

\*\*\*\*(INCLUDE BELOW IN ALL SOLICITATIONS.)\*\*\*\*

## SECTION M - EVALUATION FACTORS FOR AWARD

\*\*\*\*(THE ITEM BELOW SHOULD BE USED WHEN THE CONTRACTING OFFICER HAS DETERMINED THAT PAST PERFORMANCE SHOULD NOT BE EVALUATED AND THE CONTRACT IS EXPECTED TO BE VALUED AT LESS THAN \$650,000. Further, this paragraph gives paramount consideration to technical proposals and considers all evaluation factors other than cost/price, when combined, significantly MORE important than cost/price. The paragraph also describes the selection process when the evaluation reveals two or more offerors are approximately equal in combined non-price/cost evaluation factors. If this does not describe your intent, FAR Part 15 allows cost/price to be EQUAL TO or significantly MORE important than combined non-cost/price evaluation factors. If your intent is other than the paragraph below, you should coordinate revised language with your Section Chief or his/her Deputy prior to incorporation into the SOLICITATION.)\*\*\*\*

### 1. GENERAL

The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of all factors other than cost or price. The Government intends to make an award(s) to that offeror(s) whose proposal provides the best overall value to the Government.

\*\*\*\*(USE BELOW WHEN PAST PERFORMANCE IS TREATED AS A "STAND ALONE" FACTOR. NOTE THAT PARAMOUNT CONSIDERATION IS GIVEN TO TECHNICAL PROPOSALS, WITH COST/PRICE BEING MORE IMPORTANT THAN PAST PERFORMANCE. IF THIS IS NOT CONSISTENT WITH YOUR REQUIREMENT, CHANGE THE NARRATIVE TO APPROPRIATELY REFLECT THE RELATIONSHIP OF PAST PERFORMANCE TO TECHNICAL AND COST FACTORS.)\*\*\*\*

**Note:** *If the evaluation of Past Performance is waived, it will be necessary to modify the text below. In any event, please carefully review this paragraph and make any changes necessary to assure that the language used accurately reflects the evaluation/award process that you deem necessary for your requirement .*

### 2. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost/price/approximately equal to cost/price/significantly less important than cost or price . The

Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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\*\*\*\*(USE BELOW WHEN PAST PERFORMANCE IS A TECHNICAL EVALUATION FACTOR WHICH WILL BE EVALUATED AND SCORED BY GOVERNMENT REVIEWERS ON THE TECHNICAL EVALUATION PANEL.

DO NOT USE IF A PEER REVIEW IS TO BE CONDUCTED.

IN THIS EXAMPLE, TECHNICAL PROPOSALS (INCLUDING PAST PERFORMANCE INFORMATION) ARE MORE IMPORTANT THAN COST/PRICE. IF THIS IS NOT CONSISTENT WITH YOUR REQUIREMENT, CHANGE THE NARRATIVE TO APPROPRIATELY REFLECT THE RELATIONSHIP OF COST TO TECHNICAL FACTORS.)\*\*\*\*

**Note:** *Please carefully review this paragraph and make any changes necessary to assure that the language used accurately reflects the evaluation/award process that you deem necessary for your requirement .*

### 3. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors), and cost/price factors. Although technical factors are of paramount consideration in the award of the contract and cost/price is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost/price/approximately equal to cost/price/significantly less important than cost or price . The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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\*\*\*\*(INCLUDE BELOW IN ALL SOLICITATIONS.)\*\*\*\*

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

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

#### **ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:**

- **Second and Third Paragraphs [within brackets]:** If the contract will contain cost-reimbursement line items (other than Other Direct Costs) remove the brackets and include the two paragraphs within the brackets. Otherwise, remove these paragraphs and this item will consist of only the first paragraph.

#### 4. **COST/PRICE EVALUATION**

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

[Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.]

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\*\*\*\*(USE BELOW IN ALL SOLICITATIONS THAT WILL RESULT IN THE AWARD OF A MULTI-YEAR CONTRACT.)\*\*\*\*

#### 5. **MULTI-YEAR CONTRACT**

The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement to assess whether the contractor's anticipated costs are unbalanced and to ensure that the proposed costs are consistent with the proposed effort across all program years. Within the context of FAR Subpart 17.1, "program year" has the same meaning as "contract year."

If the Government determines before award that only the first contract year requirements are needed, the Government's evaluation of the offeror's price and ability to perform shall consider only the first year.

