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)

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 one nonsubstantive change to the currently approved collection on May 31, 2024. The proposed modification is minor edits to the Institutional Assurance statement #6. The modifications clarify when the investigator will inform individual participants about the Certificate protections and limitations and when there are any changes to those protections and limitations. For consistency, the terms used when referring to the person that provided informed consent were modified. The modifications do not change the scope of the inquiry, the method of collection, the population of participants outlined in the original application, or the estimated burden of the collection.

For the proposed modifications to the Institutional Assurance statement #6, we are clarifying NIH's expectation of whom will be informed of the Certificate protections and limitations to the Certificate protections and when there is a change to the protections and limitations. The current language in statement 6 is as follows: "*All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate and disclosures that are outside the scope of coverage of the Certificate (e.g. public health reporting as required by Federal, State, or local laws, or requirements for child or elder abuse reporting). Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them*." The current language asserts that all participants will be informed of the Certificate protections and limitations. It would be burdensome for an investigator to inform participants of the Certificate protections and limitations when consent is not otherwise required, such as when research is being conducted on existing information and materials (i.e., secondary research) or when the IRB waived the requirement to obtain informed consent from individuals. Note the applicable regulations at 45 CFR 46 do not require investigators to obtain informed consent when the study meets certain conditions, such as in secondary research. Furthermore, the current statement is silent on informing individuals who

previously provided informed consent that the Certificate may not cover data collected after the Certificate expires or is terminated. It is important to provide participants updated, relevant information about changes to the Certificate protections, since such a change may affect the participant's willingness to continue participating in the research study. Lastly, for consistency throughout Statement 6, we updated the language referencing "subjects" and "research participants" to "individuals from whom informed consent will be obtained". Modifying these terms encompasses all persons from whom the investigator obtains informed consent, including research participants, parents (who provide parental permission/informed consent for their child to be enrolled in the research) and legally authorized representatives (who provide informed consent for individuals who are unable to give their own consent, such as an unconscious individual).

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

Original Question	**Proposed Change**
Institutional Assurance Statement 5: All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate and disclosures that are outside the scope of coverage of the Certificate (e.g. public health reporting as required by Federal, State, or local laws, or requirements for child or elder abuse reporting). Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.	Institutional Assurance Statement 5: All individuals from whom informed consent will be obtained will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate and disclosures outside the scope of coverage of the Certificate (e.g., public health reporting as required by Federal, State, or local laws, or requirements for child or elder abuse reporting). Individuals who give informed consent and continue study participation after the expiration or termination of the Certificate will be informed that the protections of the Certificate may not cover any new data that is collected after the expiration or termination. Any individual entering the project after expiration or termination of the Certificate from whom informed consent will be obtained will be informed that the protection afforded by the Certificate does not apply to them.

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Pamela R. Kearney, M.D.

Pamela R. Kearney -S

Digitally signed by Pamela R. Kearney -S
Date: 2024.11.04 14:22:41 -05'00'

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