Chimpanzee Research Use Form

This document presents the Chimpanzee Research Use Form

- Part 1: Chimpanzee Research Use Form displayed as Screen Shots
- Part 2: Text only of the Chimpanzee Research Use Form

Part 1: Chimpanzee Research Use Form displayed as Screen Shots

First Screen After Login—Assignments

User sees assignments and clicks on CRU Report # (hotlink) to access the form. User submits one form per research application or proposal that involves use of chimpanzees or chimpanzee biomaterials.

User sees only his/her research proposals. He/She cannot access proposal by other investigators. Project-level information has been redacted from the image below.



Second Screen—Initiate CRU Report — NO REVISIONS



Initiate CRU Report Back to My Assignments

OMB No: 0925-0705, Expiration date: 10/31/2017

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 3rd 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
- 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 organization or his/her designee. 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 boxes.

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. Information must be submitted electronically via the Chimpanzee Research Use Reporting System.

Questions about the online form can be emailed to the DPCPSI@od.nlh.gov. If the applicant or offeror notices that the report requires a change after it has been submitted, contact the NIH's Division of Program Coordination, Planning, and Strategic initiatives at DPCPSI@od.nlh.gov. Submissions that are incomplete by the due date may delay consideration by the NIH.



Third Screen—Project Information – NO REVISIONS

For grant applicants (external to NIH), the information on this screen is pre-populated with information they submitted in the applicant's grant application. Note: On this screen the users see the icon ① that allows them to access additional information about the item. The text can be found in the revised CRU Report Guidance.

Division of Program Coordination, Planning	, and Strategic In	itiatives (DPCPSI)	NIH National Institutes of H	lealth 🕌	U.S. Department of Health and Human Services
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Project information Noninvasive De	termination	Attachments			
		Submitting	g Organization		
Signing Official 🚺	Signing Official	Name	Signing Official Phone		Signing Official e-mail
	Chris	•	1234567890		Bnih.gov
	Certification Let	tter			Sample SO Certification Letter
	Add Certifica	ation Letter			
	This field is requ	lired if the person submitt	ing is not the Signing Official.		
Organization	Organization Na	ame			Organization DUNS Number
	UNIVERSITY	(OF			
	Organization Ad	ddress			
	Office of Re	search Services			
	Organization W	ork Phone	Organization Email		
		Research Pro	ject Information		
PIName		PiName	,		
		Lora Pl	-		
Research Funding Mechanism		Funding Type Project Num1		ber	
		Contract Proposal		test	
Project Title					
burden statement test					
Project Summary/Abstract. Specific Aims. and Public Health Relevance					
					10000 Characters Remain.
		Save	Submit Next		

Sample Certification Letter - Completed by the Signing Official - NO REVISIONS

The investigator also uploads a letter completed by the signing official that certifies the accuracy of the information in the CRU system. A template is located in the Third Screen (previous page) to reduce time to complete the entry.

Sample Certification Letter for Signature by the Signing Official

Updated: 06/22/2016

The following should be on institutional letterhead and signed by the Signing Official (Authorized Organizational Representative).

[Date]

Dear NIH DPCPSI,

I certify that:

(1) I understand that I will receive a "Submission Received on [Date]" verification screen showing the date and time NIH received the submission. If I do not receive a verification screen after clicking "Confirm", I may contact <u>dpcpsi@od.nih.gov</u> to confirm receipt by NIH.

(2) 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.

(3) 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.

(4) 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.

(5) I am the Signing Official with all rights, authority, and responsibilities appropriate to that role for the organization provided above. As the Signing Official, I am the individual, named by the applicant or offeror organization, who is authorized to act for the applicant or offeror and to assume the obligations imposed by applicable Federal laws, regulations, requirements, and conditions.

(6) 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.

(7) 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. If the NIH disagrees with the organization's assessment that the research is "noninvasive," 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.

(3) 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

Fourth Screen—Project Information for Noninvasiveness Determination – NO REVISIONS

This screen allows the user to assess whether his/her proposed research is noninvasive.

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) NIH) National Institutes of Health
CRUREPORTING CHIMPANZEE RESEARCH USE REPORTING SYSTEM Reports + Help + Welcome Lora PI +
Initiate CRU Report Back to My Assignments
Project Information Noninvasive Determination Attachments
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. Addinistration 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.
Additional Information
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.
Complete the text box with sufficient detail about the research project for agency officials to verify that the proposed research is "noninvasive":
This field is required. Enter response above or attach a document with your response (maximum of two pages at 12pt type, equations may use smaller type).
Attach File



Prev Save Submit Next

Fifth Screen—Attachments – NO REVISIONS

The screen allows the user to attach supplemental information, e.g., images. Attachments are optional.

