Supporting Statement A for

The Clinical Trials Reporting Program (CTRP) Database (NCI)

OMB #0925-0600, Expiration Date 5/31/2016

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Yellow highlights indicate changes from the previous submission.

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Check off which applies:

- ▪ New
- X Revision
- ▪ Reinstatement with Change
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A. Justification

This is a request for a revision of the "The Clinical Trials Reporting Program (CTRP) Database" for an additional three years. CTRP is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP website to complete the initial trial registration for each protocol. Subsequent to registration, up to four amendments and four study subject accrual updates occur per protocol annually. This request is for approval of the aesthetic changes to the website and the technology that currently supports this information collection. There are no changes to the questions asked or the order in which the information is collected.

A.1 Circumstances Making the Collection of Information Necessary

The National Cancer Institute (NCI) developed the Clinical Trials Reporting Program (CTRP) Database (http://www.cancer.gov/clinicaltrials/search) 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 was enabled by public funds expended pursuant to the American Recovery and Reinvestment Act of 2009. In addition, deployment of this resource has allowed the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research.

In 2005, the National Cancer Advisory Board (NCAB) (see **Attachment 1**), 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 (see **Attachment 2**) 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.

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).*

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 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.

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. In the past three years CTRP has collected information on thousands of clinical trials that receive funding support from NCI, and has fully implemented the design as specified in the 2011 AACI CTRP Strategic Subcommittee report (see

Attachment 11) and presented to the NCI's Clinical Trials and Translational Research Advisory Committee (CTAC) (see **Attachment 1**).

This information provides NCI with a near real-time picture, not previously available, of the NCI-supported cancer clinical enterprise. CTRP provides NCI detailed information on the clinical trial activity at NCI-designated Cancer Centers, a program which comprises a significant portion of the NCI clinical research investment. This information has previously only been available in summary form in an unstructured format that didn't support analysis or comparison across the Cancer Centers and the rest of the NCI clinical research program such as the national networks. NCI's disease specific steering committees, managed by the NCI's Coordinating Center for Clinical Trials, use the active trial data in CTRP in their comparative analysis of proposed trials, comparing by disease, intervention, biomarker, etc., to help determine which proposed trials should be approved. In addition, in 2015 NCI changed the source of the NCI Cancer.gov clinical trials search utility, http://www.cancer.gov/about-cancer/treatment/clinical-trials/search, to CTRP to ensure prioritized display of and accurate information is available for NCI-support cancer clinical trials. This will help promote visibility of and accrual to NCI clinical trials, and is a resource for researchers and the public interested in the NCI clinical trial portfolio.

The approval of this information collection will allow NCI to improve the user interface and functionality of this system, and continue to maintain up to date information on its portfolio of clinical trials.

A.2 Purpose and Use of the Information Collection

The CTRP Database provides a comprehensive real-time view of the state of NCI-funded cancer clinical trials, which enables NCI to make informed prioritization decisions via disease-specific steering committees. Accordingly, this resource allows 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;
- Provide appropriate public access to cancer research information;
- Streamline the reporting burden for grantees;
- Enable Investigators to be aware of trials addressing similar questions that are already completed or in process to avoid duplication of efforts; and,
- Provide Researchers with a comprehensive view of the clinical research enterprise which supports the cancer research community's ability to prioritize efforts.

