

## **Chimpanzee Research Use Form**

This document presents the Chimpanzee Research Use Form in two ways.

Part 1 displays the screen shots from the CRU Reporting System with noted revisions

Part 2 provides the form in text only (for greater readability) in final version (no markup)

PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

Part 1: Screen Shots from CRU Reporting System

First Screen After Login—Assignments - **UNCHANGED**

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.

The screenshot displays the CRU Reporting System interface. At the top, it features the logos for the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), the National Institutes of Health (NIH), and the U.S. Department of Health and Human Services. The main header includes the text "CRU REPORTING CHIMPANZEE RESEARCH USE REPORTING SYSTEM" and navigation links for "Reports", "Change Password", "Log off", and "Help".

The "Assignments" section contains a table with the following data:

CRU Report #	Grant/Protocol/Contract #	Project Title	PI Name	Status
<a href="#">I-00099</a>	SAMPLE-12-34	Sample Research Project Title		In Progress (Deadline: 8/1/2014)

Below the table, there is a footer area with the text "This page last reviewed: February 1, 2014" and a list of links: "NIH Office of the Director", "Contact Us", "Site Map", "Privacy Policy", "Accessibility", "FOIA", and "Disclaimers". The footer also includes the address "Division of Program Coordination, Planning, and Strategic Initiatives • National Institutes of Health • Bethesda, Maryland 20892" and logos for NIH, the U.S. Department of Health and Human Services, and USA.gov. The slogan "NIH...Turning Discovery Into Health®" is displayed at the bottom.

**Second Screen—Initiate CRU Report - REVISIONS ARE IN THE TEXT BELOW**

Revisions indicated in highlighted areas

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 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, the CRUP, 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 to the CRUP and the Council, 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

## PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

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 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.nih.gov](mailto: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](mailto:DPCPSI@od.nih.gov). Submissions that are incomplete by the due date may delay consideration by the NIH.

PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

**Third Screen—Project Information - REVISIONS ARE OUTLINED BELOW**

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 ⓘ that allows them to access additional information about the item. The text can be found in the revised CRU Report Guidance.

Revisions to the Original Screen Shot Below

- Tab “Exemption Determination” will change to “Noninvasive Determination”
- Tabs “CRU Justification” and “Personnel” will be removed

The screenshot displays the 'Initiate CRU Report' page within the 'CHIMPANZEE RESEARCH USE REPORTING SYSTEM'. The page header includes the NIH logo and the U.S. Department of Health and Human Services. The main navigation bar contains 'CRU REPORTING', 'CHIMPANZEE RESEARCH USE REPORTING SYSTEM', and links for 'Reports', 'Change Password', 'Log off', and 'Help'. Below the header, there are five tabs: 'Project Information' (highlighted in blue), 'Exemption Assessment', 'CRU Justification', 'Attachments', and 'Personnel'. The form is divided into several sections: 'Submitting Organization' with fields for 'Signing Official' (name, phone, e-mail), 'Organization' (name, DUNS number, address, work phone, email), and 'Research Project Information' (PI Name, Funding Type, Project Number). A 'Project Title' field is also present. At the bottom, there is a 'Project Summary/Abstract, Specific Aims, and Public Health Relevance' text area with a character count of 9820. The page concludes with 'Save', 'Submit', and 'Next' buttons.

**Fourth Screen—Exemption Assessment - REVISIONS ARE OUTLINED BELOW**

This screen allows the user to assess whether his/her proposed research is noninvasive. Note: On this screen the users see the icon ⓘ that allows them to access additional information about the item. The text can be found in the CRU Report Guidance.

Revisions to the Original Screen Shot Below

- Tab “Exemption Determination” renamed to “Noninvasive Determination”
- “Option A: Exempt from CRUP Consideration” and “Option B: Subject to CRUP Consideration” removed.
- Text changes follow

The screenshot shows the 'Initiate CRU Report' page in the CRU Reporting System. The page title is 'Exemption Determination'. It features two tabs: 'Project Information' and 'Exemption Assessment', with the latter being active. The main content area contains a heading 'Exemption Determination' followed by a paragraph: 'The following types of research involving chimpanzees or chimpanzee biomaterials are exempt from CRUP consideration:'. Below this are three bullet points detailing exemption criteria. A note states: 'If any portion of the proposal fails to satisfy the criteria for research exempt from CRUP consideration, select option B, "Subject to CRUP Consideration" and complete the items under the section "Research subject to CRUP Consideration".' Two radio button options are presented: 'Option A: Exempt from CRUP Consideration ⓘ' (selected) and 'Option B: Subject to CRUP Consideration ⓘ'. A text box for providing details is shown with the word 'sample' entered. A character count '6994 Characters Remain.' is visible. At the bottom, there is an 'Attach File ...' button and 'Prev', 'Save', and 'Submit' buttons.

## PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

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.

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



\*\*\*\*

After entering information into this section, the user may attach file and may submit the materials. User is then brought to Certifications and then the report is complete. In the original Chimpanzee Research Use Form, the user had the option to complete sections of the form relevant to research that formerly was subject to CRUP consideration, i.e., invasive research. These portions of the form would have been triggered by selecting “Option B: Subject to CRUP Consideration,” which are now obsolete.



# PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

## Option B Screen: **REVISION – OPTION B WILL BE REMOVED**

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)  National Institutes of Health  U.S. Department of Health and Human Services

# CRU REPORTING

 CHIMPANZEE RESEARCH USE REPORTING SYSTEM [Reports](#) [Change Password](#) [Log off](#) [Help](#)

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## Initiate CRU Report

[Back to My Assignments](#)

[Project Information](#) [Exemption Assessment](#) [CRU Justification](#) [Attachments](#) [Personnel](#)



### Exemption Determination

The following types of research involving chimpanzees or chimpanzee biomaterials are exempt from CRUP consideration:

- The use of any biomaterials, including pathological specimens, collected and/or stored prior to submission of the research application, proposal, or protocol, as part of a research project that has undergone CRUP consideration and subsequent NIH approval, or as part of regular veterinary (health) examinations; (Exempt under this criteria include research projects using samples or other biomaterials collected and/or stored as part of research projects that were previously approved by the NIH as part of consideration by the Council of Councils and the Working Group on the Use of Chimpanzees in NIH-Supported Research.)
- Other observational or non-interventional studies, such as behavioral observations in the wild that do not result in contact or otherwise interfere with the chimpanzees being observed; or (This includes noninvasive collection of samples from captive chimpanzees in a manner that does not result in contact or otherwise interfere with the chimpanzees during the collection.)
- Noninvasive collection of samples from the wild in a manner that does not result in contact or otherwise interfere with the chimpanzees during the collection.\* (Examples include collection of fecal samples from the wild.)

If any portion of the proposal fails to satisfy the criteria for research exempt from CRUP consideration, select option B, "Subject to CRUP Consideration" and complete the items under the section "Research subject to CRUP Consideration".

Select whether the organization believes the proposed research is exempt from, or subject to, CRUP consideration.

Option A: Exempt from CRUP Consideration   Option B: Subject to CRUP Consideration 

[Prev](#) [Save](#) [Submit](#) [Next](#)

