# G.400 - PHS 398 Research Plan Form

The PHS 398 Research Plan form is used only for research, multi-project, and SBIR/STTR applications.

This form includes fields to upload several attachments, including the Specific Aims and Research Strategy.

The Research Plan, together with the rest of your application, should include sufficient information needed for evaluation of the project, independent of any other documents (e.g., previous application). Be specific and informative, and avoid redundancies.

View larger image

## Quick Links



Your application should represent a sound approach to the investigation of an important biomedical research, behavioral research, technological, engineering, or scientific question, and be worthy of support under the stated criteria of the NOFO. It should be self-contained and written with the care and thoroughness accorded to papers for publication.

Review the application carefully to ensure you have included information essential for evaluation. The scientific and technical merit of the proposed research is the primary

concern for all research supported by the National Institutes of Health (NIH) and other PHS agencies.

Read all the instructions in the NOFO before completing this form to ensure that your application meets all IC-specific criteria.

**Who should use the PHS 398 Research Plan Form:**

Use the PHS 398 Research Plan Form only if you are submitting a research, multi-project, or SBIR/STTR application.

**Additional Instructions for SBIR/STTR:**

You are strongly encouraged to contact agency program staff for pre-application guidance and/or for more specific information on the research topics described in the solicitation. See HHS Small Business Program Managers for Institute and Center representatives.

CRP uses SBIR funding but is not a Phase I/II/IIB or Fast-Track application. However, CRP applications should follow all Phase II-specific instructions and those in the CRP solicitations.

Sample SBIR / STTR applications can be found on the Prepare Your Application page.

**Applicants must follow all policies and requirements related to formatting, page limits, and proprietary information. See the following pages for more information:**

- Format Attachments
- Page Limits
- NIH Grants Policy Statement, Section 2.3.11.2: Confidentiality of Information
- NIH Grants Policy Statement, Section 2.3.11.2.2: The Freedom of Information Act

## Introduction

### 1. Introduction to Application (for Resubmission and Revision applications)

**Who must complete the "Introduction to Application" attachment:**

An "Introduction to Application" attachment is required only if the type of application is resubmission or revision or if the NOFO specifies that one is needed. An introduction is not allowed for new or renewal applications.

See Types of Applications for descriptions.

**Format:**

Follow the page limits for the introduction in the NIH Table of Page Limits unless otherwise specified in the NOFO.

Attach this information as a PDF file. See NIH's Format Attachments page. Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

**Content:**

**Resubmission applications:** See specific instructions on the content of the introduction on the NIH's Resubmission Applications page.

> Note: For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided in the introduction.

**Competing Revisions:** See specific instructions on the content of the introduction on the NIH's Competing Revisions page.

**Additional Instructions for Multi-project:**

**Overall Component:** The “Introduction” attachment is required for all resubmission and revision applications.

**Other Components:** The "Introduction” attachment is optional for resubmissions and revisions applications. Although the “Introduction” attachment is optional, you may get a system warning if there is no attachment.

## Research Plan Section

### 2. Specific Aims

**Who must complete the "Specific Aims" attachment:**

The “Specific Aims” attachment is required unless otherwise specified in the NOFO.

**Format:**

Follow the page limits for the Specific Aims in the NIH Table of Page Limits unless otherwise specified in the NOFO. A “Specific Aims” attachment that exceeds the page limit will be flagged as an error by the Agency upon submission.

Attach this information as a PDF file. See NIH's Format Attachments page. Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

**Content:**

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have on the research field(s) involved.

List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology).

**Additional Instructions for Multi-project:**

**Overall Component:** The "Specific Aims" attachment is required.

**Other Components:** The "Specific Aims" attachment is required.

**Additional Instructions for SBIR/STTR:**

**Phase I Applications**: State the specific objectives of the Phase I research and development effort, including the technical questions you will try to answer to determine the Phase I feasibility of the proposed approach and the impact of the proposed research and development. State concisely and realistically what the proposed R&D is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed process or service to ultimately be developed. Include clear and measurable milestones for each of the aims as these will be used in the evaluation process.

