Supporting Statement A for

CTEP Branch and Support Contracts Forms and Surveys

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Michael Montello, Pharm. D.
Cancer Therapy Evaluation Program (CTEP)
Division of Cancer Treatment and Diagnosis (DCTD)
National Cancer Institute
9609 Medical Center Drive
Rockville, MD 20850
Phone: (240) 276-6080
Fax: (240) 276-7892
Email: montellom@mail.nih.gov

Check off which applies:

- New
- X Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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    - Data Management
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A. JUSTIFICATION

This is a revised information collection for OMB control number #0925-0753, expiration 6/30/2020 for three years. The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP implements programs to register clinical site investigators and clinical site staff, and to oversee the conduct of research at the clinical sites. CTEP and DCP also oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The combined systems and processes for initiating and managing clinical trials is termed the Clinical Oncology Research Enterprise (CORE) and represents an integrated set of information systems and processes which support investigator registration, trial oversight, patient enrollment, and clinical data collection. The information collected is required to ensure compliance with applicable federal regulations governing the conduct of human subjects research (45 CFR 46 and 21 CRF 50), and when CTEP acts as the Investigational New Drug (IND) holder (FDA regulations pertaining to the sponsor of clinical trials and the selection of qualified investigators under 21 CRF 312.53). Information is also collected through surveys to assess satisfaction, provide feedback to guide improvements with processes and technology, and assess health professional's interests in clinical trials.

A.1 Circumstances Making the Collection of Information Necessary

The Public Health Service Act, and Section 413 (42 USC § 285a) authorizes NCI to establish and support programs to facilitate the participation of qualified investigators on CTEP and DCP supported studies, and to institute programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program.

The Public Health Service Act, Section 411 (42 USC § 285a) authorizes the National Cancer Institute (NCI) to collect information in order to develop a National Cancer Program which consists of "an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute," as well as " other programs and activities of the Institute." This scope of work includes programs to register qualified investigators, provide a Central Institutional Review Board, provide administrative support, and maintain a quality assurance program which includes onsite auditing of participating clinical sites. There is significant information system and process integrations between the branches and contractors represented in this submission. For example, the maintenance of institution and person roster information by the CTSU is based upon the investigator and clinical site staff registrations managed by the Pharmaceutical Management Branch (PMB). The institution roster information maintained by the CTSU is in turn integrated with the Clinical Trials Monitoring Branch (CTMB) Audit Information System (AIS) to schedule and document onsite audits. The integration of these processes minimizes redundancy, and reduces the overall cost of maintaining a robust treatment and prevention trials program.

The CTSU was established by the NCI to reduce redundancy and administrative burden. The CTSU provides central regulatory review services, institution and person roster services, central posting of clinical trial protocols and related document, data management, and patient enrollment services. In addition, CTSU develops and maintains systems to support each of the above listed activities and integrates with several other CTEP systems.

The CIRB is operated through the Cancer Therapy Evaluation Program (CTEP), within the Division of Cancer Treatment and Diagnosis at NCI. The CIRB is an NCI Initiative utilizing the time and expertise of Board members that are representative of the oncology community outside of the NCI. The NCI provides funding as well as logistical and operational support to the CIRB. This support is handled by CTEP and its contractors. While the CIRB reviews CTEP sponsored studies, CIRB Board members or reviewers are not affiliated with CTEP, nor does CTEP's support of the CIRB influence CIRB Member decision making. The CTSU is operated through CTEP but does not utilize expertise or staffing outside of contractor or subcontract staff.

CTMB is a branch of CTEP and is responsible for ensuring the quality of data for CTEP-sponsored trials through training, quality reviews, and a robust auditing program. Participating clinical sites are audited at least once every 36 months by each of the member National Clinical Trials Network (NCTN) Groups and the NCORP Research bases. The scheduling, results and follow up of each audit are tracking in AIS.

PMB is a branch of CTEP and is responsible for the management of investigational agents on CTEP-sponsored research including the registration of qualified investigators and other clinical research staff key to the conduct of trials at participating sites. PMB is currently approved by OMB (0925-0613 expiration 3/31/2019) for collection of annual registration information from participating investigators. Inclusion in this revision is for the automation of investigator registration process and use of the electronic system to enhance registration of key staff at the clinical sites.

CTIS, Inc. is the CTEP contractor responsible for the development and maintenance of the CTEP Enterprise system including the AIS, Drug Authorization, Review and Tracking System (DARTS) and Registration and Credential Repository (RCR). CTIS staff work closely with the technical teams at the CTSU and CIRB to facilitate system integration.

