DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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TO: Office of Management and Budget (OMB)
Through: Reports Clearance Officer, DHHS _____
Project Clearance Chief, NIH Mikia Currie

FROM: Dr. Pamela Kearney, Director, Division of Human Subjects Research
Office of Extramural Research (OER)

Pamela R. Kearney -S
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Date: 2024.05.21 13:08:06 -04'00'

SUBJECT: Non-substantial Change Request to Electronic Application for NIH Certificates of Confidentiality (CoC E-application System) (OMB# 0925-0689); (Expiration Date: 04/30/2025)

We are writing to request approval of one non-substantial change to the data collection instrument for use as part of the Electronic Application for NIH Certificates of Confidentiality (CoC E-application System) (OMB# 0925-0689). OMB approved two nonsubstantive changes to the currently approved collection on October 12, 2023. The proposed modification is a minor edit to the Institutional Assurance statement #5, to clarify the institutions' responsibility to conduct research in compliance with 45 CFR 46, including the relevant subparts. The modification does not change the scope of the inquiry, the method of collection, or the population of participants outlined in the original application, or the estimated burden of the collection.

For the proposed modification in the Institutional Assurance statement #5, we are clarifying NIH's expectation that institutions submitting a CoC request will comply with the entirety of 45 CFR Part 46, including the informed consent requirements and the relevant subparts (i.e., Subparts B, C, and D). The current language in statement 5 is as follows: "the institution and personnel involved in the conduct of the research will comply with the informed consent requirements of the *applicable* Federal regulations, including 45 CFR Part 46." In addition, question 4 in the CoC application, which is completed by a staff member (e.g., investigator, study coordinator) states: "Will the activity be conducted in accordance with all applicable federal, state, and local laws and regulations, including, but not limited to, 45 CFR 46?" The question 4 requirement is not included in the current Institutional Assurance statement. We revised the Institutional Assurance statement #5 language to include the requirement from question 4, so the Institutional Official will attest that the research will be conducted in accordance with 45 CFR Part 46 and relevant subparts (even if not specifically required by regulation) as well as all applicable federal, state, and local laws and regulations throughout the life of the study.

Proposed wording changes are highlighted in YELLOW below. No other questions or statements have been added or removed to the data collection instrument.

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Original Question	Proposed Change
Institutional Assurance Statement 5: The institution and personnel involved in the conduct of the research will comply with the informed consent requirements of the applicable Federal regulations, including 45 CFR Part 46.	Institutional Assurance Statement 5: The research will be conducted in accordance with 45 CFR 46 and relevant Subparts (even if not specifically required by regulation), as well as all applicable federal, state, and local laws and regulations throughout the life of the study.

Pamela R. Kearney, M.D.

Attachment 1:
Screenshot of Proposed Change to Electronic Application Institutional Assurance Statement for NIH Certificates of Confidentiality (CoC E-application System)