



DATE: November 19, 2019

TO: Pamela R Kearney, MD
Division of Human Subjects Research
Office of the Director (OD)

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: Electronic Requests for NIH Certificates of Confidentiality (CoC) (OD)

I have reviewed the Electronic Requests for NIH Certificates of Confidentiality (CoC) (OD) submission to OMB referenced above. In 2015, NIH launched an on-line application system for researchers to request a CoC from NIH. Information is collected to allow confirmation of eligibility for a CoC and to issue a Certificate. Eligible requestors will receive an electronic Certificate once approved.

CoCs protect research participants, researchers, and institutions by prohibiting disclosure of identifying information about participants to persons not connected to the research, with limited exceptions. NIH, through its 24 funding Institutes and Centers (ICs), has issued Certificates of Confidentiality since 1997 to researchers who request this protection. NIH-funded researchers are now deemed issued a Certificate upon award of NIH funding and no longer need to request a Certificate through the system. Non-NIH funded researchers may continue to request a CoC through the online system.

I have determined that the Privacy Act will apply to this data collection, which includes the collection of personally identifiable information (PII) such as first and last name, phone number, address, email and other identifiers stored in a system designed to be retrieved by a personal identifier.

The data collection is covered by NIH Privacy Act Systems of Record 09-25-0156, "*Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD.*" If you have questions, please contact me at (301) 402-6201.

Celeste Dade-Vinson

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NIH Privacy Act Officer