Supporting Statement A for

Application Process for Clinical Research Training and Medical Education at the Clinical Center and its impact on Course and Training Program Enrollment and Effectiveness

OMB #0925-0698; expires 7/31/2020

Date: 6/15/2020

Check off which applies:

- New
- X Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing w/o OMB approval

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Table of contents

Attachments (save file names to match what is being referenced: (ex: x.baseline; y.screener)

1. Attachment 1: Clinical Electives Program (CEP)
2. Attachment 2: Graduate Medical Education (GME) Program
3. Attachment 3: Medical Research Scholars Program (MSRP)
4. Attachment 4: Resident Electives Program (REP)
5. Attachment 5: Bioethics Fellowship Program
6. Attachment 6: Privacy Impact Assessment
7. Attachment 7: Privacy Act Memo
8. Attachment 8: 60 Day Comment Log
9. Attachment 9: Published 30 Day Notice

A. Justification

The existing information collection proposed for revision allows on-going assessment of the eligibility and qualifications of candidates applying for participation in clinical research training programs provided by the Office of Clinical Research Training and Medical Education located in the NIH Clinical Center (CC) over a ten year follow-up period. The information received from respondents is evaluated by training program directors for the purpose of selecting qualified and competent participants in these resource-limited training programs operating within the Intramural Research Program (IRP) of the National Institutes of Health, and the NIH Clinical Center, located in Bethesda, Maryland. The information collected is also required to validate the compliance of graduate medical education training programs sponsored by the CC with the requirements of external accrediting organizations, specifically the Accreditation Council for Graduate Medical Education located in Chicago, IL. Applicant data are also used to assess the effectiveness of efforts to inform the applicant pool and the public about clinical research training within the IRP.

The request for revision of the information collection involves the discontinuation of the following existing program applications: Introduction to the Principles and Practice of Clinical Research (IPPCR), NIH-Duke Training Program in Clinical Research (NIH-DUKE), Ph.D. Student Summer Course in Clinical and Translational Research, Principles of Clinical Pharmacology Course (PCP), Sabbatical in Clinical Research Management, and the Clinical Research Training On-Line Course for Principal Investigators.

A.1 Circumstances Making the Collection of Information Necessary

The Office of Clinical Research Training and Medical Education (OCRTME) is a major component of the NIH Clinical Center, a 200 bed clinical research hospital at the National Institutes of Health (NIH) located in Bethesda, Maryland. The OCRTME supports the NIH Clinical Center's mission, which is:

To provide the NIH a versatile clinical research environment to improve human health by:

- investigating the pathogenesis of disease;
- conducting first-in-human clinical trials with an emphasis on rare diseases and diseases of high public health impact;
- developing state-of-the-art diagnostic, preventive, and therapeutic interventions;
- training the current and next generations of highly competent clinical and translational researchers; and,
- assuring that clinical and translational research is ethical, efficient, and of high scientific quality.

To accomplish the mission of "training the current and next generations of clinical and translational researchers," the OCRTME develops, administers and/or supports, and evaluates a comprehensive portfolio of clinical research training and medical education initiatives, including:

- Clinical Electives Program (CEP)
- Graduate Medical Education Program (GME)
- Medical Research Scholars Program (MSRP)
- Resident Electives Program (REP)
- NIH Clinical Center Bioethics Fellowship Program

An online application is in place currently for each program to collect data required for the evaluation of applicant qualifications and to permit selection of highly qualified candidates for participation in training programs administered or supported by the OCRTME.

The data under this request are collected under the authority of the Public Health Act, 42 USC 241.

A.2 Purpose and Use of the Information Collection

The primary objective of the information collection is as an application process is to allow OCRTME to evaluate applicants' qualifications to determine applicants' eligibility for training programs managed by the office. Applicants must provide the required information requested in the respective applications to be considered a candidate for participation. Information submitted by candidates for training programs is reviewed initially by OCRTME administrative staff to establish eligibility for participation. Eligible candidates are then referred to the designated training program director or training program selection committee for review and decisions regarding acceptance for participation. A secondary objective of the application process is to track enrollment in courses and training programs over time.

Because some training programs and courses initially managed by OCRTME have transitioned to the NIH Office of Clinical Research, program applications for Introduction to the Principles and Practice of Clinical Research (IPPCR), NIH-Duke Training Program in Clinical Research (NIH-DUKE), Ph.D. Student Summer Course in Clinical and Translational Research, Principles of Clinical Pharmacology Course (PCP), Sabbatical in Clinical Research Management, and Clinical Research Training On-Line Course for Principal Investigators will be discontinued for the revised information collection.

