

## Update to the Interim Agency Policy, NIH Extramural and Intramural Research Involving Chimpanzees

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**Notice Number:** **NOT-OD-14-024**

### Key Dates

**Release Date:** November 25, 2013

### Related Announcements

[NOT-OD-13-026](#)

[NOT-OD-12-116](#)

[NOT-OD-12-025](#)

### Issued by

National Institutes of Health ([NIH](#))

### Purpose

The National Institutes of Health (NIH) is issuing this Notice to communicate to the research community an update to the interim agency policy, [NIH Research Involving Chimpanzees \(NOT-OD-12-025\)](#). This update:

- Informs investigators that grant applications involving chimpanzees will be accepted for peer review beginning with applications submitted for the January 25, 2014 due date;
- Informs offerors that contract proposals involving chimpanzees will be accepted for peer review or technical evaluation in accordance with the due date specified in the Request for Proposals;
- Informs investigators in the NIH intramural research program that protocols involving chimpanzees will be accepted for Scientific Director review as of the date of this notice;
- Informs third party investigators that research involving chimpanzees will be accepted beginning in March 2014 for review by the NIH and the Chimpanzee Research Use Panel, as applicable;
- Describes the Chimpanzee Research Use Panel process and timeline that the agency will follow to consider whether research proposing the use of chimpanzees is consistent with the principles and criteria outlined by the Institute of Medicine (IOM);
- Clarifies that certain observational, non-interventional, or biomaterials research involving chimpanzees will be exempt from consideration by the Chimpanzee Research Use Panel; and,
- Rescinds a previous clarification to the interim agency policy ([NOT-OD-12-116](#)) because applications, proposals, and protocols requesting to use stored specimens in research are now covered under this Update to the Interim Agency Policy.

### Background

In December 2010, the NIH commissioned a study by the IOM to assess whether chimpanzees are or will be necessary for biomedical and behavioral research. The IOM issued its findings, with a primary recommendation that the use of chimpanzees in research be guided by a set of principles and criteria. On December 15, 2011, the NIH announced its acceptance of the IOM recommendations with respect to the use of NIH-owned or -supported chimpanzees in research.

As one of the first steps toward implementing the recommendations, the agency issued an interim agency policy notice in the NIH Guide to Grants and Contracts ([NOT-OD-12-025](#)) on December 21, 2011 that, effective immediately, "NIH will not fund any new or other competing projects (renewal and revisions) for research involving chimpanzees and will not allow any new projects to go forward with NIH-owned or -supported chimpanzees" while the Agency considered and issued further policies implementing the IOM recommendations. After issuing [NOT-OD-12-025](#) on December 21, 2011, the NIH received a number of

questions with respect to how that notice applied to stored samples and whether applications proposing the use of stored samples from chimpanzees may be accepted for peer review. These questions regarding stored samples were addressed in a Notice of Clarification of the Interim Agency Policy published on June 15, 2012 ([NOT-OD-12-116](#)). In [NOT-OD-12-116](#), which is now rescinded by this notice, the NIH announced it would accept for peer review competing applications proposing the use of samples obtained from chimpanzees on or before December 15, 2011.

After accepting the IOM recommendations, the NIH charged the NIH Council of Councils with assembling a working group to propose advice on implementing the IOM recommendations and to consider the size and placement of the active and inactive populations of NIH-owned and -supported chimpanzees. On January 22, 2013, the Council of Councils accepted recommendations presented by its Working Group on the Use of Chimpanzees in NIH-Supported Research and provided these recommendations to the NIH. After seeking and considering public comments, the agency accepted a majority of the Council's recommendations on June 26, 2013 (see 78 Fed. Reg. 39741 (July 2, 2013) for a summary of the comments and the agency's decision and rationale).

As explained in 78 Fed. Reg. 39741 ("the FRN"), among other things, the agency accepted the Council recommendation to establish a panel, which is independent of the existing NIH review processes (e.g., peer review of grants and technical evaluation of contracts and scientific review of NIH intramural research), to consider whether requests to the NIH to use chimpanzees in research are consistent with the IOM principles and criteria. A working group of the NIH Council of Councils, the Chimpanzee Research Use Panel (CRUP or "Panel") was created and charged with considering requests to use chimpanzees in research. The CRUP will convene before the NIH makes decisions about funding or otherwise allowing research involving chimpanzees but after the NIH peer review, technical evaluation, or other applicable review processes are completed for grant applications, contract proposals, and intramural research protocols. Consistent with the IOM report, the NIH accepted the Council's recommendation that certain observational or non-interventional research involving chimpanzees and certain research involving chimpanzee biomaterials will be exempt from the CRUP's consideration.

