Supporting Statement A for

**Application and Impact of Online Clinical Research Training Programs on Healthcare Professionals in Industry, Academia, and Clinical Research, Office of Clinical Research, OD, NIH**

September 2019

Check off which applies:

X New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing


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## A. Abstract

The request for a new clearance number for information collection allows the on-going assessment of the long-term impact and outcomes of 4 clinical research training programs provided by the Office of Clinical Research located in the NIH Office of the Director on an annual basis previously cleared under OMB#s 0925-0602 Exp. Date 9/30/2019 and 0925-0698 Exp. Date 7/31/2020. The 4 programs, the Introduction to the Principles and Practice of Clinical Research and Principles of Clinical Pharmacology, Sabbatical in Clinical Research Management, and the NIH Summer Course in Clinical and Translational Research, were formerly a part of the Office of Clinical Research Training and Medical Education in the NIH Clinical Center, but were transitioned to the NIH Office of Clinical Research, Office of the Director. The information received from respondents was evaluated annually by, and incorporated into, the ongoing operational and course improvement efforts of the Office of Clinical Research, Associate Director for Clinical Research, and the Chief Scientific Officer of the Clinical Center.

The purpose of this information collection is to continue to assess the satisfaction, applicability and impact these NIH training programs have on the short- and long-term outcomes of their graduates. As the unifying office for clinical research training at NIH, it remains incumbent upon the Office of Clinical Research to assess and modify, as appropriate, its program offerings based upon trainee feedback.

## 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 supports the Office of Clinical Research's fulfillment of the mission of NIH, which is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The goals of this agency are:

- to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
- to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
- 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; and
- to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

Additionally, the mission of the Office of Clinical Research in the NIH Office of the Director is to facilitate the vision of excellence in clinical research at the NIH through development of policies, procedures, and training that optimize resource utilization and facilitate partnerships between the intramural and extramural communities. To fulfill this mission, the office provides a portfolio of clinical research training which include the following:

- Introduction to the Principles and Practice of Clinical Research (IPPCR)
- Principles of Clinical Pharmacology Course (PCP)
- NIH Summer course in Clinical and Translational Research
- Sabbatical in Clinical Research Management

**A.2 Purpose and Use of the Information Collection**

The information collected will allow the Office of Clinical Research to begin assessment of the value of the training provided by the Office of Clinical Research on an annual basis, and the extent to which this training promotes research productivity. The information collection is anticipated to begin on October 1, 2019 and end on June 30, 2019 and will be collected on an annual basis from October through June of each course year. The 7 surveys that are attached for review consist of the following: an OCR Portal Registration, IPPCR Final course evaluation, IPPCR lecture evaluation, PCP final course evaluation, PCP lecture evaluation, NIH Summer Course in Clinical and Translational Research course evaluation, and the Sabbatical in Clinical Research Management course evaluations. These surveys will provide registration and impact metrics for the 4 different training programs that fully transitioned from the former Office of Clinical Research Training and Medical Education in the Clinical Center to the Office of Clinical Research in the Office of the Director: Introduction to the Principles and Practice of Clinical Research (IPPCR), Principles of Clinical Pharmacology (PCP), NIH Summer Course in Clinical and Translational Research,

and the Sabbatical in Clinical Research Management. The information received from respondents will then be presented to, evaluated by, and incorporated into the ongoing operational improvement efforts of the Associate Director for Clinical Research in the NIH Office of the Director.

The data received from these surveys will also be presented to the training directors of the surveyed programs on a weekly and quarterly basis throughout the course year. Below are descriptions for each of the 4 training programs and the surveys that correspond with the potential respondents of each course.