**Phase II, Phase IIB, and CRP Applications:** State the specific objectives of the Phase II or CRP research and development effort including the impact of the proposed research and development will exert on the research field(s). State concisely and realistically what the proposed R&D is intended to accomplish in terms of its potential for technological innovation and commercial application. Define the proposed product, process, or service to ultimately be developed. Include clear and measurable milestones for each of the aims as these will be used in the evaluation process.

**Fast-Track Applications:** Create a heading titled “Phase I Specific Aims” and follow the instructions above for “Phase I Applications.” Note that your Phase I milestones must be clear, appropriate, and measurable. It is important to clearly state the go / no-go milestone that will determine transition to Phase II. Failure to adequately address these criteria may negatively affect the application's impact score. Next, create a heading titled “Phase II Specific Aims” and follow the instructions above for “Phase II Applications.” Note that the page limit applies to both phases in combination, not to each phase individually.

## 3. Research Strategy

**Who must complete the "Research Strategy" attachment:**

The “Research Strategy” attachment is required.

**Format:**

Follow the page limits for the Research Strategy in the NIH Table of Page Limits, unless otherwise specified in the NOFO. Although multiple sections of information are required in the Research Strategy as detailed below, the page limit applies to the entirety of the single "Research Strategy" attachment.

Attach this information as a PDF file. See NIH's Format Attachments page. Hyperlinks and URLs may not be used in this section unless specified as allowed in the funding opportunity.

**Content:**

Organize the Research Strategy in the specified order and use the instructions provided below unless otherwise specified in the NOFO. Start each section with the appropriate heading – Significance, Innovation, Approach.

Cite published experimental details in the Research Strategy attachment and provide the full reference in G.220 - R&R Other Project Information Form, Bibliography and Reference Cited.

**Note for Applications Proposing the Use of Human Fetal Tissue**: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application you must include specific information in the Approach section of the Research Strategy attachment. See specific instructions below in Section 3. Approach. This information must be provided regardless of whether Human Subjects research is proposed or not.

Applications proposing HFT that do not address these requirements will be administratively withdrawn. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions.

**Note for Applications Proposing the Involvement of Human Subjects and/or Clinical Trials:**

- Do not duplicate information in the Research Strategy and the PHS Human Subjects and Clinical Trials Information form. Use the Research Strategy attachment to discuss the overall strategy, methodology, and analyses of your proposed research. Use the PHS Human Subjects and Clinical Trials Information form to provide detailed information for human subjects studies and clinical trials.
- The PHS Human Subjects and Clinical Trials Information form will capture detailed study information, including eligibility criteria; inclusion of women, minorities, and individuals across the lifespan; protection and monitoring plans; and statistical design and power.
- You are encouraged to refer to information in the PHS Human Subjects and Clinical Trials Information form as appropriate in your discussion of the Research Strategy (e.g., see Question 2.4 Inclusion of Women and Minorities).

**Note for Applicants with Multiple Specific Aims:** You may address the Significance, Innovation, and Approach either for each Specific Aim individually or for all of the Specific Aims collectively.

### 1. Significance

- Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
- Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

**Additional Instructions for Research:**

Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

**Additional Instructions for Multi-project:**

**Overall and Other Components:** Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

**Additional Instructions for SBIR/STTR:**

Explain the project's potential to lead to a marketable product, process, or service.

**Phase II, CRP, Fast-Track, and Phase IIB Competing Renewals:** Explain how the commercialization plan demonstrates a high probability of commercialization.

### 2. Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

### 3. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted, and reference any Resource Sharing Plans and the Data Management and Sharing (DMS) Plan, as appropriate. Resources and tools for rigorous experimental design can be found at the Enhancing Reproducibility through Rigor and Transparency website.
- For trials that randomize groups or deliver interventions to groups, describe how your methods for analysis and sample size are appropriate for your plans for participant assignment and intervention delivery. These methods can include a group- or cluster-randomized trial or an individually randomized group-treatment trial. Additional information is available at the Research Methods Resources webpage.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For

example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for applications proposing to study only one sex. Refer to the NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for additional information.
- Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research attachment below.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be chosen, provide a strong justification for why an appropriate cell line cannot be chosen from the registry at this time.