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)	NIH National Institutes of Health	U.S. Department of Health and Human Services			
CRUREPORTING CHIMPANZEE	E RESEARCH USE SYSTEM Reports +	Help 👻 Welcome Lora PI 👻			
Initiate CRU Report Back to My Assignments					
Project Information Noninvasive Determination Attachments					
Attachments					
Although NIH allows you to submit attachments, consideration of these mat Noninvasive Determination tab. All information must be in English and attac					
Applicants and offerors are strongly discouraged from resubmitting their grant Research Use Form.	ant application, contract proposal	, or protocols as an attachment to the Chimpanzee			
Browse	Enter File Description	Add			



Sixth Screen—Final Certification by the Investigator – NO REVISIONS

Upon hitting "Submit" the Investigator is presented with the following certification.

and time NIH re		If I do not receive a verificati	e]" verification screen showing the date Ion screen after clicking "Confirm", I ma
to validate that	determination. If the N	IH disagrees with the organiz	H will consider the submitted informati zation's assessment that the research is
			e Investigator contact the program will not fund invasive research involvin

Part 2: Text only of the Chimpanzee Research Use Form

First Screen After Login—Assignments

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User sees only his/her research proposals. He/She cannot access proposal by other investigators.

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OMB No: 0925-0705, Expiration date: 10/31/2017

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Burden Disclosure Statement

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Purpose

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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

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- 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 organization or his/her designee. 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 <u>NOT-OD-16-095</u>. 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 boxes.

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. Information must be submitted electronically via the Chimpanzee Research Use Reporting System.

Questions about the online form can be emailed to the DPCPSI@od.nih.gov. If the applicant or offeror notices that the report requires a change after it has been submitted, contact the NIH's Division of Program Coordination, Planning, and Strategic Initiatives at DPCPSI@od.nih.gov. Submissions that are incomplete by the due date may delay consideration by the NIH.

Third Screen—Project Information – NO REVISIONS

For grant applicants (external to NIH), the information on this screen is pre-populated with information they submitted in the applicant's grant application. Note: On this screen the users see the icon ① that allows them to access additional information about the item. The text can be found in the revised CRU Report Guidance.

Submitting Organization

Complete only if the submitter is not the Signing Official and attach a certification letter signed by the Signing Official. Use the following <u>template</u> to create the SO Certification Letter.

Signing Official

Signing Official is the individual, named by the applicant or offeror organization authorized to act for the applicant or offeror and to assume the obligations imposed by applicable Federal laws, regulations, requirements, and conditions.

Signing Official Name	Chris Ji	-
0 0		

Chris

Signing Official Phone

Signing Official e-mail

Certification Letter

|--|

This field is required if the person submitting is not the Signing Official.

Sample SO Certification Letter [SEE PAGE 14]
Organization
Organization Name UNIVERSITY OF
Organization DUNS Number 00211545641516
Organization Address Office of Researc
Organization Work Phone
Organization Email

Research Project Information

PI Name
Pl Name
Lora PI
Research Funding Mechanism
Funding Type
Project Number
Project Title
test

Project Summary/Abstract, Specific Aims, and Public Health Relevance 0

A project summary or abstract summarizes the proposed research activity. 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.

Specific aims provides the research with the broad, long-term objectives and the 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 describes 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.

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	-

10000 Characters Remain.

Sample Certification Letter – Completed by the Signing Official – NO REVISIONS

The investigator also uploads a letter completed by the signing official that certifies the accuracy of the information in the CRU system. A template is located in the Third Screen (previous page) to reduce time to complete the entry.

Sample Certification Letter for Signature by the Signing Official

Updated: 06/22/2016

The following should be on institutional letterhead and signed by the Signing Official (Authorized Organizational Representative).

[Date]

Dear NIH DPCPSI,

I certify that:

(1) I understand that I will receive a Submission Received on [Date]" verification screen showing the date and time NIH received the submission. If I do not receive a verification screen after clicking "Confirm", I may contact <u>dpcpsi@od.nih.gov</u> to confirm receipt by NIH.

(2) 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.

(3) 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.

(4) 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.

(5) I am the Signing Official with all rights, authority, and responsibilities appropriate to that role for the organization provided above. As the Signing Official, I am the individual, named by the applicant or offeror organization, who is authorized to act for the applicant or offeror and to assume the obligations imposed by applicable Federal laws, regulations, requirements, and conditions.

(6) 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.

(7) 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. If the NIH disagrees with the organization's assessment that the research is "noninvasive," 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.

(3) 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

Fourth Screen—Project Information for Noninvasiveness Determination – NO REVISIONS

This screen allows the user to assess whether his/her proposed research is noninvasive.

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.

Additional Information

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.

Complete the text box with sufficient detail about the research project for agency officials to verify that the proposed research is "noninvasive":

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This field is required. 7000 Characters Remain.

Enter response above or attach a document with your response (maximum of two pages at 12pt type, equations may use smaller type).

Attach File ...

Fifth Screen—Attachments – NO REVISIONS

The screen allows the user to attach supplemental information, e.g., images. Attachments are optional.

Attachments

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, image, or MS Word file types.

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

Sixth Screen—Final Certification by the Investigator – NO REVISIONS

Upon hitting "Submit" the Investigator is presented with the following certification.

I Certify that:

* I understand that I will receive a "Submission Received on [Date]" verification screen showing the date and time NIH received the submission. If I do not receive a verification screen after clicking "Confirm", I may contact dpcpsi@od.nih.gov to confirm receipt by NIH.

By indicating that the research is noninvasive, I understand that NIH will consider the submitted information to validate that determination. If the NIH disagrees with the organization's assessment that the research is noninvasive, NIH consider the project to be invasive and suggest the investigator contact the program officer or other appropriate federal official. I acknowledge that NIH will not fund invasive research involving chimpanzees.