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
Marilyn Tuttleman, NIH Project Clearance Officer, OPERA
Vivian Horovitch-Kelley, NCI OMB Project Clearance Liaison Office

FROM: John Niederhuber, M.D.
Director, National Cancer Institute

SUBJECT: NIH NCI Clinical Trials Reporting Program (CTRP) Database: Determination of Necessity for Implementation of the American Recovery and Reinvestment Act of 2009, P.L. 111-5

In accordance with OMB Memorandum M-09-15 and pursuant to Sections 407(a)(4) and 410(8) of the Public Health Service Act (codified at 42 USC §§ 285a-2(a)(2)(D) and 285a-2(a)(1)), the NCI hereby determinates that the collection of information through the NIH NCI Clinical Trials Reporting Program (CTRP) Database is necessary in order to implement the provisions of the American Recovery and Reinvestment Act of 2009, P.L. 111-5 ("Recovery Act").

The Recovery Act presents the NCI with a unique opportunity to invest in significant expansions to its efforts to modernize the cancer clinical trials reporting infrastructure. These investments will vastly improve the agency's ability to conduct the nation's cancer research program and comply with its statutory information collection obligations while substantially reducing the reporting burden of the NCI-supported clinical research community. NCI's role as the sponsor of a large number of cancer clinical trials implemented across a wide range of venues uniquely positions the Institute to take a global view of emerging knowledge about the effectiveness of cancer therapies, and to identify and disseminate important patterns and insights in a timely way. Furthermore, these patterns and insights can be fed quickly back into NCI's program planning and prioritization activities to better identify global patterns in cancer trials as well as other diseases occurring in these large populations and avoid duplication of effort.

The information collection needs to commence by July 1, 2009 so that NCI can conduct effective prototyping of the database in order to deploy it systematically on a production basis by October 1, 2009 within the timelines of the Recovery Act. Given the long term nature of this project, the

NCI cannot reasonably comply with the normal clearance procedures because the 60-day/30-day notice and comment periods will interfere with the timely collection of information. As documented in the attached Supporting Statement A, NCI has taken all practicable steps to consult with interested agencies and members of the public in order to minimize the burden of the proposed collection of information. Therefore, NCI further requests that OMB waive the requirement to publish a notice in the Federal Register prior to commencing the information collection.

Respectfully submitted,

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Director, National Cancer Institute