**Special Instructions for Applications Proposing the Use of Human Fetal Tissue**: If the use of human fetal tissue obtained from elective abortions (HFT) (as defined in the NIH Grants Policy Statement) is included in the proposed application

- Use the specific heading: “Human Fetal Tissue Research Approach”.
- Describe the proposed characteristics, procurement, and procedures for the research use of HFT. The description should be sufficiently detailed to permit meaningful evaluation by NIH.
- Justify the use of HFT in the proposed research by indicating the following:
    - Why the research goals cannot be accomplished by using an alternative to HFT.
    - What methods were used (e.g. literature review, preliminary data) to determine that alternatives could not be used.
    - Results from a literature review used to provide justifications.
    - Plans for the treatment of HFT and the disposal of HFT when research is complete.
    - Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained.

Applications proposing HFT that do not address these requirements will be administratively withdrawn. For further information on HFT policy refer to the NIH Grants Policy Statement, Section 2.3.7.11 Human Fetal Tissue from Elective Abortions, Section 4.1.14 Human Fetal Tissue Research and Section 4.1.14.2 Non-Transplantation Research on Human Fetal Tissue from Elective Abortions.

**Additional Instructions for SBIR/STTR:**

Provide a tentative sequence or timetable for the project.

**As applicable, also include the following information as part of the Research Strategy, keeping within the three sections (Significance, Innovation, and Approach) listed above.**

### Preliminary Studies for New Applications:

For new applications, include information on preliminary studies. Discuss the PD/PI’s preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and can help to establish the likelihood of success of the proposed project. Early stage investigators should include preliminary data.

**Additional Instructions for SBIR/STTR:**

**Phase I Applications:** Preliminary data are not required for Phase I Applications; however, such results may assist reviewers in assessing the likelihood of success of the proposed project and may be included in the Research Strategy attachment.

**Fast-Track Applications:** While not required, preliminary data are expected for Fast-Track Applications.

**SBIR Direct Phase II:** Summarize the specific aims of the preliminary work that forms the basis for this Phase II application, quantitative milestones (i.e., a quantitative definition of success) for each aim, and the importance of the findings. Additionally, emphasize the progress made toward each aim's achievement. Describe the technology developed, its intended use, and who will use it. Provide data or evidence of the capability, completeness of design, and efficacy, along with the rationale for selection of the criteria used to validate the technology, prototype, or method. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed on IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved). List the generic and/or commercial names of products. A list of publications, patents, and other printed materials should be included in Item 5 (Progress Report Publication List) – do not include that information here.

### Progress Report for Renewal and Revision Applications:

Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy.

For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. In the Progress Report, you should:

- Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement.
- Explain any significant changes to the specific aims and any new directions, including changes resulting from significant budget reductions.
- Discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.) for any studies meeting the NIH definition for clinical research. Use the Progress Report section to discuss, but not duplicate information collected elsewhere in the application.

Do not include a list of publications, patents, or other printed materials in the Progress Report. That information will be included in the "Progress Report Publication List" attachment.

**Renewal Applications**: For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change and include the required Multiple PD/PI Leadership Plan. A rationale for a change from a multiple PD/PI to a single PD/PI application must also be provided.

**Additional Instructions for SBIR/STTR:**

**Phase II, Phase IIB, and CRP Competing Renewal and Revision Applications:** In the Progress Report, in addition to what's listed above, describe the technology developed from the previously supported SBIR / STTR award, and if different from the proposed application, its intended use, and who will use it. Describe the current status of the product (e.g., under development, commercialized, in use, discontinued). If applicable, describe the status of FDA approval for your product, process, or service (e.g., continuing pre-IND studies, filed on IND, in Phase I (or II or III) clinical trials, applied for approval, review ongoing, approved, not approved).

## 4. Progress Report Publication List

**Who must complete the "Progress Report Publication List" attachment:**

A "Progress Report Publication List" attachment is required only if the type of application is renewal.

See Types of Applications for descriptions.