## Actions

This Guide Notice applies to requests to the NIH to use chimpanzees (*Pan troglodytes*) or chimpanzee biomaterials in research, including all:

- NIH new and other competing grant applications, including renewals, revisions, and resubmissions;
- NIH contract proposals;
- NIH intramural research protocols; and,
- Third party research protocols (research that is not funded by the NIH but requests to use NIH-owned or -supported chimpanzees in the research).

For grant applicants, it is important to note that research applications proposing the use of chimpanzees in research could experience extra time needed to complete the pre-award process. Investigators planning to conduct chimpanzee research should submit the grant application at least 12 months before funding is needed. See additional information in the "Due Dates" section below.

## Definitions

**Chimpanzee Biomaterials:** For purposes of this notice, the NIH defines chimpanzee biomaterials to include biological specimens obtained from a chimpanzee or collected during post-mortem procedures, habitat cleanup, or some other circumstance. Examples of samples include tissue, blood, bone marrow, urine, feces, saliva, hair, and other sources of biological material.

**Chimpanzee Research Use Form:** A form used by the NIH to obtain additional information from the applicant or offeror (see "Due Dates" section below) about the proposed use of chimpanzees for research. As stated in the FRN, "Investigators proposing to the NIH to conduct research using chimpanzees must demonstrate that their proposed research is consistent with the IOM principles and criteria. The supplemental information that these investigators provide must address all of the questions posed in the decision making algorithm in the Council Working Group report..." The form is designed to obtain information that allows the NIH to assess whether the proposed chimpanzee use meets the definition of "research exempt from CRUP consideration" or whether the proposed use of chimpanzees is "research subject to CRUP consideration" and

therefore will be considered by the CRUP (see below). Completion of this form is a mandatory step for research involving chimpanzees. Failure to complete this form will prevent the agency from taking funding action on a research project involving chimpanzees or otherwise allowing the research to proceed. Information about the CRUP will be available at <http://dpcpsi.nih.gov/council/index.aspx>.

**Chimpanzee Research Use Panel (CRUP):** A working group of the NIH Council of Councils, an NIH advisory body. The Council charged the CRUP with considering whether requests to the NIH to use chimpanzees in research are consistent with the IOM principles and criteria. As a working group of the Council of Councils, the CRUP will provide its findings to the Council for consideration and further recommendation to the NIH.

**Council of Councils (or Council):** The NIH advisory body that provides advice to the NIH Director and other appropriate delegated officials on matters related to the policies and activities of the NIH Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), such as the Division's Chimpanzee Management Program. The Council of Councils established the CRUP in August 2013.

**Research Exempt from CRUP Consideration:** 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.
- 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.
- 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.

**Research Subject to CRUP Consideration:** Research that undergoes consideration by the CRUP and the Council of Councils, which will forward its recommendation to the appropriate NIH IC Director(s).

## Completing the Chimpanzee Research Use Form

The NIH will contact applicants and offerors to complete the Chimpanzee Research Use Form when the proposed research involves the use of chimpanzees and/or chimpanzee biomaterials and meets the following criteria:

- A grant application involving chimpanzees is being considered for funding by an NIH IC;
- A contract proposal involving chimpanzees is determined to be in the competitive range;
- An intramural research protocol has been reviewed by the IC Scientific Director, determined to be scientifically meritorious and fundable; or
- A third party requests to use NIH-owned or -supported chimpanzees in research.

The Chimpanzee Research Use Form will address the following, consistent with the IOM principles and criteria:

- Whether the proposed research meets the definition of research exempt from CRUP consideration, as defined previously.
- Whether the purpose of the research is primarily to improve the health and well-being of chimpanzees or for the benefit of humans.
- In the case of research that benefits humans, why the research in question cannot be performed ethically on human subjects with the prospect of achieving comparable results.
- Why forgoing the use of chimpanzees for the research in question will significantly slow or prevent important scientific advancements or important advances in the prevention or treatment of life-threatening or debilitating human conditions.
- Why other suitable models are not available (such as in vitro, nonhuman in vivo, or other models).
- How the physical, psychological, and emotional burdens on the chimpanzees for the research will be limited.
- How the remaining physical, psychological, and emotional burdens on the chimpanzees for the research are outweighed by the possible benefits to humankind and to science.
- The facility or facilities where the chimpanzees will be maintained.
- Whether the number of chimpanzees proposed is statistically or scientifically justified.

Members of the CRUP will have access to only the information provided through the Chimpanzee Research Use Form. The CRUP does not require and will not have access to the investigator's grant application, contract proposal, intramural protocol, third party protocol, or the results of peer review or technical evaluation (e.g., summary statement or technical evaluation report). Applicants and offerors are strongly discouraged from resubmitting their grant application, contract proposal, or protocols as an attachment to the Chimpanzee Research Use Form.