This page last reviewed: February 1, 2014

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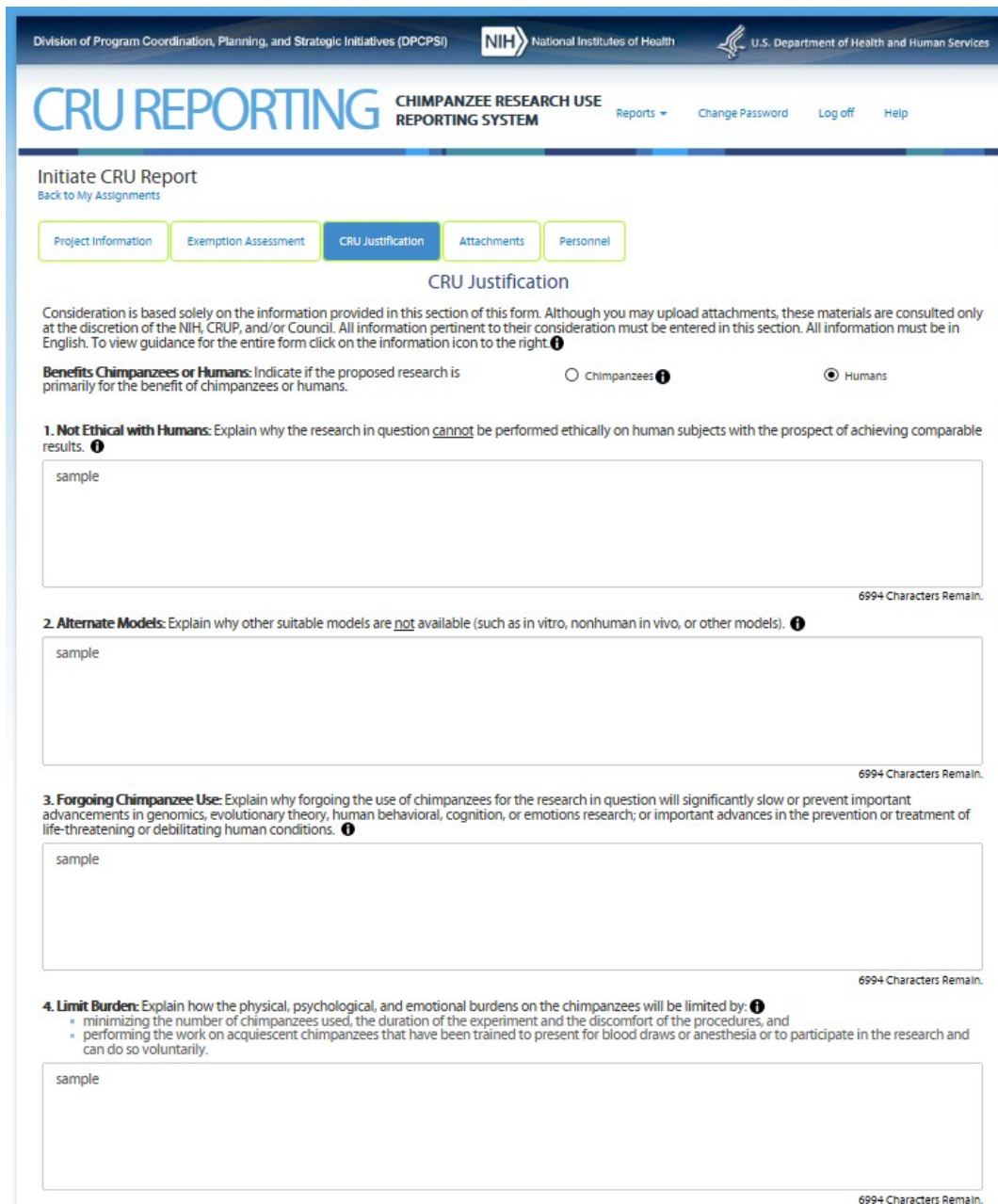


**Fifth Screen—CRU Justification (top portion) - REVISION - WILL BE REMOVED**

The Fifth Screen captures information to allow the Chimpanzee Research Use Panel to assess whether the proposed research is consistent with NIH interim policy on the use of chimpanzees.

Note: On this screen the users see the icon  that allows them to access additional information about the item. The text can be found in Attachment 8 CRU Report Guidance.

Enumerated items 1 and 3 are available for entry only if “Humans” is selected. If “Chimpanzees” is selected an additional text box appears asking user to “Explain how the research is in the best interest of the chimpanzee and how it addresses the mission of the NIH.”



The screenshot shows the 'Initiate CRU Report' page in the 'CHIMPANZEE RESEARCH USE REPORTING SYSTEM'. The page has a navigation bar with 'Project Information', 'Exemption Assessment', 'CRU Justification' (selected), 'Attachments', and 'Personnel'. Below the navigation is the 'CRU Justification' section. It includes a header with the NIH and U.S. Department of Health and Human Services logos, and a sub-header 'Initiate CRU Report'. The main content area contains a paragraph of instructions, a radio button selection for 'Chimpanzees' (selected) or 'Humans', and four numbered text entry fields. Each field contains the word 'sample' and has a '6994 Characters Remain.' indicator at the bottom right.

