DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: June 5, 2009

TO: Office of Management and Budget (OMB)

Through: Seleda Perryman, DHHS Report Clearance Officer
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FROM: John Speakman
National Cancer Institute

SUBJECT: NIH NCI Clinical Trials Reporting Program (CTRP) Database

This is a request for OMB to approve the NIH NCI Clinical Trials Reporting Program (CTRP) Database for 6 months. The Federal Register Notices, supporting statements, and various attachments accompany this memorandum.

The National Cancer Institute (NCI) is developing an electronic resource to serve as a single, definitive source of information about all NCI-supported clinical research, thereby enabling the NCI to execute its mission to reduce the burden of cancer and to ensure an optimal return on the nation's investment in cancer clinical research. Deployment and extension of the CTRP Database is an infrastructure development project that will be enabled by public funds expended pursuant to the American Recovery and Reinvestment Act of 2009, P.L. 111-5 ("Recovery Act"). In addition, deployment of this resource will allow the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information will be submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research.

Authorization for emergency processing pursuant to 5 CFR 1320.13 is requested so that the information collection can begin by July 1, 2009. Attached, in accordance with OMB Memorandum M-09-15, is a written determination that this information collection is necessary to implement the provisions of the Recovery Act. In addition, information demonstrating that the NCI has taken all practicable steps to consult with interested agencies and members of the public in order to minimize the burden of the collection of information in included in the attached Supporting Statement A.