**Format:**

Attach this information as a PDF file. See NIH's Format Attachments page. Use of hyperlinks and URLs in this section is not allowed unless specified in these instructions or in the funding opportunity.

**Content:**

List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively.

You are allowed to cite interim research products. **Note:** interim research products have specific citation requirements. See related Interim Research Product FAQs on citing interim research products and claiming them as products of your NIH award.

Provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each of the following:

- Articles that fall under the Public Access Policy,
- Articles that were authored or co-authored by the applicant and arose from NIH support,
- Articles that were authored or co-authored by the applicant and arose from AHRQ funding provided after February 19, 2016 (see the Guide Notice on Policy for Public Access to AHRQ-Funded Scientific Publications).

If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal – In Process." NIH maintains a list of such journals.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. Active hyperlinks are not allowed.

**Additional Instructions for Multi-project:**

**Overall and Other Components:** If you include a "Progress Report Publication List" attachment, you can include it in either the Overall Component or within each Other Component, but do not attach the same information in multiple locations.

**Additional Instructions for SBIR/STTR:**

**Phase II, Phase IIB, and CRP Applications:** List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, copyrights, trademarks, invention reports and other printed materials, if any, that resulted from the Phase I or describe patent status, trade secrets or other demonstration of IP protection, and other printed materials that have resulted from the Phase I effort.

## Other Research Plan Section

### 5. Vertebrate Animals

**Who must complete the "Vertebrate Animals" attachment:**

Include a "Vertebrate Animals" attachment if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the G.220 - R&R Other Project Information Form.

**Format:**

Attach this information as a PDF file. See NIH's Format Attachments page.

Do not use this attachment to circumvent the page limits of the Research Strategy.

**Content:**

If live vertebrate animals are involved in the project, address each of the following criteria:

1. **Description of Procedures:** Provide a concise description of the proposed procedures to be used that involve live vertebrate animals in the work outlined in the "Research Strategy" attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. **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).
3. **Minimization of Pain and Distress:** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints that will be used to minimize discomfort, distress, pain, and injury.

Each of the criteria must be addressed. Failure to adequately address the criteria may negatively affect the application's impact score. In addition to the 3 criteria above, you should also:

- Identify all project performance (or collaborating) sites and describe the proposed research activities with vertebrate animals that will be conducted at those sites.

- Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

**See the following pages for more information:**

- NIH's Office of Laboratory Animal Welfare website
- NIH's Vertebrate Animals Section Worksheet
- See the NIH Grants Policy Statement, Section 4.1.1: Animal Welfare Requirements (an applicable Animal Welfare Assurance will be required if the recipient organization does not have one)

**Additional Instructions for Multi-project:**

**Overall Component:** The "Vertebrate Animals" attachment is optional unless specifically requested in the NOFO.

**Other Components:** Complete the "Vertebrate Animals" section if you answered "Yes" to the question "Are Vertebrate Animals Used?" on the G.220 - R&R Other Project Information Form.

## 6. Select Agent Research

**Who must complete the "Select Agent Research" attachment:**

Include a "Select Agent Research" attachment if your proposed activities involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any performance site.

**Format:**

Attach this information as a PDF file. See NIH's Format Attachments page.

**For more information:**

Select agents are hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. The Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) Select Agent Programs jointly maintain a list of these agents. See the Federal Select Agent Program website.

See also the NIH Grants Policy Statement, Section 4.1.24.1.1: Select Agents.

**Content:**

**Excluded select agents:** If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this "Select Agent Research" attachment to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available on the Select Agents and Toxins Exclusions website.

**Applying for a select agent to be excluded:** If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to HHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.

**All applicants proposing to use select agents:** Address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities* where select agent(s) will be used.
   - If the performance site(s) is a foreign organization, provide the name(s) of the country or countries where select agent research will be performed.
   - *An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."
3. Provide a description of all facilities where the select agent(s) will be used.
   - Describe the procedures that will be used to monitor possession, use, and transfer of select agent(s).
   - Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
   - Describe the biocontainment resources available at all performance sites.

