

Chimpanzee Research Use form

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Privacy Notice This collection of information is authorized by 42 U.S.C. 241, 282, 282b, 284a, and 48 CFR Subpart 15.3. Certain information provided through this form may be used by National Institutes of Health (NIH) to identify and contact the submitter about the proposed research. Unless otherwise specified in a written agreement between NIH and the submitter, all information, including proprietary information, submitted through the form, attached to it, or referenced in it may be accessed by the NIH and/or the Council. NIH staff and contractors who have signed confidentiality and non-disclosure statements will use the information for administrative purposes, e.g., reviewing materials for completeness, routing materials and managing subsequent steps related to discussions about the proposed research.

Burden Disclosure Statement Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0705). Do not return the completed form to this address.

Purpose The purpose of this form is to obtain information needed by the NIH to assess whether the proposed research satisfies the NIH's policy for research involving chimpanzees, as announced in the Federal Register and NIH Guide. These announcements inform the research community that NIH will support only "noninvasive" research involving chimpanzees.

The NIH will consider the information submitted through this form prior to the agency making funding decisions or otherwise allowing the "noninvasive" research to begin. Completion of this form is a mandatory step toward receiving NIH support or approval for such research. Failure to complete this form by the due date may delay consideration by the NIH.

Who Can Submit the Form Only applicants and offerors notified by the NIH are required to complete this form. If the NIH has contacted you about completing this form, it is because you have requested that the agency support or otherwise approve a grant, contract, intramural project, or third-party research activity involving chimpanzees or chimpanzee biomaterials, and the agency requires additional information before making funding decisions or otherwise allowing the

research to begin. The NIH requires applicants and offerors to complete the form when the proposed research:

1. Requests the use of chimpanzees (*Pan troglodytes*) or chimpanzee biomaterials in research, and
2. Is being considered for funding (grants), is in the competitive range (contracts), is scientifically meritorious and fundable (NIH intramural research), or was otherwise submitted for consideration (3rd party projects).

The form may be submitted by the Signing Official for an extramural organization or his/her designee. For intramural programs, the Scientific Director (or their designee) will serve as the Signing Official. The Signing Official is the individual, named by the applicant or offeror's organization, authorized to act for the applicant or offeror and to assume the obligations imposed by applicable Federal laws, regulations, requirements, and conditions.

What Information Gets Considered Applicants and offerors are required to describe their proposed research and how it satisfies the agency announcement in NIH Guide NOT-OD-16-095. Depending on the nature of the research, the NIH will determine if the activity is "noninvasive" (e.g., observational research or research involving stored biospecimens), or if the research is "invasive." Consideration is based solely on the information provided in the Noninvasive Determination section of this form. Although attachments may be submitted, they are optional. The NIH may consult attached materials at its discretion. All information pertinent to their consideration must be entered into the Noninvasive Determination text box.

How and When to Submit the Form and How to Revise Submitted Information Unless otherwise specified by the NIH, applicants and offerors have 15 calendar days to submit the completed report after they have been contacted by the NIH. For grants and cooperative agreements, information must be submitted electronically via the eRA Just-in-Time (JIT) module. For other transaction authority, information must be submitted electronically via the eRA Request for Additional Materials (RAM) module. For contracts, intramural, and third-party proposals or projects, the form must be submitted via email to olawdoa@mail.nih.gov.

Questions about the form can be emailed to olawdoa@mail.nih.gov. If the applicant or offeror notices that the report requires a change after it has been submitted, contact the NIH's Office of Laboratory Animal Welfare (OLAW) at olawdoa@mail.nih.gov. Submissions that are incomplete by the due date may delay consideration by the NIH.

