Supporting Statement A for

Impact of Clinical Research Training and Medical Education at the NIH Clinical Center (CC) on Physician Careers in Academia and Clinical Research

OMB #0925-0602; expires 3/31/2016

Request for Revision

Date

8/26/2016

Contact:	Robert Lembo, MD
Address:	10 Center Drive/1N252C
	Bethesda, MD 20892-1352
Telephone:	301-496-2636
Fax:	301-435-5275
Email:	robert.lembo@nih.gov

Table of contents

LIST OF ATTACHMENTS:

1. Attachment 1: Titled ‘Attach 1’: Physician and Student Surveys
   I. Medical Research Scholars Program (MSRP), formerly the Clinical Research Training Program (CRTP)
   II. Introduction to the Principles and Practice of Clinical Research (IPPCR)
   III. Principles of Clinical Pharmacology Course (PCP)
   IV. Clinical Electives Program (CEP)

2. Attachment 2: Titled ‘Attach 2’: Physician Surveys
   I. Graduate Medical Education (GME) Program
   II. NIH-Duke Training Program in Clinical Research

3. Attachment 3: Titled ‘Attach 3’: Other Surveys
   I. Sabbatical in Clinical Research Management
   II. Ph.D. Student Summer Course in Clinical and Translational Research
   III. Summer Internship Program

4. Attachment 4: Titled ‘Attach 4’: Survey Modification Supplemental Document
   I. NIH-Duke Training Program in Clinical Research Outcomes Survey
   II. Introduction to the Principles and Practice of Clinical Research (IPPCR) End-of-Course Participant Evaluation
   III. Principles of Clinical Pharmacology (PCP) End-of-Course Participant Evaluation

5. Attachment 5: Titled ‘Attach 5’: Privacy Impact Assessment

Abstract

The existing information collection proposed for revision allows on-going assessment of the long-term impact and outcomes of 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 annually by, and incorporated into, the ongoing operational improvement efforts of the Director of the Office of Clinical Research Training and Education, the Director of the CC, and select NIH committees, including the trans-NIH Graduate Medical Education Committee. The information collected is also required to validate the effectiveness of graduate medical education training programs sponsored by the CC in accordance with requirements of external accrediting organizations, specifically the Accreditation Council for Graduate Medical Education located in Chicago, IL.

The request for revision of the information collection involves the discontinuation of the Resident Electives Program Survey; the addition of 6 new surveys, which include 3- and 5-year follow-up surveys for the PhD Summer Course, the Summer Internship Program and the Sabbatical Program participants; and modifications of three existing surveys. These requested changes are needed in order to streamline the evaluation process and capture additional data for more meaningful and more effective program outcome evaluations. Accordingly, these additions and modifications 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**

This survey helps fulfill the requirements of:

- Executive Order 12862, 'Setting Customer Service Standards," which directs Agencies to continually reform their management practices and operations to provide service to the public that matches or exceeds the best service available in the private sector; and

- The March 3, 1998 White House Memorandum, "Conducting Conversations with America to Further Improve Customer Service,' which directs Agencies to determine the kind and quality of service its customers want as well as their level of satisfaction with existing services.

This survey also continues to support the Office of Clinical Research Training and Medical Education's (OCRTME) fulfillment of the NIH Clinical Center (CC)'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 continue fulfillment of the mission of "training the current and next generations of clinical and translational researchers," the Office of Clinical Research Training and Medical Education (OCRTME) in the CC administers 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)
- Sabbatical in Clinical Research Management
- Summer Internship Program

This information collection's purpose is to continue to assess the degree of impact these NIH training programs have had on the short- and long-term outcomes of their graduates. The CC is the nation's largest hospital dedicated to clinical research. As the CC's central office for clinical research training and medical education, it remains incumbent upon the OCRTME to assess and modify, as appropriate, its program offerings based upon trainee feedback and outcomes.

A.2 Purpose and Use of the Information Collection

The information collected to date has allowed the OCRTME to begin assessment of the long-term value of the training provided by the OCRTME over a planned ten year follow-up period, and the extent to which this training has promoted (a)

professional competence; (b) research productivity and independence; and (c) future career development within clinical, translational, and academic research settings. The information received from respondents has been presented to, evaluated by, and incorporated into the ongoing operational improvement efforts of the Director of the Office of Clinical Research Training and Medical Education, the Clinical Center Director, and select NIH committees, including the NIH Graduate Medical Education Committee. The information collected continues to be required in order to validate the effectiveness of graduate medical education training programs at the NIH in accordance with requirements of external accrediting organizations, specifically the Accreditation Council for Graduate Medical Education located in Chicago, IL.

