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 Number 0925-0698, expires 5/31/2017

Request for Revision

Date

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Abstract

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 (OCRTME) 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 in accordance 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 existing information collection involves a modification that expands the scope of applicants to the Clinical Electives Program. Accordingly, this revision, combined with an increase in the applicant pool for all OCRTME programs since the original submission in 2014, will result in an increase in both the annual total number of survey respondents and the estimated annual total burden hours, respectively, for the existing information collection as described in section A.12 below.

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)
- Introduction to the Principles and Practice of Clinical Research (IPPCR)
- Graduate Medical Education Program (GME)
- Medical Research Scholars Program (MSRP) (launched 2012), formerly the Clinical Research Training Program (CRTP) (1997-2012)
- 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)
- Resident Electives Program (REP)
- Sabbatical in Clinical Research Management
- NIH Clinical Center Bioethics Fellowship Program
- Clinical Research Training On-Line Course for Principal Investigators

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 courses and 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 courses and 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.

I. Clinical Electives Program (CEP) [application to be modified]

The National Institutes of Health (NIH) offers four- to twelve-week clinical elective rotations to 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 and establish eligibility. 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. The system will be expanded to accommodate applications from MD-PhD or DO-PhD students enrolled in allopathic or osteopathic medical schools in the United States for one of five new rotations with a duration of 3 months each.

II. Introduction to the Principles and Practice of Clinical Research (IPPCR)

The Introduction to the Principles and Practice of Clinical Research is a two semester course developed initially for individuals currently working at NIH and engaged or planning to become engaged in clinical or translational research and wishing to acquire in-depth knowledge of clinical trial design, ethical concerns and human subject protection requirements, regulatory aspects of clinical research and the investigational new drug application (IND) process, including responsibilities of the clinical investigator. The course has expanded and is offered to qualified biomedical trainees at extramural domestic and international sites who enroll and participate through distance learning technologies supported by the NIH Clinical Center. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications and establish eligibility. 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. 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 and establish eligibility. 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. 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, osteopathic, 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. 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.

V. NIH-Duke Training Program in Clinical Research (NIH-DUKE)

This collaborative training program between the NIH Clinical Center and the Duke University School of Medicine provides formalized academic training in the quantitative and methodological principles of clinical research for health professionals at the NIH. Designed primarily for physicians who are training for careers in clinical research, the program offers formal courses in research design, research management, medical genomics, and statistical analysis leading to a Master of Health Sciences in Clinical Research degree awarded by Duke University. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications and establish eligibility. 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.

VI. Ph.D. Student Summer Course in Clinical and Translational Research

The Ph.D. Student Summer Course in Clinical and Translational Research is a 2-week introductory course for graduate students in the basic sciences early in the course of their graduate degree program. The course aims to expose students to Ph.D. role models and showcase the many roles scientists have in clinical and translational research. Of equal importance, the course aims to equip students with the fundamentals of clinical and translational research and offer practical experiences such as guidance on preparing grant applications, learning about team sciences and their critical roles, as well as many other functionally useful tools. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to

effectively and efficiently review applications and establish eligibility. 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.

VII. Principles of Clinical Pharmacology Course (PCP)

Because most medical schools lack a formal course in clinical pharmacology, and physicians, pharmacists, and other scientists in training may not have access to a formal educational curriculum in this discipline, this course was designed to assist interested individuals who are preparing to take the certifying examinations of the American Board of Clinical Pharmacology. Likewise, this course is offered to meet the needs of researchers with an interest in the pharmacologic aspects of contemporary clinical drug development and utilization. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications and establish eligibility. The electronic registration/application system enables the OCRTME staff to conduct analysis of demographics of the applicant pool to evaluate the type of audience the OCRTME attracts.

VIII. Resident Electives Program (REP)

The OCRTME administers short term (~1 month) clinical elective rotations for 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/qualifications of applicants for rotations.

IX. Sabbatical in Clinical Research Management

The Clinical Research Management Sabbatical at the NIH Clinical Center is designed for established/experienced clinical investigators and others working in domestic and international clinical research settings. Participants have the opportunity to come to the NIH Clinical Center for varying lengths of time, depending on each individual's specific interests, to learn about the foundational elements required to manage a clinical or translational research enterprise. The program provides participants with training in the country's largest hospital dedicated to clinical and translational research and provides a

unique opportunity for participants to learn first-hand the essential functions of the federal government in oversight of the clinical research process. The online application system allows applicants to submit applications electronically and allows OCRTME administrative staff to effectively and efficiently review applications and establish eligibility. 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.