## 7. Multiple PD/PI Leadership Plan

**Who must complete the "Multiple PD/PI Leadership Plan" attachment:**

Any applicant who designates multiple PD/PIs (on the G.240 - R&R Senior/Key Person Profile (Expanded) Form) must include a Multiple PD/PI Leadership Plan. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the G.240 - R&R Senior/Key Profile (Expanded) Form, even those at organizations other than the applicant organization.

Do not submit a Multiple PD/PI Leadership Plan if you are not submitting a multiple PD/PI application.

**Additional Instructions for Multi-project:**

**Overall Component:** The "Multiple PD/PI Leadership Plan" attachment is required if more than one PD/PI is specified on the Overall Component's G.240 - R&R Senior/Key Profile (Expanded) Form.

**Format:**

Attach this information as a PDF file. See NIH's Format Attachments page.

**Content:**

A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Multiple PD/PI Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Grant Award.

**Resubmission Applications:** For resubmission applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the introduction and include the required Multiple PD/PI Leadership Plan.

**Renewal Applications:** For renewal applications changing from a single PD/PI to multiple PD/PIs, changing the number or makeup of the multiple PD/PIs, the applicant must provide a rationale for the change in the progress report within the research strategy and include the required Multiple PD/PI Leadership Plan.

**For more information:**

For background information on the multiple PD/PI initiative, see NIH's Multiple Principal Investigators page.

## 8. Consortium/Contractual Arrangements

**Who must complete the "Consortium/Contractual Arrangements" attachment:**

Include a "Consortium/Contractual Arrangements" attachment if you have consortiums/contracts in your budget.

**Format:**

Attach this information as a PDF file. See NIH's Format Attachments page.

**Content:**

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the recipient.

**Note:** The signature of the authorized organization representative in G.200 - SF 424 (R&R), Authorized Representative signifies that the applicant and all proposed consortium participants understand and agree to the following statement:

> *The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.*

**For more information:**

Refer to the NIH Grants Policy Statement, Section 15: Consortium Agreements for more information.

**Additional Instructions for Multi-project:**

**Overall and Other Components:** Unless otherwise specified in the NOFO, you have the option to:

- include a single consolidated “Consortium/Contractual Arrangements” attachment in the Overall Component, or
- include component-specific “Consortium/Contractual Arrangements” attachment(s) within the components that include subawards, or
- include a “Consortium/Contractual Arrangements” attachment in the Overall Component and include component-specific attachments within the components that include subawards. Each filename must be unique.

**Additional Instructions for SBIR/STTR:**

**SBIR:**

**Phase I Applications:** Normally, a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business. The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 33% of the total amount requested (direct, F&A / indirect, and fee). Occasionally, deviations from these requirements may occur. Deviations must be approved in writing by the funding agreement officer after consultation with the agency SBIR Program Manager/Coordinator.

**Phase II and Phase IIB Applications:** Normally, a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business. The total amount of consultant and contractual arrangements to third parties for portions of the scientific and technical effort generally may not exceed 50% of the total Phase II amount requested (direct, F&A/indirect, and fee). Occasionally, deviations from these requirements may occur. Deviations must be approved in writing by the funding agreement officer after consultation with the agency SBIR Program Manager / Coordinator.

**Phase I and Phase II Applications:** The basis for determining the percentage of work to be performed by each of the cooperative parties in Phase I or Phase II will be the total requested costs (direct, F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in this attachment.

**Fast-Track SBIR Applications:** Create two separate sections entitled “Phase I Consortium/Contractual Arrangements” and “Phase II Consortium/Contractual Arrangements,” and complete the sections following the instructions provided above for each phase.

**STTR:**

**Phase I, Phase II and Phase IIB STTR Applications:** At least 40% of the work must be performed by the small business and at least 30% of the work must be performed by the single partnering research institution. The basis for determining the percentage of work to be performed by each of the cooperative parties will be the total of the requested costs (direct, F&A/indirect, and fee) attributable to each party, unless otherwise described and justified in this attachment.

Certification showing the cooperative R&D arrangement between the small business and the research institution will be requested prior to an award.

The single partnering research institution must certify at the time of application that at least 30% of the work of the STTR project will be performed by the research institution. This 30% requirement applies to the single collaborating organization identified as the “research institution.”

