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 (CC)

OMB #0925-0602; expires 8/31/2019

Date: 5/30/2019

Check off which applies:

- New
- X Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing w/o OMB approval

Federal Government Employee Information:

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

Attachments (save file names to match what is being referenced: (ex: x.baseline; y.screener)

1. Attachment 1: Medical Research Scholars Program (MSRP), formerly the Clinical Research Training Program (CRTP)
2. Attachment 2: Summer Internship Program
3. Attachment 3: Graduate Medical Education (GME) Program
4. Attachment 4: Clinical Electives Program (CEP)
5. Attachment 5: Privacy Impact Assessment
6. Published 30 Day Notice

A. Justification

The existing information collection proposes a revision to allow an 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 Chief Executive Officer 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 following existing surveys: Introduction to the Principles and Practice of Clinical Research Course Evaluation, Principles of Clinical Pharmacology Course Evaluation, NIH-Duke Training Program in Clinical Research Alumni survey, the Sabbatical in Clinical Research Management Alumni surveys, and the Ph.D. Student Summer Course in Clinical and Translational Research Alumni surveys, and proposed content modification for the MRSP/CRTP Alumni survey, Clinical Electives 1 Year Alumni survey, and the Summer Internship Program Alumni survey in order to capture additional data for more meaningful and more effective program outcome evaluations. As the number of training program alumni continue to grow each year, both the annual total number of survey respondents and the estimated annual total burden hours will increase 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)
- Graduate Medical Education Program (GME)
- Medical Research Scholars Program (MSRP) (launched 2012), formerly the Clinical Research Training Program (CRTP) (1997-2012)
- 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 Chief Executive Officer of the Clinical Center , 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. In addition, OCRTME continues to modify program surveys to reflect the current information needs of program administrators and program needs to capture additional data for meaningful evaluation more effectively.

Because some training programs initially managed by OCRTME have transitioned to the NIH Office of Clinical Research, the Introduction to the Principles and Practice of Clinical Research Course Evaluation survey Principles of Clinical Pharmacology Course Evaluation survey, NIH Duke Clinical Research Training Program Alumni survey, Sabbatical in Clinical Research Alumni surveys, and Ph.D. Course in Translation Research Alumni surveys will be discontinued for the revised information collection.

I. Clinical Electives Program (CEP)

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 former participants transitioning from student status to physician-in-training status, in order to assess the effectiveness of this clinical research oriented experience on professional development.

II. Graduate Medical Education (GME) Training Program

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.

III. 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 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.

IV. Summer Internship 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 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 (see 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 also medical, PhD, veterinary 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.8.1 Comments in Response to the Federal Register Notice

The 60 Day Notice was published in the Federal Register on June 12, 2019, page 27336 (Vol. 84, No. 113 FR 27336) and allowed 60 days for public comment. No comments were received.

A.8.2 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.

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.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

The estimated number of respondents per year to all surveys in this request for revision is 1,434. While response rates of graduates 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) and 75% among student course

participants/training program graduates (undergraduate, post-baccalaureate, and graduate students).

The annual burden hours for this request for revision were calculated using a maximum time allotment of 20 minutes for completion of each survey. The maximum time allotment was established previously by direct assessment of doctoral level respondents to the GME training program survey, which is the most detailed of the surveys cited above. The estimated total burden hours requested, therefore, is 478.

Table 12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CRTP/MRSP Alumni Survey	Post Doctoral Students	704	1	20/60	235
Summer Internship Program Alumni Survey	Pre Doctoral Students	280	1	20/60	93
Graduate Medical Education Graduate Survey	Physicians	350	1	20/60	117
Clinical Electives Program 1 Year Alumni Survey	Physicians	100	1	20/60	33
Total		1,434	1,434	n/a	478

A.12.2 Annual Cost to Respondent

The annualized cost to respondents in table A.12-2 was calculated using the median of the distribution of mean hourly wages for Family Physicians, General Internists, Obstetricians/Gynecologists, General Pediatricians, Psychiatrists and Surgeons obtained from the Healthcare Practitioners and Technical Occupations Section (29-0000) of the May, 2018 Bureau of Labor Statistics Occupational Employment Statistics (https://www.bls.gov/oes/current/oes_stru.htm) for Physicians and Surgeons (see section 29-1060) for both Graduate Medical Education and Clinical Elective Respondents, and 2019 NIH annual post-doctoral student stipend data for NIH Clinical Research Training/Medical Research Scholars Program https://policymanual.nih.gov/chapter/attachment/download/5033. 2019 NIH annual pre-doctoral stipend data was used for the Summer Internship Program respondents https://policymanual.nih.gov/chapter/attachment/download/5034

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate	Respondent Cost
Post Doctoral Students	235	$45.19	$10,604.73
Pre Doctoral Students	93	$19.69	$1,837.66
Physicians	150	$104.00	$15,600.00
TOTAL	478		$28,042.39

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	$57,510	10		$5, 751
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 content for the CRTP/MRSP Alumni Survey, Clinical Electives 1 Year Alumni Survey, the Summer Internship Program Alumni Survey, and the GME Graduate Survey. Some survey questions and content will be deleted with new questions and content added to adequately capture needed alumni data. Additionally, some training programs initially managed by OCRTME have transitioned to the NIH Office of Clinical Research, the Introduction to the Principles and Practice of Clinical Research Course Evaluation survey

Principles of Clinical Pharmacology Course Evaluation survey, NIH Duke Clinical Research Training Program Alumni survey, Sabbatical in Clinical Research Alumni surveys, and Ph.D. Course in Translation Research Alumni surveys will be discontinued for this information collection. With the increase of training program alumni for the surveys that will be continued under this collection, both the estimated number of survey respondents will increase from 960 to 1,434 respondents and the estimated total burden will increase from 320 to 478 hours, respectively.

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 OMB approval, then December to January of each calendar year

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

OMB number and expiration will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.