Supporting Statement A For:

The Clinical Trials Reporting Program **(CTRP)** Database (NCI)
OMB #0925-0600
Expiry Date: 1/31/2010

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Revisions to the original submission are made in yellow throughout this document.

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A. Justification

A.1 Circumstances Making the Collection of Information Necessary

In 2005, the National Cancer Advisory Board (NCAB), the federal advisory committee that advises the National Cancer Institute (NCI) on the national cancer program, approved the recommendation of its Clinical Trials Working Group (CTWG) to consolidate reporting, aggregate information and reduce redundant submissions. The NCAB also charged NCI program staff with implementing this recommendation. Subsequent reports to the NCI Clinical Trials Operating Committee (CTROC), the group within NCI responsible for implementing the CTWG recommendations, indicate that the agency's current approach to clinical trials reporting prevents NCI from fully executing its mission. In effect, advances in information technology have rendered obsolete NCI's current framework for complying with its statutory data collection and dissemination obligations.

As a consequence, the NCI has developed an electronic resource, the NCI Clinical Trials Reporting Program (CTRP) Database (http://www.cancer.gov/clinicaltrials/ctrp/page2), which is designed to contain comprehensive, up-to-date information about all clinical research supported by the NCI. The resource is intended 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. Following OMB approval of the initial submission in July 2009, NCI began the first phase of information collection through the CTRP Database under OMB #:0925-0600, Expiry Date: 1/31/2010. This revised submission is not only proposing that all NCI-funded institutions conducting cancer clinical research continue to submit information to register trials in the CTRP Database, but also to begin submitting study subject accrual information.

NCI is charged by the National Cancer Act, 42 USC § 285, with managing the Nation's cancer program. Specifically, NCI is required to:

- ***Collect, analyze and disseminate all data useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank*** to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person involved in cancer research in any country. *Stated in Section 407(a)(4) of the Public Health Service Act (codified at 42 USC § 285a-2(a)(2)(D); expanded in National Cancer Amendments of 1974 and the Health Research Extension Act of 1985 consolidated cancer communication activities and highlighted the International Cancer Research Data Bank.*

- Take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the National Cancer Institute and the other scientific, medical and biomedical disciplines and organizations nationally and internationally. *Stated in Section 410(8) of the Public Health Service Act, codified at 42 USC § 285a-2(a)(1).*

- Prepare in consultation with the National Cancer Advisory Board and submit to the President for transmittal to the Congress a report on the activities, progress, and accomplishments under the National Cancer Program during the preceding calendar year and a plan for the Program during the next five years. *Stated in Section 410A(b) of the Public Health Service Act, codified at 42 USC § 285a-4(b).*

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"). The Recovery Act presents the NCI with a unique opportunity to invest in significant expansions to its efforts to modernize the existing cancer clinical trials reporting infrastructure, which was previously instantiated through the NCI's PDQ/Cancer.gov clinical trials submission portal. 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 the inefficiency that results from duplication of clinical trials (e.g., two trials on broadly the same agent and condition being conducted simultaneously) and/or clinical trials conducted out of sequence (e.g., a Phase II trial being initiated after a Phase III trial of the same agent/condition has already begun).

The establishment of the CTRP Database was approved by the National Cancer Advisory Board (NCAB) in June 2005 following the report and recommendations of its Clinical Trials Working Group (CTWG) (See Attachment 1). The CTWG report envisioned an enhanced cancer clinical trials enterprise in which increased participation by the extramural community in the prioritization process more effectively focuses resources on those trials judged *most* likely to facilitate advances in treatment. As indicated in the CTWG report, the NCI does not currently have this management capability, which has notably led to redundant trial sponsorship and funded trials without patients. The current state of reporting, the reporting process and supporting systems do not allow the NCI to effectively manage the nation's investment in cancer research.

The rapid pace of scientific progress has created an ever-increasing number of novel therapies to test. Only through an open, collaborative prioritization system involving all the critical stakeholders can the best decisions be made as to which agents and disease targets warrant an investment of taxpayer dollars in clinical trials.

Building a national clinical trials enterprise founded on the best science requires a new level of coordination and cooperation by ensuring that comprehensive information on cancer clinical trials is readily available for all stakeholders. This in turn will enhance scientific quality and prioritization so that NCI supports the best-designed trials, addressing the most important questions, leveraging the most significant scientific advances. It will also enhance standardization of tools and procedures for trial design, data capture, data sharing, and administrative functions to decrease effort and minimize duplication.