This request for a new clearance number involves the administration of 7 surveys: registration, post-completion, and lecture evaluations for the Introduction to the Principles and Practice of Clinical Research course, the Principles of Clinical Pharmacology course, Sabbatical in Clinical Research Management, and the NIH Summer Course in Clinical and Translational Research course that were formerly under different OMB clearance numbers (OMB #0925-0602 Exp. Date 9/30/2019 and OMB #0925-0698 Exp. Date 7/31/2020) which will respectively undergo revision by the Office of Clinical Research Training and Medical Education. Information needs to be collected through these surveys to streamline the evaluation process for all of these training programs and capture additional data for more meaningful and effective program outcome evaluations.

**I. Introduction to the Principles and Practice of Clinical Research (IPPCR) [Attachments 1, 2, 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 health professionals at extramural domestic and international sites who enroll and participate in the lectures and presentations through distance learning technologies.

**II. Principles of Clinical Pharmacology Course (PCP) [Attachments 1,3,5]**

This course is an online lecture series covering the fundamentals of clinical pharmacology as a translational scientific discipline focused on rational drug development and utilization in therapeutics. The course focuses on the following core principles of pharmacology: pharmacokinetics; drug metabolism and transport; drug therapy in special populations; assessment of drug effects; drug discovery and development; pharmacogenomics and pharmacotherapy. This

course is offered to meet the needs of researchers with an interest in the pharmacologic aspects of contemporary clinical drug development and utilization.

**III. NIH Summer Course in Clinical and Translational Research [Attachments 1 and 6]**

The NIH Summer Course in Clinical and Translational Research is a two-week intensive introductory course offered by the NIH Office of Clinical Research. The purpose of the course is to demonstrate the role of PhD scientists in clinical and translational research, provide an overview and examples of how basic science and clinical observations lead to translational research, and increase awareness and access to PhD role models, research resources, and potential career opportunities at the NIH.

**IV. Sabbatical in Clinical Research Management [Attachments 1 and 7]**

The Sabbatical in Clinical Research Management at the National Institutes of Health is a 4- to 8-week independent study for clinical research investigators and managers of clinical research programs. While on approved sabbatical from their place of employment, participants are connected with NIH experts to learn best practices and develop new solutions to manage a clinical research enterprise. Sabbatical participants do not engage in clinical research at the NIH.

## A.3 Use of Information Technology and Burden Reduction

All information will be collected electronically to minimize participant time and survey burden. See Attachment 9, a Privacy Impact Assessment by the NIH Center for Information Technology Business Application Systems Division (CIT BAS), the Office of the Director Privacy Officer, and the Office of the Director Information Systems Security Officer (ISSO).

## 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 Office of Clinical Research training mission.

## A.5 Impact on Small Businesses or Other Small Entities

The respondents are primarily physicians, dentists, medical scientists, and medical, PhD, pharmacy, nursing, 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 program participants. Less frequent distribution would not permit meaningful longitudinal assessment and validation of program quality and effectiveness in accordance with the training mission of the NIH Office of Clinical Research, since these courses are offered on an annual basis.

## 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

Notice was published in the Federal Register, Friday, July 12, 2019, Volume 84, pages 33270- 33272.

No public comments were received in response to notice.

## 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 system requirements for personally identifiable information to be private under the Privacy Act are identified, reviewed, and approved by the OD Information Systems Security Officer (OD/ISSO); see attachment 8, *Privacy Act Memo*. Additionally, a Privacy Impact Analysis (PIA) will also be performed; please see attachment 9, *PIA form for OCR*. 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.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

Based on Office of Clinical Research program participation data for calendar year 2018, the estimated number of respondents per year to all surveys included in this request is around approximately 9,540.

The annual burden hours for this request for revision were calculated using a maximum time allotment of 10 minutes for completion of each survey. The estimated total burden hours requested, therefore, is 1,589.

