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 Education and Collaboration Outreach, OIR, NIH
OMB # 0925-0764 [Exp. 02/28/2026]

Date: May 2024

Check off which applies:

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

Contact: Rebecca Hwang
Address: 1 Center Drive/208A
Bethesda, MD 20892-0155
Telephone:
Fax:
Email: rebecca.hwang@nih.gov

Table of contents

LIST OF ATTACHMENTS:

1) Attachment 1: Titled ‘OCRECO Learning Portal Registration’
2) Attachment 2: Titled ‘IPPCR Lecture Evaluation’
3) Attachment 3: Titled ‘PCP Lecture Evaluation’
4) Attachment 4: Titled ‘IPPCR Final Course Evaluation’
5) Attachment 5: Titled ‘PCP Final Course Evaluation’
6) Attachment 6: Titled ‘NIH Summer Course in Clinical and Translational Research Course Evaluation’
7) Attachment 7: Titled ‘Sabbatical in Clinical Research Management Course Evaluation’
8) Attachment 8: Titled ‘Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online) Final Course Evaluation’
9) Attachment 9: Titled ‘Privacy Act Memo’
10) Attachment 10: Titled ‘PIA form for OCRECO’

A. Abstract

The request for a revision under the existing clearance number 0925-0764 for information collection will continue to allow the assessment of the long-term impact and outcomes of clinical research training programs provided by the Office of Clinical Research Education and Collaboration Outreach (OCRECO), located in the NIH Office of Intramural Research on an annual basis. This revision request will also allow for the addition of a new clinical research training course to be delivered online through the same online learning management system as the other courses. The clinical research training programs include: the Introduction to the Principles and Practice of Clinical Research and Principles of Clinical Pharmacology, Sabbatical in Clinical Research Management, the NIH Summer Course in Clinical and Translational Research, and the new course, the Ethical and Regulatory Aspects of Clinical Research Course (Asynchronous/Online). Please note that the Office of Clinical Research Education and Collaboration Outreach (OCRECO) was formerly titled the Office of Clinical Research, until March 2023 with the change of office leadership.

The purpose of this revision 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 education at NIH, it remains incumbent upon the NIH Office of Clinical Research Education and Collaboration Outreach 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 Education and Collaboration Outreach'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 Education and Collaboration Outreach in the Office of Intramural Research is to facilitate the vision of excellence in clinical research at the NIH through the development of training and collaborations 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
- Ethical and Regulatory Aspects of Clinical Research Course (Asynchronous/Online)

A.2 Purpose and Use of the Information Collection

The information collected will allow the Office of Clinical Research Education and Collaboration Outreach to continue to assess the value of the training provided by the Office of Clinical Research Education and Collaboration Outreach on an annual basis, and the extent to which this training promotes research productivity. Under the existing OMB clearance number, successful information collection continued for 4 courses through 7 surveys. Due to the addition of a new course and a corresponding survey, there are now 5 courses using 8 surveys

included in this revision request for approval. The information collection would begin September 1, 2024 and end August 1, 2025, and continue to be offered on an annual basis from September through August of each course year. The 8 surveys that are attached for review consist of the following: an OCRECO 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, the Sabbatical in Clinical Research Management course evaluations, and the new Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online) final course evaluation. These surveys will provide registration and impact metrics for the portfolio of clinical research training programs in the Office of Clinical Research Education and Collaboration Outreach. The data received from these surveys will continue to 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 5 training programs and the surveys that correspond with the potential respondents of each course.

This request for a revision under the existing clearance number will continue to allow the administration of 8 surveys: registration, post-completion, 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, the NIH Summer Course in Clinical and Translational Research course, and the Ethical and Regulatory Aspects of Clinical Research Course (Asynchronous/Online). Information needs to continue 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 Education and Collaboration Outreach. 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.

V. Ethical and Regulatory Aspects of Clinical Research [Attachments 1 and 8]

The Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online) course is a new online course recently developed in partnership with the NIH Clinical Center's Bioethics Department to teach the ethics of clinical research with human subjects to participants external to the NIH. Course objectives include and are not limited to: utilizing a systematic framework for evaluating the ethics of a clinical research protocol, identifying, defining and considering ethical issues in the conduct of human subject research, applying appropriate codes and regulations governing the ethical conduct of human subject research to one's own research, and appreciating ethical challenges with conducting international collaborative research in low- and middle-income countries.