A.2 Purpose and Use of the Information Collection

This information collection is proposed to fulfill responsibilities of the National Cancer Institute (NCI). It includes modifications to OMB-approved forms, removal of previously approved forms that are no longer in use, addition of electronic forms, and the addition of forms that were previously approved under another submission. Removal of obsolete forms reduces the burden on NCI, their contractors, and clinical sites participating on trials. Use of electronic forms and submissions also reduces the

burden and cost on participating clinical sites as electronic forms can be completed more quickly, saved for future use, and it removes any burden associated with the cost of mailing or shipping paper forms. The consolidation of forms from the PMB and CTMB in this submission reduces the administrative burden and cost on NCI staff and contractors to maintain approval under the Paperwork Reduction Act (PRA).

A detailed description of each form/survey collected is given by area in the next section.

CTSU

The CTSU has established services for providing protocol and program information to the participating clinical sites, NCI, NCI grant holders, and NCI contracting staff including CIRB. To ensure consistency in processing of information and to guarantee the quality of the information collected, CTSU has instituted standard forms. Standard CTSU forms are collected to facilitate many activities. CTSU forms were developed to ensure that data is collected in a consistent manner for specific project tasks. These tasks are critical to project functions such as the collection of participating site regulatory information, patient accrual, and data collection.

CTSU Forms: The CTSU standard forms fall into six categories: Regulatory, Membership, Data Management, Patient Enrollment, Administrative, and Delegation of Task Log (DTL).

CTSU Regulatory Forms (Attachments A01-A04)

The Regulatory documents have been created to collect information required to ensure institutions participating in CTEP-supported clinical trials have received Institutional Review Board (IRB) approval. Minor wording and formatting updates were made to form A01-A04 to improve form flow and enhance user instruction. There are no changes in the annual burden of data collection due to these changes.

- Attachment A01 – CTSU IRB/Regulatory Approval Transmittal Form
- Attachment A02 – CTSU IRB Certification Form
- Attachment A03 – Optional Form 1 – Withdrawal from Protocol Participation Form
- Attachment A04 – Site Addition form

The CTSU processes approximately 6,500 packets of regulatory-related submissions per month for all NCI-supported phase I, II and III NCTN, Experimental Therapeutics Clinical Trial Network (ETCTN), and other supported network studies. Regulatory packets are a mix of IRB approvals, protocol specific requirements (PSRs), or both. Packets can be submitted as part of the automated link between the CIRB and CTSU, or by the local site via email, fax, or website upload. Packets can range from a single site submitting documentation on a single protocol to a large local network such as the Southeast Cancer Consortium submitting local annual renewal documentation on multiple sites (80+) and multiple studies. The regulatory data is shared with CTEP, other CTSU systems such as OPEN, and the

NCTN Groups in near real time to support patient enrollments, drug shipment, and data management.

Regulatory processing is facilitated by systems integration with CIRB's IRBManager system, which pushes IRB approval data for participating sites to the Regulatory Support System (RSS), thereby eliminating the need for sites to submit a separate approval to the CTSU Regulatory Office. CIRB IRB approvals are averaging 60% of the total IRB approvals processed each month. Local IRB approvals and other protocol specific requirements (PSRs) are submitted by the site to the CTSU Regulatory Office as noted above. Local IRB approvals are accepted in the form of IRB approval letters, *Protection of Human Subjects Assurance Identification/Certification/Declaration*, and the CTSU IRB Certification form, or a mix of forms such as a signed IRB approval letter and the CTSU IRB Certification form. Information collected on the CTSU IRB Certification form includes, CTEP site code identifiers; FWA Assurance information; IRB number information required to meet the Food and Drug Administration Amendment Act (FDAAA) regulations; and more detailed information on the review process such as the level of review and approval dates. Use of the form is not mandatory, but is strongly encouraged as it reduces processing time and site follow up time to collect required information.

Other standard regulatory forms are also not mandatory. They have been designed to allow participating sites to submit information on local protocol withdrawal and document additional sites under their IRB review.

CTSU Membership Forms (Attachments A05-A07)

CTSU Membership Forms have been created to maintain the CTSU person membership and support ordering of Investigational Brochures (IBs) and study supplies such as laboratory kits. The CTSU is comprised of approximately 30,000 active investigators and associates and 2,400 active sites that are aligned with the NCTN, ETCTN and other CTEP-supported networks. The Roster Update Form is primarily used to designate the primary points of contact at each site. CTSU maintains two primary points of contact at each enrolling site to ensure that a responsible point of contact is identified for study notifications and to support data management.

