Supporting Statement A for

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

Date

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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. Resident Electives Program (REP)
   III. 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 Research Program

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 supports the Office of Clinical Research Training and Medical Education's (OCRTME) fulfillment 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 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
- Summer Research Program

This survey's purpose is to assess the degree of impact these NIH training programs have had on the short- and long-term outcomes of their graduates. The Clinical Center is the nation's largest hospital dedicated to clinical research. As the Clinical Center's central office for clinical research training and medical education, it is incumbent upon the office 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 allows us to assess the long-term value of the training provided by the OCRTME over a ten year follow-up period, and the extent to which this training promotes (a) patient safety; (b) research productivity and independence; and (c) future career development within clinical, translational, and academic research settings. The information received from respondents is presented to, evaluated by, and incorporated into the ongoing operational improvement efforts of the Director of the Office of Clinical Research Training and Education, the Clinical Center Director, and select NIH committees, including the NIH Graduate Medical Education Committee. The information is also required 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 surveyed the 2010 and 2011 graduates of our Graduate Medical Education (GME) programs. We have also begun to survey those trainees who participated in the Clinical Research Training Program since its inception in 1997. Currently, we are in the process of surveying the graduates of our other programs, and analyzing the data obtained from the 2011 cohort. The data received from our 2010 GME graduates has been presented to Clinical Center leadership, as well as the training directors of the surveyed programs. They affirmed the value of the survey and the data generated from it and have expressed a desire for annual updates specific to the GME programs. As a result, there will be an expanded model of ongoing operational assessment and improvement applied to the OCRTME's GME programs to ensure that clinical research training and medical education of the highest quality is provided to each trainee.

Recognizing that response rates may decrease over time, these GME training directors committed to personally contacting their graduates in the future to ensure ongoing participation in this outcomes project. We intend to apply this same approach to our other OCRTME alumni surveys, relative to their distribution, analysis, presentation, and action.

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 Program tracks the short term career placements of participants to assess the effectiveness of this clinical experience.

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

The Introduction to the Principles and Practice of Clinical Research education program was 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 education program has expanded and is offered to qualified biomedical trainees at extramural domestic and international sites who enroll and participate in the program through distance learning technologies supported by the NIH Clinical Center. The course administrators 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) 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 Program longitudinally tracks perception of clinical competence as well as career paths and long-term academic outcomes of graduates, including academic appointments, tenure, grants and publications, to assess effectiveness of training.

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

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 Program tracks career placements and academic outcomes to assess effectiveness.

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 course administrators track subsequent involvement of participants in clinical or translational research to assess effectiveness.

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

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 Program intends to track the short-term career placements of participants to assess effectiveness.

IX. Sabbatical in Clinical Research Management

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 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 program tracks short-term subsequent professional and career path outcomes of participants to assess effectiveness.

X. Summer Research Program

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 paid summer research opportunities at the National Institutes of Health (NIH) Clinical Center. 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.

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 trainees and their accomplishment 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 77, No. 135/Friday, July 13, 2012, page 41431. 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 program assessment and are not asked.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

The estimated number of respondents per year to all surveys is 785.
While response rates vary annually by course or program, analysis of previous responses to the surveys cited above by type of respondent indicates a 50% response rate among doctoral level course participants/Program graduates (MD, DDS, DVM, PhD holders), 75% among student course participants/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 were calculated using a maximum time allotment of 20 minutes for completion of each survey. The maximum time allotment was determined by direct assessment of doctoral level respondents to the GME program survey, which is the most detailed of the surveys cited above. The estimated total burden hours requested, therefore, is 261.

A.12-1: ESTIMATES OF HOUR BURDEN

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Maximum Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Doctoral Level	354	1	20/60	118
Students	403	1	20/60	134
Other	28	1	20/60	9
Total	785	……	……	261

Annualized cost to respondents was calculated using median weekly wage data from the 2011 Current Population Survey obtained from the Bureau of Labor Statistics, and annual student stipend data obtained from the NIH Medical Research Scholars Program. Hourly wages were calculated assuming a 40 hour work week. Doctoral level respondents included the following categories from the Current Population Survey: physicians, surgeons, dentists, veterinarians and medical scientists. Other respondents included the following categories from the

Current Population Survey: nurses, physician assistants, and health diagnosing and treating practitioners.

A.12-2: ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Number of Respondents	Frequency of Response	Maximum Time per Respondent (hours)	Hourly Wage Rate	Respondent Cost
Doctoral Level	354	1	20/60	$46.50	$5,487.00
Students	403	1	20/60	$16.00	$2,149.33
Other	28	1	20/60	$30.50	$284.67
Totals	**785**				**$7,921.00**

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 analysis of survey results for program assessment are calculated based on an estimated annual 10% effort for a GS-0343-09 level FTE, at an estimated total cost of $5,163 annually. The annual maintenance fee for electronic systems to administer survey instruments and facilitate data analysis is $15,000. Thus, the estimated annualized cost to the Federal Government is $20,163.

A.15 Explanation for Program Changes or Adjustments

This is an ongoing project request for a reinstatement with change. The request includes the survey tools previously approved by the OMB with the addition of new surveys for the Medical Research Scholars Program, the Ph.D. Student Summer Course in Clinical and Translational Research, and the Resident Electives Program.

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.