Supporting Statement A for

Inclusion Enrollment Form (OD/OPERA)

OMB# 0925-0770
Expiration Date 09/30/2024

Date: September 3, 2021

Check off which applies:

☑ Extension

Name: Kasima Garst

Address: 6705 Rockledge Drive, Bethesda, MD 20892-7974

Telephone: 301-402 2541

Fax: 301-435-3059

Email: kasima.garst@nih.gov

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A. Justification

NIH is requesting an extension of a currently approved collection. NIH converted the Inclusion Enrollment Report form (IER) to a common from during the last approval cycle which included the Department of Defense (DoD). Previously, the form was housed in NIH's Pre/Post grant application and forms clearances approved under OMB#s 0925-0002 and 0925-0002 (expiration date 1/31/2026).

A.1. Circumstances Making the Collection of Information Necessary

Information collection requirements are specified in regulations governing the PHS research program, including 42 CFR Part 52, 42 CFR 66.204, and 45 CFR 75 (for instructions and form). NIH had refined methods for reporting data on inclusion of participants by sex/gender, race and ethnicity by research condition and disease category as part of implementing the 21st Century Cures Act and responding to recommendations from the Government Accountability Office (GAO). Presently, the Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants.

A.2. Purpose and Use of the Information Collection

Information collected will continue to be used by Federal agency staff , Public Advisory Committees and National Advisory Boards and Councils as a basis for evaluating compliance with requirements to include women, minorities, and indivudals across the lifespan in research. Information received from the current collection enables PHS agencies to receive demographic information on the proposed and actual participants in research studiess. The Inclusion Enrollment form had been a part of NIH's larger

submissions OMB # 0925-0001 (expiration date 1/31/2026), “PHS Applications and Pre-Award Related Reporting” and OMB # 0925-0002 (expiration date 1/31/2026), “PHS Research Performance Progress Report and Other Post-award Reporting” and our Inclusion Enrollment form which is a part of a larger set of forms was converted to a Common form to assist the Department of Defense (DoD).

DoD was directed by US Senate Appropriations Subcommittee on Defense to develop a plan to ensure the appropriate representation of women and minorities in its extramural research in Congressional report 115-290, page 213, which accompanied H.R. 6157, the Department of Defense Appropriations Act of 2019. The report stated that the Congressionally Directed Medical Research Programs (CDMRP) (under DoD) shall work in coordination with the National Institutes of Health (NIH) to develop a plan that provides for: "(1) representation of women and minorities in each clinical trial, as well as data on specific challenges researchers face in seeking to include women and minorities in their studies; (2) examination of biological variables, including the appropriate analysis of differential outcomes by sex, in clinical research; (3) practice of making clinical findings, subgroup analyses, and data publicly available, as appropriate and applicable; and (4) requirements (including, but not limited to, programmatic controls) and updated guidelines to ensure the appropriate representation of women in clinical research."

In accordance with NIH policy and resulting CDMRP policy on the inclusion of Women and Minorities as Subjects in Clinical Research, submission of the "Inclusion Enrollment Report” is required by researchers at the time of proposal submission annually for funded investigators so that CDMRP may track anticipated and actual enrollment of participants by sex/gender, race and ethnicity.

The NIH continues to support efforts to remain a global leader in scientific discovery and innovations by encouraging participation of individuals from groups that are underrepresented in the biomedical, clinical, behavioral, and social sciences. Applicants to diversity-related career development funding opportunity announcements will be required to provide a description of the candidate's contribution to program goals. Since the last OMB approval, there has been no change to NIH policies on the inclusion of clinical research participants. NIH is requesting an extension on the clearance of the IER. There are no changes to the forms, and the forms use will remain the same. NIH anticipates changes may be required in a subsequent revision submission or change memo to implement the Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (OMB Statistical Policy Directive No. 15) following final determinations from HHS and NIH and final implementation of accompanying system changes. NIH is working with HHS on the implementation plans to meet the 2029 deadline in the directive.

A.3. Use of Information Technology and Burden Reduction

NIH worked closely with Grants.gov to develop a process for the electronic submission of the Inclusion Enrollment Report. The submission process implemented by Grants.gov, in combination with the eRA Application Submission System & Interface for Submission Tracking (ASSIST) enables appicants to enter inclusion information electronically either by directly entering the numbers into the Inclusion Enrollment Report tables or through submission of a Comma Separated Values (.csv) file. Use of the .csv file reduces the burden of aggregating

participant data for applicants. System-to-system users may submit the Inclusion Enrollment Report directly through Grants.gov in conjunction with the application package.

The electronic Research Administration (eRA) Commons which is an electronic infrastructure NIH uses to provide secure agency receipt of applications submitted electronically through Grants.gov, and electronic administration by grantees and PHS staff for the complete grant life cycle. It allows grantees to conduct business with PHS electronically, and automatically transfers information to the NIH enterprise database, IMPAC II, for processing. All relevant business areas--application receipt, referral, review, council, grants management, award processing, program and fiscal administration, reporting, and close-out--are accommodated in the eRA Commons. This initiative represents improved administrative operations through information technologies and reengineered business processes. Inclusion Enrollment Reports may be modified or updated in the eRA Human Subjects System (HSS), available to applicants through the eRA Commons. The eRA Human Subjects System provides a centralized location for submission of information related to research involving human participants. As part of the eRA enterprise system, HSS leverages existing data in the eRA infrastructure, and allows for import and export of data with Clinicaltrials.gov, minimizing the need for duplicate entry of information in multiple systems.

Along with eRA Commons and IMPAC II, the NIH Office of Extramural Research (OER) public website is used to provide access to all forms, instructions and business processes in an electronic, accessible environment. NIH grant systems, such as eRA and IMPAC II are all covered by a Privacy Impact Assessment; see attachment 1.