## When is the Form Due?

This notice includes a "Due Dates" section that conveys the approximate date for the NIH to receive the completed form. The agency will specify a final due date and submission process for receipt of the Chimpanzee Research Use Form when the agency contacts the applicant or offeror to complete the form. Submission by the due date will allow the agency to review the form for completeness, determine whether the proposed research is exempt from CRUP consideration, prepare material subject to CRUP consideration, and if necessary, identify *ad hoc* CRUP members with specific scientific expertise to serve on the panel. Because these activities are anticipated to require time to coordinate, forms submitted after the due date may delay consideration by the NIH. Applicants and offerors are strongly discouraged from submitting a completed form before the NIH requests the information. Unsolicited information may be destroyed and/or returned to the submitter and may not be considered by the NIH or the CRUP, as applicable.

## Consideration by the CRUP and Council of Councils

CRUP members will convene before the NIH makes funding decisions or otherwise allows the research to proceed but after the NIH peer review, technical evaluation, or other applicable reviews are completed for grant applications, contract proposals, and intramural research protocols. In accordance with laws governing the federal advisory committee process, the CRUP will present its recommendations to the Council of Councils, which, in turn, will make recommendations to the appropriate NIH IC Director(s).

## When Does the CRUP Meet?

The CRUP will meet three times per year, as needed, and after the NIH IC Advisory Councils or Boards convene and recommend grant applications for funding. Although the CRUP schedule is tied to extramural advisory bodies that advise the NIH on grants, the CRUP meeting schedule in the "Due Dates" section applies to contracts, intramural research, and third party research as well. Due to discussions of proprietary information that are expected to occur, CRUP meetings will not be open to the public.

## When Does the Council of Councils Meet?

After the CRUP considers the requests to use chimpanzees in research, they will inform the NIH Council of Councils of their findings during its closed session discussion. The Council of Councils meets three times per year, according to the schedule in the "Due Dates" section. Recommendations from the Council of Councils will be transmitted to the appropriate NIH IC Director (s) to be taken into consideration when making funding decisions or otherwise determining whether the research should proceed.

## Implementation

The NIH will implement the notice as follows:

- Grant applications proposing the use of chimpanzees in research will be accepted for peer review starting with applications submitted for the January 25, 2014 due date. For grant applicants, the first due date for the Chimpanzee Research Use Form is November 1, 2014.
- Contract proposals requesting the use of chimpanzees in research will be accepted for peer review or technical evaluation in accordance with the due date specified in the Request for Proposals. For offerors, the first due date for the Chimpanzee Research Use Form is March 1, 2014.
- Intramural research protocols proposing the use of chimpanzees in research will be accepted for IC Scientific Director review as of the date of this notice. For intramural researchers, the first due date for the Chimpanzee Research Use Form is March 1, 2014.
- Third parties proposing research using NIH-owned or -supported chimpanzees should contact [dpcpsi@od.nih.gov](mailto:dpcpsi@od.nih.gov) to obtain access to the Chimpanzee Research Use Form. For third party investigators, the first due date for the Chimpanzee Research Use Form is March 1, 2014.

## Due Dates

This section contains general information about due dates as they relate to research involving chimpanzees. The first meeting of the CRUP will occur in or around May 2014 for contract offerors, intramural researchers, and third party researchers. Subsequent CRUP meetings will occur approximately every four months.

	Receipt*	Scientific Review*	Advisory Council Review*	Form Due**	CRUP Meeting***	Council of Councils Review****
Applicable to contract offerors, intramural research, and third party research				Mar 1, 2014	May 2014	Jun 20, 2014
				Jul 1, 2014	Aug 2014	Sep 5, 2014
<b>Cycle I</b>	Jan–Feb 2014	May-Jun 2014	Sep-Oct 2014	Nov 1, 2014	Dec 2014	Jan 30, 2015
<b>Cycle II</b>	May-Jun 2014	Sep-Oct 2014	Jan-Feb 2015	Mar 3, 2015	May 2015	Jun 19, 2015
<b>Cycle III</b>	Sep-Oct 2014	Jan-Feb 2015	May-Jun 2015	Jul 1, 2015	Aug 2015	Sep 1, 2015
<p>* applicable only to grant applications. Due dates for contract proposals and intramural research protocols are specified by the contracting office and/or NIH IC.</p> <p>** dates are approximate. The NIH will communicate the final due date at the time the agency asks the applicant or offeror to complete the Chimpanzee Research Use Form.</p> <p>*** applicable to only research determined by the NIH to be subject to CRUP consideration.</p> <p>**** future dates will be available at: <a href="http://dpcpsi.nih.gov/council/futuremeetings.aspx">http://dpcpsi.nih.gov/council/futuremeetings.aspx</a></p>						

## Inquiries

For questions regarding a specific grant application, please contact the NIH program officer associated with the application. For questions regarding a specific Request for Proposals, please contact the assigned NIH Contracting Officer. NIH intramural researchers, third parties, and others may direct questions to [dpcpsi@od.nih.gov](mailto:dpcpsi@od.nih.gov).

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