

Supporting Statement A for

Chimpanzee Research Use Form - OD

OMB Control Number: 0925-0705

Expires: September 30, 2023

Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

Office of the Director (OD)

National Institutes of Health (NIH)

Date: January 24, 2023

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension**
- Emergency
- Existing

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## **Attachments**

- Attachment 1: IOM Report, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*
- Attachment 2: NIH Guide Notice (NOT-OD-12-025): NIH Research Involving Chimpanzees
- Attachment 3: Working Group Report
- Attachment 4: Announcement of Agency Decision
- Attachment 5: NIH Guide Notice (NOT-OD-14-024): Update to the Interim Agency Policy, NIH Extramural and Intramural Research Involving Chimpanzees
- Attachment 6: NIH Announcement Regarding Future Chimpanzee Research
- Attachment 7: U.S. Fish and Wildlife Federal Register Notice: Endangered and Threatened Wildlife and Plants; Listing All Chimpanzees as Endangered Species; Final Rule
- Attachment 8: The Use of Chimpanzees in NIH-Supported Research
- Attachment 9: Chimpanzee Research Use Form (0925-0705)
- Attachment 10: Applicability of the Privacy Act: Chimpanzee Research Use Form

## A. Justification

Abstract: The National Institutes of Health (NIH) requests to extend the Chimpanzee Research Use Form (OMB Control No. 0925-0705). The purpose of this form is to obtain information needed by the NIH to assess whether the proposed research satisfies the agency policy for research involving chimpanzees. The NIH considers the information submitted through this form prior to the agency making funding decisions or otherwise allowing the research to begin. Completion of this form is a mandatory step toward receiving NIH support or approval for research involving chimpanzees. **This is an extension of a previously approved submission.**

### A.1 Circumstances Making the Collection of Information Necessary

In 2010, 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 (**Attachment 1**), with a primary recommendation that the use of chimpanzees in research be guided by a set of principles and criteria. Based on its deliberations, the IOM committee concluded that “while the chimpanzee has been a valuable animal model in past research, most current use of chimpanzees for biomedical research is unnecessary.” The committee also concluded, however, that certain areas of science may continue to require the use of chimpanzees. While the committee encouraged NIH to continue development of non-chimpanzee models and technologies, it acknowledged that new, emerging, or re-emerging diseases may present challenges that may require the use of chimpanzees. After careful consideration, the NIH Director, Francis S. Collins, M.D., Ph.D., accepted the IOM committee recommendations and decided not to fund new research involving chimpanzees until the NIH considered and issued policy implementing the IOM recommendations (**Attachment 2**). To advise the agency in formulating its policy, the NIH established the [Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research](#) in 2012. In January 2013, the Working Group presented its recommendations to the NIH Council of Councils, which accepted the Working Group’s report (**Attachment 3**) and recommended that NIH accept them as well. After considering public comments on the Council report, the NIH accepted (**Attachment 4**) most of their recommendations in June 2013. Among other things, the agency accepted the Council recommendation to establish a panel, which is independent of the existing NIH review processes such as peer review of grants, technical evaluation of contracts, scientific review of NIH intramural research, and agency review of privately supported (or 3rd party) projects (**Attachment 5**). The panel considered 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), was created and charged with considering requests to the agency to use chimpanzees in research. To fulfill its charge, the CRUP needed information consistent with an information collection on how investigators proposed to use chimpanzees in research. The NIH used the Chimpanzee Research Use Form (OMB control number 0925-0705) to collect the relevant information for the [CRUP’s purpose](#).

In November 2015, the NIH announced (**Attachment 6**) that the agency would no longer support a colony of chimpanzees for future research due to reduced demand and the U.S. Fish and Wildlife Service designated captive chimpanzees as endangered (**Attachment 7**). Further, in February 2016, the agency announced that it would support only “noninvasive” research involving chimpanzees (**Attachment 8**). This announcement prompted a revision to and simplification of the Chimpanzee Research Use Form (control

0925-0705), which OMB approved. The current request is to extend the form for another 3 years. We propose only minor edits to update cost estimates. See **Attachment 9** for visuals of the current system.

The legislative authority that makes the collection of this information necessary is Title 42, Chapter 6A, Subchapter II, Part A, Section 241 – Research and investigations generally.

## **A.2 Purpose and Use of the Information Collection**

The purpose of this form is to obtain information needed by the National Institutes of Health (NIH) to assess whether the proposed research satisfies the agency policy for research involving chimpanzees (**Attachment 8**). The NIH considers the information submitted through this form prior to the agency making funding decisions or otherwise allowing the research to begin. Completion of this form is a mandatory step toward receiving NIH support or approval for research involving chimpanzees.

Research undertaken in the last 3 years under 0925-0705 met NIH's determination of "non-invasive." More specifically, research involved: 1) live animal activities that were purely observational of animals in the wild; 2) observational of behavioral procedures performed with willing subjects in a sanctuary or other captive setting; 3) the use of specimens collected during routine veterinary exams or necropsy, archived samples, or biosamples left in the environment and collected after animals have left the area; or the use of commercially available cell lines.