Attachment A05: CTSU Roster Update Form – mandatory form mainly used to designate the primary points of contact at each site and used to assign primary contact roles to the CTSU roster. Persons assuming these contact roles must sign that they agree to act as a central point of contact for their institution.

Attachment A06: CTSU Request for Clinical Brochure - Clinical Brochures are essential to the investigator's understanding of the mechanism of action for the study agent, and are required documentation to the IRB to support the review process. As

the clinical brochures are proprietary, the form allows for collection of information on the investigator to perform checks ensuring they are eligible to receive the brochure. The form is being modified to include updated submission information. There is no change in burden

Attachment A07: CTSU Supply Request Form - A subset of the studies supported by the CTSU require the clinical sites to obtain supplies to conduct the study. The CTSU Supply Request Form facilitates site requests for supplies that CTSU distributes by providing information on the site to ensure they are approved for the study, eligible to receive supplies, and provides shipping information. The form is being modified to include updated submission information. There is no change in burden.

CTSU Data Management Forms (Attachments A08-A14)

CTSU Data Management Forms have been developed for the common purpose of efficiently managing and processing received data. Please note that over time, CTSU may also remove data management forms as studies close to data collection, or data collection is transferred back the Lead Protocol Organization (LPO).

Data Management Forms:

Attachment A08: Site Initiated Data Update Form – Support data management activities and is based upon a common header template with modifications per protocol that outline each study's Case Report Form (CRF) submission requirements and/or study specific instructions.

Attachment A09: Data Clarification Form – Support data management activities and is based upon a common header template with modifications per protocol that outline each study's Case Report Form (CRF) submission requirements and/or study specific instructions.

Attachment A10: RTOG 0834 CTSU Data Transmittal Form – Support data management activities and is based upon a common header template with modifications per protocol that outline each study's Case Report Form (CRF) submission requirements and/or study specific instructions.

Attachment A12: CTSU Generic Data Transmittal Form – represents a generic data transmittal form that will be implemented for future studies.

CTSU Patient Enrollment Forms (Attachments A15-A16)

CTSU Patient Enrollment Forms have been developed to collect information for processing patient enrollments including information on the enrolling site, enrolling investigator, and study. Patient enrollment forms are required when enrollment and transfer functions cannot be completed in OPEN.

Attachment A15: CTSU Patient Enrollment Transmittal Form – collects required information for processing CTSU enrollments not available in the OPEN system, or when manual enrollment is required because of a technical issue or need to override automated checks in OPEN. The form captures the CTEP site code, the treating investigator identifiers, and information critical to site payment and audit responsibilities.

Attachment A16: CTSU Patient Transfer Form – collects information needed to complete the patient transfer process and/or update treating investigator information, thereby ensuring compliance with regulatory requirements, and correct shipment of study agent.

CTSU Administrative Form (Attachments A17-A18)

CTSU Administrative Forms have been created to facilitate account requests to the RSS and manage administrative information necessary for OPEN setup.

Attachment A17: CTSU System Access Request Form (CSARF) – is used to process account request for specific components of the CTSU Enterprise System from NCI, contractor, and NCTN, ETCTN, and other network administrative staff. It is not used by clinical site staff. CTSU processes approximately 15 account requests each month. The form includes the list of authorizers for each organization.

The CTSU is adding an administrative form completed by the LPOs to support setup of patient enrollment forms in the OPEN.

Attachment A18: CTSU-OPEN Rave Request Form – this administrative form supports the setup and testing of studies in OPEN. The form provides information critical to ensuring eligible patients are enrolled to NCI-sponsored studies, and to supporting integrations with several other systems including the clinical data management system, Medidata Rave®.

CTSU is adding the Delegation of Task Log (DTL) application to this submission. The DTL is a web-based application which documents the assignment of qualified site personnel to study tasks under the direction of the site Clinical Investigator who is responsible for conduct of the study at the clinical

site. The DTL applications has two components: LPO setup of study-specific DTLs, and clinical site completion and maintenance of the study-specific DTL. The DTL application is integrated with other CTEP Core systems including the RCR to ensure clinical site staff with the appropriate training and qualifications are assigned to study-related tasks. NCI as the funding source and sponsor will determine which protocols require a DTL with a primary focus on studies with CTEP-held INDs and/or studies that may be used to support registrations with the FDA. Completion of the DTL will help to ensure compliance with federal regulations. In addition the data collected will be used to support site auditing and made available to regulatory agencies as needed.