In order to achieve these objectives, the resource contains information that is structured to facilitate comparison across trials and that complies with Federal guidelines related to health information standards. The information is 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 contains 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 contains 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. In addition, information about the protocol registration (including lead organization, principal investigator, responsible party, trial type and purpose, etc.) and study subject accrual elements (date of birth, race/ethnicity, gender, and zip code) are collected. **Attachment 3a** details the trial registration process using the CTRP web interface. Respondents can use **Attachment 3a** on the web interface or complete both **Attachments 5a** and **5b** Excel files to complete registration. The web interface will take an hour and the completion of the two Excel forms will take a total of one hour (or half an hour each for each Excel files). **Attachment 3b** details the trial update process, a trial may be updated if only minor changes are required such as a status update. **Attachment 3c** details the trial amendment process. A trial amendment is a significant scientific change which requires IRB approval, the amendment requires submission of the revised protocol document, and a trial may be updated during the amendment process. Depending on the type of trial, **Attachment 3d** details the process for web-based study subject level detailed accrual reporting, **Attachment 3e** details aggregate accrual (cumulative count) reporting. An Institutional trial, i.e. a trial led by an NCI-designated Cancer Center, would require detail study subject level accrual reporting. Whereas an Industrial trial, i.e. a trial sponsored and led by a pharmaceutical company where the Cancer Center is a participant, requires aggregate reporting. Note that most accrual submissions use the CTRP Accrual Batch File Tool (**Attachment 5C**) which is an Excel template for a system-generated report; this system reporting method significantly reduces the burden of accrual reporting.

The NCI Clinical Trials Reporting Office (CTRO), a unit in the Office of the NCI Director, supports the NCI's CTRP, extracts 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 are 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 are 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.

Since the last approval, the portions of the NCI CTRP Database that pertain to the description of clinical research projects have been made publicly accessible via the NCI's Cancer.gov clinical trials search website, http://www.cancer.gov/clinicaltrials/search. The NCI is researching how it might be possible to make summarized information on accrual publicly accessible. This availability facilitates 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, how to provide such access is being explored. All nonpublic parts of the resource will be maintained confidentially in accordance with appropriate security access controls pursuant to applicable policies.

While no additional information is being collected beyond that which was submitted in the previous application, significant effort has been made by the NCI to continue to further improve the reporting process within CTRP, via backend system enhancements to improve system response times, streamlined user interfaces based on analysis of user interactions and feedback from the user community, and extensive communications and training efforts with the user community.

A.3 Use of Information Technology and Burden Reduction

Development of the NCI CTRP Database is managed by the NCI Center for Biomedical Informatics and Information Technology (CBIIT); it is built on a state-of-the-art information technology platform using a common, web-based services architecture and compliant with current biomedical data standards such as HL7® Version 3 and CDISC®. A current Privacy Impact Assessment (PIA) is in place and the IT system name is, "NIH NCI Enterprise Services and Clinical Trials Reporting Program" (see **Attachment 4**).

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, study subject accrual reporting, and ongoing reporting:

- Online registration, update, and amendment of individual trials and submission of study subject accrual information via the CTRP web portal (see **Attachments 3a – 3e**)
- Batch registration, update, and amendment of multiple trials, and batch submission of study subject accrual information, uploadable directly to the CTRP Database via a Microsoft Excel file
- System to system connection via CTRP REST web-based services for seamless near-real-time update of the CTRP Database

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 3**) 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.

The NCI has worked with the user community to develop study subject accrual reporting mechanisms which are similar to those already in place for reporting on NCI sponsored clinical trials to the NCI, reporting on these trials is done separately via established mechanisms and that information is supplied to CTRP electronically within the NCI to reduce reporting burden. The primary mechanism used for accrual reporting is a series of excel templates (see **Attachment 5c**) though a web interface is provided for trials/sites with minimal study subject accrual (see **Attachment 3d**).

There is also a CTRP Registration Site User's Guide (see **Attachment 6**) and CTRP Accrual User's Guide (**Attachment 7**) which provides the users reference material should they need assistance during the registration or amendments of the clinical trials and submission of study subject accrual information.

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.

CTRP remains unique today, in terms of the scope of and focus on cancer clinical trials, the information about those trials, and the consistent abstraction and structured approach to data capture applied by the NCI. Alternative systems such as the National Library of Medicine's (NLM) ClinicalTrials.gov do not focus on cancer clinical trials, do not use cancer-specific ontologies for indexing trial data such as disease, nor do they capture NCI-specific information such as the funding program which is important for NCI's portfolio management.