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\*\*\*\*(USE BELOW FOR ANY MULTI-YEAR CONTRACT THAT WILL BE AWARDED USING A LOW PRICE/TECHNICALLY ACCEPTABLE SELECTION PROCESS.)\*\*\*\*

The evaluated price will be determined by comparing the lowest priced proposal for the first program year to the lowest priced proposal for the entire multi-year period of performance. If the lowest priced proposal for the first program year is also the lowest priced proposal for the entire multiyear period of performance, then that proposal is the lowest priced proposal. If the lowest priced proposal for the first program year is not the same as the lowest priced proposal for the entire multiyear period, the lowest priced proposal will be determined by assessing the probability that the contract will continue for the entire multiyear period together with the magnitude of the price difference between the proposals. For example, if the Government determines that it is nearly certain that the contract will continue for the entire multiyear period,

the proposal with the lowest price over the entire multiyear period will most probably be considered to be the low priced proposal.

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\*\*\*\*(USE BELOW IN STUDIES THAT WILL INVOLVE HUMAN SUBJECTS.)\*\*\*\*

## 6. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

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

### ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph a:** Identify applicable I/C in the text box provided.

#### a. Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by \_\_\_ that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

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#### b. Women and Minorities

Women and members of minority groups and their subpopulations must be

included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide <https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm>, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

**OR**

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),

**OR**

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects, and

- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

### c. **Children**

Children (i.e. individuals under the age of 18) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

\*\*\*\*(USE BELOW FOR SOLICITATIONS THAT WILL RESULT IN THE CONDUCT OF A CLINICAL TRIAL(S).)\*\*\*\*

### d. **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with

risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation factors in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

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

**e. HIV Antiviral Treatment Trials**

The offeror's proposal must address a plan to have host countries authorities and/or other stakeholders identify sources available, if any, to provide antiretroviral treatment to HIV affected populations that have participated in the contract funded HIV antiretroviral treatment trial, OR describe why the offeror believes that there are no such sources available. The information provided must be in accordance with Section L.2.b. Technical Proposal Instructions.

The Project Officer (PO) and/or the Contracting Officer Representative (COR) will evaluate the documentation provided. While an offeror's documentation of the lack of available sources for antiretroviral treatment will not, of itself, constitute denial of a contract award, priority for contract awards may be given to those offerors who identify sources for the provision of antiretroviral treatment following the completion of the trial.

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\*\*\*\*(USE BELOW FOR R&D SOLICITATIONS INVOLVING LIVE VERTEBRATE ANIMALS [INCLUDING THEIR USE AS A SOURCE OF TISSUES.]\*\*\*\*



## 7. LIVE VERTEBRATE ANIMALS EVALUATION

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following criteria. (See NIH Guide Notice NOT-OD-16-006 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html>):

- a. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
- b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
- c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
- d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

\*\*\*\*(INCLUDE BELOW WHEN MANDATORY QUALIFICATION CRITERIA ARE NECESSARY.)\*\*\*\*

**ADDITIONAL INFORMATION ABOUT THIS ITEM:**

1. The documentation which supports that the qualification criterion has been met **MUST** be contained in the offerors proposal. The Contracting Officer should decide and indicate below whether the offeror will be required to either put all the qualification information into one area of the proposal or to provide an index in the proposal that will direct reviewers to the specific area of the proposal that addresses a particular mandatory qualification. Additionally, if the mandatory criteria must be met at some time other than at the time of Final Proposal Revisions, the CO should modify the language below.
2. **For Solicitations that include SECTION 508 COMPLIANCE requirements:** See HHSAR 315.304. A solicitation for EIT products and services (including EIT deliverables such as electronic documents and **reports** , unless the EIN products and/or services are incidental the project) shall include a separate technical evaluation factor (which may be in the form of a technical evaluation criterion or a **mandatory qualification criterion (but not both)** , as appropriate) developed by the CO, PO, and OPDIV Section 508 Coordinator to determine vendor compliance with applicable Section 508 accessibility standards. For a list of Section 508 Coordinators see: <https://ocio.nih.gov/ITGovPolicy/NIH508/Pages/Section508Coordinators.aspx> Section 508 Coordinators at NIH ICs.

**ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:**

1. **First Paragraph:** Select from the bracketed information, that which best describes the way the Contracting Officer would like to see the qualification information presented in the proposal. Delete the sentence that does not apply.
2. **Second Paragraph:** If it is anticipated that the contract will be awarded **WITHOUT** discussions, make sure that you select the phrase "Technical Proposals" from the drop-down box.
3. **Text Box:**
  - Include the specific qualification criterion that must be met.
  - When the Contracting Officer determines that **SECTION 508 COMPLIANCE** will be evaluated as a Mandatory Qualification Criterion, the HHS Section 508 Product Assessment Template should be used for evaluation purposes.

