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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Clinical Research Education, Collaboration, and Outreach (OCRECO), Office of the Director (OD), National Institutes of Health, will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Anne Zajicek, M.D., Pharm.D., Program Director, Office of Clinical Research Education, Collaboration, and Outreach, NIH Office of the Director, Building 1, Room 201, MSC-0155, Bethesda, Maryland, 20892 or call non-toll-free number (301) 480-9913 or email your request, including your address to: zajiceka@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public

and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research, 0925-0764, exp., date 02/28/2026, Revision Office of Clinical Research Education and Collaboration Outreach (OCRECO), National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: The purpose of this revision is to: update the name of the office responsible for these on-line training programs (from Office of Clinical Research to Office of Clinical Research Education and Collaboration Outreach); revise the course evaluation survey questions; add an additional on-line course, "Ethical and Regulatory Aspects of Clinical Research"; change the course opening and close dates from Oct-June to Sept-July. The survey will continue to assess the long-term impact and outcomes of clinical research training programs provided by the newly formed Office of Clinical Research Education, Collaboration, and Outreach (previously the Office of Clinical Research) located in the NIH Office of the Director (OD) over a ten-year follow-up period. The information received from respondents will provide insight on the following: impact of the courses on (a) promotion of professional competence, (b) research productivity and independence, and (c) future career development within clinical, translational, and academic research settings. These surveys will provide

preliminary data and guidance in 1) developing recommendations for collecting outcomes to assess the effectiveness of the training courses, and 2) tracking the impact of the curriculum on participants' ability to perform successfully in academic, non-academic, research, and non-research settings.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 820.

Estimated Annualized Burden Hours

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	1000	1	5/60	83
	General Public	500	1	5/60	42
IPPCR Lecture Evaluation (Attachment 2)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42
	General Public	250	1	5/60	21
IPPCR Final Course Evaluation (Attachment 4)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42
	General Public	250	1	5/60	21
PCP Lecture Evaluation (Attachment 3)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42
	General Public	250	1	5/60	21
PCP Final Course Evaluation (Attachment 5)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42
	General Public	250	1	5/60	21
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		**9,790**		**820**

Dated: July 25, 2023.

Tara A. Schwetz,

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National Institutes of Health.

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