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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LIST OF ATTACHMENTS:

5. Attachment 5: Titled ‘Attach 5’: Physician, Nurse, and Other Survey, Draft

A.1 Circumstances Making the Collection of Information Necessary

This survey will help 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.

Need:

The mission of the NIH Clinical Center is:

As the nation's clinical research center, the NIH Clinical Center is dedicated to improving human health by providing an outstanding environment that facilitates:

- Development of diagnostic and therapeutic interventions
- **Training of clinical researchers**
- Development of processes to ensure the safe, efficient, and ethical conduct of clinical research…

To accomplish the mission of 'Training of clinical 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)
- Clinical Pharmacology Research Associate Training (ClinPRAT)
- Clinical Research Curriculum Certificate (CRCC)
- Graduate Medical Education (GME)
- NIH-Duke Training Program in Clinical Research (NIH-DUKE)
- Principles of Clinical Pharmacology Course (PCP)
- Resident Electives Program (REP)

These programs and services are aimed at educating about and improving the conduct of clinical and translational research.

The purpose of the survey is to gather information regarding the long-term outcomes of the programs that the particular individual has participated in. The Clinical Center is the nation's largest hospital dedicated to clinical research. As the Clinical Center's central office of clinical research training and medical

education, it is incumbent upon the office to re-adjust and refine the content of the programs so that they have an appropriate impact on the physicians that are trained and ultimately, the patient care that they deliver. Currently, there are no long-term consistent data collection projects regarding the outcomes of physician education.

A.2 Purpose and Use of the Information Collection

The information that is collected is aimed at assessing the value of our program to former trainees and the extent to which they continue to be engaged in clinical research as they advance in their careers in academia, government agencies, or pharmaceutical industry. The information is shared with the Office of Clinical Research Training and Education office Director, and the Clinical Center Director. Programs that will be included in the survey include participants from those listed below.

The information collected from each of the program's participants will be the tool to determine the outcome assessment as identified above and the results will be used to determine if any modifications to programs would be needed to improve the education and competency of the participants.

I. Clinical Electives Program (CEP)

The National Institutes of Health (NIH) offers a variety of short-term clinical rotations and research elective opportunities, as well as specialized "year out" programs designed to provide advanced training in basic science, translational research, or clinical research, to highly qualified medical and dental students.

II. Clinical Pharmacology Research Associate Training (ClinPRAT)

The Clinical Pharmacology Research Associate (ClinPRAT) Program was intended for physicians who wish to acquire specialized clinical and laboratory training in pharmacological sciences. The goal of the program was to develop a cadre of scientists capable of conducting both basic and applied clinical pharmacology research.

III. Clinical Research Curriculum Certificate (CRCC)

The Clinical Research Curriculum Certificate (CRCC) program was developed for individuals currently 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, and responsibilities of the clinical investigator.

IV. Graduate Medical Education (GME) Program

- The Accreditation Council for Graduate Medical Education is a private, non-profit council that evaluates and accredits medical residency programs in the United States. The mission of the ACGME is to improve health care by assessing and advancing the quality of resident physicians' education through accreditation.
- The Accreditation Council for Graduate Medical Education (ACGME) is responsible for the Accreditation of post-MD medical training programs within the United States. Accreditation is accomplished through a peer review process and is based upon established standards and guidelines. The ACGME is a nationally recognized organization within the nation's medical education community.

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.

VI. 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 clinical pharmacologic aspects of contemporary drug development and utilization.

VII. Resident Electives Program (REP)

Our elective rotations offer residents or clinical fellows the opportunity to have direct experience in the care of patients enrolled in investigational protocols in the disciplines of allergy and immunology, anatomic pathology, critical care medicine/internal medicine, hematopathology, infectious diseases, medical genetics, and transfusion medicine. Participants will have first-hand exposure to the design, conduct, and management of clinical trials.

A.3 Use of Information Technology and Burden Reduction

All information will be collected electronically which will minimize time and permit electronic submission of responses. The decision to use electronic submission was based on the minimal time required by the respondent and the ease of collection of data. A Systems of Record Notice (SORN) is in the process of being conducted with the Clinical Center Privacy Officer (Jerry King) and a Privacy Impact Assessment request has been made of the Clinical Center Privacy Officer (Jerry King) and the Clinical Center Information Systems Security Officer (ISSO) (John Franco).

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

Currently there is no similar information regarding the impact of clinical research training on participants academic or clinical research careers.

A.5 Impact on Small Businesses or Other Small Entities

The respondents are primarily physicians, dentists, medical students, and dental students. The impact is expected to be minimal because the format for submission of the information will be electronic.

A.6 Consequences of Collecting the Information Less Frequently

The collection of the information will help determine if the education provided to the participant has impacted the further development of clinical research or their academic careers. The National Institutes of Health has as a part of its mission and goals to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research. Thus, the effectiveness of the training of clinical researchers is key to accomplishing the mission and achieving the goals.

To reduce the burden of the collection of data, an electronic system will be used to minimize paper and time burden on the public. Additionally, a request will be made of the respondents to update their information as their professional career status changes.

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

This is not a research project. Therefore, no consultation with persons outside the agency has been made. However, the directors of the affected NIH programs have been consulted as to what metrics would be appropriate to determine the effectiveness and impact of the clinical research training experience of the individuals involved.

Federal Register, Volume 74, No. 1/Friday, January 2, 2009, page 112.
No comments were generated from the Federal Register Notice.

A.9 Explanation of Any Payment of Gift to Respondents

There will be no payment or gifts given to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

The Performance Work Statement for the contractors that will be hosting 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 will be reviewed and approved by the CC/ISSO.

A.11 Justification for Sensitive Questions

No sensitive questions will be asked.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Approximate number of respondents per year will be 825.
Frequency of response will be once a year, once, or when professional status changes.
Annual burden hours was calculated at 412. This was calculated using one-half hour for each response.

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours Per Response	Estimated Total Annual Burden Hours Requested
Doctoral Level	625	1	0.5	312.5
Students	100	1	0.5	50
Nurses	100	1	0.5	50
Total	……	……	……	412.5

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate	Respondent Cost
Doctoral Level	625	1	0.5	$75.00	$662.50
Students	100	1	0.5	N/A	$0.00
Nurses	100	1	0.5	$50.00	$125.00
Totals	**825**				**$787.50**

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

A system of collection currently in use will be used. No additional charges are expected as there is no modification to the system required.

A.14 Annualized Cost to the Federal Government

Costs to government			
Item	Cost per unit	# of units	Cost per item
Salary for design time (unit=hour)	$50	10	$500
Evaluation (unit=hour)	$50	3	$150
Electronic Maintenance (yearly fee)	$1,000	1	$1,000
Total costs			$1,650

A.15 Explanation for Program Changes or Adjustments

This is new collection of information.

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

There are no plans at this time for statistical analysis in publications.

A.16 - 1 Project Time Schedule	
Activity	**Time Schedule**
Email sent to respondents	1 - 2 months after OMB approval

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.