DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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TO: Office of Management and Budget (OMB)

Through: Seleda Perryman, DHHS Report Clearance Officer
Marilyn Tuttleman, NIH Project Clearance Officer, OPERA
Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison, OMAA

FROM: John Speakman
National Cancer Institute

SUBJECT: Revision of "Clinical Trials Reporting Program (CTRP) Database"
OMB #: 0925-0600, Expiry Date: 1/31/2010

This is a request for OMB to approve the revision of "Clinical Trials Reporting Program (CTRP) Database (OMB #: 0925-0600, Expiry Date: 1/31/2010)" for 3 years. The 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.

Clinical research administrators, as designees of the clinical investigators, will electronically access the CTRP website to complete the initial trial registration. After the clinical trial has been registered, four amendments and four study subject accrual updates occur per trial annually. The previous submission took into account the initial registration and amendment activities. This current submission will include the registration and amendment activities, as well as accrual of study subject information. It is anticipated that a total of 49,500 (16,500 annually) respondents will participate in CTRP's clinical trial database and this amounts to a total of 115,500 (38,500 annual) burden hours over a 3 year clearance period.

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 is included in the attached Supporting Statement A.