



DATE: August 5, 2020

TO: Michael Montello, Pharm. D.
Cancer Therapy Evaluation Program (CTEP)
Division of Cancer Treatment and Diagnosis (DCTD)
National Cancer Institute (NCI)

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "CTEP Branch and Support Contracts Forms and Surveys (NCI)"

I have reviewed the NCI submission to the Office of Management and Budget under the Paperwork Reduction Act. NCI CTEP and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP implements programs to register clinical site investigators and clinical site staff, and to oversee the conduct of research at the clinical sites. CTEP and DCP also oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The combined systems and processes for initiating and managing clinical trials is termed the Clinical Oncology Research Enterprise (CORE) and represents an integrated set of information systems and processes which support investigator registration, trial oversight, patient enrollment, and clinical data collection. The information collected is required to ensure compliance with applicable federal regulations governing the conduct of human subjects research, and when CTEP acts as the Investigational New Drug (IND) holder. Survey collections assesses satisfaction and provide feedback to guide improvements with processes and technology.

I have determined that the Privacy Act will apply to this data collection which involves the collection of personally identifiable information such as name, date of birth, social security number, mailing address, telephone number, medical record number, email address, gender, ethnicity, financial information, educational level, etc.

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

Celeste Dade-Vinson

cc: Diane Kreinbrink