37

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

38

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

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM :

- Modify the title below as needed and delete additional text.

ARTICLE C.1. [DESCRIPTION-SPECIFICATION-WORKSTATEMENT-STATEMENT OF WORK]

39

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

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated _____ , attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

40

****(USE BELOW WHEN THE PRIVACY ACT IS APPLICABLE TO THE REQUIREMENT.)****

b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer Representative (COR).

41

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

ARTICLE C.2. REPORTING REQUIREMENTS

42

****(USE BELOW WHEN SUBMISSION OF REPORTS IN ELECTRONIC FORMAT IS REQUIRED.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. If electronic reports are required under the contract, these reports MUST be submitted Section 508 Compliant regardless of whether or not the contract is for EIT products or services.
2. **First Paragraph:** If you do not want to receive a hardcopy of the report, remove the second sentence.
3. If you would like to receive electronic reports in a particular format, this should be discussed during negotiations and specified in the contract.
4. **Third Paragraph:** If you will not be receiving paper reports/deliverables under the contract, remove this paragraph.

All reports shall be submitted electronically. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

These reports shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: https://www.hhs.gov/web/section-508/index.html and at: https://www.section508.gov/create/documents , "Create Accessible Documents."

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

43

****(USE BELOW IN NHLBI CONTRACTS WHEN CONTRACTORS ARE REQUIRED TO INCLUDE A LEGEND ON TECHNICAL PROGRESS REPORTS THAT CONTAIN INTERIM STUDY DATA AND A CLAUSE WHICH STATES THE NHLBI'S INTENT FOR THE USE OF INTERIM STUDY DATA.

NHLBI Processes/Procedures Reviewed 9/22)****

a. **Technical Progress Reports Containing Interim Study Data**

1. **Legend for Technical Progress Reports Containing Interim Study Data**

It is recommended that the Contractor incorporate the following legend on the cover of technical progress reports and reports containing study data that are prepared for use by all working committees in their monitoring of the trial. Working committees include but are not limited to the Data and Safety Monitoring Board (DSMB), Steering Committee and Executive Committee.

"The data, if any, contained in this report/deliverable are preliminary and may contain unvalidated findings. These data are not intended for public use. Public use of these data could create erroneous conclusions which, if acted upon, could threaten public health or safety."

2. **Use of Interim Study Data**

Interim data used in technical progress reports and other reports developed for the purpose of study monitoring are not intended for public use. Premature release of such data could result in interpretations that prove to be unreliable or invalid once the study is completed and the full context for the data is known. Unreliable or invalid interpretations can threaten public health and safety by leading the public and medical practitioners to pursue inappropriate measures. In addition, an interpretation of the interim data that is contrary to study protocol could cause participants to drop out of treatment groups. This could prevent completion of the study. A secondary consequence, not in terms of public health and safety, but one that is important in its own right, is that premature release of the data can lead to financial loss to the Government, since any funds spent on a trial that does not answer the questions posed by the study would be devalued.

In consideration of the above, interim data shall be used only for internal study monitoring purposes with the exception of publications and presentations approved in accordance with the programmatic protocol and study procedures.

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****(USE BELOW IN ALL SOLICITATIONS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

b. **Technical Progress Reports**

45

****(USE BELOW IN ALL SOLICITATIONS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- 2nd Paragraph (Listing): Check only the reports which will be required under the resulting contract(s).

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the*

Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) __ hard copies of these reports will be required as follows:

[ ] Monthly
[ ] Quarterly
[ ] Semi-Annually
[ ] Annually
[ ] Annually (with a requirement for a Draft Annual Report)
[ ] Final - Upon final completion of the contract
[ ] Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

46

**** (USE BELOW IN ALL SOLICITATIONS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- Delete the "Summary of Salient Results" in its entirety if not applicable to the requirement.

Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

47

****(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 INSTITUTIONAL 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: https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- The Contractor must submit a progress report no less than on an annual basis.