The DTL application consists of the following forms (Attachments A19-A21)

Attachment A19:	Protocol-Specific DTL Template – customizable template based on a standard set of required and optional study-related tasks including the appropriate NCI registration type of the assigned individual and any study-specific training.
Attachment A20:	Site-Protocol DTL – documents assignment of study-specific tasks as directed by the Clinical Investigator.
Attachment A21:	Electronic Signature Page – documents the Clinical Investigators agreement to conduct the study per applicable NCI policies and federal regulations, and oversee staff assignments. This form can be printed as a PDF.

NCI CIRB

The NCI uses various information collection tools to support CIRB activities. Information collection tools include: worksheets and/or forms requiring completion by an institution conducting a clinical trial eligible for review by the CIRB, as well as worksheets and/or forms requiring completion by the CIRB members themselves. CIRB forms fall into four categories: Enrollment, Board Membership, Board Review, and Local Context. These forms were developed to ensure data is collected in a consistent manner for specific project needs.

The benefits to research participants include study review by individuals who represent oncology experts, as well as specialized expertise such as pediatric oncology, early drug development, and prevention. The benefits to investigators and research staff include: easier to open trials; eliminates preparation of study submissions to local IRBs, including completion of IRB application, duplication of IRB packets, subsequent submissions for amendments, continuing reviews; eliminates back-and-forth with IRB to gain study approval. Efficiencies for IRB members and IRB staff include: elimination of full board review of NCI-sponsored trials, and reduction of administrative burden. Benefits to study participants include: having dedicated review of NCI-sponsored trials for study participant

protections, access to more trials more quickly, and access to trials for rare diseases. Additionally, more trials may be opened at more institutions more quickly, accrual to trials may begin more rapidly, trials may obtain accrual goals sooner, and trial questions may be answered more quickly.

NCI CIRB Forms/Documents:

There are four general areas in which forms are collected. These areas include: NCI CIRB Enrollment, Board Membership, Board Review and Local Context documents. The detail below describes how forms are used; by whom and for what purpose the information is collected.

NCI CIRB Enrollment Forms (Attachments B01-B02)

CIRB Enrollment documents were created to collect information on institutions interested in enrolling, or having already enrolled, in the CIRB Initiative. The CIRB currently has 500 Signatory Institutions enrolled in the CIRB.

Attachment B01: NCI CIRB Authorization Agreement (AA) and Division of Responsibilities (DOR) between the NCI CIRB and Signatory Institution – this form documents the agreement for an Institutional IRB (with an FWA) to rely on the NCI CIRB for review of studies on the NCI CIRB menu. Two documents are completed, signed and submitted to the CIRB Operations Office, and then signed by an NCI Official to execute the agreement. This blank form is available via the CIRB website.

Attachment B02: NCI CIRB Signatory Enrollment Form

The CIRB Signatory Enrollment Form is used to capture essential information on the Signatory Institution (SI) enrolling in the NCI CIRB, component and affiliate institutions relying on the SI, as well as information used to establish presence within the CIRB's IT systems. In addition to SI, component and affiliate institution details, information requested includes the CTEP Site Code for the SI and contact(s) for CIRB communications.

CIRB Board Member Documents (Attachments B03-B09)

NCI CIRB Board Member documents collect information on members and potential members of the CIRB. The NCI CIRB consists of four Boards: Adult – Late Phase Emphasis (LPE), Adult – Early Phase Emphasis (EPE), Pediatric and Cancer Prevention and Control (CPC). Recruited members are invited to serve on the CIRB; information is shared regarding meeting dates, responsibilities, etc. If the candidate accepts the candidacy opportunity, and is approved by NCI, a formal invitation for membership is released and additional information is provided to the candidate. Board Members complete a CIRB Board Member Application, Conflict of Interest (COI) Screening Worksheet, and once

on the board, an additional COI Screening for CIRB meetings. Each member is expected to serve a two year term, although may be asked to serve multiple terms.

Attachment B03: CIRB Board Member Application
Attachment B08: CIRB Member COI Screening Worksheet
Attachment B09: CIRB COI Screening for CIRB Meetings

Please note, Attachments B03-B07 were consolidated into Attachment B03, CIRB Board Member Application.