**8. MANDATORY QUALIFICATION CRITERIA**

Listed below are mandatory qualification criteria. THE OFFEROR SHALL [INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL. / PROVIDE AN INDEX WITHIN ITS TECHNICAL PROPOSAL WHICH DIRECTS THE REVIEWER(S) TO THE SPECIFIC AREA(S) OF THE TECHNICAL PROPOSAL THAT ADDRESS A PARTICULAR MANDATORY QUALIFICATION.]

The qualification criteria establishes conditions that must be met at the time of receipt of [Final Proposal Revisions (FPRs)/Technical Proposals] by the Contracting Officer in order for your proposal to be considered any further for award.

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\*\*\*\*(USE BELOW WHEN THE RFP CONTAINS AN OPTION CLAUSE, THE OPTION IS NOT TO EXERCISED AT THE TIME OF AWARD, AND THERE IS A REASONABLE LIKELIHOOD THAT THE OPTION WILL BE EXERCISED.)\*\*\*\*

**Note:** *This item can be modified for use when the resultant contract will be performance based and will include Award Term(s) as the performance incentive as follows: Remove the referenced FAR Clause and all references to the word "Option(s)" and replace with the words "Award Term(s)" and add or modify the language below to be consistent with your requirement .*

## 9. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

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\*\*\* (USE BELOW FOR SOLICITATIONS INVOLVING RESEARCH AND DEVELOPMENT, INCLUDING SBIR.) \*\*\*

## 10. EVALUATION OF AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

If the offeror has proposed the use of key biological and/or chemical resources, the offeror's plan for authentication will be reviewed for adequacy.

Any concerns associated with key biological and/or chemical resource authentication raised during the review process will need to be resolved prior to award.

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\*\*\*\*(USE BELOW WHEN THE RESULTANT CONTRACT WILL GENERATE RESEARCH DATA AND MANAGEMENT AND SHARING OF THAT DATA MUST BE ADDRESSED BY EITHER PROPOSING A DATA MANAGEMENT AND SHARING PLAN OR PROVIDING A JUSTIFICATION FOR NOT SHARING DATA. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA MANAGEMENT AND GENERATION REQUIREMENTS.)\*\*\*\*

**Note :** *The plan or documentation as to the rationale for not providing a plan shall be evaluated by program staff and shall not be scored. However, weaknesses in a plan or in the rationale for not permitting the sharing of research data may be part of discussions.*

## 11. EVALUATION OF DATA MANAGEMENT AND SHARING PLAN OR ANY EXCEPTIONS

The Offeror's plan for the management and sharing of final research data, or, if data sharing is not possible, the Offeror's documentation of its inability to share research data, with justified limitations or exceptions, shall be assessed for appropriateness, adequacy, and reasonableness.

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\*\*\*\*(INCLUDE BELOW WHEN THE CONTRACT WILL GENERATE RESEARCH DATA AND SHARING OF THAT DATA IS REQUIRED. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA MANAGEMENT AND GENERATION REQUIREMENTS.)\*\*\*\*

**Note:** *The plan shall be evaluated by Program staff and shall not be scored. However, weaknesses in a plan should be part of discussions and shall be resolved before award.*

## 12. EVALUATION OF DATA MANAGEMENT AND SHARING PLAN

An Offeror's plan for the management and sharing of final research data (Data Management and Sharing Plan) shall be assessed for appropriateness, adequacy, and reasonableness.

If an Offeror's proposal does not include a Data Management and Sharing Plan (Plan) or if the Plan in an Offeror's proposal is considered "unacceptable," and the Government includes Offeror's proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), the Offeror will be afforded the opportunity to further discuss, clarify, and/or modify its Plan during discussions and in its Final Proposal Revision (FPR). However, if the Plan is still considered "unacceptable" by the Government after discussions, the Offeror may not be further considered for award.

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\*\*\*\*(USE BELOW FOR SOLICITATIONS THAT INVOLVE BIOMEDICAL RESEARCH OF MODEL ORGANISMS.)\*\*\*\*

## 13. EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

The offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further

discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award.

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\*\*\*\*(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING GENOME-WIDE ASSOCIATION STUDIES (GWAS) CONDUCTED ON OR AFTER JANUARY 25, 2008.)\*\*\*\*

#### 14. EVALUATION OF PLAN FOR SUBMISSION OF GENOME-WIDE ASSOCIATION STUDY (GWAS) DATA

The Offeror's plan for the submission of genome-wide association study (GWAS) data to the NIH-designated GWAS data repository will be assessed for appropriateness and adequacy. Proposals submitted for GWAS in which the data submission expectation cannot be met will be considered for award on a case-by-case basis.

