

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](#). Please also see OSP's sample NIH grants.gov form for additional reference: [NIH Grants.gov Adobe package version D](#).

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](#) for additional information.

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

Content: 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](#). 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.

11. Equipment (Required)

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

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](#).

Current and Pending (Only include if required by FOA)

If applicable, please refer to instructions provided here to prepare this section: [Other Support](#).

PHS 398 Research Plan

1. 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](#).

Research Plan Section

2. 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).

3. 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.

4. Progress Report Publication List (Required only for Renewals)

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. For further guidance see [Research Instructions for NIH and Other PHS Agencies: SF424 \(R&R\) Application Packages](#).

Human Subjects Section

5. Protection of Human Subjects (Required if answered yes to “Are Human Subjects Involved?”)

Refer to [Supplemental Instructions, Part II](#) for instructions on this section. Additionally, be sure to follow any specific instructions in your FOA.

6. Data Safety Monitoring Plan (Required if answered yes to “Clinical Trial?”)

Refer to [Supplemental Instructions, Part II, Section 4.1.5: Data and Safety Monitoring Plan](#) for instructions on this attachment.

7. Inclusion of Women and Minorities (Required if answered yes to “Are Human Subjects Involved?” and the research does not fall under Exemption 4)

Refer to [Supplemental Instructions, Part II, Section 4.2: Inclusion of Women and Minorities](#) for instructions on this section.

Refer to [R.500 - PHS Inclusion Enrollment Report](#) as well as the [Supplemental Instructions, Part II](#) for more information on submitting the PHS Inclusion Enrollment Report as part of your application.

8. Inclusion of Children (Required if answered yes to “Are Human Subjects Involved?” and the research does not fall under Exemption 4)

Refer to the [Supplemental Instructions, Part II](#) (Section 4.4: Inclusion of Children and Section 5.8: NIH Policy on Inclusion of Children) for instructions on this section.

Other Research Plan Section

9. Vertebrate Animals (Include if answered “Yes” to “Are Vertebrate Animals Used?”)

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. 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. Provide a concise, complete description of the animals and proposed procedures. Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in those sites. Explain when and how animals are expected to be used if plans for the use of animals have not been finalized.

10. Select Agent Research (Include if your proposed activities involve the use of select agents at any time during the proposed project period)

Excluded select agents: If using a strain(s) of a select agent or toxin which has been excluded from those listed in 42 CFR 73.3, 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 but you have applied or intend to apply to HHS for an exclusion from the list, indicate the status of your request or your intent to apply for an exclusion, providing a brief justification for the exclusion.

All applicants proposing to use select agents: Briefly address the following three points for each site at which select agent research will take place:

- Identify the select agent(s) to be used.
- Provide the registration status of all entities where select agent(s) will be used. For foreign institutions, provide the name(s) of the country/countries where select agent research will be performed.
- 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.

11. Multiple PD/PI Leadership Plan (Required if multiple PD/PIs listed on R&R Senior/Key Person Profile Form)

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

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.

12. Consortium/Contractual Arrangement (Include if you have consortiums/subcontracts 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.

13. Letters of Support (Combine all letters into a single PDF to attach here, no page limit unless specified by FOA or Activity Code)

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.

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.

14. 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. Specific FOAs may require that all applications include this information regardless of the dollar level. For more information, see the NIH Data Sharing Policy or the NIH Guide Notice on Sharing Research Data.

Sharing Model Organisms: 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 [Supplemental Instructions, Part III, Section 1.5.2: Sharing Model Organism Policy](#) and the NIH Guide Notice on [Sharing Model Organisms for Biomedical Research](#).

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. For more information see the NIH GDS Policy, the NIH Guide Notice on Genomic Data Sharing Policy, and the GDS website. An institutional certification will be requested as Just-in-Time (JIT) information prior to award and must be submitted and accepted before the award can be issued.

For more information see [Supplemental Instructions, Part III, Section 1.5: Sharing Research Resources](#).

15. Authentication of Key Biological and/or Chemical Resources (Suggested limit of 1 page)

If applicable, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies.

For more Information see NIH's page on [Rigor and Reproducibility](#).

Appendix

16. Appendix (Specified in FOA whether allowable, maximum limit of 10 PDF attachments)

Content-The only allowable appendix materials are:

For applications proposing clinical trials (unless FOA provides other instructions):

- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND), as appropriate.

For all applications:

- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments
- FOA-specified items

If appendix materials are required in FOA, review criteria for the FOA will address those materials, and applications submitted without those Appendix materials will be considered incomplete and will not be reviewed.

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.

NOTE: Applications that do not follow the appendix requirements will not be reviewed. Applications submitted for due dates on or after January 25, 2017 will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this section. For further information see [Appendix Policy Frequently Asked Questions](#)

If more than 10 Appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. For additional information regarding appendix material and page limits, refer to the NIH Guide Notice on Compliance with NIH Application Format and Content Instructions.