



**DATE:** February 11, 2022

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

**FROM:** NIH Senior Official for Privacy

**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 2020, NIH launched a new on-line application system for researchers to request a CoC from NIH. The information is now stored within a module of the NIH Electronic Research Administration (eRA) system.

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 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 09-25-0225, "*NIH Electronic Research Administration (eRA) Records, HHS/NIH/OD/OER.*" If you have questions, please contact me at (301) 402-6201.

*Celeste Dade-Vinson*

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