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) NIH National Institutes of Health U.S. Department of Health and Human Services

# CRU REPORTING

## CHIMPANZEE RESEARCH USE REPORTING SYSTEM

Reports Change Password Log off Help

### Initiate CRU Report

[Back to My Assignments](#)

Project Information Exemption Assessment **CRU Justification** Attachments Personnel

### CRU Justification

Consideration is based solely on the information provided in this section of this form. Although you may upload attachments, these materials are consulted only at the discretion of the NIH, CRUP, and/or Council. All information pertinent to their consideration must be entered in this section. All information must be in English. To view guidance for the entire form click on the information icon to the right.

**Benefits Chimpanzees or Humans:** Indicate if the proposed research is primarily for the benefit of chimpanzees or humans.

Chimpanzees  Humans

**1. Not Ethical with Humans:** Explain why the research in question cannot be performed ethically on human subjects with the prospect of achieving comparable results.

sample

6994 Characters Remain.

**2. Alternate Models:** Explain why other suitable models are not available (such as in vitro, nonhuman in vivo, or other models).

sample

6994 Characters Remain.

**3. Forgoing Chimpanzee Use:** Explain why forgoing the use of chimpanzees for the research in question will significantly slow or prevent important advancements in genomics, evolutionary theory, human behavioral, cognition, or emotions research; or important advances in the prevention or treatment of life-threatening or debilitating human conditions.

sample

6994 Characters Remain.

**4. Limit Burden:** Explain how the physical, psychological, and emotional burdens on the chimpanzees will be limited by:

- minimizing the number of chimpanzees used, the duration of the experiment and the discomfort of the procedures, and
- performing the work on acquiescent chimpanzees that have been trained to present for blood draws or anesthesia or to participate in the research and can do so voluntarily.

sample

6994 Characters Remain.

**Fifth Screen—CRU Justification (continued) REVISION - WILL BE REMOVED**

Note: On this screen the users see the icon ⓘ that allows them to access additional information about the item. The text can be found in Attachment 8 CRU Report Guidance.

**5. Benefit vs. Burden:** Explain how the remaining physical, psychological, and emotional burdens on the chimpanzees are outweighed by the possible benefits to humankind and to science. ⓘ

sample

6994 Characters Remain.

**6. Number of Chimpanzees:** Demonstrate that the number of chimpanzees proposed is statistically or scientifically justified. ⓘ

sample

6994 Characters Remain.

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

Attach File ...

**Ethologically Appropriate Facility:** Indicate the possible facility or facilities where the chimpanzee(s) will be maintained. ⓘ

Other (non pre-approved)

sample

6994 Characters Remain.

Prev Save Submit Next

**Sixth Screen—Attachments - REVISIONS OULINED BELOW**

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

**Revisions**

- **Minor text changes are below**

The screenshot displays the 'Initiate CRU Report' page in the 'CHIMPANZEE RESEARCH USE REPORTING SYSTEM'. The page header includes the NIH logo and the U.S. Department of Health and Human Services logo. The main navigation bar contains 'CRU REPORTING', 'CHIMPANZEE RESEARCH USE REPORTING SYSTEM', and links for 'Reports', 'Change Password', 'Log off', and 'Help'. The 'Initiate CRU Report' section has a 'Back to My Assignments' link and five tabs: 'Project Information', 'Exemption Assessment', 'CRU Justification', 'Attachments', and 'Personnel'. The 'Attachments' tab is selected. Below the tabs, there is a heading 'Attachments' followed by two paragraphs of text. The first paragraph states that consideration by the NIH, the CRUP, and the Council is based solely on information provided through the CRU Justification tab, and that all information must be in English and attachments should be in pdf, image, or MS Word file types. The second paragraph states that applicants and offerors are strongly discouraged from resubmitting their grant application, contract proposal, or protocols as an attachment to the Chimpanzee Research Use Form. Below the text is a file upload area with a 'Browse...' button, an 'Enter File Description' text box, and an 'Add' button. At the bottom of the form are 'Prev', 'Submit', and 'Next' buttons. The footer contains the text 'This page last reviewed: February 1, 2014' and a list of links: 'NIH Office of the Director', 'Contact Us', 'Site Map', 'Privacy Policy', 'Accessibility', 'FOIA', and 'Disclaimers'. It also includes the NIH logo, the USA.gov logo, and the slogan 'NIH... Turning Discovery Into Health®'.

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.

PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

**Seventh Screen—Personnel – REVISION – WILL BE REMOVED**

This screen requires the user to provide information to NIH that will allow staff to avoid conflicts of interest when selecting members for the Chimpanzee Research Use Panel. Users may also upload a file (e.g., publications list) if preferred.

The screenshot shows the 'Initiate CRU Report' page in the 'CHIMPANZEE RESEARCH USE REPORTING SYSTEM'. The page has a header with the NIH logo and 'National Institutes of Health' text, and the U.S. Department of Health and Human Services logo. Below the header, the title 'CRU REPORTING' is displayed in large blue letters, followed by 'CHIMPANZEE RESEARCH USE REPORTING SYSTEM'. Navigation links include 'Reports', 'Change Password', 'Log off', and 'Help'. The main content area is titled 'Initiate CRU Report' with a 'Back to My Assignments' link. A series of tabs are shown: 'Project Information', 'Exemption Assessment', 'CRU Justification', 'Attachments', and 'Personnel' (which is highlighted in blue). Below the tabs, the section is titled 'Personnel Involved'. A paragraph states: 'NIH requires information about the personnel involved in the proposed research in order to avoid conflicts of interest when considering Panel members for the CRUP.' Below this, instructions read: 'In the box below, please provide individual names and institutions for the following:' followed by a bulleted list: '▪ Major Professional Roles (NOT-OD-13-010 has the general policy for managing COI for grants and cooperative agreements.) — Include additional PDs/Pis, or individuals listed on the application as Senior/Key Personnel, Project/Site/Core Directors, Other Significant Contributors, collaborators, and consultants.' '▪ Individuals who provided letters of support or enthusiasm for the proposed research.' '▪ Authors on the Principal Investigator's publications for the past 3 years (other than review articles, position papers, or professional group or conference reports).' A large text input box contains the word 'sample'. To the right of the box, it says '6994 Characters Remain.'. Below the box, a note says 'If you prefer, you may attach this information in pdf or MS Word format.' followed by an 'Attach File ...' button and a file upload area. At the bottom of the form are 'Prev', 'Save', and 'Submit' buttons.

This page last reviewed: February 1, 2014  
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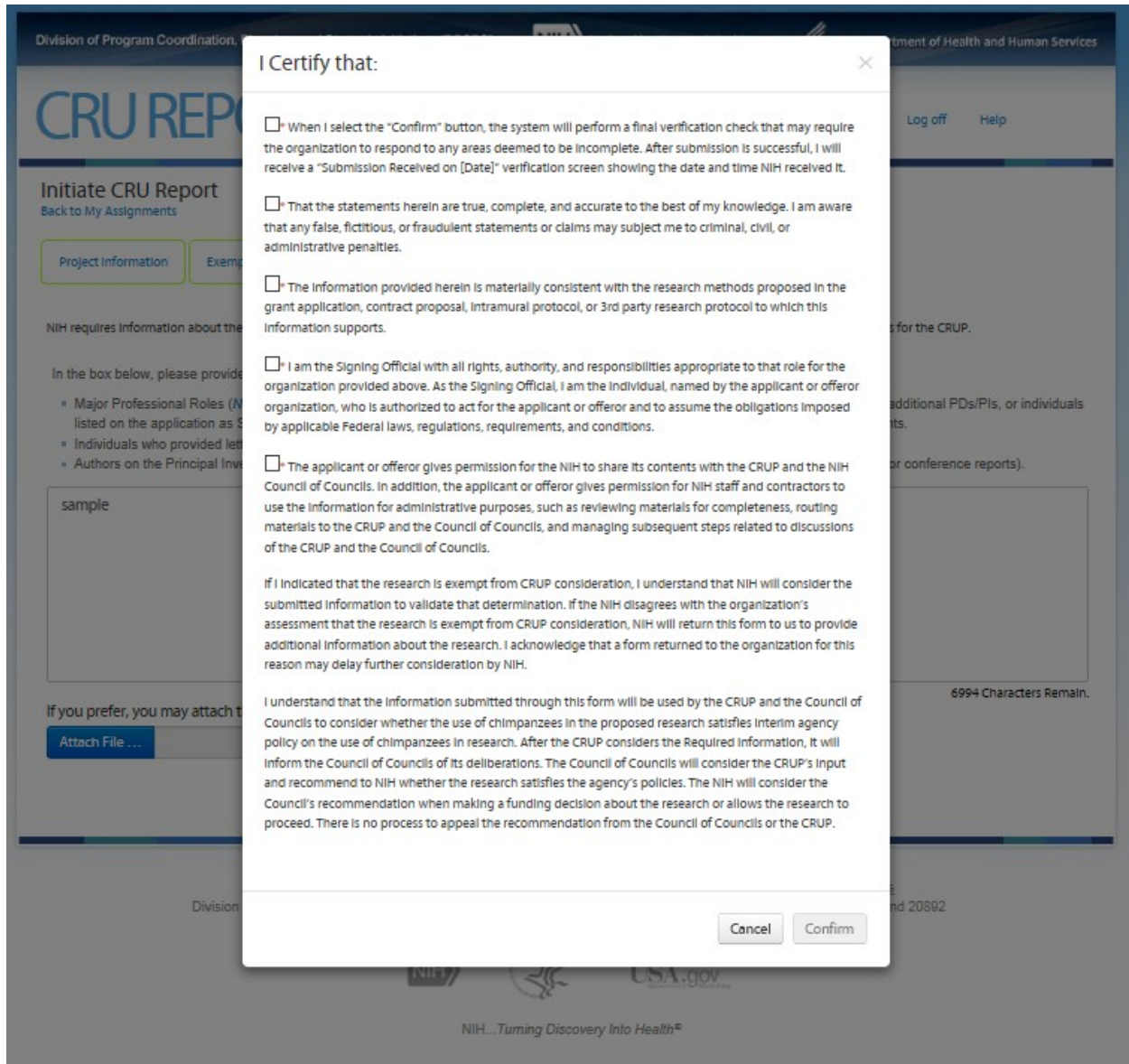


