

Supporting Statement A for

Chimpanzee Research Use Form
OMB Control Number: 0925-0705
Expires: October 31, 2017

NIH, Office of the Director
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

August 2, 2017

Check off which applies:

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

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List of 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)

A. Justification

The National Institutes of Health 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 National Institutes of Health (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.

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 technical edits. 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 (<http://www.law.cornell.edu/uscode/text/42/241>).

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.

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/offerrer. 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 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A.8A This proposed information collection was published in the Federal Register on June 2, 2017 (82 FR 25609) and allowed 60 days for public comment. The NIH received no requests to view the form and one comment expressing the opinion that chimpanzee research should be discontinued but did not receive any public comments on the form itself.

A.8B No Federal agency outside of the NIH has been consulted on the form due to the NIH-specific nature of the collection requirement.

In the past, the agency requested input from the Council of Council Working Group on the Use of Chimpanzees in NIH-Supported Research (Attachment 3) provided the information requirements for the form in a “decision-making algorithm” (pages 42-46). This working group included 10 researchers, primatologists and veterinarians who are peers to the population of researchers who will fill out the form.

The NIH modified the form in 2016 after a policy change and relied on information investigator feedback in the NIH Office of Research Infrastructure Programs and Office of Laboratory Animal Welfare to modify the information collection instrument. Individuals consulted on the current form include:

NIH Official	Title and Organization	Contact Information
James M. Anderson, M.D., Ph.D.	Director, Division of Program Coordination, Planning, and Strategic Initiatives	james.anderson2@nih.gov (301) 402-9852
Patricia Brown, V.M.D., M.S.	Director, Office of Laboratory Animal Welfare	brownp@mail.nih.gov (301) 496-7163
Harold Watson, Ph.D.	Program Director, Office of	watsonh@mail.nih.gov

	Research Infrastructure Programs	(301)435-0744
Anna Jacobs, J.D., M.S.	Senior Attorney, Office of General Counsel	anna.jacobs2@nih.gov (301) 496-0689

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.

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 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.

A.12 – 1 Estimates of Hour Burden

Estimated Annualized Burden Hours

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

A.12 – 2 Estimates of Cost Burden

The total cost to the respondents is \$899.04. The wage rate of \$89.90 used below matches the salary limitation for NIH grants per NIH Guide Notice NOT-OD-17-087. 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 \$187,000. To get the hourly rate we divided \$187,000 by 2080 hours per year then rounded to the nearest penny to get the result of \$89.90.

Annual Cost to Respondent

Type of Respondent	Number of Respondents	Total Annual Burden Hours	Wage Rate *	Respondent Cost
Scientific Researcher	20	10	\$89.90	\$899.04
TOTAL				\$899.04

*Wage rate used matches the salary limitation for NIH grants per NIH Guide Notice NOT-OD-17-087 <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-087.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 \$6,919. 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.

Cost Descriptions	Grade/Step	Salary	% Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Director, Office of Laboratory Animal Welfare	AD	\$230,000	1%		\$2,300
Sr. Advisor	GS-15/10	\$161,900	1%		\$1,619
Contractor Cost					
IT System Support (contractor)		\$200,000	1.5%	included	\$3,000
Travel					\$0
Other Cost					\$0
Total					\$6,919

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.

The schedule for receipt and consideration of the Chimpanzee Research Use (CRU) Form is below:

Activity	Schedule
CRU Forms due for projects that involve use of chimpanzees and likely to be funded e.g., grants, contracts, intramural projects, 3 rd 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
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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.