Standard NIH Proposal Outline

**Note:** This outline addresses key development components of a standard NIH Research (R) application; however, it does not address all elements required to complete the application or budget. Complete instructions are available in the grant solicitation and the [*Research Instructions for NIH and Other PHS Agencies: SF424 (R&R) Application Packages*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/research-forms-e.pdf). Please also see OSP’s *NIH ASSIST Sample Application* for additional reference.

Proposal Contents

# RESEARCH & RELATED Other Project Information

## 7. Project Summary/Abstract (Required, limited to 30 lines of text)

Please see *Project Summary/Abstract Template* for instructions.

## 8. Project Narrative (Required, limited to 3 sentences)

Please see *Project Narrative Template* for instructions.

## 9. Bibliography & References Cited (Required, unless otherwise noted in FOA)

Please see [*Format Attachments: Citations*](https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/format-attachments.htm) for additional information.

## 10. Facilities & Other Resources (Required, unless otherwise noted in FOA)

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or from unique subject populations or how studies will employ useful collaborative arrangements.

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards and any other potentially dangerous substances.

Note: Information about select agents must be described in the Research Plan, Select Agent Research.

For early stage investigators (ESIs), describe institutional investment in the success of the investigator. *See* [*NIH's New and Early Stage Investigator Policies*](https://grants.nih.gov/policy/early-investigators/index.htm). Description may include the following elements:

* Resources for classes, travel, or training;
* Collegial support, such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI’s project, and availability of organized peer groups;
* Logistical support, such as administrative management and oversight and best practices training;

Financial support, such as protected time for research with salary support

**Additional Instructions for Mulit-Project:**

Unless specific instructions are provided in the FOA, applicants have the option of including the “Facilities & Other Resources” attachment in the Overall Component, Other Components, or both.

## 11. Equipment (Required)

List major items of equipment already available for this project and, if appropriate, identify the equipment's location and pertinent capabilities.

**Additional Instructions for Multi-project:**

Unless specific instructions are provided in the FOA, applicants have the option of including the “Equipment” attachment in the Overall Component, Other Components, or both (whichever is most appropriate for your application). User-defined bookmarkers provided in the Equipment attachment will be included with the bookmarkers of the assembled application image in eRA Commons. If you include the “Equipment” attachment only in the Overall Component, you may want to use bookmarks to organize equipment by component.

## 12. Other Attachments

Attach a file to provide additional information only in accordance with the FOA and/or agency-specific instructions.

If applicable, attach a “Foreign Justification” here.

# RESEARCH & RELATED Senior/Key Person Profile

## Biographical Sketch (Required, Limited to 5 pages per person including table at top of first page)

Use sample format provided here to prepare this section: *Biographical Sketch Format Page*. Figures, tables, or graphics are not allowed. For additional information see [*Research Instructions for NIH and Other PHS Agencies: SF424 (R&R) Application Packages*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf)*.*

## Current and Pending (Only include if required by FOA)

If applicable, please refer to instructions provided here to prepare this section: [*Other Support*](https://grants.nih.gov/grants/forms/othersupport.htm).

# PHS 398 Research Plan Form

This form is used only for research, multi-project, and SBIR/STTR applications.

## Introduction

### Introduction (Only for Resubmission, Revision, or if required by FOA, Limited to 1 page)

An introduction is not allowed for new or renewal applications. For Resubmission and Competing Revisions see specific instructions in [Research Instructions for NIH and Other PHS Agencies: SF424 (R&R) Application Packages](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf)*.*

## Research Plan Section

### Specific Aims (Required, unless otherwise specified in FOA, Limited to 1 page)

* 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:** The “Specific Aims” attachment is required for the Overall Component and Other Components.

### Research Strategy (Required, Specific to activity code, varies from 6 to 12 pages or as specified in FOA)

Please see *Research Strategy Template* for instructions.

### Progress Report Publication List (Only for Renewal Applications)

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 [*Frequently Asked Questions*](https://grants.nih.gov/grants/interim_product_faqs.htm) on citing interim research products and claiming them as products of your NIH award.

For further guidance [*Research Instructions for NIH and Other PHS Agencies: SF424 (R&R) Application Packages*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf).

**Additional Instruction for Multi-project:**

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.

## Other Research Plan Section

### Vertebrate Animals

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

* **Description of Procedures:** Provide a concise description of proposed procedures to be used involving vertebrate animals in the work outlined in the “Research Strategy” attachment. The description must include sufficient detail to allow evaluation of the procedures. Identify 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.
* **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).
* **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.

**Additional Instructions for Multi-project:**

The “Vertebrate Animals” attachment is optional for Overall component unless specifically requested by the FOA. If you answered “Yes” to the questions “Are Vertebrate Animals Used” complete the “Vertebrate Animals” section in Other Components.

### Select Agent Research

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 application organization or at any performance site.

**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*](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&r=PART&n=42y1.0.1.6.61), 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*](https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html) 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.

