

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 6/30/2024

Date: 7/15/2024

Check off which applies:

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

Federal Government Employee Information:

Contact: Thomas R, Burklow, MD  
Address: 10 Center Drive/1N262  
Bethesda, MD 20892-1352  
Telephone: 301-435-8015  
Email: [tom.burklow@nih.gov](mailto:tom.burklow@nih.gov)

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

1. Attachment 1: Clinical Electives Program (CEP) Survey
2. Attachment 2: Clinical Research Training Program (CRTP)/Medical Research Scholars Program (MRSP) Alumni Survey
3. Attachment 3: Continuing Medical Education Evaluation Survey
4. Attachment 4: Graduate Medical Education (GME) Program Alumni Survey
5. Attachment 5: Privacy Impact Assessment
6. Attachment 6: Privacy Act Memo
7. Attachment 7: Published 30 Day Notice

## A. Justification

The existing information collection expired 6/30/2024. The reinstatement request with changes proposes a changes 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 reinstatement of the information collection involves changes to questions in two survey instruments, Graduate Medical Education Graduate Alumni Survey and Clinical Research Training Program (CRTP)/Medical Research Scholars Program (MRSP) Alumni Survey, the removal of the Summer Internship Program Survey and the addition of the Continuing Medical Education (CME) Evaluation Survey. Questions being modified are to ensure information collected is applicable to the types of analyses needed to evaluate the efficacy of the training programs. The CME Evaluation Survey is a requirement of the CME provider accredited by the Accreditation Council for Continuing Medical Education.

### 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)
- Clinical Research Training Program (CRTP)/ Medical Research Scholars Program (MSRP)
- Continuing Medical Education

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. Findings have resulted in updated communication strategies, effective survey question modification, and valuable insight on the professional progression of trainees post NIH training.

#### **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. Continuing Medical Education Evaluation Survey**

Continuing Medical Education activities are required to be evaluated for their effectiveness and use of this data is used to ensure attendees objectives were met and to assist in future activities.

#### **III. 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.

#### **IV. Clinical Research Training Program (CRTP)/Medical Research Scholars Program (MSRP)**

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.

### **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 May 13, 2024, page 41446 (Vol. 89, No. 93) 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 1,970. The CRTP/MRSP Alumni Survey respondents increased to 800 since the last submission.

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 100% response rate among doctoral level course participants/training program graduates (MD, DDS, DVM, PhD holders).

The annual burden hours for this request for revision were calculated using a maximum time allotment of 20 minutes for completion all surveys except for the CME Evaluation Survey which is 10 minute time allotment. 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 537. As a new survey has been added and alumni are added to surveys each there is an increase in total respondents and burden hours.



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	Physicians	800	1	20/60	267
Graduate Medical Education Graduate Survey	Physicians	350	1	20/60	117
Clinical Electives Program 1 Year Alumni Survey	Physicians	100	1	20/60	33
Continuing Medical Education Evaluation Survey	Physicians	720	1	10/60	120
Total		1,970	1,970		537

**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, All Other obtained from the Healthcare Practitioners and Technical Occupations Section (29-0000) of the May, 2022 Bureau of Labor Statistics Occupational Employment Statistics ([https://www.bls.gov/oes/current/oes\\_stru.htm](https://www.bls.gov/oes/current/oes_stru.htm)).

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate	Respondent Cost
Physicians	1,970	\$114.76	
<b>TOTAL</b>	537		\$67,626.12

**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
<b>*Federal Oversight</b>					
Survey Administrator	GS 11/01	\$82,764	10		\$8,276
<b>Contractor Cost</b>					
Application System Maintenance and Security					\$30,000
Travel					
<b>Other operational costs</b> – technology fees, on-line survey maintenance and distribution costs, and data analysis costs					
<b>Total</b>					<b>\$38,276</b>

\* <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf>

**A.15 Explanation for Program Changes or Adjustments**

The request for reinstatement with changes of the information collection involves changes to questions in two survey instruments, Graduate Medical Education Graduate

Survey and the Clinical Research Training Program/Medical Research Scholars Program Alumni Survey. Questions are being added and removed from these surveys to ensure information collected is applicable to the types of analyses needed to evaluate the efficacy of the training programs. The request also includes the addition of the Continuing Medical Education Evaluation Survey which is required to evaluate all CME activities for effectiveness.

**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:

<b>A.16 - 1 Project Time Schedule</b>	
<b>Activity</b>	<b>Time Schedule</b>
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.