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
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Subject: Investigator Registration and Financial Disclosure for Investigational Trials in Cancer Treatment (NCI)

This is a request for OMB to approve an "existing collection in use without an OMB Number." Julie Wise had suggested that Agencies submit existing collections as part of reporting and governmental transparency. In NCI's effort to minimize violations, comply with PRA and keep an open dialogue with OMB, we are submitting this IC as such.

This information collection is titled, "Investigator Registration and Financial Disclosure for Investigational Trials in Cancer Treatment (NCI)" and the request is for 3 years of data collection. The FDA holds the NCI responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug and the response of the patient to that drug. Investigators are physicians who specialize in the treatment of patients with cancer.

The Food and Drug Administration has authorized the NCI to register investigators on an annual basis to facilitate the unique nature of our business process. The FDA registers investigators on a per protocol basis. The NCI is unique in that individual investigators participate in numerous investigational protocols. The NCI process significantly reduces the regulatory burden for investigators and facilitates the pace of research. The NCI has been using this process for 25 years and has a significant investment in the infrastructure to support the registration process. Any changes to the existing system would have a dramatic and negative effect on clinical trials in process and adversely effect the health care provided to patients undergoing investigational treatments of cancer.

The Pharmaceutical Management Branch registers and tracks a total of 17,128 investigators who support NCI sponsored studies annually. The annualized burden to the investigators is estimated at 8,564 hours, and requires 9 FTEs of government support at a cost of $514,000.