X. 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 and, therefore, this program is included in the clearance application.

XI. Clinical Research Training On-Line Course for Principal Investigators

This web-based course addresses one of the essential standards (Training and Education) approved by the NIH for performing clinical research in the Intramural Research Program. All NIH intramural principal investigators engaged in clinical research are required to register and take the course, as well as to successfully complete a final examination. Topics covered in the course are Ethical Issues in Human Subjects Research; Roles and Responsibilities of the Investigator; Roles and Responsibilities of the Institution; Regulatory Issues; and Clinical Investigators and the Mass Media. Former participants of the "Introduction to the Principles and Practice of Clinical Research" and "Ethical and Regulatory Aspects of Human Subjects Research" who have passed both courses, as exhibited by successful completion of a final exam, are not required to take the course to fulfill the training and education standard for principal investigators

A.3 Use of Information Technology and Burden Reduction

All information is collected electronically to minimize participant time and burden. Collected information is stored and maintained within an electronic data base system that complies with Federal Information Security Management Act (FISMA) regulations.

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

Currently there are no other similar applications and programs offered at the NIH.

A.5 Impact on Small Businesses or Other Small Entities

The respondents are primarily physicians, dentists, medical scientists, and medical, veterinary, dental and PhD graduate students. The impact of the application process on applicants 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 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

No consultation with persons outside the agency was necessary to create or develop the content of any of the applications referenced herein. Notice was published in the Federal Register, Volume 82, No. 45/March 9, 2017, page 13127-28. No comments were generated as a result of, or in response to, the Federal Register Notice.

A.9 Explanation of Any Payment or Gift to Respondents

No incentives, payments, or gifts will be given to the respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The Performance Work Statement for the contractors that host the electronic application database has included the NIH contract requirements for personally identifiable information as identified by the NIH Clinical Center Information Systems Security Officer (CC/ISSO). The Performance Work Statement and the contractor proposal has been reviewed and approved by the CC/ISSO. The information collected and maintained electronically in the data base is subject to the provisions of the Privacy Act of 1974. 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).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. In addition, a Privacy Impact Assessment has been completed for this information collection [Attachment 12].

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 or qualifications for participation in OCRTME courses or training programs.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

The estimated number of applicants per year to all of the above mentioned programs is 12,448. While the number of applications received vary annually by course or program, the number above represents an accounting over the 2016 fiscal year with the exception of the PCP course, which reflects accounting for registrants during FY 2015. The annual burden hours in table 12.1 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 respondents to the GME program, which is the most detailed of the programs cited above. The estimated total burden hours requested, therefore, is 4,148.

Annualized cost to applicants in table 12.2 was calculated using the data sources recorded below assuming a 40 hour work week to determine hourly wage. The estimated total annual respondent cost based on burden hours, therefore, is $130,375.79.

Table A.12-1 Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents per Year	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Pre-Doctoral (MD, DDS, DVM, PhD) Students, Post-Doctoral Students, Physicians/Surgeons, Other Health Care Practitioners/Technicians	MRSP	140	1	20/60	47
	IPPCR	6700	1	20/60	2233
	NIH-Duke	16	1	20/60	5
	PCP	800	1	20/60	267

Pre-Doctoral (MD, DDS, DVM, PhD) Students, Post-Doctoral Students, Physicians/Surgeons, Other Health Care Practitioners/Technicians	PhD Summer Course	70	1	20/60	23
	Sabbatical	10	1	20/60	3
	GME	2500	1	20/60	833
	CEP	300	1	20/60	100
	REP	90	1	20/60	30
	Bioethics	262	1	20/60	87
	Clinical Research Course	1560	1	20/60	520
Totals		**12,448**			**4148**

Table A.12-2 Annualized Cost to Respondents

Type of Respondents	Program	Number of Respondents per Year	Total Annual Burden Hours	Hourly Wage Rate*	Total Annual Respondent Cost
Pre-Doctoral (MD, DDS, DVM, PhD) Students, Post-Doctoral Students, Physicians/Surgeons, Other Health Care Practitioners/Technicians	MRSP	140	47	$17.38	$811.07
	IPPCR	6700	2233	$27.60	$61,640.00
	NIH-Duke Master Degree	16	5	$48.10	$256.53
	PCP	800	267	$27.60	$7,360.00
	PhD Summer Course	70	23	$18.68	$435.87
	Sabbatical	10	3	$27.60	$92.00