Reporting on Dual Use Research of Concern

a. Progress Report
For work involving an agent or toxin identified in the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern or "DURC policy" (see https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf), the Contractor shall report the following information in the Annual/Semi-Annual/Quarterly/Monthly Progress report:

i. Identification of agents or toxins that are listed in the DURC policy and used in research funded in this contract, and;
ii. Proposed modifications, if any, to the risk mitigation plan.

b. Special Notifications
The Contractor shall report to the Contracting Officer's Representative, within 30 calendar days of:
i. Any change in the status of the DURC project funded under this contract (including whether the research is determined by the Contractor's institutional review entity to no longer meet the definition of DURC);
ii. Details of any changes to risk mitigation plans (such changes need to be pre-approved by the Contracting Officer Representative), or;
iii. Instances of noncompliance with the DURC policy, as well as mitigation measures undertaken by the Contractor to prevent recurrences of similar noncompliance.

48

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

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **First Paragraph:** For studies funded with **ARRA Funds** , add the following (or similar) language as the second sentence:
   - **"A separate" Cumulative Inclusion Enrollment Report" shall be completed for each clinical research protocol funded with ARRA funds."**
2. **Second paragraph:** Select the sentence appropriate for the type of contract within the brackets below. If appropriate, insert required information. Make sure to delete the sentence that does not apply.

Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations (when appropriate) for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Cumulative Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. If the clinical study(s) involves US and non-US sites, the US sites and non-US sites should be reported on separate Cumulative Inclusion Enrollment Reports.

[**For a completion contract add** : The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract. **OR For a Level of Effort Contract add** : The first report shall be due _____ . Thereafter, the report shall be due on or before the _____ day following each reporting period. The final report shall be due on _____].

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as

Subjects in Clinical Research, Amended, October 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website: https://grants.nih.gov/policy/inclusion/women-and-minorities.htm.
For NIH-defined Phase III Clinical Trials: Include a description of the plans for valid analysis in the study design and outcomes. This includes designing the study in a manner that potential differences, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol could be conducted. Also, provide a description of any analyses by sex/gender, race, and/or ethnicity, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender, race and/or ethnicity.

49

**** (USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF *SELECT AGENTS OR TOXINS* AND/OR *HIGHLY PATHOGENIC AGENTS* .

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Select the **least** frequent applicable report from the drop-down box(es).

Note: This item is generally used for NIAID contracts. However, if you have a contract that involves Select Agents or Toxins, you may wish to use this or something similar to meet your needs.

NIAID Processes/Procedures Reviewed 9/22)

****

Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents

For work involving the possession, use, or transfer of a *Select Agent or Toxin* and/or a *Highly Pathogenic Agent* , the following information shall also be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report:

1. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

2. If work with a new or additional *Select Agent or Toxin* and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:
    a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;
    b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b https://www.selectagents.gov/regulations/index.htm) or listed on the U.S.

Federal Select Agents Registry restricted experiments website (https://www.selectagents.gov/compliance/guidance/restricted/index.htm);

c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.
d. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report.

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****(USE BELOW WHEN ADDITIONAL REPORTING REQUIREMENTS ARE TO BE INCLUDED IN THE CONTRACT.)****

c. **Other Reports/Deliverables**

51

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

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **First paragraph:** Select the applicable submission format from the drop-down box in the first sentence.

1. **Reporting of Financial Conflict of Interest (FCOI)**

All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in [Electronic/Hard Copy] format. Thereafter, reports shall

be due in accordance with the regulatory compliance requirements in 45 CFR Part 94. 45 CFR Part 94 is available at: https://www.ecfr.gov/current/title-45/part-94.

See Part 94.5, Responsibilities of Institutions regarding Investigator financial conflicts of interest for complete information on reporting requirements.

(Reference the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

52

****(USE BELOW IN SOLICITATIONS AND CONTRACTS INVOLVING THE USE OF USDA DESIGNATED BIOBASED PRODUCTS.)****

2. **Report of USDA-Designated Biobased Products**

In accordance with FAR clause 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts, the Contractor shall report to https://www.sam.gov/SAM/ , with a copy to the Contracting Officer any USDA-designated biobased products purchased during the period of October 1-September 30 of each contract year. **This report shall be submitted no later than October 31 of each year during contract performance and on the expiration date of the contract.**

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****(USE BELOW WHEN SOFTWARE WILL BE DEVELOPED, MODIFIED, AND/OR ENHANCED UNDER THE CONTRACT.)****