NCI CIRB Board Reviewer Documents (Attachments B10-B38)

CIRB Reviewer Worksheets are used by Board Members when reviewing information submitted to the NCI CIRB. The LPOs submit review application forms at time of initial review (IR), amendment review (AR), and continuing review (CR). The review application forms support the assigned CIRB's review of the protocol document and related materials in compliance with federal regulations (45 CFR 46 and 21 CFR 56). Applications are categorized by the type of review (IR, AR, and CR). Initial applications include information essential to the CIRB Board members to understand the scientific basis for the trial, trial hypothesis, trial intervention, risk/benefit of the intervention, and trial analysis. At continuing review, the application summarizes the conduct of the trial to date, including information that may change the risk/benefit profile of trial; amendment applications highlight the changes to the trial. There are also forms for the Study Chair to document response to CIRB review. The NCI CIRB Reviewer Worksheets are completed and submitted by Board Members once review of protocol has been assigned and completed. Additionally, there are documents completed and submitted by NCI-sponsored institutions when responding to CIRB review.

Attachment B10: CIRB Initial Review Application
Attachment B11: CIRB Initial Review Application for Exempt Studies
Attachment B12: CIRB Amendment Review Application
Attachment B13: CIRB Ancillary Studies Application for Adult / Pediatric
Attachment B14: CIRB Continuing Review Application for Adult / Pediatric
Attachment B15: Adult Initial Review of Cooperative Group Protocol
Attachment B16: Pediatric Initial Review of Cooperative Group Protocol
Attachment B17: Adult/Pediatric Continuing Review of Cooperative Group Protocol

Attachment B19: Adult Amendment of Cooperative Group Protocol
Attachment B20: Pediatric Amendment of Cooperative Group Protocol
Attachment B21: NCI CIRB Reviewer Worksheet Pharmacist Review of a Study

Attachment B23: Adult Expedited Amendment Review

Attachment B24: Pediatric Expedited Amendment Review – used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to an adult protocol by a NCTN Group or ETCTN Lead Academic Organization (LAO) submitted to the CIRB for expedited amendment review.

Attachment B25: Adult Expedited Continuing Review

Attachment B26: Pediatric Expedited Continuing Review – used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to an adult protocol by a NCTN Group submitted to the CIRB for continuing review.

Attachment B27: Adult Cooperative Group Response to CIRB Review

Attachment B28: Pediatric Cooperative Group Response to CIRB Review – used by the reviewer and provides questions to answer in regards to the response. The form is completed by the CIRB member and captures their comments, questions, and determination regarding the response.

Attachment B29: Adult Expedited Study Chair Response to Required Modifications

Attachment B31: Reviewer Worksheet - Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN) – used by reviewer to assess whether a reported event is an unanticipated problem and/or serious or continuing noncompliance issue, or neither.

Attachment B32: Reviewer Worksheet - CIRB Statistical Reviewer Form – used by subcommittee member to review a NCTN Group submission of statistical considerations for CIRB approval.

Attachment B33: CIRB Application for Translated Documents

Attachment B34: Reviewer Worksheet of Translated Documents – used by subcommittee member to review, document and provide comments for a NCTN Group submission of translated materials for CIRB approval.

Attachment B35: Reviewer Worksheet of Recruitment Material – used by subcommittee member to review a NCTN Group or ETCTN LAO submission of locally developed material for CIRB approval.

Attachment B36: Reviewer Worksheet Expedited Study Closure Review – used by subcommittee member to review a NCTN Group or ETCTN LAO submission of study closure.

Attachment B38: Reviewer Worksheet of Expedited Initial Review – used by the reviewer to indicate documents reviewed and expedited review specifics about an adult protocol by a NCTN Group or ETCTN Lead Academic Organization (LAO) submitted to the CIRB for expedited Initial Review.

CIRB Local Context Forms (Attachments B40-B46)

CIRB Local Context Documents have been created to capture information related to an institution and PI to inform the CIRB about their state and local law, resource availability, vulnerable populations that are enrolled, and language that will be added to the CIRB-approved model consent form.

Attachment B40: Annual Signatory Institution Worksheet about Local Context – this worksheet collects information during enrollment. This worksheet is completed by the Institutions Primary Contact online via IRBManager and submitted to the CIRB for review. This form is completed and updated online.

Attachment B41: Annual Principal Investigator Worksheet about Local Context - this Worksheet is completed by PI who will open a CIRB approved study and captures information specifically related to the local context of the PI. The information includes the number of support staff, any financial conflicts of interest, recruitment processes, consent process, and consent for those that don't speak English. This form is completed via IRBManager and submitted to the CIRB for review. This worksheet is completed and updated online.