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 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 involves NCI-designated Cancer Centers or other major medical centers. A small number of physicians in small practices conduct trials within the context of NCI Clinical Trials Networks and Consortia, e.g. National Clinical Trials Network (NCTN), Experimental Therapeutics Clinical Trials Network (ETCTN), NCI Community Oncology Research Program (NCORP); but these individuals will not have any additional burden as they do not report directly to the CTRP Database.

A.6 Consequences of Collecting the Information Less Frequently

The initial registration occurs once per protocol and it is estimated that there will be up to 3,000 protocol registrations per year.

For each protocol, consistent with regulatory and reporting requirements, respondents must supply an update to protocol/study information every time there is an amendment or a change in recruitment status. After analysis of the number of amendments and updates over the past couple of years, amendments and updates occurred up to four (4) times per protocol per year for some protocols. Not collecting updates and amendments will greatly compromise NCI’s ability to prioritize and monitor the system.

For accrual information reporting, the CTRP Database is designed to accept 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.8.1 Comments in Response to the Federal Register Notice

The 60-Day Federal Register notice soliciting comments regarding the extension of the existing information collection prior to submission to OMB was published on March 11, 2016 (Volume 81, page 12914). No public comments were received.

A.8.2 Efforts to Consult Outside Agency

In the past, NCI has 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 1 and 8**). 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/about-nci/organization/ccct/ctrp). In 2010, the Clinical Trials Reporting Program (CTRP) Strategic Subcommittee, co-chaired by Dr. Kevin Cullen, Director, University of Maryland Greenebaum Cancer Center, and Dr. Sheila Prindiville, Director, Coordinating Center for Clinical Trials, NCI, was formed in collaboration with members of the NCI cancer research community, leadership of NCI designated Cancer Centers and the AACI. The charge of the subcommittee was to identify current and estimated future workload and timeframe to meet CTRP information requirements for: 1) registration; 2) accrual (summary, patient level with demographics, disease coding); and 3) outcomes (see **Attachment 11**).

Ongoing consultation with NCI designated Cancer Centers occurs via quarterly CTRP User Calls, https://wiki.nci.nih.gov/display/CTRP/Site+Meeting+Minutes, attendance is voluntary. Through these calls and other interactions with NCI designated Cancer Centers as part of their regular reporting to and use of the system, NCI has continuously received feedback on the system interface and the reporting process. Feedback has included requested enhancements such as: improving system response time, making it easier for Cancer Centers to access and review the trials which they have submitted, improved messaging/communications on submission status, the ability to import trial information and indicate site participation, and general improvements to the user interface.

A.9 Explanation of Any Payment of Gift to Respondents

No gifts will be given to respondents, nor any such expectations set.

A.10 Assurance of Confidentiality Provided to Respondents

All information will be kept private to the extent allowable by law. Personally identifiable information (PII) will be collected in the form of individual level study subject information on a quarterly basis, (e.g., patient birth date, patient zip code, patient gender and race/ethnicity), this information cannot be retrieved using personal identifiers. Additionally, individually identifying information such as names, addresses, and phone numbers, are not collected.

"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 is not provided to NCI. Therefore, NCI has no mechanism by which it can link information provided pursuant to this data element with an individual subject's identity. Thus, NCI does not receive any information from submitters which it could use with the PII to re-identify research subjects or patients. The NIH Privacy Act Officer has determined that the Privacy Act does not apply to this information collection (see **Attachment 10**).

This information collection has also been reviewed by NIH Office of Human Subjects Research (see **Attachment 9**).

A.11 Justification for Sensitive Questions

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

A.12.1 Estimated Annualized Burden Hours

The annualized burden for CTRP registration, updates and amendments, and accrual is estimated to require 18,000 hours, which amounts to 54,000 burden hours over the three-year clearance period (see Table A.12-1).