3. **Source Code and Object Code**

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

54

****(INCLUDE BELOW IN SOLICITATIONS WHEN IT HAS BEEN DETERMINED THAT:
• CONTRACTOR PERSONNEL MAY REQUIRE ACCESS TO HHS-CONTROLLED FACILITIES AND/OR INFORMATION SYSTEMS, INCLUDING SENSITIVE DATA/INFORMATION, IN ORDER TO PERFORM THE CONTRACT/ORDER SOW/PWS, AND/OR ;
• THE HOMELAND SECURITY PRESIDENTIAL DIRECTIVE'S (HSPD-12) MORE STRINGENT ACCESS PROCEDURES ARE EXPECTED TO APPLY, BECAUSE ACCESS WILL BE ROUTINE AND OF LONG-TERM DURATION, OR IS ROUTINE AND OF SHORT-TERM DURATION, BUT GREATER ACCESS CONTROLS ARE DEEMED NECESSARY.
ADDITIONAL INFORMATION ABOUT THIS ITEM:)****
1. For more information, see HHS OCIO Program Policies at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/information-security-privacy-program/index.html.
2. 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 the individual responsible for Contracts (Security Language) - located in the NIH Office of the Chief Information Officer (OCIO) - Phone: 301-496-1168; Email: nihciocommunications@mail.nih.gov.

4. **HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS**

55

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE CONTRACTOR ACCESS TO FEDERAL INFORMATION OR FEDERAL INFORMATION SYSTEMS.)****

INFORMATION AND/OR PHYSICAL SECURITY

A. **Assessment and Authorization (A&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) must 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 must conduct the A&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.

B. **A&A Package Deliverables -** The Contractor (and/or any subcontractor) must provide an A&A package within 30 days of contract award to the CO and/or COR. The following

A&A deliverables are required to complete the A&A package.

C. **System Security Plan (SSP) -** due within 30 days after contract award. The SSP must 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 must 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 must 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 must update the SSP at least annually thereafter.

D. **Security Assessment Plan/Report (SAP/SAR)** - due 30 days after the contract award. The security assessment must 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.

E. **Independent Assessment -** due 90 days after the contract award. The Contractor (and/or subcontractor) must have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party must 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 must 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).

F. **Plan of Actions and Milestones (POA&M) -** due 30 days after contract award. The POA&M must be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All findings/weaknesses must be documented in the POA&M and remediated/mitigated from the date the weaknesses are formally identified and documented by the timelines below:

- Critical within 30 days;
- High within 60 days;
- Medium within 1 year; and
- Low within 1 year.

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, must 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 must be updated at least quarterly.

G. **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, must 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 must update and test the Contingency Plan at least annually.

H. **E-Authentication Questionnaire -** The contractor (and/or any subcontractor) must 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 must 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.

I. **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). To determine the designation, the Position Designation Tool (PDT) discussion is found at: https://ors.od.nih.gov/ser/dpsac/administrators/onboarding-new-staff/Pages/position-designation-tool.aspx and the link to access the tool is found at: https://pdt.nbis.mil/ .

The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Tier 5: Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility.
[ ] Tier 5SR: Reinvestigation.

[ ] Tier 4: High Risk Public Trust (HRPT).
[ ] Tier 4SR: Reinvestigation.

[ ] Tier 3: Non-Critical Sensitive, National Security, including Secret and "L" access eligibility.
[ ] Tier 3SR: Reinvestigation.

[ ] Tier 2S with Subject Interview: Moderate Risk Public Trust (MRPT).
[ ] Tier 2SR: Reinvestigation.

[ ] Tier 1: Low Risk, Non-Sensitive, including HSPD-12 Credentialing.

J. **HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12**

Roster-

The Contractor (and/or any subcontractor) must 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 must 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 must 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://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j

a. If the Contractor is filling a new position, the Contractor must 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.
b. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor must complete and submit the required forms within 30 days of the notification.
c. The Contractor must 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.
d. All contractor and subcontractor employees must 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.

e. 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 must ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
f. 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).
g. The Contractor must 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).
h. The Contractor must direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor must return all identification badges to the Contracting Officer or designee.