A.3 Use of Information Technology and Burden Reduction

All information will continue to be collected electronically to minimize participant time and survey burden. See Attachment 10, 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 Education and Collaboration Outreach 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 Education and Collaboration Outreach 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, July 31, 2023, Volume 88, pages 49472-49473. No public comments 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 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 9, *Privacy Act Memo*. Additionally, a Privacy Impact Analysis (PIA) was performed in May 2022; please see attachment 10, *PIA form for OCRECO*. 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 Education and Collaboration Outreach program participation data for calendar year 2023, the estimated number of respondents per year to all surveys included in this request is around approximately 21,290.

The annual burden hours for this request for revision were calculated using a maximum time allotment of 5 minutes for completion of each survey. The estimated total burden hours requested, therefore, is 1,773.

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
OCRECO Learning Portal Registration (Attachment 1)	Healthcare Professionals	2000	1	5/60	167
	Students	2000	1	5/60	167
	General Public	1000	1	5/60	83

IPPCR Lecture Evaluation (Attachment 2)	Healthcare Professionals	1000	1	5/60	83
	Students	2000	1	5/60	167
	General Public	1000	1	5/60	83
IPPCR Final Course Evaluation (Attachment 4)	Healthcare Professionals	1000	1	5/60	83
	Students	2000	1	5/60	167
	General Public	1000	1	5/60	83
PCP Lecture Evaluation (Attachment 3)	Healthcare Professionals	1000	1	5/60	83
	Students	2000	1	5/60	167
	General Public	1000	1	5/60	83
PCP Final Course Evaluation (Attachment 5)	Healthcare Professionals	1000	1	5/60	83
	Students	2000	1	5/60	167
	General Public	1000	1	5/60	83
NIH Summer Course in Clinical and Translational Research Course Evaluation (Attachment 6)	Healthcare Professionals	20	1	5/60	2
Sabbatical in Clinical Research Management Course Evaluation (Attachment 7)	Healthcare Professionals	20	1	5/60	2
Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online) Course (Attachment 8)	Healthcare Professionals	100	1	5/60	8
	Students	50	1	5/60	4
	General Public	100	1	5/60	8
	Total		**21,290**	……	**1,774**

A.12-2: ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Total Annual Burden Hours	Hourly Respondent	Respondent

		Wage Rate	Cost
Healthcare Professionals	511	$61.16	$31,252.76
Students	839	$18.32	$15,370.48
General Public	423	$40.72	$17,224.56
Totals	**1,773**	……	**$63,847.80**

The annualized cost to respondents in table A.12-2 was calculated using median weekly wage data from the 2023 Current Population Survey obtained from the Bureau of Labor Statistics [BLS] (https://www.bls.gov/cps/cpsaat39.pdf), and annual student stipend data obtained from the pre-doctoral NIH IRTA and Visiting Fellows reflecting the 2023 NIH pre-doctoral stipend levels for graduate students "Individual Households" (see: https://policymanual.nih.gov/2300-320-7#D31625E0. 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, pharmacists, 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 from the 2023 Current Population Survey obtained from the Bureau of Labor Statistics (https://www.bls.gov/cps/cpsaat39.pdf).

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 – Program Manager	**13/3**	**125,827**	**20%**		**$25,165.40**
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					**$52,165.40**

*The salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/html/DCB.aspx

A.15 Explanation for Program Changes or Adjustments

Survey instruments included in this revision request have revised survey questions as well as a new survey altogether to account for the addition of a new clinical research training course, the Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online) course. The total estimated number of respondents per year to all surveys included in this request is less than the previous number cited in the extension request (22,040 respondents) based on 2023 program data. The maximum time allotment for completion of each survey was also changed from 10 minutes to 5 minutes. The estimated total burden hours requested in this current revision is 1,774 as opposed to the estimation of 3,674 burden hours in the previous extension request.

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

Survey results are tabulated only for the NIH Office of Clinical Research Education and Collaboration Outreach's (OCRECO) 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	September to the next August of each calendar year
Data Analysis	Weekly and every 3 months during course year

Office of Clinical Research Education and Collaboration Outreach Program Evaluation Review	September to the next August 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.