The requisite signature, printed name, title, and date of signature of the duly authorized representative of the research institution affirming certifications made by the research institution must be included in a letter stating:

> “The small business concern and the research institution certify jointly that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution (“cooperative research and

development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project.

If the research institution is a contractor-operated Federally Funded Research and Development Center (FFRDC), the duly authorized representative of the contractor-operated Federally funded research and development center certifies, additionally, that it: "(4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein."

The applicant small business should convert the letter from the partnering research institution into a PDF attachment and include it as part of this attachment.

**Fast-Track STTR Applications:** Create two separate sections entitled "Phase I Consortium/Contractual Arrangements" and "Phase II Consortium/Contractual Arrangements," and complete the sections following the instructions provided above for each phase.

## 9. Letters of Support

**Format:**

Combine all letters of support into a single PDF file and attach this information here. Do not place these letters in the Appendix.

Follow the attachment guidelines on NIH's Format Attachments page. Use of hyperlinks and URLs in Letters of Support is not allowed unless specified in the funding opportunity.

**Content:**

Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application.

Letters should stipulate expectations for co-authorship, and whether cell lines, samples, or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only.

For consultants, letters should include rate/charge for consulting services and level of effort / number of hours per budget period anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service.

Material Transfer Agreements may be included in this section.

Letters must focus on the topics listed above and not contain data / figures / tables / graphs, preliminary data, methods, background and significance details that are expected to be found in Research Strategy section of the application. Letters of Support serve to describe terms of a collaboration or consultation and also are not de facto letters of reference from persons not actively participating in the project. Applications with letters containing such excess information may be withdrawn from the review process.

Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.

Do not include consultant biographical sketches in the “Letters of Support” attachment, as consultant biosketches should be in the “Biographical Sketch” section (see exception for SBIR/STTR Applications in the SBIR/STTR-specific instructions).

**Additional Instructions for Multi-project:**

**Overall and Other Components:** Unless specific instructions are provided in the NOFO, applicants have the option of including the “Letters of Support” attachment in the Overall Component, Other Components, or both. To avoid duplication, each letter should appear only once in the application. Letters that apply to the entire application (or to multiple components) should be presented in the Overall Component as a single PDF, while letters that apply only to a particular individual component should be presented in that component as a single PDF.

**Additional Instructions for SBIR/STTR:**

Involvement of consultants and collaborators in the planning and research stages of the project is permitted. With the application, letters are required from each individual and / or collaborator confirming their role(s) in the project. The letter(s) should be prepared on the consultant or collaborator's letterhead and addressed to the small business. One page is recommended.

At a minimum, each consultant and collaborator letter should (1) verify their commitment to the project; (2) refer to the specific project by name, acknowledging the PD/PI as the lead on the project; and (3) specify what services/tasks the consultant or collaborator will contribute (e.g. expertise, number of hours/ percent of effort, summary of tasks to be completed). For consultants, the letter should also include the rate/charge for consulting services. Also include biographical sketches for each consultant.

Letters of interest from potential commercial partners or investors and letters of commitment of funds or other resources that will enhance the likelihood of commercialization should be placed following the letters of support for consultants and collaborators. Letters from potential or current users of the technology or product proposed in the application should be limited and directly relevant to the proposed project.

**STTR only:** The single "partnering" research institution must provide a letter to the applicant small business concern certifying that at least 30% of the work of the STTR project will be performed by the research institution.

## 10. Resource Sharing Plan(s)

**Note: Effective for due dates on or after January 25, 2023, Data Management and Sharing (DMS) Plans are now included in Section 11. Other Plan(s). Plans for Genomic Data Sharing should be provided as part of the Data Management and Sharing Plan.**

**Format:**

Attach this information as a PDF file. See NIH's Format Attachments page.

**Content:**

**Sharing Model Organisms:** Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. **For more information**, see the NIH Grants Policy Statement, Section 8.2.3.2: Sharing Model Organisms.

**Research Tools:**

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. For more information, see the Research Tools Policy on the NIH Scientific Data Sharing Website and the NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources.