Additional information for GWAS is found at: <https://www.genome.gov/about-genomics/fact-sheets/Genome-Wide-Association-Studies-Fact-Sheet> and at the NIH/National Human Genome Research Institute website: <https://www.genome.gov/>.

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\*\*\*\*(USE BELOW IF THE USE OF OTHER THAN A SPECIFIED CURRENCY IS PERMITTED IN THE SOLICITATION. THE CO MUST INSERT THE SOURCE OF THE RATE TO BE USED IN THE EVALUATION OF OFFERS.)\*\*\*\*

#### 15. EVALUATION OF FOREIGN CURRENCY OFFERS , FAR 52.225-17, (FEB 2000).

If the Government receives offers in more than one currency, the Government will evaluate offers by converting the foreign currency to United States currency using [Contracting Officer to insert source of rate] in effect as follows:

- a. For acquisitions conducted using sealed bidding procedures, on the date of bid opening.
- b. For acquisitions conducted using negotiation procedures.
  1. On the date specified for receipt of offers, if award is based on initial offers; otherwise
  2. On the date specified for receipt of proposal revisions.

\*\*\*\*(INCLUDE BELOW, IN ALL SOLICITATIONS.)\*\*\*\*

**ADDITIONAL INFORMATION ABOUT THIS ITEM:**

- **For Solicitations that include SECTION 508 COMPLIANCE requirements:** See HHSAR 315.304. A solicitation for EIT products and services (including EIT deliverables such as electronic documents and reports, unless the EIT products and/or services are incidental to the project) shall include a separate technical evaluation factor (which may be in the form of a technical evaluation criterion or a mandatory qualification criterion (but not both), as appropriate) developed by the CO, PO, and OPDIV Section 508 Coordinator to determine vendor compliance with applicable Section 508 accessibility standards. For a list of Section 508 Coordinators see: <https://ocio.nih.gov/ITGovPolicy/NIH508/Pages/Section508Coordinators.aspx> Section 508 Coordinators at NIH ICs.

**ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:**

- **Last Sentence:**
  - When unweighted subfactors will be used, select the appropriate evaluation scheme from the drop-down box,
  - When no subfactors will be used, delete the last sentence.

## 16. TECHNICAL EVALUATION FACTORS

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are [listed in order of relative importance/considered to be of equal importance].

\*\*\* (USE BELOW FOR SOLICITATIONS INVOLVING RESEARCH AND DEVELOPMENT, INCLUDING SBIR, INCLUDE THE PARAGRAPH ON ROBUST APPROACH AND RELEVANT BIOLOGICAL VARIABLES AS A SUBCRITERION UNDER THE TECHNICAL PLAN/APPROACH CRITERION. THE FIRST SENTENCE REGARDING SCIENTIFIC PREMISE SHOULD BE INCLUDED FOR BROAD AGENCY ANNOUNCEMENTS UNLESS SCIENTIFIC PREMISE WAS ADDRESSED DURING CONCEPT REVIEW

For RFPs, Program staff need to determine if the scientific premise has been addressed by the government in formulating the contract requirement(s) or if it should be addressed by the Offerors and evaluated in peer review. THE SUBCRITERION MAY OR MAY NOT BE INDIVIDUALLY SCORED, AS DEEMED APPROPRIATE BY THE COR AND CO.)\*\*\*\*

**ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:**

- Insert additional variables in the text box below. Delete if this is not needed.

### a. DEMONSTRATION OF A STRONG SCIENTIFIC PREMISE FOR THE TECHNICAL PROPOSAL

Sufficiency of proposed strategy to ensure a robust and unbiased approach, as appropriate for the work proposed. Adequacy of proposed plan to address relevant biological variables, including sex, [ *if deemed necessary by the IC, additional variables may be included here*] for studies in vertebrate animals and/or human subjects.

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\*\*\*\*(USE BELOW IN SOLICITATIONS THAT INVOLVE THE DEVELOPMENT, ACQUISITION, MAINTAINANCE, OR USE ELECTRONIC AND INFORMATION TECHNOLOGY (EIT) PRODUCTS AND SERVICES SUBJECT TO SECTION 508 OF THE REHABILITATIONS ACT OF 1973 AS AMENDED, INCLUDING EIT DELIVERABLES SUCH AS ELECTRONIC DOCUMENTS AND REPORTS.)\*\*\*\*

**Note:** *Exceptions to this requirement can be found in FAR 39.204.*

#### 17. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

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\*\*\*\*(USE BELOW WHEN PAST PERFORMANCE WILL BE TREATED AS A STAND ALONE FACTOR AND THE EVALUATION OF PAST PERFORMANCE INFORMATION WILL BE CONDUCTED INDEPENDENT OF THE TECHNICAL EVALUATION. THE RATING METHOD PRESENTED HERE IS A POSITIVE-NEGATIVE NUMERICAL SCHEME.)\*\*\*\*

##### **ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:**

1. Make sure that this item is consistent with the first paragraph of this Section M., entitled, GENERAL.
2. **First Paragraph:** Select the appropriate paragraph from the first two, below, when the past performance evaluation will be conducted after the initial technical evaluation. The first should be used when award with discussions is contemplated, the second if award without discussions is expected.