K. **CONTRACT INITIATION AND EXPIRATION**

a. **General Security Requirements** - The Contractor (and/or any subcontractor) must 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 must follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Directive (2018) located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf . HHS EA requirements located at: https://www.hhs.gov/sites/default/files/eplc-policy-dec-2016.pdf and NIH EA requirements are located at: https://ocio.nih.gov/PM/Pages/EPLC.aspx .
b. **System Documentation** - Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, 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.
c. **Sanitization of Government Files and Information** - As part of contract closeout and at expiration of the contract, the Contractor (and/ or any subcontractor) must 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.

d. **Notification** - The Contractor (and/ or any subcontractor) must notify the CO and/ or COR and system ISSO within fifteen days before an employee stops working under this contract.

e. **Contractor Responsibilities Upon Physical Completion of the Contract-** The Contractor (and/ or any subcontractors) must 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 must 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.

f. The Contractor (and/or any subcontractor) must 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 must be made available to the CO and/ or COR upon request.

g. **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 must be submitted to the Contracting Officer (CO) and/ or CO Representative (COR) prior to performing any work under this acquisition.

h. **Vulnerability Scanning Reports -** The Contractor must report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report must be submitted under a separate cover on monthly basis.

i. **Government Access for Security Assessment.** In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) must 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:

    i. 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.

ii. 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.

iii. 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.

iv. Cooperate with inspections, audits, investigations, and reviews.

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****(USE BELOW IN MULTIPLE YEAR SOLICITATIONS AND CONTRACTS OVER THE SIMPLIFIED ACQUISITION THRESHOLD WHICH CONTAIN THE ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY ARTICLE IN SECTION H OF THE CONTRACT.)****

5. **Section 508 Annual Report**

The Contractor must submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer

(CO)/Contracting Officer Representative (COR). The Section 508 Report Template and Instructions for completing the report are available at: https://www.hhs.gov/sites/default/files/web/508/contracting/technology/section_508_annual_report.doc.

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****(USE BELOW WHEN THE SOLICITATION INCLUDES LANGUAGE FOR MULTIPLE PRINCIPAL INVESTIGATORS.)****

6. **Multiple Principal Investigators Leadership Plan**
The Contractor must submit a revised/updated Leadership Plan in the event of a change in any of the Principal Investigators named in the Key Personnel Article in SECTION G of this contract. The revised plan is subject to review and approval by the Contracting Officer.

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****(NHLBI: USE BELOW FOR CONTRACTS THAT INCLUDE THE NHLBI POLICY FOR DATA SHARING FROM CLINICAL TRIALS AND EPIDEMIIOLOGICAL STUDIES CLAUSE IN SECTION H.
NHLBI Processes/Procedures Reviewed 9/22)****

7. **NHLBI Policy for Data Sharing from Clinical Trials and Epidemiological Studies**

The Contractor must provide data sets for the study with full documentation. The data set and documentation shall be prepared in accordance with the NHLBI's Data Set policy at: https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing-from-clinical-trials-and-epidemiological-studies.

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****(USE BELOW IN NIAID SOLICITATIONS AND CONTRACTS REQUIRING THE SUBMISSION OF ELECTRONIC CONTRACT DELIVERABLES SUBMITTED VIA eRDS.
NIAID Processes/Procedures Reviewed 9/22)****

8. **REPORTING REQUIREMENTS FOR USE WITH THE ELECTRONIC REPORT DELIVERABLE SUBMISSION (eRDS) SITE**

All reports required herein must be submitted in electronic format. All electronic contract deliverables must be submitted via the NIAID electronic Report Deliverable Submission (eRDS) Site, available at the following website: https://erds.niaid.nih.gov/ . All electronic reports submitted must be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at https://www.hhs.gov/web/section-508/index.html and at: https://www.section508.gov/create/documents , "Create Accessible Documents."

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHICH CONTAIN EITHER OF THE FOLLOWING PATENT RIGHTS CLAUSES: 52.227-11, Patent Rights-Ownership by the Contractor; or 52.227-13, Patent Rights-Ownership by the Government.)****

Note: *52.227-11 is included in the general clause listings for R&D contracts. See FAR 27.303(e) for applicability information relating to 52.227-13.*

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **First paragraph:** Select the applicable clause from the drop-down box in the first sentence.
2. **Second paragraph:**
   a. Select the sentence appropriate for the type of contract within the brackets below. If appropriate, insert required information. Make sure to delete the sentence that does not apply.
   b. Include complete address.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by [FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor/FAR Clause 52.227-13, Patent Rights-Ownership by the Government] including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

[**For a completion or fixed-price contract add:** The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract/ **For a**

level of effort contract add: The first annual utilization report shall be due on or before _____ . Thereafter, reports shall be due on or before the __ [Calendar/Working] day following the reporting period.] The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
_____
Office of Acquisition
_____
_____ , Room __
Bethesda, Maryland 20892 - __

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.