	Program	Number of Respondents	Total Burden Hours	Hourly Wage Rate*	Total
Pre-Doctoral (MD, DDS, DVM, PhD) Students, Post-Doctoral Students, Physicians/Surgeons, Other Health Care Practitioners/Technicians	GME	2500	833	$48.10	$40,083.33
	CEP	300	100	$18.68	$1,868
	REP	90	30	$48.10	$1,443.00
	Bioethics Fellowship	262	87	$23.29	$2,033.99
	Clinical Research Course	1560	520	$27.60	$14,352.00
Totals		**12,448**	**4148**		**$130,375.79**

* Data Sources:

Pre-Doctoral (MD, DDS, DVM, PhD) Students: NIH Student Initial Stipend Levels (revised), effective May 1, 2017 at http://oma1.od.nih.gov/manualchapters/person/2300-320-7/Appendices/Predoc14.PDF, and stratified for use based on prior education/training completed as follows:
PhD graduate students in PhD Summer Course (2-3 years prior experience);
MD, DDS or DVM students in MRSP (> 3 years prior experience);
MD students in CEP (>3 years prior experience).

Post-Doctoral (PhD) Students: NIH Postdoctoral and Visiting Fellow Stipend Levels (revised), effective May 1, 2017 at http://oma1.od.nih.gov/Manualchapters/person/2300-320-7/Appendices/PD14.PDF? , and stratified for use based on prior education/training completed as follows:
Bioethics Program Fellow respondents (0-1 years of experience).

Median weekly earnings for Physician and Surgeon (MD, DO), 2016 Bureau Labor of Statistics Current Population Survey, table 39 at https://stats.bls.gov/cps/cpsaat39.pdf , for:
NIH-Duke Masters, GME and REP program respondents.

Median weekly earnings for Healthcare Practitioners and technical occupations, 2016 Bureau Labor of Statistics Current Population Survey, table 39, at https://stats.bls.gov/cps/cpsaat39.pdf for:
IPPCR, PCP, Sabbatical and Clinical Research Course respondents.

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

There is no additional cost burden to the applicants 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 Analyst	11/Step 1	$66,510	33%		$21,948
Contractor Cost					
Application Data Base Hosting/ Maintenance					$42,500
Travel					
Other Cost					
Total					**$64,448**

Office personnel costs for administration of data collection systems, including interaction with contractors and program constituents, and evaluation of applicants for program are calculated based on an estimated annual 33% effort for a GS-11, Step 1 FTE employee, adjusted for locality in the Washington-Baltimore-Northern Virginia region, at a salary of $66,510 annually (available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB.pdf). The annual maintenance fee for electronic systems to administer the application instruments and facilitate analysis is $42,500. Thus, the estimated annualized cost to the Federal Government is $64,448.30.

A.15 Explanation for Program Changes or Adjustments

This is a request for a revision of a previously approved collection. The submission reflects a program need to modify an existing application in order expand the scope of eligible and qualified applicants for the Clinical Electives Program. In addition, the submission reflects the need to continue the collection in response to increased interest in and numbers of applicants for participation in existing OCRTME training programs annually.

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

Program	Activity	Schedule
CEP	All applicants must submit at least 8-12 weeks before their anticipated start date	Rolling Applications
Duke	Electronic Application Period	January - April
	Evaluation of Applicants	April-June
	Program Starts	August
GME	All applicants must submit at least 8-12 weeks before their anticipated start date	Rolling Applications
IPPCR	Electronic Application Period	August - October
	Program Starts	October
MRSP	Electronic Application Period	October - January
	Evaluation of Applicants	February - March
	Program Starts	August
PCP	Electronic Application Period	July - September
	Program Starts	September
Ph.D. Summer students	Application opens electronically	January
	Evaluation of Applicants	April-May
	Program Starts	July
REP	All applicants must submit at least 8-12 weeks before their anticipated start date	Rolling Applications
Sabbatical	All applicants must submit at least 8-12 weeks before their anticipated start date	Rolling Applications
NIH Clinical Center Department of Bioethics Fellowship Program	Electronic Application Period	January- May
	Evaluation of Applicants	May-July
	Program Starts	September
Clinical Research Training On-Line Course for Principal Investigators	Continuous open registration and enrolment on line	Rolling Applications

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.