## **A.3 Use of Information Technology and Burden Reduction**

Submission will be made via the secure Chimpanzee Research Use Reporting System (CRU Reporting System) website (<https://cru.dpcpsi.nih.gov/Account/Login> ). The agency decided to use this means of collection to assure security of potentially proprietary and sensitive information, improve data quality, reduce collection burden, and improve agency efficiency and responsiveness over paper-based submission. The CRU Reporting System will integrate with the NIH grant processing system, allowing NIH to pre-populate certain fields for grant applicants. Per the NIH Senior Privacy Officer, a Privacy Impact Assessment is not required because Personally Identifiable Information (PII) is not collected.

## **A.4 Efforts to Identify Duplication and Use of Similar Information**

There is no similar information collected from applicants or offerors.

## **A.5 Impact on Small Businesses or Other Small Entities**

No small businesses will be involved.

## **A.6 Consequences of Collecting the Information Less Frequently**

The information is collected once per applicant/offeror. If the collection does not occur, the NIH will not be able to assess if the grant applicant, intramural researcher, contract offeror, or 3rd party researcher has addressed the NIH policy. Once an NIH funding institute or center decides it is likely to fund a project

involving chimpanzees, the agency asks the Principal Investigator to complete the Chimpanzee Research Use form so the NIH has the necessary information to conduct its evaluation.

#### **A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

There are no special circumstances.

#### **A.8.1 Comments in Response to the Federal Register Notice**

This proposed information collection was previously published in the Federal Register on February 21, 2023 (88 FR 10527) and allowed 60 days for public comment. The NIH received no requests to view the form and no comments expressing any opinion about the proposed collection.

#### **A.8.2 Efforts to Consult Outside Agency**

No Federal agency outside of the NIH has been consulted on the form due to the NIH-specific nature of the collection requirement.

#### **A.9 Explanation of Any Payment of Gift to Respondents**

Respondents will not receive payment and/or gifts for completing the form.

#### **A.10 Assurance of Confidentiality Provided to Respondents**

Respondents are provided with assurance that NIH staff and contractors are bound by confidentiality agreements. The NIH Senior Official for Privacy reviewed the form and determined that the Privacy Act is not triggered because the agency is not requesting the submission of personal information (**Attachment 10**).

#### **A.11 Justification for Sensitive Questions**

No information commonly considered to be personally private will be asked of those responding to this form. No personally identifiable information (PII) is collected.

#### **A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs**

The research community will be the respondents to this form. Up to 20 respondents will be asked to complete the form per year. The frequency of the data collection will be once per application for funding or proposal for contract award (competitive renewals usually occur every 3-5 years) and the respondent should take no more than 30 minutes to complete the form. The form was tested and reviewed by less than 9 NIH researchers to obtain this estimate. For grant applicants, some portions of this form will pre-populate from NIH's grant application system, further reducing the hourly burden by using some of the information (e.g., research abstract, title, contact information) initially submitted during the grants application process.

**Table 12-1 Estimated Annualized Burden Hours**

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Chimpanzee Research Use Form	Research Community	20	1	30/60	10
<b>TOTAL</b>			20		10

**A.12-2 ANNUAL COST TO RESPONDENT**

The total cost to the respondents is \$1,081.70. The wage rate of \$108.17 used below matches the salary limitation for NIH grants per NIH Guide Notice NOT-OD-20-065\*. That notice provides the salary limitation for NIH grant and cooperative agreement awards and extramural research and development contract awards. The notice sets the maximum annual salary at \$225,000. To get the hourly rate we divided \$225,000 by 2080 hours per year then rounded to the nearest penny to get the result of \$108.17.

**Table 12-2 Annualized Cost to Respondents**

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Scientific Researcher	10	\$108.17	\$1,081.70
<b>TOTAL</b>			\$1,081.70

\*Wage rate used matches the salary limitation for NIH grants per NIH Guide Notice NOT-OD-20-065 based on 2080 hours, <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-076.html>

**A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers**

The respondents will not incur any additional costs for providing this information.

**A.14 Annualized Cost to the Federal Government**

The Annual Cost to the Federal Government is \$7,005. The method to estimate costs is to calculate the percent effort for Division of Program Coordination, Planning, and Strategic Initiatives staff and contractors and the Office of Laboratory Animal Welfare involved in the data collection and then calculate the annual labor costs associated with that effort.

<b>Cost Descriptions</b>	<b>Grade/Step</b>	<b>Salary*</b>	<b>% Effort</b>	<b>Fringe (if applicable)</b>	<b>Total Cost to Gov't</b>
<b>Federal Oversight</b>					
Director, Office of Laboratory Animal Welfare	AD	\$230,000	1%		\$2,300
Health Science Policy Analyst	GS-15/10	\$170,532	1%		\$1,705
<b>Contractor Cost</b>					
IT System Support (contractor)		\$200,000	1.5%	included	\$3,000
Travel					\$0
Other Cost					\$0
<b>Total</b>					<b>\$7,005</b>

\*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/RUS.pdf>

**A.15 Explanation for Program Changes or Adjustments**

This is an extension for an existing data collection, 0925-0705.

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

There are no plans for statistical analyses in publications. The data received from the respondents will not be published.

A.16 - 1 Project Time Schedule
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Activity	Time Schedule
CRU Forms due for projects that involve use of chimpanzees and likely to be funded e.g., grants, contracts, intramural projects, 3 <sup>rd</sup> party activities.	Applications are received three times per year, at approximately: November 1 March 1 July 1
NIH Review and Decision	In the months of December, May, and August

**A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

Not applicable to this request.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

Not applicable to this request.