## 11. Other Plan(s)

**Who Must Complete This Section:** Refer to the list of NIH activity codes subject to the DMS Policy and your NOFO to determine if your application is required to provide an attachment and address a Data Management and Sharing (DMS) Plan. Applicants proposing to conduct research that will generate scientific data are subject to the NIH Data Management and Sharing Policy and must attach a Data Management and Sharing (DMS) Plan. Scientific data is defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings. Scientific data does not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.

The NIH Genomic Data Sharing Policy expects applicants seeking funding for research that generates large-scale human or non-human genomic data to provide a plan for sharing of these data as part of their DMS Plan.

Applicants subject to both the NIH Data Management and Sharing Policy and the NIH Genomic Data Sharing Policy must attach a single Plan including elements for both policies. For more on applicability of each policy, see research subject to the NIH Data Management and Sharing Policy and the research subject to the NIH Genomic Data Sharing Policy.

**Format:** Attach this information as a PDF file. See NIH's Format Attachments page.

A sample format is provided on the Data Management and Sharing Plan Format Page to assist applicants with preparation of this attachment. Do not include hyperlinks in this attachment. Recommended not to exceed two pages.

**Content:** Follow the expectations of the NIH Policy for Data Management and Sharing and address the Elements of an NIH Data Management and Sharing Plan described below.

**Additional expectations:** A Data Management and Sharing Plan should reflect the proposed approach at the time the application is prepared. For some programs and data types, NIH and/or NIH Institutes, Centers, Offices, or programs have developed additional data sharing requirements (e.g., specifying which scientific data to share, relevant standards, repository selection, timelines) that apply and should be reflected in a Plan. These additional requirements may be listed on NIH Institute and Center Data Sharing Policies or in specific funding opportunities. Note that some NIH Institutes, Centers, Officers, or programs have developed additional expectations for sharing genomic data that may be listed on NIH Institute and Center Genomic Data Sharing Expectations or in specific funding opportunities.

**Elements of a Data Management and Sharing Plan:**

Data Type: Briefly describe the scientific data to be managed, preserved, and shared, including a general summary of the types and estimated amount of scientific data to be generated and a description of which scientific data from the project will be preserved and shared as well as the rationale for doing so. Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Related Tools, Software and/or Code: State whether specialized tools are needed to access or manipulate shared scientific data to support replication or reuse, and name(s) of the needed tool(s) and software. If specialized tools or software are needed, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Standards: State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources (e.g., data formats, data dictionaries, data identifiers, definitions, unique identifiers, and other data documentation), and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Data Preservation, Access, and Associated Timelines: Provide plans and timelines for data preservation and access, including the name of the repository(ies) where scientific data and metadata arising from the project will be archived (do not include hyperlinks); how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools; and when (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) the scientific data will be made available to other users (e.g., the larger research community, institutions, and/or the broader public) and for how long. See Selecting a Data Repository on the NIH Scientific Data Sharing website.

Access, Distribution, or Reuse Considerations: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data generated from NIH-funded or conducted research, consistent with privacy, security, informed consent, and proprietary issues. Describe and justify any applicable factors affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, any restrictions imposed by federal, Tribal, or state laws, regulations, or policies, or existing or anticipated agreements, or any other considerations that may limit the extent of data sharing. See Data Management & Sharing Policy FAQs for examples of justifiable reasons for limiting sharing of data. State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

**Genomic Data Sharing Policy:** For proposed research subject to the GDS Policy, state whether data, including genomic summary results, will be made available through controlled or unrestricted access; see instructions for describing Genomic Summary Results in Data Management and Sharing Plans.

If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures). See NIH's Scientific Data Sharing page for additional information on protecting human research participant privacy when sharing data.

**Genomic Data Sharing Policy:** For proposed research generating human genomic data within the scope of the GDS Policy, applicants should complete the Data Management and Sharing Plan anticipating sharing according to the assurances of the Institutional Certification.

If there is any element of the Institutional Certification that the institution (in consultation with the IRB) has determined cannot be met, please state which element and provide a detailed explanation for why the element cannot be met. In

such cases, the data management and sharing plan should describe how genomic data will be shared to the maximal extent possible (for example, sharing data in a summary format).