Routine review of safety, efficacy, and administrative data reported from ongoing NCI-funded clinical trials is essential to the timely recognition and appropriate dissemination of emerging insights on the safety and efficacy of new treatments, while also assuring that NCI's resources are invested productively, and that its program planning and prioritization activities are based on the best and most recent available data. At present, this review of incoming data is constrained both by the absence of comprehensive data reporting and by limited capacity to evaluate such data critically. To assure an optimal return on the nation's investment in cancer clinical trials, it is imperative not only that the completeness of data reporting be assured, but that sufficient capacity to monitor incoming data from all sponsored trials be present.

Fundamental to the success of this strengthened clinical trials prioritization process is access to comprehensive, up-to-date information about the status of cancer clinical trials. Accordingly, one of the CTWG report's recommendations was the creation of an electronic database that would afford the following benefits:

- When preparing new trial concepts and proposals, investigators can take into account other trials already completed or underway addressing similar questions, and thus eliminate unnecessary duplication of effort.
- Clinical trial prioritization is enhanced by having available a full picture of the cancer clinical trials enterprise.

- Patient accrual to trials is enhanced because physicians and patients are aware of relevant opportunities for participation in clinical trials.

- Potential patient harm is reduced because toxicity and adverse events that are recognized in active trials can be rapidly disseminated to other investigators and practicing clinicians.

- Patients benefit because patterns of favorable outcomes that are recognized in active trials can be rapidly disseminated to the clinical trials community.

A.2 Purpose and Use of the Information

The CTRP Database will provide a comprehensive real-time view of the state of NCI-funded cancer clinical trials, which will enable NCI to make informed prioritization decisions via disease-specific steering committees. Accordingly, this resource will allow the NCI to:

- Manage its portfolio of cancer clinical research investments effectively;

- Consolidate and streamline existing reporting to individual programs within the NCI by aggregating the information already collected and eliminating the need for redundant submissions to the NCI;

- Comply with regulatory reporting requirements when acting as the sponsor of FDA-regulated clinical investigations;

- Prepare the detailed performance, financial management and administrative accountability reports required of Executive Branch agencies, including those required by Executive Orders or OMB Circulars, Memoranda and Guidelines; and

- Provide appropriate public access to cancer research information.

Additional benefits include:

- The reporting burden for grantees will become increasingly streamlined.

- Investigators will be aware of trials addressing similar questions that are already completed or in process to avoid duplication of efforts.

- Researchers will have a comprehensive view of the clinical research enterprise that will support the cancer research community's ability to prioritize efforts.

In order to achieve these objectives, the resource must contain information that is structured to facilitate comparison across trials and that complies with Federal guidelines related to health information standards. The information must be detailed enough to fully describe the rich portfolio of clinical research supported by NCI and updated in a regular, timely fashion so that effective, real-time decision making can be made. Further, in order to assess the performance of the NCI's research portfolio, the resource needs up-to-date information on accrual and outcomes, collected at an individual level with most identifiers removed as described below. For effective decision-making, the database will need to contain information for every clinical research activity supported either directly through awards for a specific project, or indirectly through funding support for technical or administrative infrastructure. More specifically, the resource will need to contain complete, standards-based, structured information on development phase, type of intervention or treatment, study design, and program through which funding is provided. The database must contain information concerning all clinical interventional and observational research conducted at institutions that receive NCI funding, including NCI Cooperative Group trials, externally peer-reviewed trials, institutionally supported investigator-initiated trials, and industry-sponsored studies.

Submissions should include the trial protocol document, the template informed consent document, and IRB approval documentation, if available, and the following data elements:

- Protocol registration information:
  - Lead organization
  - Lead organization trial identifier
  - NCT number
  - Principal investigator
  - Protocol title
  - Trial type
  - Trial phase
  - Trial purpose
  - Sponsor

- Responsible Party indicator: PI or Sponsor
- Responsible Party Contact/Generic Contact
- Responsible party's work email address
- Responsible party's work phone number
- Summary 4 funding type
- Summary 4 funding sponsor
- Program Code
- NIH grant funding mechanism
- NIH institute code
- Serial number
- NCI division/program code
- Current trial status
- Current trial status date
- Trial start date (actual or anticipated)
- Primary completion date (actual or anticipated)
- IND/IDE number
- IND/IDE grantor
- IND/IDE holder type
- Expanded access (yes/no)
- Expanded access type (if applicable)

- Study subject accrual information:
  - Submission title
  - Submission cut off date (MM/DD/YYYY)
  - Description
  - Study subject ID
  - Study subject birth date (MM/YYYY)*
  - Study subject gender
  - Study subject race
  - Study subject ethnicity
  - Study subject zip code*
  - Study subject country
  - Registration date (MM/DD/YYYY)
  - Study subject method of payment
  - Disease
  - Participating site name

All submitters will be expected to provide individual level study subject accrual information to the CTRP Database on a quarterly basis. The two asterisked elements, patient birth date and patient zip code, are considered "personally identifiable information" (PII).

