DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DATE: August 10, 2015

TO: David Sharlip
National Library of Medicine

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "Information Program on Clinical Trials: Maintaining a Registry and Results Databank (NLM)"

I have reviewed the National Library of Medicine (NLM) submission to OMB under the Paperwork Reduction Act which proposes to extend the existing clearance for the ClinicalTrials.gov website, which is the largest and most comprehensive clinical trial registry and results database in the world.

The information collection will enable compliance with statutory requirements of the Section 801 of the Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA) and satisfy the purposes of the original clinical trial information collection that was established to comply with the FDA Modernization Act of 1997 (FDAMA). The information collection is necessary to allow researchers and organizations who are not subject to FDAAA or FDAMA to voluntarily register trials and other clinical studies. The information collection will provide patients, family members, clinicians, and researchers with timely access to up-to-date information about clinical trials, other types of clinical studies and their results. Alone or when combined with collected results information, the information collection can contribute to better-informed decisions about medical treatment, and reduce inadvertent and unnecessary duplication of clinical research studies.

Information is collected via electronic submission to the ClinicalTrials.gov Protocol Registration System, available at https://clinicaltrials.gov/ct2/manage-recs/register. The expanded clinical trials registry provides basic information about the studies, their implementation, and how to enroll. The results portion of the databank summarizes the outcomes of the trial and helps ensure that scientists have access to the latest scientific information about potential treatments for disease, as much of this information is not published in the scientific literature. The information can help scientists to better plan new research projects, and avoid duplication that can expose human volunteers to unnecessary risks. It can also ensure that treatment decisions are based on a more complete set of scientific evidence.

I have determined that the Privacy Act will not apply to this information collection because although personally identifiable data elements such as gender, age, contact information and unique protocol ID will be collected, the principal purpose of the clinical trials registry databank is to enhance patient enrollment and provide a mechanism to track the progress of clinical trials, not to identify a particular clinical study participant. If you have any questions, please contact me at (301) 496-2832.

Karen Plá
NIH Privacy Act Officer

cc: David Sharlip, NLM