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

| Form Name | Type of Respondents | Estimated Number of Respondents | Number of Responses per Respondent | Average Burden Per Response (in hours) | Total Annual Burden Hours |
|---|---|---|---|---|---|
| OCR Learning Portal Registration (Attachment 1) | Healthcare Professionals | 2000 | 1 | 10/60 | 333 |
| | Students | 1000 | 1 | 10/60 | 167 |
| | General Public | 500 | 1 | 10/60 | 83 |
| IPPCR Lecture Evaluation (Attachment 2) | Healthcare Professionals | 750 | 1 | 10/60 | 125 |
| | Students | 500 | 1 | 10/60 | 83 |
| | General Public | 250 | 1 | 10/60 | 42 |
| IPPCR Final Course Evaluation (Attachment 4) | Healthcare Professionals | 750 | 1 | 10/60 | 125 |
| | Students | 500 | 1 | 10/60 | 83 |
| | General Public | 250 | 1 | 10/60 | 42 |
| PCP Lecture Evaluation (Attachment 3) | Healthcare Professionals | 750 | 1 | 10/60 | 125 |
| | Students | 500 | 1 | 10/60 | 83 |
| | General Public | 250 | 1 | 10/60 | 42 |
| PCP Final Course Evaluation (Attachment 5) | Healthcare Professionals | 750 | 1 | 10/60 | 125 |
| | Students | 500 | 1 | 10/60 | 83 |
| | General Public | 250 | 1 | 10/60 | 42 |

| | | | | | |
|---|---|---|---|---|---|
| NIH Summer Course in Clinical and Translational Research Course Evaluation (Attachment 6) | Healthcare Professionals | 20 | 1 | 10/60 | 3 |
| Sabbatical in Clinical Research Management Course Evaluation (Attachment 7) | Healthcare Professionals | 20 | 1 | 10/60 | 3 |
| | **Total** | | **9,540** | …… | **1,589** |

**A.12-2: ANNUALIZED COST TO RESPONDENTS**

| Type of Respondents | Total Annual Burden Hours | Hourly Respondent Wage Rate | Respondent Cost |
|---|---|---|---|
| Healthcare Professionals | 839 | $40.30 | $33,811.70 |
| Students | 499 | $16.54 | $8,253.46 |
| General Public | 251 | $22.15 | $5,559.65 |
| **Totals** | **1,589** | …… | **$47,624.81** |

The annualized cost to respondents in table A.12-2 was calculated using median weekly wage data from the 2018 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 2018 NIH pre-doctoral stipend levels for graduate students "Individual Households" (see: https://policymanual.nih.gov/2300-320-7#97EB5176. Hourly wages were calculated assuming a 40-hour work week. Doctoral level respondents, "Healthcare Professionals," included the following categories from the BLS

Current Population Survey: physicians, surgeons, dentists, and medical scientists. "General Public" included the following categories from the BLS Current Population Survey: nurses, nurse practitioners, and physician assistants. 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 2018 Current Population Survey obtained from the Bureau of Labor Statistics at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-036.html and from the 2018 NIH pre-doctoral stipend levels for graduate students available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-036.html

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

Not applicable.

### 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 – Course Coordinator** | **11/3** | **74,221** | **20%** | | **$14,844** |
| **Contractor costs** – NIH CIT BAS technology fees, on-line survey maintenance and distribution costs, and data analysis costs | | | | | **$27,000** |
| **Travel** | | | | | **$0** |
| **Other Cost** | | | | | **$0** |
| **Total** | | | | | **$41,844** |

*the Salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/19Tables/html/DCB.aspx

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

This is a new information collection request.

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

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

The schedule going forward will be as follows:

| A.16 - 1 Project Time Schedule | |
|---|---|
| **Activity** | **Time Schedule** |
| Open surveys on course portal | 1 week after OMB approval* |
| Survey notification sent electronically to respondents through course portal | October to June of each calendar year |
| Data Analysis | Weekly and every 3 months during course year |
| Office of Clinical Research Program Evaluation Review | October to January of each calendar year |

*We are aiming to open our surveys by October 1, 2019 so that surveys are aligned with course start dates.

**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.