



**DATE:** February 13, 2012

**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 NLM submission to OMB which proposes to expand the *ClinicalTrials.gov* registry and make available to the public, a searchable data bank of summary information about the results of certain controlled clinical trials of drugs, biological products, and devices. This expanded patient access to information about clinical trials will increase a patient's therapeutic options while enabling them to contribute to the development of advances in the treatment, diagnosis, and prevention of diseases and conditions, including those that are serious and life-threatening.

I have determined that the Privacy Act will not apply to this data collection which allows patients and their family members to learn about relevant clinical trials and facilitate possible enrollment. The information collection will allow researchers and organizations to voluntarily register trials as a means of enhancing enrollment or to comply with policies of other scientific and regulatory organizations.

*ClinicalTrials.gov* is the largest and most comprehensive clinical trial registry and results database in the world. It is the registry many trial sponsors and principal investigators choose to use to satisfy their obligation to meet the requirements of Section 801 of the Food and Drug Administration Amendments Act of 2007.

If you have any questions, please contact me at (301) 496-2832.

Karen Plá