However, as none of the data elements for individual level study subject data request individually identifying information, e.g., names, addresses, or phone numbers, NCI will not collect any individual information through CTRP that can be retrieved using personal identifiers (See Section A.10).

For purpose of clarification, it is noted that the data element "study subject ID" refers to a code assigned by an individual trial site where a research subject or patient is accrued on a study. The code is unique to the study subject within the context of the specific protocol but does not replace any individual identifiers and cannot be derived from any information related to the individual. Further, any key associated with such code will not be provided to NCI. Therefore, NCI will have no mechanism by which it can link information provided pursuant to this data element with an individual subject's identity. In other words, NCI will not receive any information from submitters which it could use with the PII to re-identify research subjects or patients.

The NCI Clinical Trials Reporting Office (CTRO), a new unit formed in the Office of the NCI Director to support the NCI's Clinical Trials Reporting Program, will extract additional information from submitted documents, including information describing any limitations on data use or limitations that may affect the submission or affect re-disclosures. Awardees will be responsible for reviewing any documents governing the conduct of study or use or disclosure of information collected during the study (e.g., informed consent documents, clinical trial agreements, material transfer agreements, and other sponsored funding or resource sharing agreements) and notifying NCI of any restrictions that could affect NCI's use or disclosure of the submitted information. With respect to trials subject to proprietary restrictions, awardees will only be expected to submit the protocol title, the name of the principal investigator, the sponsor,

and the accrual data listed above though additional information may be submitted voluntarily. In some instances, certain entities funded by NCI may be expected to submit additional information as compared to previous reporting patterns.

OMB approval pursuant to the Paperwork Reduction Act is currently requested for this revised information collection to extend the expiry date three years and to allow for capture of study subject accrual data. Over the next year, NCI intends to extend the CTRP Database to enable results reporting for registered trials. NCI will update this Paperwork Reduction Act submission prior to expansion of the CTRP Database to include data elements that are specified in connection with these subsequent development activities.

The portions of the NCI CTRP Database that pertain to the description of clinical research projects and summarized information on accrual will be publicly accessible. This availability will facilitate the cancer community's development of research proposals by providing up-to-date information on the existing portfolio of research activities, thereby reducing duplication of effort by accessing a full picture of the cancer clinical research enterprise. Patient accrual and recruitment will be enhanced through better physician/patient access to clinical research data. All nonpublic parts of the resource will be maintained confidentially in accordance with appropriate security access controls pursuant to applicable policies.

A.3 Use of Improved Information Technology and Burden Reduction

Development of the NCI CTRP Database is managed by the NCI Center for Biomedical Informatics and Information Technology (CBIIT) under its cancer Biomedical Informatics Grid (caBIG®) program; it is therefore built on a state-of-the-art information technology platform using a shareable, common semantic services-oriented architecture and compliant with current biomedical data standards such as HL7® Version 3 and CDISC®. A current Privacy Impact

Assessment (PIA) is in place for this IT System. The IT system name is, "NIH NCI Clinical Trials Reporting Program (CTRP)." A revised PIA is currently being processed due to the inclusion of personally identifiable information (see Section A.10).

The CTRP Database receives electronic data feeds from existing NCI systems to the extent available, thereby reducing the reporting burden. The data received from these systems represent the vast majority of trial registrations and accruals in the NCI-supported clinical research enterprise. For the remaining trials, the CTRP Database will support three methods for registration and reporting:

- Online registration, amendment of individual trials and submission of study subject accrual information via the CTRP web portal (see Attachment 2)
- Batch registration of multiple trials, uploadable directly to the CTRP Database via a Microsoft Excel file
- Direct connection of site systems to NCI Enterprise Services for seamless near-real-time update of the CTRP Database (to be available in the near future)