* Identify the select agent(s) to be used in the proposal research.
* Provide the registration status of all entities where select agent(s) will be used.
	+ If the performance site(s) is a foreign institution, 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*](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&r=PART&n=42y1.0.1.6.61) as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”
* 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.

### Multiple PD/PI Leadership Plan

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

For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role the R&R Senior/Key Profile (Expanded) Form, even those at organizations other than the applicant organization.

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.

For more information see NIH’s [Multiple Principal Investigators](https://grants.nih.gov/grants/multi_pi/index.htm) page.

### Consortium/Contractual Arrangement (Include if you have Consortiums/Subawards in your budget)

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 grantee.

**Additional Instructions for Multi-project (Unless otherwise specified in the FOA) you have the option to:**

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

For more information please see NIHs [Grants Policy Statement, Section 15: Consortium Agreements](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15.1_general.htm).

### Letters of Support

Attach a file with all letters of support (in a single PDF file), 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.

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).

### Resource Sharing Plan(s)

**Data Sharing Plan:** Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&A) in any budget period are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible (for example human subject concerns, the Small Business Innovation Development Act provisions, etc.). Specific FOAs may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the FOA carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. For more information, see the NIH [Data Sharing Policy](https://grants.nih.gov/grants/policy/data_sharing/) or the [NIH Grants Policy Statement, Section 2.3.7.10: NIH Genomic Data Sharing](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.3_application_information_and_processes.htm?tocpath=2%20The%20National%20Institutes%20of%20Health%20as%20a%20Grant-Making%20Organization%7C2.3%20Application%20Information%20and%20Processes%7C_____0#2.3_Application_Information_and_Processes_..1) and [Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm?tocpath=8%20Administrative%20Requirements%7C8.2%20Availability%20of%20Research%20Results%3A%20Publications%2C%20Intellectual%20Property%20Rights%2C%20and%20Sharing%20Research%20Resources%7C_____0#8.2_Availability_of_Research_Results__Publications,_Intellectual_Property_Rig...).

**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](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm?tocpath=8%20Administrative%20Requirements%7C8.2%20Availability%20of%20Research%20Results%3A%20Publications%2C%20Intellectual%20Property%20Rights%2C%20and%20Sharing%20Research%20Resources%7C_____0#8.2_Availability_of_Research_Results__Publications,_Intellectual_Property_Rig...).

**Genomic Data Sharing (GDS):** Applicants seeking funding for research that generates large-scale human or non-human genomic data are expected to provide a plan for sharing of these data. Examples of large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS provides examples of genomic research projects that are subject to the Policy. **For more information** see the [*NIH GDS Policy*](https://osp.od.nih.gov/scientific-sharing/policies/)*, the* [Section 8.2.3.3: Genomic Data Sharing (GDS) Policy/ Policy for Genome-Wide Association Studies (GWAS)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm?tocpath=8%20Administrative%20Requirements%7C8.2%20Availability%20of%20Research%20Results%3A%20Publications%2C%20Intellectual%20Property%20Rights%2C%20and%20Sharing%20Research%20Resources%7C_____0#8.2_Availability_of_Research_Results__Publications,_Intellectual_Property_Rig...), and the [GDS](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/) website.

**Note on GDS:** For proposed studies generating human genomic data under the scope of the [*GDS Policy*](https://osp.od.nih.gov/scientific-sharing/policies/), an institutional certification may be submitted at the time of application submission, but it is not required at that time. The institutional certification, however, will be requested as Just-in-Time (JIT) information prior to award. The institutional certification, or in some cases, a provisional institutional certification, must be submitted and accepted before the award can be issued.

**For more information:** see the [*NIH Grants Policy Statement, Section 8.2.3: Sharing Research Resources*](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2_availability_of_research_results_publications__intellectual_property_rights__and_sharing_research_resources.htm?tocpath=8%20Administrative%20Requirements%7C8.2%20Availability%20of%20Research%20Results%3A%20Publications%2C%20Intellectual%20Property%20Rights%2C%20and%20Sharing%20Research%20Resources%7C_____0#8.2_Availability_of_Research_Results__Publications,_Intellectual_Property_Rig...).

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

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**: see NIH's page on [*Rigor and Reproducibility*](https://grants.nih.gov/reproducibility/index.htm).

## Appendix

### Appendix

Refer to the FOA to determine whether there are any special appendix instructions for you application.

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 FOA 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 FOAs may have different instructions for the Appendix. Always follow the instructions in your FOA 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 FOA.

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 FOA. For example, do not include material transfer agreements (MTA) in the appendix unless otherwise specified in the FOA.

Additional instructions for Multi-project: The “Appendix” attachment is optional.

# PHS Human Subjects and Clinical Trials Information

All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question “Are human subjects involved?” on the  *[R&R Other Project Information Form.](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf)*

Please complete the human subjects section of the [*R&R Other Project Information Form*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf) prior to completing this form.

Please see *PHS Human Subjects and Clinical Trials* for further instructions on this section.