



DATE: January 26, 2017

TO: Dr. Julia Slutsman
Office of Human Subjects Research Protections
Office of the Director (OD)

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: Materials to Support NIH Serving as an Institutional Review Board (IRB) of Record or a Single IRB for Outside Institutions

I have reviewed the OD submission to the Office of Management and Budget under the Paperwork Reduction Act which proposes to collect personally identifiable information (PII) to provide the NIH Human Research Protections Program (HRPP) and the NIH IRBs with the information necessary to maintain regulatory compliance in its conduct of human subject protections review when an NIH IRB serves as an IRB of record for multi-site research, and to provide high quality and timely human subject protections reviews.

The NIH and the Department of Health and Human Services have recently established the Public Health Emergency Research Review Board (PHERRB) mechanism for human subject protections review of certain, typically multi-site, public health emergency research studies. Any of the 12 NIH intramural IRBs can be designated to serve as the PHERRB for review of a public health emergency research protocol. Additionally, the NIH HRPP is preparing to implement the recent "NIH Policy on the Use of a Single Institutional Review Board (sIRB) of Record for Multi-Site Research," which requires the use of a single IRB of record for human subject protections review of certain multi-site studies. To meet all of these needs, researchers at outside institutions will need to provide information to the NIH HRPP, which includes the NIH intramural IRBs. To facilitate and systematize collection of the necessary information, NIH has developed a set of required materials. These include the Application for PHERRB Review (APR); the Initial Review Local Context Worksheet (IRLCW); and the Continuing Review Local Context Worksheet (CRLCW).

I have determined that the Privacy Act will apply to this data collection, which includes the collection of the investigator's name, work address, phone, fax, email and curriculum vitae via the APR. The IRLCW and CRLCW forms will collect the name and affiliated institution of principal investigators and the name of regulatory points of contact.

The data collection is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." If you have any questions, please contact my office at (301) 402-6201.



Celeste Dade-Vinson
NIH Privacy Act Officer

cc: Mikia Currie, NIH Project Clearance Branch