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## PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

### Eighth Screen—Certifications – REVISIONS OUTLINED BELOW

Upon hitting “Submit” the Signing Official is presented with the following certifications.



The image shows a screenshot of a web application interface for initiating a CRU Report. A modal dialog box titled "I Certify that:" is overlaid on the page. The dialog contains four checkboxes, each followed by a paragraph of text. The first checkbox is unchecked and its text is: "When I select the 'Confirm' button, the system will perform a final verification check that may require the organization to respond to any areas deemed to be incomplete. After submission is successful, I will receive a 'Submission Received on [Date]' verification screen showing the date and time NIH received it." The second checkbox is also unchecked and its text is: "That 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 third checkbox is unchecked and its text is: "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 fourth checkbox is unchecked and its text is: "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." Below these checkboxes, there is a paragraph of text: "The applicant or offeror gives permission for the NIH to share its contents with the CRUP and the NIH Council of 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 to the CRUP and the Council of Councils, and managing subsequent steps related to discussions of the CRUP and the Council of Councils." Below this paragraph, there is another paragraph: "If I indicated that the research is exempt from CRUP consideration, 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 exempt from CRUP consideration, NIH will return this form to us to provide additional information about the research. I acknowledge that a form returned to the organization for this reason may delay further consideration by NIH." At the bottom of the dialog, there is a paragraph: "I understand that the information submitted through this form will be used by the CRUP and the Council of Councils to consider whether the use of chimpanzees in the proposed research satisfies interim agency policy on the use of chimpanzees in research. After the CRUP considers the Required Information, it will inform the Council of Councils of its deliberations. The Council of Councils will consider the CRUP's input and recommend to NIH whether the research satisfies the agency's policies. The NIH will consider the Council's recommendation when making a funding decision about the research or allows the research to proceed. There is no process to appeal the recommendation from the Council of Councils or the CRUP." At the bottom right of the dialog, there are two buttons: "Cancel" and "Confirm".

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 [dpcpsi@od.nih.gov](mailto:dpcpsi@od.nih.gov) to confirm receipt by NIH.

(2) 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.



## PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

(3) 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.

(4) 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.

(5) The applicant or offeror gives permission for the NIH to share its contents within the agency and the NIH Council of 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 to the Council of Councils, and managing subsequent steps.



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.

**Intramural Project Review Acknowledgement:** The Scientific Director has provided a statement verifying that the IC convened a review panel to assess the scientific merit of the protocol and determined that the protocol is scientifically highly meritorious and the IC Director has signed off that the project meets the IC's scientific mission and priorities. [Conditional on the applicant identifying as an intramural researcher.