Submitting Organization

Signing Official Name:

Signing Official Phone:

Signing Official E-mail:

Organization Name:

Organization UEI:

Organization Address:

Research Project Information

PI Name:

Research Funding Mechanism:

Project Number:

Project Title:

Project Summary or Abstract: *Summarize the proposed research activity in a self-contained description of the project that includes a statement of objectives and methods to be employed. Use language that is understandable to a scientifically or technically literate lay reader.*

Specific Aims: *Describe the broad, long-term objectives and goal of the specific research proposed. For example, 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.*

Public Health Relevance: *Describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.*

Noninvasive Determination

The following types of research involving chimpanzees or chimpanzee biomaterials are considered “noninvasive”:

- Visual observation.
- Behavioral studies designed to improve the establishment and maintenance of social groups. These activities may cause stress as a result of novel

interactions between chimpanzees and caregivers, but they are not considered invasive as long as they are intended to maximize the well-being of the chimpanzees.

- Medical examinations as deemed necessary to oversee the health of the chimpanzees, in the least invasive manner possible. Collection of samples routinely obtained during a physical examination for processing during this time is also considered noninvasive since a separate event is not required.
- Administration and evaluation of environmental enrichment used to promote the psychological well-being of the chimpanzees.
- Actions taken to provide essential medical treatment to an individual chimpanzee exhibiting symptoms of illness. This applies only to serious illness that cannot be treated while the chimpanzee remains within the colony.
- Observational studies and collection of biomaterial in the wild without interfering with the chimpanzee.
- Collections of biological materials (e.g., saliva, oral or other cavity specimens, urine, feces, or hair) obtained voluntarily from a chimpanzee that has been trained through positive reinforcement to cooperate in the collection. This excludes venipuncture or other more invasive methods.

If any portion of the proposal fails to satisfy the description of “noninvasive” research involving chimpanzees, contact your program officer or other federal official responsible for administering the award. If the organization believes the entire research project is “noninvasive,” provide sufficient detail about the proposed research to allow NIH to verify this designation. If the agency agrees with your designation, then the proposed research may be considered for funding. If NIH disagrees with the designation, the project will be considered “invasive” and the investigator will be directed to consult with the program officer or other appropriate federal official.

Determination *[Check only one of the following] (required)*

- This project was identified in error and does not involve any research with live chimpanzees or chimpanzee biomaterials. *[Skip to the Institutional Certifications section]*
- This project includes only “noninvasive” research, consistent with the definition above. *[Proceed to the Justification section]*
- Other *[Proceed to the Justification section]*

Justification *(required if the Project is “noninvasive” or Other box is checked)*

Provide sufficient detail about the research project for agency officials to verify that the proposed research is “noninvasive.” *[Limit response to no more than 2 pages]*

Attachments (optional)

Although NIH allows you to submit attachments, consideration of these materials by the NIH is discretionary. All pertinent information must be entered into the

Noninvasive Determination tab. All information must be in English and attachments should be in pdf file type.

Applicants and offerors are strongly discouraged from resubmitting their grant application, contract proposal, or protocols as an attachment to the Chimpanzee Research Use Form.

Institutional Certifications *(required)*

By submitting this form, I certify that:

- I understand that consideration by the NIH to affirm its status of “noninvasive” is based on the assumption that a Scientific Review or other Evaluation Group (for grants and contracts) or the Scientific Director (for Intramural projects) has reviewed the project and already determined it to be scientifically meritorious.
- The statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.
- The information provided herein is materially consistent with the research methods proposed in the grant application, contract proposal, intramural protocol, or 3rd party research protocol to which this information supports.
- The applicant or offeror gives permission for the NIH to share its contents with the NIH and applicable advisory councils. In addition, the applicant or offeror gives permission for NIH staff and contractors to use the information for administrative purposes, such as reviewing materials for completeness, routing materials, and managing subsequent steps related to discussions of the proposed research.
- If I indicated that the research is “noninvasive” based on [NIH Guide Notice NOT-OD-16-095](#), I understand that NIH will consider the submitted information to validate that determination. I understand that further information may be requested before a determination can be made. NIH will notify the organization of its decision and recommend the organization contact the program official or other federal official to discuss the proposed research.
- I acknowledge that NIH will not fund “invasive” research involving chimpanzees, and research that proposes such research may delay further consideration by NIH. There is no process to appeal NIH’s determination on whether research is “noninvasive” or “invasive.”

Signing Official/Scientific Director Signature and Date