



DATE: June 30, 2010

TO: Charles L. Hall, RPh. MS
Branch Chief,
Pharmaceutical Management Branch, CTEP, DCTD
National Cancer Institute (NCI)

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "The Drug Accountability Record (NCI)"

I have reviewed the NCI submission to OMB entitled, "The Drug Accountability Record," a form 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 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) 496-2832.

Karen M. Plá

Attachment

cc: Vivian Horovitch-Kelley