NCI's statutory collection obligations under the National Cancer Act, as well as its objective to consolidate existing reporting to individual programs within the NCI, aggregate the information already collected by these programs and eliminate the need for redundant submissions to the NCI, were major considerations in establishing this system. The CTRP Database has been designed so that as much as possible of the burden is shouldered by the staff of the NCI CTRO rather than by the respondent. In brief, the registration process is as follows:

1. The respondent registers the trial with the NCI Clinical Trials Portal (see Attachment 2) by entering the data elements identified above in Section A.2 and uploading the protocol document file. The system sends an electronic notification to staff at the CTRO that the protocol has been registered.
2. CTRO staff members perform quality control (QC) on the registration submission and then abstract the remaining protocol elements used by the CTRP Database. Other CTRO staff members perform quality assurance (QA) on a sample of abstracted data.

3. The system generates a "trial summary report", detailing the data that have been abstracted, and sends it via e-mail to the respondent for review. The coding letter e-mail message includes a "verification link" on which the respondent can click to either:

    a. approve the data as correct, or
    b. query, or request change, to abstracted data.

There is also a CTRP Registration Site User's Guide that has been updated recently which allows the users reference material should they need assistance during the registration or amendments of the clinical trials (Attachment 3).

A.4 Efforts to Identify Duplication and Use of Similar Information

The Clinical Trials Working Group conducted a comprehensive review of current systems managing protocol information at the NCI. Due to initial scope, purpose, and data structure, it was determined that a new comprehensive system was necessary to accommodate the evolving NCI clinical trials enterprise. Existing systems were determined to be inappropriate for the purpose of pan-NCI trial prioritization, management and monitoring. Accordingly, the NCAB approved the establishment of an electronic resource to address these needs.

The CTRP Database, which serves to modernize the existing cancer clinical trials reporting infrastructure previously instantiated through the NCI's PDQ/Cancer.gov clinical trials submission portal, is also designed as an operational database for active, efficient and ongoing prioritization and management of cancer clinical trials. For example, in terms of data elements, several key concepts, such as objectives and structured eligibility criteria, are embedded in the CTRP Database specifications. In addition, the CTRP Database allows the specification of data elements of interest within conditions (e.g., in cancer clinical stage, histological type, grade of tumor), or qualifiers (e.g., "unresectable", "localized", "recurrent"). With respect to timing of collection, the CTRP Database enables investigators to update current data elements quarterly nearly in real-time. Real-time

submission by NCI awardees of accrual, outcome and adverse event data directly into the CTRP Database is critical if NCI is to be able to perform this kind of portfolio management. Further, as the data elements relating to outcomes are finalized, NCI expects the scope of information to be solicited to be much broader and more detailed, given the role of the CTRP Database in terms of facilitating NCI's portfolio management responsibilities.

A.5 Impact on Small Businesses or Other Small Entities

The vast majority of data collection for clinical trials will involve NCI-designated Cancer Centers or other major medical centers. A small number of physicians in small practices conduct trials within the context of NCI Cooperative Groups.

A.6 Consequences of Collecting the Information Less Frequently

The initial registration of the protocol is a one-time event. However, consistent with regulatory and reporting requirements, updates to protocol/study information are accepted every time there is an amendment, i.e., a major scientific change requiring approval by the site's Institutional Review Board approval (IRB). Not collecting amendments will greatly compromise NCI's ability to prioritize and monitor the system.

The CTRP Database is designed to accept accrual data submissions on a quarterly basis, consistent with the schedule for NCI-sponsored trials in fulfillment of NCI's reporting obligations to the Food and Drug Administration. This synchronization is intended to minimize the burden of accrual reporting. Indeed, collecting accrual information less frequently could even increase the burden on NCI awardees as they might have to keep to two distinct schedules for different kinds of trials.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No special circumstances are anticipated.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments regarding the revision of the existing information collection and expansion to include new data elements prior to submission to OMB was published on November 9, 2009, Vol. 74, p. 57684-5. Two public comments were received. The first comment, received November 11, 2009, questioned the purpose and safety of clinical trials conducted outside of the United States. An email response was sent on January 6, 2010, acknowledging the commenter's concern. The response noted that the NCI's Clinical Trials Reporting Program is an information collection activity intended to assist the NCI in management of the NCI's clinical trials portfolio, which is global in nature. The response further stated that while CTRP is not directly related to the conduct of a clinical trial, the NCI hopes to use the information to facilitate routine review of safety, efficacy, and administrative data reported from on-going cancer trials. On January 6, 2010, the same commenter sent a subsequent comment concerning corruption in clinical trials conducted by large pharmaceutical companies. The NCI sent an email response on January 8, 2010 thanking the commenter for her additional comments and noting that they would be taken into consideration.