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

Similar information does not exist, and thus there is no other method for collection.

A.5. Impact on Small Business or other Small Entities

The impact on small business or other small entities is anticipated to be negligible.

A.6. Consequences of Collecting Information Less Frequently

NIH uses the information in the Inclusion Enrollment Report to ensure compliance with 42 U.S. Code § 289a–2, requiring the inclusion of women and members of minority groups in NIH-funded clinical research. Without collection of planned and actual enrollment, NIH reviewers and program staff could not adequately ensure compliance with this requirement. In addition, NIH leverages the information in the Inclusion Enrollment Report to comply with 42 U.S. Code § 282, whichrequires the NIH Director provide a triennial report identifying study populations by certain demographic variables, and 42 U.S. Code § 289-2(f)), which requires NIH Advisory Councils make publicly available triennial reports specifying the inclusion of women, members of minority groups, and relevant age categories, including pediatric subgroups, in NIH-supported clinical research. NIH could not provide this information without collection of the Inclusion Enrollment Report. It is not possible to collect the information less frequently.

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

This study complies fully with the guidelines of 5 CFR 1320.5. No exceptions to the guidelines are required.

A.8.1 Comments in Response to the Federal Register Notice

An announcement was placed in the Federal Register, on July 23, 2024, pages 59746-59747 (89 FR 59746) for public comment, no comments were received.

A.8.2 Efforts to Consult Outside Agency

In accordance with NIH policy and resulting CDMRP policy on the inclusion of Women and Minorities as Subjects in Clinical Research, submission of the "Inclusion Enrollment Report" is required by researchers at the time of proposal submission annually for funded investigators so that CDMRP may track anticipated and actual enrollment of participants by sex/gender, race and ethnicity. The members of CDMRP/DoD previously reached out to NIH requesting that this be made into a common form so that they can report DoD burden.

NIH is working with HHS on the implementation plans to meet the 2029 deadline to implement the Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (OMB Statistical Policy Directive No. 15). NIH anticipates changes may be required in a subsequent revision submission or change memo following final determinations from HHS and NIH and final implementation of accompanying system changes.

A.9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

A.10. Assurance of Confidentiality Provided to Respondents

The Privacy Act applies to this collection. The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0036, *Extramural Awards*

and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH: http://oma.od.nih.gov/ms/privacy/pa-files/0036.htm.The SORN was published in the Federal Register on September 26, 2002 (Vol. 67, No. 187). Release of information is fully explained in all grant related information collections.

A.11. Justification for Sensitive Questions

The Inclusion Enrollment Report includes collection of de-identified data on sex/gender, race, ethnicity, and age at enrollment to ensure compliance with Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) requirements to ensure inclusion and reporting of clinical research participants by sex/gender, race, ethnicity, and age. Provision of this information is voluntary for clinical research participants and no individual will be denied any right, benefit, of privilege provided by law because of refusal to disclose the information. This data is provided as part of annual progress reports and is not part of the application reviewed by the Advisory Committeees or funding component. All analyses utilizing other voluntarily provided data such as month/year of birth, gender, race and ethnicity report aggregate statistical findings only and do not identify individuals. All sensitive data are maintained in a Privacy Act record system (09-25-0036).

NIH anticipates changes may be required in a subsequent revision submission or change memo to implement the Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (OMB Statistical Policy Directive No. 15) following final determinations from HHS and NIH and final implementation of accompanying system changes. NIH is working with HHS on the implementation plans to meet the 2029 deadline in the directive.

A.12.1 Estimated Annualized Burden Hours

This revision request does not include changes to estimates of burden hours.

Estimated Annualized Burden Hours

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Inclusion enrollment form	69,888	1	1	69,888
Total Annual Burden Hours	----------	**69,888**	----------	**69,888**

A.12-2 Annualized Costs to Respondents

Data is from the Bureau of Labor Statistics Life, Physical, and Social Sciences Occupations 19-0000, This request covers many types of research institutions in both the private and public sectors, teaching and non-teaching setting etc.

A.12-2 Annualized Cost to the Respondents

Information Collection Forms	Total Annual Burden Hours	Hourly Wage Rate	Total Respondent Cost
PHS Inclusion Enrollment Report	69,888	$38.00	$2,655,744
Total			**$2,655,744**

https://www.bls.gov/oes/current/oes_nat.htm#19-0000

A.13. Estimate of Other Total Annual Cost to Respondents or Record keepers

Other annual costs to respondents or record keepers are associated with customary and usual business or practices of organizations applying for PHS funding. There are no additional costs to the respondents.

A.14. Annualized Cost to the Federal Government

The estimated annual cost to the NIH is approximately $39,594. This information is calculated based on the NIH Systems Policy Analyst and a Supervisory Grants Management Specialist salary and percentage of effort devoted to preparing this submission. These expenses would not have been incurred without this collection of information.

Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Government
Federal Oversight					
NIH Systems Policy Analyst	14/6	162,629	2%		3,253
NIH Supervisory Grants Management Specialist	15/4	180,359	20%		36,071
Contractor Cost					
Travel					
Other Cost					
Total					**$39,594**

**the Salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf.

A.15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments.

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

There is no tabulation, publication, or project time schedule associated with use of this form.

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

The OMB number and expiration date will be appropriately displayed on all information collection instrument, including all electronic modules and paper forms.

Grants.gov forms develops and creates the form for NIH and other agency use. Grants.gov did not include the final burden statement on the form in production. NIH will raise this to Grants.gov for resolution prior to the revision requests for the implementation of the Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (OMB Statistical Policy Directive No. 15) following final determinations from HHS and NIH.

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

No exceptions are requested.