

Supporting Statement A for

Chimpanzee Research Use Form

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

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Table of Contents

LIST OF ATTACHMENTS:.....	3
A. JUSTIFICATION.....	4
A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....	4
A.2 PURPOSE AND USE OF THE INFORMATION COLLECTION.....	5
A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....	5
A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....	5
A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....	6
A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....	6
A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....	6
A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE AGENCY.....	6
A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS.....	8
A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....	8
A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS.....	8
A.12 ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS.....	8
A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS.....	9
A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....	9
A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....	10
A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....	10
A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....	10
A.18 Exceptions to Certification for Paperwork Reduction Act Submissions.....	10

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: Chimpanzee Research Use Form Sample
- Attachment 7: Chimpanzee Research Use Form Guidance
- Attachment 8: Email Notifications from Chimpanzee Research Use Reporting System

A. Justification

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 3rd party projects. (Third parties are entities such as pharmaceutical or other companies that do not require NIH funding but wish to use NIH-owned or -supported chimpanzees in research.) The panel would 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), was created and charged with considering requests to the agency to use chimpanzees in research. To fulfill its charge, the CRUP will meet three times per year -- before the NIH makes decisions about funding or otherwise allows research involving chimpanzees to proceed but after the NIH peer review or technical evaluation processes or agency review are completed for grant applications, contract proposals, intramural research protocols, or 3rd party projects. 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 (Attachment 5).

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 triggers consideration by the Chimpanzee Research Use Panel (CRUP) and the NIH Council of Councils (Council), and if so, whether the research satisfies the interim agency policy for research involving chimpanzees (Attachment 5). The CRUP is a working group of the Council that has been charged with considering whether research proposing to use chimpanzees is consistent with principles and criteria for research involving chimpanzees, as discussed in the 2011 Institute of Medicine report, *[Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity](#)* (Attachment 1) and as implemented through interim agency policy (Attachment 5).

The NIH, the CRUP, and/or the Council, will consider 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

Due to the recent decision by the NIH regarding the use of chimpanzees in research and the creation of the Chimpanzee Research Use Panel (CRUP) to evaluate the request to use chimpanzees in NIH-supported research, at this time, 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 CRUP has the necessary information to conduct its evaluation. The CRUP meets three times per year in advance of the Council of Councils meetings. After the CRUP convenes, it will report its findings to the Council for their subsequent recommendation to agency officials.

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

A8A The NIH 60-day notice for this information collection appeared on the Federal Register Vol. 79 page 27318 on May 13, 2014. The agency received two requests to view the CRU Form: one from a pharmaceutical company and another from an animal rights advocacy group. In response, NIH provided the form in Word format by email. Neither requested provided comments on the form itself after receiving it. In addition, we received one email expressing an opinion against using chimpanzees for research but did not request the form.

A8B No Federal agency outside of the NIH has been consulted on the form due to the NIH-specific nature of the collection requirement. The report 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.

Members of the Working Group on the Use of Chimpanzees in NIH-Supported Research
(February 2012 through January 2013)

Member	Specialty	Institution
Daniel H. Geschwind, M.D., Ph.D.	Neurology, Psychiatry, Human Genetics	UCLA
K.C. Kent Lloyd, D.V.M., Ph.D.	Anatomy	UC Davis
Alan D. Barrett, Ph.D.	Pathology, Microbiology and Immunology	U. of Texas Medical Branch
R. Alta Charo, J.D.	Medical History and Bioethics	U. of Wisconsin
Beatrice H. Hahn, M.D.	Medicine and Microbiologist	U. of Pennsylvania
Stephen Ross, Ph.D.	Conservation of Apes	Lincoln Park Zoo, Chicago
Patricia Turner, M.Sc., D.V.M., D.V.Sc.	Pathobiology and Laboratory Animal Science	U. of Georgia

After seeking public comment on the Council report and its 28 recommendations and considering the 12,500 comments received, NIH accepted most Council recommendations, including the decision-making algorithm and implementation of the Chimpanzee Research Use Panel. The agency subsequently designed the Chimpanzee Research Use Form. Several drafts of the form were vetted to the following NIH officials who provided input.

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
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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. Members of the Chimpanzee Research Use Panel are bound by NIH rules governing working groups, and Council of Council members are bound by Federal rules governing Federal advisory committees (FACA). Findings from the Chimpanzee Research Use Panel will be discussed only in closed session of Council meetings, as articulated in NIH’s Announcement of Agency Decision (Attachment 4).

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 2 hours 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	2	40

A.12 – 2 Estimates of Cost Burden

The wage rate of \$87.26 used below matches the salary limitation for NIH grants per NIH Guide Notice NOT-OD-14-052. 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 \$181,500. To get the hourly rate we divided \$181,500 by 2080 hours per year then rounded to the nearest penny to get the result of \$87.26

Estimated Annualized Cost Burden

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Wage Rate *	Total Annual Cost Burden
Chimpanzee Research Use Form	Research Community	20	1	2	\$87.26	\$3,490.40

*Wage rate used matches the salary limitation for NIH grants per NIH Guide Notice [NOT-OD-14-052](#).

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 method to estimate costs is to estimate the percent effort for each Division of Program Coordination, Planning, and Strategic Initiatives staff member involved in the data collection and then calculate the annual labor costs associated with that effort.

Staff Position	Salary (Grade/Step)_	% Effort	Total Labor Cost
Director	\$300,585 (AD)	1%	\$3,006
Sr. Advisor	\$157,100 (GS-15/10)	10%	\$15,710
Support Staff (contractor)	\$199,035 (loaded rate)	10%	\$19,903
Support Staff (contractor)	\$115,780 (loaded rate)	5%	\$5,789

Total Annual Cost to Government: \$44,408.

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

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
CRUP Meeting	In the months of December, May, and August
Council of Councils Meeting and Recommendation to agency officials (end of process)	Month after CRUP meeting

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.