



DATE: March 19, 2013

TO: Jose Galvez
Center for Biomedical Informatics and Information Technology
Office of the Director
National Cancer Institute

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "NCI Clinical Trials Reporting Program (CTRP) Database"

I have reviewed the NCI submission to OMB which requests the approval of the CTRP database be extended. The database serves as a single, definitive source of information about all clinical interventional and observational research conducted at institutions that receive NCI funding, including Cooperative Group trials, externally peer-reviewed trials, institutionally supported investigator-initiated trials, and industry-sponsored studies.

The database provides a comprehensive real-time view of the state of the NCI-supported clinical research, which enables NCI to make informed prioritization decisions via disease-specific steering committees. The information stored in the CTRP database is collected to manage the portfolio, comply with regulatory and administrative report obligations and disseminate appropriate cancer research information to the public.

I have determined that the Privacy Act will not apply to this data collection. The database will store study subject accrual information that is collected on a quarterly basis (i.e., race/ethnicity, date of birth, gender and zip code). However, the database was not designed to retrieve information about the study subject by a personal identifier. Although a study subject ID code will be assigned by the individual trial site where a research subject or patient is accrued on a study, the code will be unique to the study subject within the context of the specific protocol. The code will not replace any individual identifier and cannot be derived from any information related to the individual. Further, any key associated with the code will not be provided to NCI in order to re-identity research subjects or patients.

The portions of the CTRP database that pertain to the description of clinical research projects and summarized information on accrual will be publicly accessible. All non-public data will be maintained in accordance with appropriate security access controls and limited to designated staff with a direct business need. If you have questions, contact me at (301) 402-6201.

Karen M. Plá

cc: V. Horovitch-Kelley, NCI OMB Project Clearance Liaison Office