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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)

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 two non-substantial changes 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 a nonsubstantive change to the currently approved collection on June 30, 2023. The first proposed modification is minor edits to the Institutional Assurance statement #2, to clarify the institutions' responsibility when utilizing third parties or entities to collect personally identifiable information in the research study. The second proposed modification is the removal of a cited regulation in the Institutional Assurance statement #3 which allows voluntary disclosure of information that is protected by a Certificate of Confidentiality, and conflicts with the statute (42 U.S.C. §241(d)) which prohibits voluntary disclosure of protected information, except under specific, limited circumstances. These modifications do 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 first proposed modification in the Institutional Assurance statement #2, approved in June 2023, we became aware that the word "ensure" may be misinterpreted by institutions and not accurately convey the institutions' responsibility when utilizing third parties or entities. We revised the Institutional Assurance statement #2 language to "...In addition, this institution will not utilize third parties or entities (e.g., contractors, online platform vendors) to collect or store information that cannot or will not protect against the compelled disclosure of the personally identifiable information" to describe the institutions responsibility more accurately.

For the second proposed modification in the Institutional Assurance statement #3, NIH Office of Science Policy staff pointed out that 1979 regulation at 42 CFR § 2a permits the voluntary disclosure of protected information by the institution and conflicts with the 21st Century Cures Act and subsequently amended Public Health Service Act (42 U.S.C. §241(d)) regarding when protected information may be disclosed. To ensure that the Institutional Assurance statement #3 accurately reflects the statutes disclosure



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restrictions, we removed reference to 42 CFR § 2a from the Institutional Assurance statement #3, which now reads, "The institution understands that research information protected by a Certificate of Confidentiality is subject to the protections and the disclosure requirements noted in 42 U.S.C 241. Any investigator or institution conducting research protected by a Certificate of Confidentiality SHALL NOT disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research without the specific consent of the individual to whom the information pertains or as otherwise permitted in accordance with 42 U.S.C 241."

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

Table with 2 columns: Original Question and Proposed Change. The table compares the original Institutional Assurance Statement 2 with a proposed change that adds support and defense of the authority of the Certificate against legal challenges and removes the requirement to support and defend the authority of the Certificate.



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<p>Institutional Assurance Statement 3:</p> <p>The institution understands that research information protected by a Certificate of Confidentiality is subject to the protections and the disclosure requirements noted in 42 U.S.C 241 and 42 CFR § 2a. Any investigator or institution conducting research protected by a Certificate of Confidentiality SHALL NOT disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research without the specific consent of the individual to whom the information pertains or as otherwise permitted in accordance with 42 U.S.C 241 and 42 CFR § 2a.</p>	<p>Institutional Assurance Statement 3:</p> <p>The institution understands that research information protected by a Certificate of Confidentiality is subject to the protections and the disclosure requirements noted in 42 U.S.C 241. Any investigator or institution conducting research protected by a Certificate of Confidentiality SHALL NOT disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research without the specific consent of the individual to whom the information pertains or as otherwise permitted in accordance with 42 U.S.C 241.</p>
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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)