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

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A.1 Circumstances Making the Collection of Information Necessary

The Office of Clinical Research Training and Medical Education's (OCRTME) is a major component of the NIH Clinical Center's mission, which is:

> To provide a versatile clinical research environment enabling the NIH mission 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 Office of Clinical Research Training and Medical Education (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 Program
- 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 online program applications are similar to print version forms approved for use previously. However, these online applications have not been approved for data collection.

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 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)

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.

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 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 educate and promote the career development of highly-competent academic physicians who will make meaningful contributions to improving the health of the nation. 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), formerly the Clinical Research Training Program (CRTP)

The National Institutes of Health (NIH) Medical Research Scholars Program, formerly known as the Clinical Research Training Programs, 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 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)

Elective rotations offer residents or clinical fellows enrolled in training programs not sponsored by the NIH 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 research intensive academic career among this group 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.

IX. Sabbatical in Clinical Research Management Program

The Clinical Research Management Sabbatical Program at the NIH Clinical Center is designed for 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 subjects 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 authority and management of the Department of Bioethics, the Office of Clinical Research Training and Medical education supports and hosts the on line application process and hence this program is included in the clearance application.

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

- This is a web-based course that 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 clinical principal investigators are required to take the course and successfully complete a final exam. 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) 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.

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, PhD, veterinary and dental students. The impact of the application process 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 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 78, No. 191/Wednesday, October 2, 2013, page 60885. 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, nor 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 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.

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 for participation.

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 6,629. 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 2,210.

A.12-1: Estimate of Annualized Burden Hours

Type of Applicants	Estimated Number of Applicants	Estimated Number of Applications per Applicant	Burden Hours Per Application	Total Annual Burden Hours
Doctoral Level	6,488	1	20/60	2,163
Pre-Doctoral Students	82	1	20/60	32
Other (administrators, nurses, etc.	59	1	20/60	20
Total	6,629	……	……	2,210

In Table 12-1 (above), Doctoral Level respondents (applicants) include the following occupational categories: physicians, surgeons, dentists, veterinarians and medical scientists; as well as senior year medical, dental or veterinary students. Other Respondents (applicants) include the following occupational categories: nurses, physician assistants, health diagnosing and treating practitioners, and hospital or research enterprise administrators.

Annualized cost to respondents (applicants) was calculated using median weekly wage data from the Bureau of Labor Statistics 2012 Current Population Survey (CPS), which reports median weekly earnings of full-time wage and salary workers stratified by occupational category and is available at http://www.bls.gov/cps/aa2012/cpsaat39.pdf, and from NIH annual initial stipend data for pre-doctoral and post-doctoral trainees, obtained from the following NIH Manual Chapter sources: http://oma1.od.nih.gov/manualchapters/person/2300-320-7/Appendices/Predoc14.PDF , and http://oma1.od.nih.gov/manualchapters/person/2300-320-7/Appendices/PD14.PDF . Hourly wages were calculated assuming a 40 hour work week.

Included in Table A.12-2 (below) are costs to respondents (applicants) stratified by program-specific application form. Respondents submitting application forms to the Duke, GME, and REP programs and the Clinical Research Training On-Line Course are physicians or surgeons, and the hourly wage provided was calculated from the 2012 CPS, which provides median weekly earnings for full-time physicians and surgeons.

Respondents submitting application forms to the MRSP and CEP programs are doctoral level students with 3 years of post-baccalaureate training, and the hourly wage provided was calculated from NIH stipend data (http://oma1.od.nih.gov/manualchapters/person/2300-320-7/Appendices/Predoc14.PDF).

Respondents submitting application forms to the Ph.D. Student Summer Course are pre-doctoral students usually with 2-3 years of post-baccalaureate experience, and the hourly wage provided was calculated from NIH stipend data

(http://oma1.od.nih.gov/manualchapters/person/2300-320-7/Appendices/Predoc14.PDF).

Respondents submitting application forms to the NIH Clinical Center Bioethics Fellowship Program include post-baccalaureate and post-doctoral students. The hourly wage provided for this composite group of respondents was the highest NIH pre-doctoral trainee initial stipend.

Respondents submitting applications forms to the IPPCR and the PCP courses include physicians, surgeons, dentists, veterinarians, medical scientists, nurses, physician assistants, pharmacists, and pre-doctoral or post-doctoral students. The hourly wage provided for this variable composite group of respondents was the highest occupational hourly wage of all applicants submitting applications forms, which is that for physicians. The hourly wage for physicians was calculated from the median weekly earnings of full-time physicians reported in the 2012 CPS (http://www.bls.gov/cps/aa2012/cpsaat39.pdf).

Respondents submitting applications forms to the Sabbatical Program are physicians or health care administrators with non-medical doctoral degrees. The hourly wage provided for this group of respondents was the highest occupational hourly wage of all applicants submitting applications forms, which is that for physicians. The hourly wage for physicians was calculated from the median weekly earnings of full-time physicians reported in the 2012 CPS (http://www.bls.gov/cps/aa2012/cpsaat39.pdf).

A.12-2: Estimated Annualized Cost to Respondents

Form	Number of Applicants	Frequency of application	Maximum Time per Application (hours)	Hourly Wage Rate	Total Costs
MRSP	139	1	20/60	$16.37	$758.48
IPPCR	2072	1	20/60	$47.18	$32,585.65
Duke	16	1	20/60	$47.18	$251.63
PCP	1171	1	20/60	$47.18	$18,415.93
Ph.D. Student Summer Course	46	1	20/60	$15.34	$235.21
Sabbatical Program	19	1	20/60	$47.18	$298.81
GME	2500	1	20/60	$47.18	$39,316.67
CEP	300	1	20/60	$16.37	$1,637.00
REP	74	1	20/60	$47.18	$1,163.77
NIH Clinical Center Department of Bioethics Fellowship Program	275	1	20/60	$16.37	$1,500.58
Clinical Research Training On-Line Course	17	1	20/60	$47.18	$267.35
Total	6,629				$96,431.08

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

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 33% effort for a GS-11, Step 1FTE employee, adjusted for locality in the Washington-Baltimore-Northern Virginia region, at a salary of $63,091 annually (available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB.pdf). The annual maintenance fee for contractor provided electronic systems used to administer the application instruments and facilitate analysis is $22,500.00. Thus, the estimated annualized cost to the Federal Government is $43,320.03.

A.15 Explanation for Program Changes or Adjustments

This is an existing collection in use without an OMB control number. The program was collecting data using enclosed forms because the program did not realize that PRA clearance was necessary prior to their use. Specifically, the program did not realize that applications are covered under the PRA. Once the violation was discovered, the program worked closely with the NIH PRA office to make the collection of information conform to the PRA.

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. Student Summer Course	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 Program	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 and expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions
No exceptions are requested.