\*\*\*\*\*

If a user other than the Signing Official submits the form, he/she is presented with only the first certification check box plus the two paragraphs under number (5), and must attach the full certification text on agency letterhead signed by the Signing Official. In this case, the "Sample SO Certification Letter" link and a required attach file tool labeled "Add Certification Letter..." will appear on the Project Information screen to allow the user to attach the signed certification letter.

PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)  National Institutes of Health  U.S. Department of Health and Human Services

# CRU REPORTING

**CHIMPANZEE RESEARCH USE REPORTING SYSTEM** [Reports](#) [Change Password](#) [Log off](#) [Help](#)

## Initiate CRU Report

[Back to My Assignments](#)

Project Information

Exemption Assessment

CRU Justification

Attachments

Personnel

### Submitting Organization

Signing Official ⓘ

Signing Official Name

Tiny Littleman

Signing Official Phone

333-444-5555

Signing Official e-mail

james.smith2@nih.gov

Certification Letter

Add Certification Letter ...

This field is required.

[Sample SO Certification Letter](#)

Organization

Organization Name

Harvard University

Organization DUNS Number

047006379



## Part 2: Final Revised Text

(provided for readability)

Black text contains notes for the reader of this document. [Blue text](#) is what is onscreen.

### **First Screen After Login—Assignments**

User sees assignments and clicks on CRU Report # (hotlink) to access the form. Users see the following information for the research project(s) they have in the system.

[CRU Report #, Grant/Protocol/Contract #, Project title, PI Name, Status \(Deadline\)](#)

### **Second Screen—Initiate CRU Report**

[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 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, the CRUP, 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 to the CRUP and the Council, 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**

## PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

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
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 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.nih.gov](mailto: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](mailto:DPCPSI@od.nih.gov). Submissions that are incomplete by the due date may delay consideration by the NIH.

### Third Screen—Project Information

For grant applicants (external to NIH), the information on this screen is pre-populated with information they submitted in their grant application. Prepopulate fields are designated with underline.

Note: On this screen the users see the icon  that allows them to access additional information about the item. The text can be found in the CRU Report Guidance.

#### Signing Official

Signing Official Name (dropdown)

Signing Official Phone

Signing Official e-mail

#### Organization

Organization Name

Organization DUNS Number

Organization Address

Organization Work Phone

Organization Email

#### PI Name

PI Name (dropdown)

#### Research Funding mechanism


Funding Type

Project Number

#### Project Title

Project Summary/Abstract, Specific Aims, and Public Health Relevance (Limit 10,000 characters) 

## Fourth Screen—Noninvasive Determination

Note: On this screen the users see the icon  that allows them to access additional information about the item. The text can be found in the CRU Report Guidance.

### 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.

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

[text box] (Limit 7,000 characters)

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

[attach file option]

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User can then Submit and is then brought to Certifications and then the report is complete.

## Fifth Screen—Certifications

## PROPOSED REVISIONS TO THE CHIMPANZEE RESEARCH USE FORM

Upon hitting "Submit" the Signing Official (SO) is presented with the following certifications. User must check each box to confirm.

I certify that:

- When I select the "Submit" button, the system will perform a final verification check that may require the organization to respond to any areas deemed to be incomplete. After submission is successful, I will receive a "Submission Received on [Date]" verification screen showing the date and time NIH received it.
- That 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.
- 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.
- The applicant or offeror gives permission for the NIH to share its contents within the agency and the NIH Council of 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 to the Council of Councils, and managing subsequent steps.
- 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.
- Intramural Project Review Acknowledgement: The Scientific Director has provided a statement verifying that the IC convened a review panel to assess the scientific merit of the protocol and determined that the protocol is scientifically highly meritorious and the IC Director has signed off that the project meets the IC's scientific mission and priorities. [Conditional on the applicant identifying as an intramural researcher.

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If a user other than the Signing Official submits the form, he/she is presented with only the first certification check box plus the two paragraphs under number (5) and must attach the full certification text on agency letterhead signed by the Signing Official. In this case, the "Sample SO Certification Letter" link and a required attach file tool labeled "Add Certification Letter..." will appear on the Project Information screen to allow the user to attach the signed certification letter.