

## Supporting Statement A for

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

Date: March 3, 2026

OMB #0925-0600, Expiration Date 02/28/2026

Yellow highlights indicate changes from the previous submission.

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing Collection in Use Without an OMB Number

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## **Table of contents**

A.	JUSTIFICATION	1
A.1	Circumstances Making the Collection of Information Necessary	1
A.2.	Purpose and Use of the Information Collection	5
A.3	Use of Information Technology and Burden Reduction	7
A.4	Efforts to Identify Duplication and Use of Similar Information	8
A.5	Impact on Small Businesses or Other Small Entities	9
A.6	Consequences of Collecting the Information Less Frequently	9
A.7	Special Circumstances Relating to the Guidelines of 5 CFR 1320.5	9
A.8	Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency	9
A.9	Explanation of Any Payment of Gift to Respondents	10
A.10	Assurance of Confidentiality Provided to Respondents	10
A.11	Justification for Sensitive Questions	11
A.12	Estimates of Hour Burden Including Annualized Hourly Costs	11
A.13	Estimate of Other Total Annual Cost Burden to Respondents or Record keepers	12
A.14	Annualized Cost to the Federal Government	12
A.15	Explanation for Program Changes or Adjustments	12
A.16	Plans for Tabulation and Publication and Project Time Schedule	13
A.17	Reason(s) Display of OMB Expiration Date is Inappropriate	13
A.18	Exceptions to Certification for Paperwork Reduction Act Submissions	13

## List of Attachments

Attachment 1 – NCI Advisory Boards

Attachment 2 – NCI Clinical Trials Working Group Report

### Attachment 3 – NCI CTRP Application Workflow and Screen Shots

Attachment 3A – CTRP Initial Trial Registration Workflow and Screen Shots

Attachment 3B – CTRP Trial Registration Update Workflow and Screen Shots

Attachment 3C – CTRP Trial Registration Amendment Workflow and Screen Shots

Attachment 3D – CTRP Accrual Workflow and Screen Shots

Attachment 3E – CTRP Aggregate Accrual Workflow and Screen Shots

### Attachment 4 – CTRP Privacy Impact Assessment

### Attachment 5 – CTRP Batch Submission Templates

Attachment 5A – CTRP Trial Registration Participating Sites

Attachment 5B – CTRP Accrual Batch File Tool

### Attachment 6 – NCI CTRP Registration Site User's Guide

### Attachment 7 – NCI CTRP Accrual Site User's Guide 2026

Attachment 8 – Organizations Outside NCI

Attachment 9 – NIH OHSR Statement of Exemption

### Attachment 10 - Memo from NIH Privacy Act Officer

Attachment 11 – CTRP Strategic Subcommittee Report

## A. Justification

This is a request for OMB to approve a Reinstatement With Change 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 a Reinstatement With Change of information collection.

### A.1 Circumstances Making the Collection of Information Necessary

The National Cancer Institute (NCI) developed the Clinical Trials Reporting Program (CTRP) Database (<https://www.cancer.gov/about-nci/organization/ccct/ctrp>) 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 revision 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, the 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 and Translational Research Operations 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 the 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 a 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, and leveraging the most significant scientific advances. It will also enhance the 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. CTRP has fully implemented the design as specified in the 2011 AACI CTRP Strategic Subcommittee report (see **Attachment 11**) and presented it to the NCI's Clinical Trials and Translational Research Advisory Committee (CTAC) (see **Attachment 1**). CTRP has implemented recommended changes to the structure and output of the database in order to make the data more accessible in response to the 2017 NCI Clinical Trials Informatics Working Group (CTIWG) report presented to the NCI CTAC. These changes included:

- Development of query and reporting tools to facilitate NCI and public access to CTRP data
- Making non-proprietary biomarker information in CTRP publicly available
- Making aggregate accrual data in CTRP publicly available as appropriate

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 that 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 the 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 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 a 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 the 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, purpose, etc.) and study subject accrual elements (date of birth, race/ethnicity, sex, and zip code) are collected. **Attachment 3a details the initial trial registration process using the CTRP web interface. Respondents can use Attachment 3a on the web interface in combination with Attachment 5a Excel file (Participating Sites) to complete registration. 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 that 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 detailed 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 5b) 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, and 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 the 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 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 collection of information has gone smoothly and as expected.** Responses, and information submitted to the system, have been supportive of meeting NCI's mission by providing the NCI with a comprehensive and up-to-date view of the NCI-supported clinical trial portfolio. Furthermore, 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> as part of the Cancer Moonshot Initiative. This information helps the public, including cancer patients, find information on cancer clinical trials. All nonpublic parts of the resource are maintained confidentially in accordance with appropriate security access controls pursuant to applicable policies.

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 summary of changes to information collection are provided in Section A15.

### 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<sup>®</sup> and CDISC<sup>®</sup>. A current Privacy Impact Assessment (PIA) is in place and the IT system name is, "NIH NCI Enterprise Services and Clinical Trials Reporting Program" which was updated in May of 2025 (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 submission of study subject accrual information (see Attachment 5b)
- System to system connection via CTRP REST web-based services for a 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 3a) 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 that 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 5b**) 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 2026 (**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 the 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 the 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 the 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 three (3) 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**

There are no special circumstances relating to the guidelines of 5 CFR 1320.5 that would impact the information collection.

### **A.8.1 Comments in Response to the Federal Register Notice Agency**

**The 60-day Federal Register notice soliciting comments was published on December 23, 2025, Vol. 90, No. 244, Page 60112. No comments were received.**

### **A.8.2 Efforts to Consult Outside Agency**

NCI regularly solicits and receives 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, the 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**).

