

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved?

Yes No

1.a If YES to Human Subjects

Is the Project Exempt from Federal regulations? Yes No

If yes, check appropriate exemption number. 1 2 3 4 5 6

If no, is the IRB review Pending? Yes No

IRB Approval Date:

Human Subject Assurance Number:

2. * Are Vertebrate Animals Used?

Yes No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? Yes No

IACUC Approval Date:

Animal Welfare Assurance Number

3. * Is proprietary/privileged information included in the application?

Yes No

4.a. * Does this project have an actual or potential impact on the environment?

Yes No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?

Yes No

4.d. If yes, please explain:

5. * Is the research performance site designated, or eligible to be designated, as a historic place?

Yes No

5.a. If yes, please explain:

6. * Does this project involve activities outside of the United States or partnerships with international collaborators?

Yes No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. * Project Summary/Abstract

Add Attachment

Delete Attachment

View Attachment

8. * Project Narrative

Add Attachment

Delete Attachment

View Attachment

9. Bibliography & References Cited

Add Attachment

Delete Attachment

View Attachment

10. Facilities & Other Resources

Add Attachment

Delete Attachment

View Attachment

11. Equipment

Add Attachment

Delete Attachment

View Attachment

12. Other Attachments

Add Attachments

Delete Attachments

View Attachments

RESEARCH & RELATED Other Project Information

1 Are Human Subjects Involved?

If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving human subjects are not planned at any time during the proposed project at any performance site, select no and skip the rest of block 1. This field is required. See [Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan](#) for additional information.

1a If YES to Human Subjects

Enter the remaining information in 1a.

Is the project Exempt from Federal Regulations? If yes, check the appropriate exemption number.

The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for the Protection of Human Subjects. The exemptions are outlined in the [Code of Federal Regulations, 45 CFR §46, Subpart A](#)

If the project is NOT exempt, is the IRB review pending?

Enter the latest IRB approval date. Leave blank if pending. IRB approval date is not required at the time of submission but may be requested later in the pre-award process as Just-in-Time data. If provided, date cannot be in the future.

If Human Subjects = Yes, the Human Subject Assurance Number: FWA00004218

2 Are Vertebrate Animals Used?

Select Yes or No.

2a If YES to Vertebrate Animals

Enter the remaining information in 2a.

IACUC Approval Date not required at the time of submission, but may be required later in the pre-award process in Just-in-Time data. If provided, date cannot be in the future.

Animal Welfare Assurance Number: A3248-01

3 Proprietary/Privileged Information

Select Yes or No. This field is required.

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, check yes and clearly mark each line or paragraph on the pages containing the proprietary/privileged information with a legend similar to: "The following contains proprietary/privileged information that (name of applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation."

4a Environmental Impact

Select Yes or No. If yes, enter explanation in 4b.

4b If YES to 4a

Most NIH research grants are not expected to individually or cumulatively have a significant effect on the environment, and NIH has established several categorical exclusions allowing most applicants to answer 'No' to this question unless a specific FOA indicates that the National Environmental Policy Act (NEPA) applies. However, if an applicant expects that the proposed project will have an actual or potential impact on the environment, or if any part of the proposed research and/or project includes one or more of the following categorical exclusions listed below, the box marked "Yes" should be checked and an explanation provided in field 4.b.

1. The potential environmental impacts of the proposed research may be of greater scope or size than other actions included within a category.
2. The proposed research threatens to violate a Federal, State, or local law established for the protection of the environment or for public health and safety.
3. Potential effects of the proposed research are unique or highly uncertain.
4. Use of especially hazardous substances or processes is proposed for which adequate and accepted controls and safeguards are unknown or not available.
5. The proposed research may overload existing waste treatment plants due to new loads (volume, chemicals, toxicity, additional hazardous waste, etc.)
6. The proposed research may have a possible impact on endangered or threatened species.
7. The proposed research may introduce new sources of hazardous/toxic wastes or require storage of wastes pending new technology for safe disposal.
8. The proposed research may introduce new sources of radiation or radioactive materials.
9. Substantial and reasonable controversy exists about the environmental effects of the proposed research.

4c If this project has an actual or potential impact on the environment, has an exemption been authorized or an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) been performed?

Select Yes or No. If yes, enter explanation in 4d.

4d Explain

If YES to 4c, enter explanation.

5 Is the research performance site designated, or eligible to be designated, as a historic place?

Select Yes or No

5a If YES to 5a

Enter explanation

6 Does this project involve activities outside of the United States or partnerships with International Collaborators?

Select Yes or No

Foreign Component. The performance of any significant scientific element or segment of a project outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended. Activities that would meet this definition include, but are not limited to, (1) the involvement of human subjects or animals; (2) extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sampling, and similar activities; or (3) any activity of the grantee that may have an impact on U.S. foreign policy through involvement in the affairs or environment of a foreign

country. Examples of other grant-related activities that may be significant are: collaborations with investigators at a foreign site anticipated to result in co-authorship; use of facilities or instrumentation at a foreign site; or receipt of financial support or resources from a foreign entity. Foreign travel for consultation is not considered a foreign component.

6a If Yes, Identify Countries

Enter the names of the countries, if 6 is YES

6b Optional Explanation

Enter an explanation for involvement with outside entities (optional). If desired, you can provide the information in a separate file, and attach by clicking Add Attachments located to the right of Item 12, Other Attachments.

If you have checked “Yes” to 6, applicants to the NIH and other PHS agencies must describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area. Provide this information in a separate file, attaching it as Item 12, Other Attachments. In the body of the text, begin the section with a heading indicating “Foreign Justification.” When saving this file, please name it “Foreign Justification” as well.

7 Project Summary/Abstract

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information.

If the application is funded, the Project Description will be entered into an NIH database and made available on the NIH Research Portfolio Online Reporting Tool (RePORT, available at <http://report.nih.gov>) and will become public information.

The attachment must be in PDF format.

8 Project Narrative

Provide Project Narrative in accordance with the announcement and/or agency-specific instructions.

9 Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.

Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly “Literature Cited”) should include any references cited in the PHS 398 Research Plan form (see Section 5.5 for details on completing that form). When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference

number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. 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." A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

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 (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

10 Facilities & Other Resources

Attach a PDF file listing facilities/other resources, if any. This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.

For submissions to the NIH and other PHS agencies, 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 subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, 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; and financial support such as protected time for research with salary support.

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

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about select agents must be described in the Research Plan, Section 11 (Select Agent Research).

11 Equipment

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

12 Other Attachments

Only provide Other Attachments when requested in the FOA.