It is estimated that there will be approximately 500 trials submitted from small institutions and 2,500 trials submitted from the medium to large institutions; this amounts to a total of 3,000 trials annually. 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 amendments (major scientific change requiring IRB approval) and/or updates (minor changes such as trial status which do not require IRB approval) will occur up to four (4) times per year. However, some protocols have no changes and others change more frequently.

In addition to trial registration, updates and amendments; institutions are expected to report accrual quarterly on the approximately 3,000 trials. Accrual reporting entails providing demographic information at the study subject level and the aggregate numbers are the cumulative count depending on the trial type.

This burden estimate is very conservative because it assumes that no respondent will take advantage of the electronic batch upload or service features of the CTRP Database.

Type of Respondents	Form	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Clinical Trials	Initial Registration (Attachment 3a or 5a & 5b)	3,000	1	1	3,000
	Amendment (Attachment 3c)	1,500	4	1	6,000
	Update (Attachment 3b)	1,500	4	1	6,000
	Accrual Updates (Attachment 5c or 3d or 3e)	3,000	4	15/60	3000
Total		9,000	27,000		18,000

A.12-2 Annualized Cost to Respondents

The annualized cost to the respondents is estimated at $352,620 (see Table A.12-2). Cost estimates are based upon burden hours at an average cost of $19.59 per hour for clinical research administrators to complete the information. This hourly rate is based on the Bureau of Labor Statistics' rate for "Medical and

Clinical Lab Technicians" (29-2012) – mean hourly wage rate of $19.59. http://www.bls.gov/oes/current/oes292012.htm. This amounts to a total cost of approximately $1.06 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.

A.12 - 2 Annualized Cost to Respondents				
Type of Respondents	Form	Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Clinical Trials	Initial Registration	3,000	$19.59	$58,770
	Updates/Amendments	12,000	$19.59	$235,080
	Accrual Updates	3,000	$19.59	$58,770
Totals		18,000		$352,620

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

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

A.14 Annualized Cost to the Federal Government

The annualized cost to the government is $6.3 million. This includes NCI staff salaries, overheads and contractors. The contractor costs are composed of three components: Development, the Operations office (CTRO) which is responsible for abstraction and maintenance of submitted clinical trial protocol data, and Program Support which is responsible for program coordination and data analysis.

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Personnel Costs					**$30,740.40**
NIH Project Oversight Officer	15 / 6	$153,702	20%		$30,740.40
Contractor Cost					**$6,267,520.12**
CTRP Development Team			100%		2,313,028.52
CTRO Team 28 person team			100%		2,737,417.60

Program Support Team 7 person team			100%		1,217,074.00
Travel					**N/A**
Other Cost					**N/A**
Total					**$6,298,260.52**

A.15 Explanation for Program Changes or Adjustments

This application seeks a revision for an additional 3 more years. Changes to the program have focused on improving system performance, reporting capability to support NCI information needs, and user interface enhancements. There are no changes to the information collected and no new data elements have been added.

In the 2013 OMB submission, it was estimated there would be about 5,500 trial registrations submitted annually. This estimate was due to clinical research administrators catching up on a backlog of trials considered in scope for CTRP registration. Now that all the administrators are current with trial registration, and after several years of monitoring submission rates, it is apparent that the number of annual clinical trial submissions does not exceed 3,000 trials submitted annually. This amounts to a decrease of 2,500 clinical trial submissions/year. This information collection request is proposing 18,000 burden hours which is a decrease in 15,000 burden hours from the original 33,000 approved burden hours in the previous information collection request.

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

There are no plans for tabulation.

CTRP is fully deployed and registration, amendments and updates occur 4 times per year and will continue to occur.

Table A.16-1: Implementation Time Schedule

Activity	Start Date after OMB Approval	Completion Date after OMB Approval
Production Deployment of CTRP Database		
Registration and Updates/Amendments of New Trials	Immediately	Ongoing
Submission of Study Subject Accrual Information	Immediately	Ongoing

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

All instruments display the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions: None

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