## **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 sex, 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 the information provided pursuant to this data element with an individual subject’s identity. Thus, NCI does not receive any information from submitters that 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 the 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 Estimates of Hour Burden Including Annualized Hourly Costs**

The estimated annualized burden for CTRP registration, updates, 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 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 changes requiring IRB approval) and/or updates (minor changes such as trial status which do not require IRB approval) will occur up to three (3) 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.

**Table 12-1 Estimated Annualized Burden Hours**

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hours
Initial Trial Registration (Attachment 3a or 3a & 5a <sup>1</sup> )	Individuals	3,000	1	1	3,000
Trial Registration Update (Attachment 3b)		1,500	3	1	4,500
Trial Registration Amendment (Attachment 3c)		1,500	3	1	4,500
Accrual Updates (Attachments 3d or 3e or 5b)		3,000	4	30/60	6,000
<b>Totals</b>		<b>9,000</b>	<b>24,000</b>		<b>18,000</b>

**A.12-2 Annualized Cost to Respondents**

The annualized cost to the respondents is estimated at \$565,380.00 (see Table A.12-2).

**Table 12-2 Annual Cost to Respondent**

Type of Respondent	Annual Burden Hours	Hourly Wage Rate *	Respondent Cost
Individuals	18,000	\$31.41	\$565,380.00
<b>Total</b>			<b>\$565,380.00</b>

\*Cost estimates are based on the Bureau of Labor Statistics rate for "Clinical Laboratory Technologists and Technicians" (29-2010). <https://data.bls.gov/oes/#/industry/000000> This amounts to a total cost of approximately \$1,696,140.00 million over the three-year clearance period.

**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 \$6,412,305.66. This includes NCI staff salaries, overheads, and contractors.

<sup>1</sup> Note: 3a & 5a combined is estimated to take up to 1-hour average response time.

Staff	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>					
NIH Project Oversight Officer	15 / 10	\$197,200	20%		\$39,440
<b>Contractor Cost</b>					\$6,373,265.66
Overhead/Supplies					\$0
Other Cost					\$0
<b>Total</b>					<b>\$6,412,704.66</b>

\*\*The salary in the table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/26Tables/html/DCB.aspx>

### A.15 Explanation for Program Changes or Adjustments

This is a Reinstatement With Change submission. Changes are noted in the table below.

Item Change	Explanation
Removal of CTRP Registry Complete Batch Template	In 2022 "CTRP_Registry_Complete_Batch_Template 5.10.22.xlsm" was included in the 2022 PRA submission and was labeled as Attachment 5a. CTRP never implemented the batch registration process and there are no plans to implement a batch registration process in the next 3 years. We are removing the "CTRP Registry Complete Batch Template" from the 2025 PRA submission to provide a more accurate representation of the current and planned future state.
Renamed Attachment 5 series	Updated identification labels in 2025 submission: <ul style="list-style-type: none"> <li>Attachment 5a is now "CTRP Trial Registration Participating Sites 2026"</li> <li>Attachment 5b is now- "CTRP Accrual Batch File Tool 2026"</li> </ul>
Changed Gender to Sex	The word "Gender" was changed to "Sex" to comply with Executive Order 14168. These are shown in the following Attachments: <ul style="list-style-type: none"> <li>Attachment 3d - CTRP Accrual Screenshots 2026.pdf Attachment 5b Accrual Batch File Tool 2026.xlsm</li> <li>Attachment 7 - CTRP Accrual User Guide 2026</li> </ul>
SSA: Updated Tables A12-2 &14	Annual updates to cost of living for federal and labor costs. Removed burden of registering trials via batch upload. Updated footnote.
Attachment 3a - CTRP Initial Trial Registration Screenshots 2026.pdf	Data Elements Now Showing in Application: <ul style="list-style-type: none"> <li>Institutional Review Board (IRB) Section now included</li> </ul>
Attachment 3b - CTRP Trial Registration Update Screenshots 2026.pdf	Screen Changes: <ul style="list-style-type: none"> <li>All previous Submission "Search Clinical Trials" data elements are now included across 2 tabs for easier user searching: "Search Clinical Trials" tab and "Trials to Verify" tab. Organization and display of certain data elements have been modified;</li> </ul> Data Elements No Longer Showing in Application: <ul style="list-style-type: none"> <li>DCP Identifier</li> </ul> Data Elements Now Showing in Application: <ul style="list-style-type: none"> <li>Investigator</li> <li>Investigator Title</li> <li>Investigator Affiliation</li> <li>Institutional Review Board (IRB) Section</li> <li>Trial Data Verifications Section</li> <li>FDA IND/IDE information for applicable trials Section</li> </ul>

Attachment 3c - CTRP Trial Registration Amendment Screenshots 2026.pdf	<p>Screen Changes:</p> <ul style="list-style-type: none"> <li>All previous Submission "Search Clinical Trials" data elements are now included across 2 tabs for easier user searching: "Search Clinical Trials" tab and "Trials to Verify" tab. Organization and display of certain data elements have been modified:</li> </ul> <p>Data Elements No Longer Showing in Application:</p> <ul style="list-style-type: none"> <li>DCP Identifier</li> </ul> <p>Data Elements Now Showing in Application:</p> <ul style="list-style-type: none"> <li>Institutional Review Board (IRB) Section</li> </ul>
Attachment 5b: CTRP Accrual Batch File Tool	<p>Changed Maximum Age  Changed Gender to Sex  Updated Disclaimer</p>

**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 multiple times per year and will continue to occur.

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

There is no request for exemption from displaying the expiration date for OMB approval.

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

There are no exceptions to the Certification for Paperwork Reduction Act Submissions.