

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 (see <http://www.hhs.gov/ohrp>). **Do not insert the human subjects assurance number of any collaborating institution in the space provided.**

2. Are Vertebrate Animals Used? YES NO

If studies 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.

- **If Company will be working with CRO(s)**, review special instructions on pg 3 before completing rest of form.
- **If multiple activities involving animal subjects are planned**, review special instructions on pg 3 before completing rest of form.

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.

To determine if your organization holds an Animal Welfare Assurance, see <http://grants.nih.gov/grants/olaw/olaw.htm#assur>. 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. 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 IACUC approval is still pending at time of award then affected components of the award will be restricted. Failure to obtain IACUC approval within the agreed upon time frame may result in the termination of an award.

3. Is proprietary/privileged information included in this form? YES NO

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in form only when such information is necessary to convey an understanding of the proposed project. If the form 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. 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 or CROs. Check yes or no.

Check "Yes" if Company is a foreign entity or if the project includes a foreign component or CRO.

4.a. If yes, identify countries

Enter the countries with which international cooperative activities are involved.

➤ Special Instructions: Multiple Studies, Companies using CRO(s):

If Company will be doing research with human or animal subjects through CRO(s):

- In the **Human or Animal Assurance fields:**
 - enter "CRO – see attached"
- **IRB/IACUC Pending and IRB/IACUC Approval fields:**
 - leave blank (even if CRO has current approval)
- Provide this information for each CRO in Attachment A-1
- Attach copies of IRB or IACUC approval(s)

If Company has multiple human or animal studies:

- **IRB/IACUC Pending and IRB/IACUC Approval fields:**
 - leave blank
- Provide this information for each study in Attachment A-1

Date Completed