Oversight of Data Management and Sharing: Describe how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom at the applicant institution (e.g., titles, roles).

**For more information on developing a Data Management and Sharing Plan**, see Writing a Data Management and Sharing Plan on the NIH Scientific Data Sharing website.

**For more information on the DMS Policy**, including expectations for data management and sharing, protecting research participant privacy, and identifying data repositories, see the NIH Data Management and Sharing Policy on the NIH Scientific Data Sharing website and the NIH Grants Policy Statement, Section 8.2.3.1: Data Sharing Policy. See also Data Management & Sharing Policy FAQs for additional information on the DMS Policy on these and other topics.

**For more information on the GDS Policy** see the NIH Genomic Data Sharing Policy on the NIH Scientific Data Sharing website and the NIH Grants Policy Statement, Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS).

**Additional Instructions for Multi-project:**

**Overall Component** Include a single consolidated “Data Management and Sharing Plan” in the Overall Component.

**Other Components:** Do not include a “Data Management and Sharing Plan” within other components. Any component-specific information should be described within the overall “Data Management and Sharing Plan” attachment in the Overall Component.

**Additional Instructions for SBIR/STTR:**

SBIR and STTR recipients may retain the rights to data generated during the performance of an SBIR or STTR award for up to 20 years after the award date, per Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Policy Directive. An acceptable Data Management and Sharing (DMS) Plan can reference and incorporate these data rights. Further information about SBIR and STTR data rights are enumerated in the NIH Grants Policy Statement.

## 12. Authentication of Key Biological and/or Chemical Resources

**Format:**

Attach this information as a PDF file. See NIH's Format Attachments page.

**Content:**

If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. A maximum of one page is suggested.

**For more Information:**

Key biological and/or chemical resources are characterized as follows.

- Key biological and/or chemical resources may or may not have been generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.
- Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals.
- See NIH's page on Rigor and Reproducibility for more information.

## Appendix

### 13. Appendix

Refer to the NOFO to determine whether there are any special appendix instructions for your application. See the updated NIH Guide Notice on the Appendix Policy.

**Additional Instructions for Multi-project:**

**Overall and Other Components:** The "Appendix" attachment is optional.

**Additional Instructions for SBIR/STTR:**

**Phase I SBIR/STTR Applications:** Do not include appendices unless specifically solicited by NIH.

**Format:**

A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 allowable appendix attachments are needed, combine the remaining information into attachment #10.

Use filenames for attachments that are descriptive of the content.

A summary sheet listing all of the items included in the Appendix is encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment.

**Content:**

The only allowable appendix materials are:

- Blank data collection forms, blank survey forms, and blank questionnaire forms - or screenshots thereof
- Simple lists of interview questions

  **Note:** In your blank forms and lists, do not include items such as: data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, descriptions or drawings/figures/diagrams of data collection methods or machines/devices.

- Blank informed consent/assent forms
- Other items *only if* they are specified in the NOFO as allowable appendix materials

No other items are allowed in the Appendix. Simply relocating disallowed materials to other parts of the application will result in a noncompliant application.

Some NOFOs may have different instructions for the Appendix. Always follow the instructions in your NOFO if they conflict with these instructions.

**Note:** Applications will be withdrawn and not reviewed if they do not follow the appendix requirements in these instructions or in your NOFO.

Information that expands upon or complements information provided in any section of the application – even if it is not required for the review – is not allowed in the Appendix unless it is listed in the allowed appendix materials above or in your NOFO. For example, do not include material transfer agreements (MTA) in the appendix unless otherwise specified in the NOFO.

**For more information:**

- The NIH Guide Notice on Reminder: NIH Applications Must Be Complete and Compliant With NIH Policy and Application Instructions At Time of Submission.
- Failure of reviewers to address non-required appendix materials in their reviews is not an acceptable basis for an appeal of initial peer review. For more information, see the NIH Grants Policy Statement, Section 2.4.2: Appeals of Initial Scientific Review.
- Appendix Policy Frequently Asked Questions