Since our last submission for OMB clearance, we have continued to survey participants who have completed the training initiatives and programs cited above. The data received from these surveys have been presented to Clinical Center leadership, as well as the training directors of the surveyed programs. Leadership has affirmed the value of these surveys and the data generated from them. However, leadership has also identified the need for modifications of selected survey instruments and the expansion or discontinuation of others. As a result, the NIH-Duke Training Program Survey, will be modified [Attachment 4], and both 3- and 5-year follow-up surveys will be added for the Ph.D. Student Summer Course in Clinical and Translational Research, the Summer Internship Program and the Sabbatical Program to reflect the current information needs of program administrators and program needs to capture additional data for meaningful evaluation more effectively. The Introduction to the Principles and Practice of Clinical Research Course and the Principles of Clinical Pharmacology Course 1-year post-completion follow up surveys will be discontinued and replaced by modified, end-of-course on-line evaluations that will be submitted by participants at the time of course completion annually [Attachment 4].
In addition and as stated previously, the one-year post-completion survey for the Resident Elective Program will be discontinued.

I. Clinical Electives Program (CEP) [Attachment 1]

The National Institutes of Health (NIH) offers four- to twelve-week clinical research oriented elective rotations to senior medical and dental students in a multitude of specialty fields and biomedical disciplines at the CC. 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 Program continues to track the short term career placements of participants to assess the effectiveness of this clinical research oriented experience.

II. Introduction to the Principles and Practice of Clinical Research (IPPCR) [Attachments 1 and 4]

The Introduction to the Principles and Practice of Clinical Research course was developed initially for individuals currently working at NIH and who were 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 in the lectures and presentations through distance learning technologies supported by the CC. The course administrators continue to track the impact of the curriculum on participants' ability to perform successfully in an academic or research setting and perform successfully in a nonacademic or non-research setting, in order to assess effectiveness.

III. Graduate Medical Education (GME) Training Program [Attachment 2]

Physician trainees enrolled in NIH graduate medical education training 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 training 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 through biomedical research. The Program continues to longitudinally track the perception of clinical competence as well as the details of career paths and long-term academic outcomes of graduates, including academic appointments, tenure, grants, and publications in order to assess effectiveness of training.

IV. Medical Research Scholars Program (MSRP), formerly the Clinical Research Training Program (CRTP) [Attachment 1]

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 career paths and outcomes of graduates of the former CRTP and the current MRSP continue to be tracked longitudinally to determine the effectiveness of this pre-doctoral medical education training program in promoting both early and mid-career academic success.

V. NIH-Duke Training Program in Clinical Research (NIH-DUKE) [Attachment 2 and 4]

This collaborative training program between the CC 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 Program continues to track career placements and academic outcomes of graduates to assess effectiveness.

VI. Ph.D. Student Summer Course in Clinical and Translational Research [Attachment 3]

The Ph.D. Student Summer Course in Clinical and Translational Research is a 2-week introductory course for graduate students in the basic sciences that is offered early in the course of their university's graduate degree program. The course aims to expose these pre-doctoral 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 these students with the fundamentals of clinical and translational research and offer practical experiences such as guidance on preparing grant applications, learning about team science and their critical roles as participants in such teams, as well as many other functionally useful tools. The course administrators continue to track subsequent involvement of participants in clinical or translational research to assess effectiveness.

VII. Principles of Clinical Pharmacology Course (PCP) [Attachments 1 and 4]

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 course administrators continue to track the impact of the curriculum on the research and professional career development of participants to assess course effectiveness.

VIII. Sabbatical in Clinical Research Management [Attachment 3]

The Clinical Research Management Sabbatical 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 CC 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 program continues to track the subsequent short-term professional and career path outcomes of participants in order to assess program effectiveness.

IX. Summer Internship Program [Attachment 3]

Students in high school, college, graduate programs, and nursing and medical schools meeting specified eligibility criteria are selected annually through a nationwide application process to participate in stipend supported summer research opportunities at the CC. The Program is designed to promote career development in the basic and biomedical sciences among participants at formative educational stages. The Program tracks short-term career placements and outcomes to assess effectiveness.

A.3 Use of Information Technology and Burden Reduction

All information will continue to be collected electronically to minimize participant time and survey 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. In addition, a Privacy Impact Assessment has been completed for this information collection [Attachment 5].

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 medical, PhD, 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

These surveys are distributed annually, and not more frequently, to former program participants. Less frequent distribution would not permit meaningful longitudinal assessment and validation of program quality and effectiveness in accordance with the NIH Clinical Center's training mission.

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 surveys referenced herein.

Notice was published in the Federal Register, Volume 80, No. 240/Tuesday, December 15, 2015, page 77647-77648. No comments were generated as a result of, or in response to, the Federal Register Notice.

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.

A.11 Justification for Sensitive Questions

Sensitive questions are not relevant to course or training program assessment and are not asked.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Based on Office of Clinical Research Training and Medical Education (OCRTME) program participation data for calendar year 2015, the estimated number of respondents per year to all surveys included in this request for revision will now increase from approximately 785 to 960. While response rates of program graduates or course completers vary annually by course or training program, an analysis of previous responses to the surveys cited above by type of respondent indicated a 50% response rate among doctoral level course participants/training program graduates (MD, DDS, DVM, PhD holders), 75% among student course participants/training program graduates (undergraduate,

post-baccalaureate, and graduate students), and 66% among other participants/graduates (nurses and other health care administrators or providers).

