



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

**DATE:** July 3, 2024

**TO:** Tali Johnson  
Chief, Pharmaceutical Management Branch  
Cancer Therapy Evaluation Program  
National Cancer Institute (NCI)

**FROM:** NIH Privacy Act Officer

**SUBJECT:** Applicability of the Privacy Act: "Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute/DCTD/CTEP)"

I have reviewed the NCI submission for OMB to approve the request for Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer (National Cancer Institute/DCTD/CTEP). The purposes of the collection are to provide a standardized method of tracking agent disposition across all institutions participating in trials for which the NCI provides agents. Institutional auditors verify information on the agent accountability forms for compliance. In addition, PMB staff review Investigational Agent Accountability Record Forms against records maintained in PMB systems to ensure no inappropriate use or diversion of investigational agents.

I have determined that the Privacy Act will apply because the application involves the collection of personally identifiable information (PII) and that information is used as unique identifiers to retrieve records. The PII that will be collected are name, email address, phone number, education records, certificates, mailing address, month and year of birth, medical licenses, patient identification, patient initials, and clinical trial support history and trainings. This data collection is covered by NIH Privacy Act System of Records 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD."

If you have questions, please contact me at (301) 402-6469.

Dustin Close  
NIH Privacy Act Officer

Cc: Diane Kreinbrink, NCI PRA Liaison