DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: December 7, 2018

TO: Charles L. Hall, Jr., RPh, MS
Branch Chief,
Pharmaceutical Management Branch, CTEP, DCTD
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"

I have reviewed the NCI submission to the Office of Management and Budget under the Paperwork Reduction Act which proposes to collect and maintain information via forms developed by NCI to help investigators using investigation drugs under NCI-sponsored protocols meet FDA requirements and ensure drugs are not diverted for inappropriate protocol or patient use.

I have determined that the Privacy Act will apply to this data collection which involves the collection of personally identifiable information such as patient's initials, patient ID, NCI protocol number and title, NCI investigator number and information pertaining to the drug and its dose form and strength. Although individual patient names are not required on the form, it can be compared with patient protocol flow sheets, which if linked, could identify the patient. Without this reference, drug accountability would be impossible.

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 any questions, please contact my office at (301) 402-6201.

Celeste Dade-Vinson

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Attachment

cc: Vivian Horovitch-Kelley