I. Clinical Electives Program (CEP)

The National Institutes of Health (NIH) offers four- to twelve-week clinical elective rotations to visiting senior medical and dental students in a multitude of specialty fields and biomedical disciplines at the NIH Clinical Center. The purpose of these elective rotations is to introduce these students to the conduct of well-designed clinical and translational research, to teach clinical skills requisite for the care of patients enrolled in human investigational protocols at the NIH Clinical Center, and to promote research career development among participants. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications, establish eligibility, and vet qualifications of applicants. The electronic application

system also enables the OCRTME staff to conduct analysis of demographics of the applicant pool to evaluate the type of audience the OCRTME attracts for participation in this program.

II. Graduate Medical Education (GME) Program

Physician trainees who are enrolled in NIH graduate medical education programs develop skills in diagnosis, disease management, and clinical investigation at the cutting edge of modern medicine by seeing patients and working with internationally-renowned physician investigators at the world's largest hospital dedicated to human subject research, the NIH Clinical Center. The intent of these programs is to train and promote the career development of highly-competent academic physicians who will make meaningful contributions to improving the health of the nation through clinical or translational research. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications, establish eligibility, and vet qualifications of applicants. The electronic application system enables the OCRTME staff to conduct analysis of demographics of the applicant pool to evaluate the type of audience the OCRTME attracts.

III. Medical Research Scholars Program (MSRP)

The National Institutes of Health (NIH) Medical Research Scholars Program is a comprehensive, year-long research enrichment program designed to attract the most creative, research-oriented medical, dental, and veterinary students to the intramural campus of the NIH in Bethesda, MD. Scholars learn the principles of basic science, translational, or clinical research design, and then apply their knowledge through direct participation in a mentored basic, clinical, or translational research project in an area that matches their personal interests and professional career goals. The Program is designed to promote the early academic development of students with strong potential for careers as physician scientists or clinician investigators. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications and establish eligibility/vet qualifications. The electronic application system enables the OCRTME staff to conduct analysis of demographics of the applicant pool to evaluate the type of audience the OCRTME attracts.

IV. Resident Electives Program (REP)

The OCRTME administers short term (~1 month) clinical elective rotations for visiting medical or surgical residents and clinical fellows enrolled in extramural training programs not sponsored by the NIH. These rotations provide physicians-in-training the opportunity to have direct experience in the care of patients enrolled in investigational protocols in a variety of disciplines at the NIH Clinical Center. The REP is designed to promote interest in research intensive academic careers among these groups of physician trainees, and to encourage qualified individuals to consider applying for advanced clinical research training in NIH sponsored

fellowship training programs. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications and establish eligibility/vet qualifications of applicants for rotations.

V. NIH Clinical Center Department of Bioethics Fellowship Program

The NIH Clinical Center Department of Bioethics offers a limited number of two-year post-doctoral and pre-doctoral (post-baccalaureate) fellowships which begin in September of each year. Through this program, fellows have the opportunity to learn many aspects of bioethics, and develop and implement an independent scholarship agenda with guidance from faculty mentors. Bioethics Fellows participate in the activities and the intellectual life of the department, and study ethical issues related to conduct of research, clinical practice, genetics, and health policy. Fellows conduct mentored conceptual and empirical research related to the ethics of health policy, human subject research, international research ethics, genetics, or other bioethical topics of interest. For a typical fellow, this research yields multiple first-authored publications in premier academic journals. While this program operates under the authority and management of the Department of Bioethics, the OCRTME provides general administrative oversight for the program's application process and, therefore, this program is included in the clearance application.

A.3 Use of Information Technology and Burden Reduction

All information is collected electronically to minimize participant time. and burden) A Systems of Record Notice (SORN) and a Privacy Impact Assessment have been conducted by the Clinical Center Privacy Officer and the Clinical Center Information Systems Security Officer (ISSO). In addition, a Privacy Impact Assessment has been completed for this information collection (see attachment 6).

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

Currently there are no other similar efforts underway at the NIH to prospectively track and assess the outcomes of its clinical research trainees and their accomplishments in fulfillment of the Clinical Center's training mission.

A.5 Impact on Small Businesses or Other Small Entities

The respondents are primarily physicians, dentists, medical scientists, and also medical, PhD, veterinary and dental students. The impact of the survey on respondents is minimal because the format for submission of the information is electronic.

A.6 Consequences of Collecting the Information Less Frequently

Each training program has specific application cycle lengths. The application cycles are not altered and are determined based on the purpose and goals of each program.

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

The proposed data collection is consistent with 5 CFR 1320.5

A.8.1 Comments in Response to the Federal Register Notice

The 60 Day Notice was published in the Federal Register on April 16, 2020 page 21255 (Vol. 85, No. 74 FR 21255) and allowed 60 days for public comment. One comment was received see Attachment 8.

A.8.2 Efforts to Consult Outside Agency

No consultation with persons outside the agency was necessary to create or develop the content of any of the surveys referenced herein.