The annual burden hours for this request for revision were calculated using a maximum time allotment of 20 minutes for completion of each survey, including new and modified surveys. The maximum time allotment was established previously by direct assessment of doctoral level respondents to the GME training program survey, which was and continues to be the most detailed of the surveys cited above. The estimated total burden hours requested, therefore, is 320.

A.12-1: ESTIMATES OF HOUR BURDEN BY RESPONDENT TYPE

Type of Respondents	Estimated Number of Respondents	Number of Responses per Respondent	Maximum Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Doctoral Level	515	1	20/60	172
Students	415	1	20/60	138
Other Respondent Types	30	1	20/60	10
Total	**960**	……	……	**320**

The annualized cost to respondents in table A.12-2 was calculated using median weekly wage data from the 2014 Current Population Survey obtained from the Bureau of Labor Statistics [BLS] (http://www.bls.gov/cps/cpsaat39.pdf), and annual student stipend data obtained from the pre-doctoral NIH Medical Research Scholars Program reflecting the 2015 NIH pre-doctoral stipend levels for graduate students (see: https://oma1.od.nih.gov/Manualchapters/person/2300-320-7/Appendices/Predoc15.PDF?PHPSESSID=6207461d0b4f0fea0eeaa4e400af15e4). Hourly wages were calculated assuming a 40 hour work week. Doctoral level respondents included the following categories from the BLS Current Population Survey: physicians, surgeons, dentists, and medical scientists. Other respondents included the following categories from the BLS Current Population Survey: nurses, nurse practitioners, and physician assistants.

A.12-2: ANNUALIZED COST TO RESPONDENTS BY TYPE

Type of Respondents	Number of Respondents	Frequency of Response	Maximum Time per Respondent (hours)	Hourly Wage Rate	Respondent Cost
Doctoral Level	515	1	20/60	$40.30	$6,918.17
	415	1	20/60	$16.54	$2,288.03

Students					
Other Respondent Types	30	1	20/60	$36.60	$366.00
Totals	**960**	……	……	……	**$9,572.20**

Wages included for each category of respondents in this table were calculated as averages for the aggregate respondents listed above based on data obtained from the 2014 Current Population Survey obtained from the Bureau of Labor Statistics at http://www.bls.gov/cps/cpsaat39.pdf and from the 2015 NIH pre-doctoral stipend levels for graduate students available at: https://oma1.od.nih.gov/Manualchapters/person/2300-320-7/Appendices/Predoc15.PDF?PHPSESSID=6207461d0b4f0fea0eeaa4e400af15e4

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					
Survey Administrator	GS 09/01	$52,668	10		$5, 267
Contractor Cost		$0			
Travel					
Other operational costs – technology fees, on-line survey maintenance and distribution costs, and data analysis costs					**$57,695**
Total					**$62,962**

A.15 Explanation for Program Changes or Adjustments

This is an ongoing project with a request for revision. The request for revision includes the survey tools previously approved by the OMB with modifications of the NIH-Duke Program, the Introduction to the Principles and Practice of Clinical Research, and the Principles of Clinical Pharmacology Programs; the addition of 3- and 5-year surveys for the Ph.D. Student Summer Course in Clinical and Translational Research, the Summer Internship Program, and the Sabbatical

Program; and the discontinuation of the Resident Elective Program Survey. The NIH-Duke Survey is being modified to incorporate more appropriate and specific questions about program alumni outcomes. The modifications made to this survey will reflect questions currently included in the MRSP/CRTP survey, which have been previously approved. As cited previously, the 1-year alumni survey for the Introduction to the Principles and Practice of Clinical Research Course and the Principles of Clinical Pharmacology Course will be discontinued and converted to participant evaluations administered on-line annually at the completion of each course.

Based on OCRTME program participant data collected during calendar year 2015, the modification of the surveys described above would be burden-neutral (not adding or reducing hours for respondents). The addition of the 6 new surveys, however, would add 37 hours and 40 minutes annually to the participant burden but be offset, in large part, by a 23 hour, 40 minute decrease in burden achieved through the discontinuation of the Resident Elective Program survey.

With this request for revision, the net results would be an increase in the estimated number of total survey respondents from 785 to 960 respondents annually, and an increase in the estimated total hour burden 261 to 320 hours annually.

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

Survey results are tabulated only for the NIH Clinical Center's internal use in assessing training program or course effectiveness. There are no plans at this time for statistical analysis in publications.

The time schedule for surveying program participants has been established previously in OMB 0925-0602. The schedule going forward will be as follows:

A.16 - 1 Project Time Schedule

Activity	Time Schedule
Survey notification e-mail sent to respondents	5 to 7 months after OMB approval, then March to April of each calendar year
Survey opens electronically	8 - 10 months after OMB approval, then May to July of each calendar year

Data Analysis	12 months after OMB approval, then September of each calendar year
Office of Clinical Research Training and Medical Education Program Evaluation Review	15 months after OBM approval, then December to January of each calendar year

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate
OMB# and expiration will be displayed.

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