In addition, NCI has previously solicited and received public input from many sources, including direct input from NCI Advisory Boards and research organizations supported by the NCI, both of which include patient advocates (See Attachments 4A and 4B). In addition, the informational website for the NCI Clinical Trials Reporting Program provides a mechanism for ongoing and routine electronic communications with the public (http://www.cancer.gov/clinicaltrials/ctrp/page9.)

A.9 Explanation of Any Payment or Gift to Respondents

No gifts will be given to respondents, nor any such expectations set. However, in order to mitigate the burden associated with adjusting to this new reporting mechanism, the NCI intends to offer participating NCI-designated Cancer Centers administrative grant supplements for a minimum of 12 months. Other awardees are not expected to have significant costs during the first year of operation and therefore will be encouraged to estimate reporting costs in connection with submission of grant and contract proposals to the NCI.

A.10 Assurance of Confidentiality Provided to Respondents

All records in the possession or control of the NIH are subject to the Freedom of Information Act (FOIA), 5 U.S.C. §552, and must be released in response to a FOIA request unless NIH determines that the record is exempt from release under one of the FOIA's exemptions. Generally, NIH will seek to protect any information that if released would result in an unwarranted invasion of personal privacy as protected by FOIA Exemption 6, 5 USC §552(b)(6), including information that would identify a study subject or information that would lead to identification. If NIH receives a request for information that we believe contains information that may be exempt from release under FOIA Exemption 4, 5 USC §552(b)(4), we will give the submitter of the information an opportunity to demonstrate how release of the requested information could reasonably be expected to cause the submitter substantial competitive harm. NIH will give consideration to any such submission before making a determination on whether the information should be released. Since FOIA affords requesters an opportunity to contest an agency's determination, NCI grantees subject to this policy will be advised that records that are determined by NIH to be exempt could subsequently be required to be released in response to FOIA requests.

Although no personally identifiable information (PII) is submitted in connection with trial registration, the submission of accrual data will result in the collection of some PII, specifically, birth dates and zip codes. However, none of the CTRP Database data elements for study subject accrual request individually identifying information such as names, addresses, or phone numbers and therefore NCI will not be collecting any individual information through CTRP that can be retrieved using personal identifiers. Accordingly, the NIH Privacy Act Officer has determined that the Privacy Act does not apply to this information collection (see Attachment 5). This information collection has also been reviewed by NIH Office of Human Subjects Research (see Attachment 6).

NCI recognizes that in order to submit data to this resource, investigators and their institutions will need to comply with applicable institutional policies, local IRB rules as well as local, state and Federal laws and regulations, including *Standards for Privacy of Individually Identifiable Health Information and Security Standards for the Protection of Electronic Protected Health Information* (the HIPAA Privacy and Security Rules), 45 CFR Parts 160 and 164, *Basic HHS Policy for Protection of Human Research Subjects* (the Common Rule), 45 CFR Part 46 Subpart A, and FDA human subjects regulations, 21 CFR Parts 50 and 56). As NIH has stated in related policies concerning data sharing, the rights and privacy of people who participate in NIH-sponsored research must be protected at all times.

A.11 Justification for Sensitive Questions

No questions of a sensitive nature are included in this data collection.

A.12 Estimates of Annualized Burden Hours and Costs

The annualized burden for CTRP registration and amendments is estimated to require 38,500 hours, which amounts to 115,500 burden hours over the three year clearance period (see

Table A.12-1). A total number of 570 small, medium and large institutions are anticipated to complete the initial registration, amendments and accrual process during the year.

At these institutions, a varying number of clinical investigator designees will submit this information. As a result of the difficulty in estimating the number of designees submitting information per institution, it is more reasonable to account for the burden based on a per-trial basis. It is estimated that there will approximately 500 trials submitted from small entities and 5000 trials submitted from the medium to large institutions; this amounts to a total of 5,500 trials annually.

This burden estimate is very conservative because it assumes that no respondent will take advantage of the electronic batch upload features of the CTRP Database. As the NCI gains more experience with the program, it will be able to revise the burden estimate to reflect more accurately the actual time required for record-keeping.

