementation Guidance of the HHS Efficient Spending Policy, dated June 15, 2012. See http://oamp.od.nih.gov under Efficient Spending Policy.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **3rd Paragraph:**
  a. Complete the information in the Table for any conferences or meetings that have been approved at the time of award.
  b. Remove this paragraph, including the Table, if conferences and/or meetings have not been approved at the time of award.)****

ARTICLE H.92. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

The following conferences and/or meetings have been approved by the Contracting Officer and are hereby authorized under this contract:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS IN WHICH A NON-FEDERAL ENTITY IS COSPONSORING WITH AN INSTITUTE/CENTER (IC) A SCIENTIFIC MEETING, CONFERENCE OR WORKSHOP AND REGISTRATION FEES ARE CHARGED AND COLLECTED. See Manual Chapter 6031, "Conference Support/Collection and Retention of Registration Fees," for additional information.)****

ARTICLE H.93. REGISTRATION FEES FOR CONFERENCES, WORKSHOPS AND MEETINGS

A Non-Federal entity co-sponsoring a conference with an Institute/Center (IC) under a contract may charge and collect a registration fee from all participants for the purpose of defraying its portion of the expenses of the conference. Under these circumstances, the Contractor shall document that the registration fees associated with the event are being charged, collected and used solely by the co-sponsor.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted by the Contractor from the total cost of the conference.

In addition, prior to each conference, the Contractor shall provide the following information and documentation to the Contracting Officer's Representative (COR) and Contracting Officer:

- Co-sponsor's name
- Conference name, location, dates, times
- copy of the agenda
- A completed 'Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J).
- After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the Contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury. If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

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****(USE THE FOLLOWING IN ALL SOLICITATIONS AND CONTRACTS FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL AND RESEARCH-RELATED CONFERENCES IN WHICH REGISTRATION FEES ARE CHARGED AND COLLECTED FOR THE PURPOSE OF DEFRAYING THE COSTS OF THE CONFERENCE. See Manual Chapter 6031, "Conference Support/Collection and Retention of Registration Fees" for additional information.)****

ARTICLE H.94. REGISTRATION FEES FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL, AND RESEARCH-RELATED CONFERENCES

In accordance with the NIH Reform Act of 2006, P.L. 109-482, the NIH may authorize a Contractor procured to assist in the development and implementation of a scientific, educational or research-related conference to collect and retain registration fees from Non-HHS Federal and Non-Federal participants to defray the costs of the contract.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted from the total cost of the conference.

Prior to each conference, the Contractor shall submit a completed "Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the Contracting Officer's Representative (COR) and Contracting Officer. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the Contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury.

If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT MAY CONDUCT DOMESTIC AND/OR INTERNATIONAL SCIENTIFIC MEETINGS SPONSORED BY AND/OR RECEIVING SUPPORT FROM THE NIH.)****

ARTICLE H.95. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the Contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHERE THE POSSIBILITY EXISTS THAT THE CONTRACTOR WILL PROVIDE OR PURCHASE PROMOTIONAL ITEMS.)****

ARTICLE H.99. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given

to individuals as these are considered personal gifts for which contract funds may not be expended.

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****(USE BELOW IF NONE OF THE ABOVE CLAUSES ARE APPLICABLE.)****

THERE ARE NO ARTICLES CONTAINED IN THIS SECTION.