#### 18. PAST PERFORMANCE FACTOR

Offerors' past performance information will be evaluated prior to establishment of the competitive

range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

**OR**

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

The following rating method shall be used in the evaluation of past performance information:

**+2 Excellent** - Based on the offeror's performance record, no doubt exists that the offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again.

**+1 Good** - Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort. Sources of information state that the offeror's performance was good, better than average, etc., and that they would do business with the offeror again.



0 **None** - No past performance history identifiable.

-1 **Marginal** - Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort. Sources of information make unfavorable reports about the offeror's performance and express concern about doing business with the offeror again.

-2 **Poor** - Based on the offeror's performance record, serious doubt exists that the offeror will successfully perform the required effort. Sources of information consistently stated that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again.

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\*\*\*\*(USE BELOW WHEN PAST PERFORMANCE IS TREATED AS A STAND ALONE FACTOR AND THE EVALUATION OF PAST PERFORMANCE INFORMATION WILL BE CONDUCTED INDEPENDENT OF THE TECHNICAL EVALUATION. THE GENERAL APPROACH FOR THE EVALUATION IS DESCRIBED, HOWEVER, THE RATING METHOD IS NOT DISCLOSED.)\*\*\*\*

**ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:**

1. Make sure that this item is consistent with the first paragraph of this Section M., entitled, GENERAL.
2. **First Paragraph** : Select the appropriate paragraph from the first two, below, when the past performance evaluation will be conducted after the initial technical evaluation. The first should be used when award with discussions is contemplated, the second if award without discussions is expected.

**19. PAST PERFORMANCE FACTOR**

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

**OR**

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

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\*\*\*\*(USE BELOW WHEN PAST PERFORMANCE IS TREATED AS A STAND ALONE FACTOR AND PAST PERFORMANCE WILL BE EVALUATED BY GOVERNMENT REVIEWERS AT THE TIME OF PROPOSAL EVALUATION. IN THIS EXAMPLE, PAST PERFORMANCE SUBFACTORS ARE USED.)\*\*\*\*

**Note:** *Use of this example would require that reference checks be completed prior to the technical evaluation .*

**ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:**

1. Make sure that this item is consistent with the first paragraph of this Section M., entitled, GENERAL.
2. Past Performance Subfactors (4th Paragraph). The Contracting Officer/Contract Specialist may choose the "GENERIC" list provided below or may tailor the subfactors to the specific requirement.

## 20. PAST PERFORMANCE FACTOR

The Government will evaluate the offeror's past performance based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of relevant a performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

Listed below are past performance subfactors and the weights to be used for evaluation purposes. If no weights are given, each subfactor shall be given equal weight.

Past Performance Subfactors	Weight
Record of conforming to specifications and to standards of good workmanship.	
Record of forecasting and controlling costs under cost-reimbursement contracts.	
Adherence to contract schedules, including the administrative aspects of performance.	
Reputation for reasonable and cooperative behavior and commitment to customer satisfaction.	
Business-like concern for the interest of the customer.	

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\*\*\*\*(USE BELOW WHEN THE CONTRACTING OFFICER ELECTS TO INCLUDE THE SUBCONTRACTING PLAN AS A SCORED EVALUATION FACTOR.)\*\*\*\*

**Note:** *The following paragraph advises offerors about what the Government will be looking for in each subcontracting plan. You will need to provide additional information which advises the offeror about the scoring method that will be utilized for the evaluation .*

## 21. SUBCONTRACTING PROGRAM EVALUATION FACTORS

The offeror's proposed Small Business Subcontracting Plan will be evaluated to determine whether it represents the maximum practicable opportunity for subcontracting. Because the offeror's record of previous performance in carrying out the intent of the subcontracting program will be considered as a significant sub-factor, each offeror is encouraged to submit subcontracting plans and documentation that demonstrates their prior corporate support for small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business suppliers.

If offers are received from both large and small businesses, the small business offerors shall receive the maximum possible number of points for this factor.