A.12 - 1 Estimates of Annual Burden Hours

Type of Respondents	Survey Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hours)	Annual Burden Hours
Clinical Trials	Initial Registration	5,500	1	120/60 (2.0)	11,000
	Amendment	5,500	4	60/60 (1.0)	22,000
	Accrual Updates	5,500	4	15/60 (0.25)	5,500
Total		16,500			38,500

The annualized cost to the respondents is estimated at $1,347,500 (see Table A.12-2). This amounts to a total cost of approximately $4 million over the three year clearance period. The record-keeping burden represents an average time required for the initial registration and

amendments to the records. Cost estimates are based upon burden hours at an average cost of $35.00 per hour for clinical research administrators to complete the information.

A.12 - 2 Annualized Cost to Respondents

Type of Respondents	Survey Instrument	Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Clinical Trials	Initial Registration	11,000	$35	$385,000
	Amendments	22,000	$35	$770,000
	Accrual Updates	5,500	$35	$192,500
Totals		38,500	$35	$1,347,500

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no additional cost burden to the respondents and record-keepers.

A.14 Annualized Cost to the Federal Government

The operating budget for the CTRP Database in FY2010 is approximately $4.2 million, which includes NCI staff salaries, overheads and equipment. Additional costs will be entailed in operating the database when it is expanded to include results reporting due to the increased volume of information to be processed. Such costs are expected to be on the order of $2 million per year for the first two or three years of operation.

A.15 Explanation for Program Changes or Adjustments

This program change is being submitted as a revised information collection and includes the study subject accrual aspects of the information collection through the CTRP Database. This revision will result in an increase in burden hours and costs associated with this project. Deployment and extension of the CTRP Database is an infrastructure development project to be conducted pursuant to the American Recovery and Reinvestment Act.

A.16 Plans for Tabulation and Publication and Project Time Schedule

As noted in Section A.1, the 2005 report of the Clinical Trials Working Group envisioned an enhanced cancer clinical trials enterprise in which increased participation by the extramural community in the prioritization process more effectively focuses resources on those trials judged most likely to facilitate advances in treatment. The Clinical Trials Reporting Program is thus the information platform for this prioritization process. In the four years since the publication of the report, NCI has established the infrastructure for providing the process, by establishing an Investigational Drug Steering Committee and multiple Disease-Specific Steering Committees, all of which operate under the aegis of NCI's Clinical Trials Advisory Committee (CTAC), a federally approved advisory committee overseeing the implementation of all 22 recommendations of the Clinical Trials Working Group. The lack of availability of data from the CTRP Database is the single critical roadblock to NCI being able to use this infrastructure to effectively prioritize the nation's investment in cancer research. Accordingly, NCI needs to deploy this resource as fast as possible while minimizing disruption to the active conduct of clinical trials within the NCI-supported clinical research enterprise. In order to enable this, the CTRP Database will be deployed in phases. The proposed time schedule for implementation of CTRP is shown in Table A.16-1.

Table A.16-1: Implementation Time Schedule		
Activity	**Start Date after OMB Approval***	**Completion Date after OMB Approval**
Pilot Testing of CTRP Database		
Registration of New Trials	Immediately	5 months
Registration of Existing Trials	3 months	12 months
Submission of Study Subject Accrual Information	Immediately	Ongoing
Production Deployment of CTRP Database		
Registration of New Trials	4 to 8 months	Ongoing
Registration of Existing Trials	7 to 11 months	14 to 17 months
Submission of Study Subject Accrual Information	2 to 4 months	Ongoing

**OMB approval dates for trial registration and submission of study subject accrual data are different. Registration of new and existing trials was approved July 1, 2009 under OMB# 0925-0600; OMB approval for study subject accrual information is pending with the current request.*

Access to data in the NCI CTRP Database will be provided as follows:

Access for NCI program and administrative staff (in order to provide reports as needed for NCI's prioritization infrastructure): Full access to the data within the CTRP Database will be provided to designated, appropriate NCI employee and contractor staff for purposes of portfolio management and compliance with regulatory and administrative reporting obligations. Access will be limited to those with a direct need to access the data. Access will be granted to non-Federal staff under a non-disclosure agreement and staff will be given mandatory privacy and security training.

Public access: Appropriate open access to protocol registration information and summary level patient accrual and outcomes information will be provided to all persons not described above, including NCI intramural researchers.

Access for submitters: Individual submitters will have full access to information they have submitted; institutions of individual submitters will have access to tools that gather and present the accumulated data submitted by their individual investigators. Some cancer centers have indicated to NCI that the CTRP Database will be useful to them in order for them to manage their own clinical research portfolios.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

All instruments will display the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.