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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)

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We are writing to request approval of some 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). The proposed modifications are the addition of language to address the institutions' protection of personally identifiable information when using any third-party product or entity in the research study. 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.

We became aware that many research studies are utilizing third-party platforms to collect and or store data, and the end user agreement may state that the data collected on their platform can be disclosed upon subpoena, which is contrary to the protection of the CoC. The current Institutional Official (IO) Statement #2 does not include any language that addresses the research institution's responsibility to ensure that personally identifiable information which is collected and or stored for the research project using a third-party product or entity will be protected against compelled disclosure. To ensure the institution's agreement to the protection of participants' information that is collected and or stored using a third-party product or entity, we have added the following sentence to the current IO Statement #2: "In addition, this institution will ensure any third-party product or entity utilized for this project (e.g., contractors, online platform vendors) to collect or store information can and will protect against the compelled disclosure of the personally identifiable information." We also split the current Statement 2 into two separate sentences. 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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<b>Original Question</b>	<b>Proposed Change</b>
<p>IO Statement 2:</p> <p>This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.</p>	<p>IO statement 2:</p> <p>This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information. In addition, this institution will ensure any third-party product or entity utilized for this project (e.g., contractors, online platform vendors) to collect or store information can and will protect against the compelled disclosure of the personally identifiable information. The institution agrees to support and defend the authority of the Certificate against legal challenges.</p>

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)