A.9 Explanation of Any Payment of Gift to Respondents

No incentives are offered. Neither payment nor gifts are given to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The Performance Work Statement for the contractors that host the database has included the NIH contract requirements for personally identifiable information as identified by the Clinical Center Information Systems Security Officer (CC/ISSO). Additionally, the Performance Work Statement and the contractor proposal has been reviewed and approved by the CC/ISSO. See Privacy Act Memo, attachment 7. NIH Privacy Act Systems of Record Notice (SORN) 09-25-0014 entitled Clinical Research: Student Records, HHS/NIH/OD/OIR/OE was last published in the Federal Register, Vol. 67, No. 187/ September 26, 2002, Pages 60741-60794

A.11 Justification for Sensitive Questions

Sensitive questions are not included in these applications. Such questions are not required for the evaluation of applicants' eligibility/qualifications for participation.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

The estimated number of applicants per year to all of the above mentioned programs is 1000. While the number of applications received vary annually by course or program, the number above represents an average over the past (3) years. The annual burden hours were calculated using a maximum time allotment of 20 minutes for completion of each application. The maximum time allotment was determined by direct assessment of doctoral level respondents to the GME program, which is the most detailed of the programs cited above. The estimated total burden hours requested, therefore, is 333.

Table 12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Clinical Electives Program	Pre Doctoral Students	300	1	20/60	100
Graduate Medical Education	Physicians	100	1	20/60	33
Medical Research Scholars Program	Pre Doctoral Students	200	1	20/60	67
Resident Electives Program	Physicians	100	1	20/60	33
Bioethics Fellowship Program	Pre Doctoral, Post-Doctoral	300	1	20/60	100
Total		1,000			333

A.12.2 Annual Cost to Respondent

The annualized cost to respondents in table A.12-2 was calculated using the median of the distribution of mean hourly wages for Family Physicians, General Internists, Obstetricians/Gynecologists, General Pediatricians, Psychiatrists and Surgeons obtained from the Healthcare Practitioners and Technical Occupations Section (29-0000) of the May, 2019 Bureau of Labor Statistics Occupational Employment Statistics (https://www.bls.gov/oes/current/oes_stru.htm) for Physicians and Surgeons (see section 29-1060) for both Graduate Medical Education, Resident Elective Respondents, and Bioethics Fellowship Program

The 2019 NIH Pre-Doctoral Stipend was used for the Medical Research Program, Clinical Electives Program applicants, and Bioethics Fellowship Program https://policymanual.nih.gov/chapter/attachment/download/5034

The 2019 NIH Post-Doctoral stipend data was also used for the Bioethics Fellowship Program https://policymanual.nih.gov/chapter/attachment/download/5033.

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate	Respondent Cost
Pre-Doctoral Students	234	$19.69	$4,607.46
Post-Doctoral	33	$45.19	$1,491.27
Physicians	66	$104.00	$6,864.00
TOTAL			$12,962.73

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

There is no additional cost burden to the respondents or record keepers.

A.14 Annualized Cost to the Federal Government

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Coordinators	GS 11/01	$72,030	33%		$23,769.90
Contractor Cost					
Application System Maintenance and Security					$55,000.00
Travel					
Other operational costs – technology fees, on-line survey maintenance and distribution costs, and data analysis costs					
Total					**$78,769.90**

A.15 Explanation for Program Changes or Adjustments

This is an ongoing project with a request for revision. The request for revision includes the discontinuation of program applications for Introduction to the Principles and Practice of Clinical Research (IPPCR), NIH-Duke Training Program in Clinical Research (NIH-DUKE), Ph.D. Student Summer Course in Clinical and Translational Research, Principles of Clinical Pharmacology Course (PCP), Sabbatical in Clinical Research Management, and Clinical Research Training On-Line Course for Principal Investigators a these training programs initially managed by OCRTME have transitioned to the NIH Office of Clinical Research.

With the decrease of training program applications that will be continued under this collection, both the estimated number of survey respondents will decrease from 12,448

to 1,000 respondents and the estimated total burden will decrease from 4148 to 333 hours, respectively.

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

Applications are reviewed only for the NIH Clinical Center's internal use in assessing applicant's eligibility for programs or courses. The time schedule for evaluating program applicants will be as follows:

A.16 - 1 Project Time Schedule

Activity	Time Schedule
Clinical Electives Program	Rolling Applications
Graduate Medical Education	Rolling Applications
Medical Research Scholars Program	**Electronic Application Period** October - January **Evaluation of Applicants** February - March **Program Starts** July
Resident Electives Program	Rolling Applications
Bioethics Fellowship Program	**Electronic Application Period** January- May **Evaluation of Applicants** May-July **Program Starts** September

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

OMB number 0925-0698 and expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.