

## Research and Related Project Information

### Provide the following information to the related questions

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.

Applications proposing human subjects research may be required to submit additional information, forms, or attachments with the application, in accordance with policies covering human subject research.

**1. Are Human Subjects Involved?** YES NO

#### 1.a. If YES to Human Subjects

**Is the Project Exempt from Federal Regulations?** YES NO

**Yes:** If the project is exempt from Federal regulations, check Yes.

**No:** If the project is not exempt from Federal regulations, check No.

**If yes, Select the appropriate exemption number** 1 2 3 4 5 6

If human subject activities are exempt from Federal regulations, provide the exemption numbers corresponding to one or more of the exemption categories. 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](#).

OHPR guidance states that appropriate use of Exemptions described in 45 CFR 46 should be determined by an [authority independent from the investigators](#). Institutions often designate their IRB to make this determination. Since IRB approval is not required at the time of application, the exemptions designated often represent the opinion of the PD/PI, and the justification provided for the exemption by the PD/PI is evaluated during peer review. Human subjects research should be designated as exempt if the proposed research meets the criteria for one or more of the six exemptions.

**If no, is the IRB review Pending?** YES NO

Enter the latest Institutional Review Board (IRB) approval date. Leave blank if Pending.

Applicants should check "Yes" to the question "Is the IRB review Pending?" even if the IRB review/approval process has not yet begun at the time of submission. Also note that an IRB Approval Date is not required at the time of submission. This may be requested later in the pre-award cycle. If IRB is still pending at time of award then affected components of the award will be restricted. Failure to obtain IRB approval within the agreed upon time frame may result in the termination of an award.

## Human Subject Assurance Number

Enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number.

Insert "None" if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in item 21 on the SF424 declaring that it will comply with 45 CFR part 46 and proceed to obtain a [human subjects assurances](#) **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

**2. Are Vertebrate Animals Used?** YES NO

If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check yes. If no, skip the rest of block 2.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

### 2.a. If YES to Vertebrate Animals

**Is the Institutional Animal Care and Use Committee (IACUC) review Pending?** YES NO

#### IACUC Approval Date:

Enter the latest IACUC approval date (if available). Leave blank if Pending.

#### Animal Welfare Assurance Number:

Enter the Federally approved assurance number, if available.

For information on determining if your organization holds an Animal Welfare Assurance, see [the Office of Laboratory Animal Welfare](#). Applicants should check "Yes" to the question "Is the IACUC review Pending?" even if the IACUC review/approval process has not yet begun at the time of submission. Also note that an IACUC Approval Date is not required at the time of submission. However, the approval date and other data may be requested later in the pre-award cycle. If the applicant organization does not have an approved Animal Welfare Assurance on file with the [Office of Laboratory Animal Welfare \(OLAW\), NIH](#), enter "None" in the Animal Welfare Assurance Number field. **Do not enter the Animal Welfare Assurance number of any collaborating institution.** By inserting "None" at the time of submission, the applicant organization is essentially declaring that it will comply with the [PHS Policy on Humane Care and Use of Laboratory Animals](#) by submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OLAW. If IACC approval is still pending at time of award then affected components of the award will be restricted. Failure to obtain IACC approval within the agreed upon time frame may result in the termination of an award.

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

**YES NO**

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."

**4. Environmental Questions**

Most research grants are not expected to individually or cumulatively have a significant effect on the environment, and there are 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 line 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.

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

**YES NO**

**4.b. If yes, please explain**

Explanation of the actual or potential impact on the environment.

**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 an Environmental Impact Statement (EIS) been performed?** YES NO

**4.d. If yes, please explain**

Enter additional details about the EA or EIS. If desired, you can provide the information in a separate file, and attach by clicking **Add Attachments**

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

YES NO

If any research performance site is designated, or eligible to be designated, as a historic place, if Yes, check the Yes and then provide an explanation. Otherwise, check the No.

**5.a. If yes, please explain:**

If you checked the Yes box indicating any performance site is designated, or eligible to be designated, as a historic place, provide the explanation here.

**6. Does this project involve activities outside of the United States or partnerships with International Collaborators?** YES NO

Indicate whether this project involves activities outside of the United States or partnerships with international collaborators. Check yes or no.

Applicants to PHS agencies must check "Yes" if the applicant organization is a foreign institution or if the project includes a foreign component.

**6.a. If yes, identify countries**

Enter the countries with which international cooperative activities are involved.