

## Supporting Statement A for

### Inclusion Enrollment Form Conversion to Common Form [OD/OPERA]

OMB# 0925-XXXX  
Exp., date XX/XX/XXXX

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Submitted by:

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Check off which applies:

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

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ATTACHMENT

Attachment 1 Privacy Impact Assesment

Attachment 2 Inclusion Enrollment form

## **A. Justification**

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. NIH is converting the Inclusion Enrollment form to include the Department of Defense (DoD).

### **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). This applies to NIH and CDC small business applicants.

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

Information collected is used by Federal agency staff and Public Advisory Committees and National Advisory Boards and Councils as a basis for evaluating compliance with requirements to include women, minorities, and individuals 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 studies. The Inclusion Enrollment form has been a part of NIH's larger submissions OMB # 0925-0001, "PHS Applications and Pre-Award Related Reporting" and OMB # 0925-0002, "PHS Research Performance Progress Report and Other Post-award Reporting and is being converted to a Common form to assist the Department of Defense in its implementing of its new FY21 Congressionally Directed Medical Research Programs (CDMRP) Policy on the Inclusion of Women and Minorities in Clinical Research modeled on NIH inclusion policies and has requested to use the Inclusion Enrollment Report. 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, behaviora 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.

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

PHS is an active participant in Federal-wide electronic grant initiatives to improve efficiencies, harmonize data collection among Federal granting agencies, and provide one simple, unified electronic portal through which applicants may find funding opportunities for, and request Federal support from 26 different grant-making agencies. Grants.gov provides a standardized interface for agencies to announce their grant opportunities, and a single, secure, and reliable source for all grant applicants to find and apply for those opportunities. These efforts ultimately eliminate paper submissions and unnecessary applicant burden.

PHS utilizes *Grants.gov Find* for posting 100% of all funding opportunities; *Grants.gov Apply* is used for the majority of program opportunities. NIH worked closely with Grants.gov to develop a process for the submission of complex, multi-project applications using existing SF424 (R&R) forms and the PHS 398 forms included in this collection. The new process implemented by Grants.gov, in combination with the Application Submission System & Interface for Submission Tracking (ASSIST) on-line front-end implemented by NIH to support single- and multi-project programs, enabled NIH to accept all competing grant applications electronically through

*Grants.gov Apply*. Use of ASSIST as a submission option to Grants.gov is being expanded to other Public Health Service agencies and programs.

Privacy Impact Assessment (PIA) - NIH grant systems, such as eRA and IMPAC II) are covered by a PIA. See Attachment 1 for the latest copy of NIH's PIA.

#### **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**

All other forms in this package represent one time information collections. 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, Vol. 86 No. 76, page 21324, on April 22, 2021 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 reached out to NIH requesting that this be made into a common form so that they can report DoD burden .

### **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 Committees 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](#)).

**A.12.1 Estimated Annualized 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	3	209,664
<b>Total Annual Burden Hours</b>	-----	<b>69,888</b>	-----	<b>209,664</b>

**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	209,664	\$38.15	\$7,998,682
<b>Total</b>			<b>\$7,998,682</b>

[https://www.bls.gov/oes/2020/may/oes\\_nat.htm#19-0000](https://www.bls.gov/oes/2020/may/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 \$137,773. This information is calculated based on the NIH Branch Chief and Program Analyst’s 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
<b>Federal Oversight</b>					
Branch Chief	14/8	151,118	50%		75,559
NIH Health Scientist Administrator	13/7	124,428	50%		62,214
<b>Contractor Cost</b>					

Travel					
Other Cost					
Total					137,773

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

This is a new submission to convert the Inclusion Enrollment Report form to a Common form to include the Department of Defense (DoD).

**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.

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

no exceptions are requested.

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