Attachment B42: Study-Specific Worksheet about Local Context – this worksheet collects information regarding the local site acceptance of the CIRB review on a per protocol basis. This worksheet is completed by the PI to open a new study with the CIRB. This worksheet is completed online via IRBManager and is submitted to the CIRB for review. This worksheet is completed and updated online.

Attachment B43: Study Closure Form and Transfer of Study Review Responsibility Form – this form collects information as it relates to study closure. This form is completed by the PI to close a study with the CIRB. This form is completed in IRBManager and is submitted to the CIRB for review. This form is completed and updated online.

Attachment B44: Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form – this form collects potential unanticipated problems to the CIRB. This form is completed by the PI to report a potential unanticipated problem to the

CIRB. The form is completed in IRBManager and is submitted to the CIRB for review. This form is completed and updated online.

Attachment B45: Change of Signatory Institution PI Form – this form collects Signatory Institution PI information that conducts NCI-sponsored studies approved by the CIRB and should receive study-related correspondence. This form also confirms the contact information of Signatory Institution PI that should no longer receive study-related correspondence. This form is completed and updated online.

Attachment B46: Request Waiver of Assent Form – this form collects a request for the waiver of assent from Signatory Institution PI for a study participant has received the Waiver of Assent because the patient's ability to understand and communication skills were determined by the Principal Investigator not to be adequate to give assent. This form is completed and updated online.

Surveys:

Surveys are used to objectively measure customer satisfaction and provide data needed to continually improve services. Customer satisfaction surveys assess perceptions of our customers, as opposed to our perceptions of how well services are delivered. The methodology for sending CTSU, CIRB and CTEP surveys is similar. CTSU frequently assists CTEP with clinical trial-related surveys by providing the pool of potential participants based upon site registration and enrollment data, coordination of the survey distribution, data collection, and survey analysis. In general, the surveys are distributed by e-mail and conducted on-line using common tools such as Survey Monkey. Selected participants are generally sent reminder e-mails midway through the collection process. All surveys are voluntary and efforts are made to keep the time needed to complete the survey to a minimum. A reminder email is sent out after one week, and the survey closed after two weeks. Data are compiled from an Excel spreadsheet print out and put into a standard report and shared with CTEP and the study team to review.

Attachment C03: CTSU Oncology Patient Enrollment Network (OPEN) Survey – this survey is posted to the OPEN website and is available upon a user completing a patient enrollment. No changes requested at this time.

Attachment C04: CIRB Customer Satisfaction Survey – the customer satisfaction survey was developed to collect customer feedback pertaining to the use of the CIRB Help Desk. Any customer (local institution, member of a LPO, public inquiry, etc.) submitting a request to the Help Desk (via email or phone) can randomly receive an email request to complete the survey if they provide an email address during the discussion via phone, or have submitted an email inquiry

with valid email address. CIRB receives approximately 500 Help Desk inquiries per month. The surveys are completed online via SurveyMonkey.com.

Attachment C05: CIRB Follow-up Survey (Communication Audit) – this survey is used to inquire to CIRB stakeholders regarding their use of CIRB instruments, processes, and online presence.

Attachment C07: CIRB Board Members Annual Assessment Survey – this survey is used to inquire to Board Members regarding their experience as a CIRB member and open channels for receiving valuable feedback.

<u>The clinical trial surveys (Attachments C08-C11)</u>

Attachment C08: Protocol and Information Office (PIO) External Customer Satisfaction Survey – CTEP PIO serves to improve the protocol development and conduct processes through the use of efficient business practices and informatics tools. The CTEP PIO manages all protocol related materials and coordinating major aspects of the scientific review process. CTEP PIO staff interacts directly with multiple personnel from each of the clinical trial site locations involved in the development and management of CTEP sponsored clinical trials. The PIO Survey helps verify areas of high quality performance and areas for improvement as identified by the external stakeholders. An email is sent to the clinical trial personnel listed in the CTEP Enterprise database that includes a link to complete this on-line, annual survey. This survey was originally piloted in 2011 (OMB No. 0925-0046, Expiration Date 2/28/2013).

Attachment C09: Concept Clinical Trial Template Survey – this survey will be used to understand clinician interest in a trial while the concept is still under development and before the trial is approved by NCI. This survey is designed to identify scientific interest in the trial's research questions, the study design, and accrual challenges given the patient population. Information from this survey can help study teams learn if changes need to be made to the design or concept in order to increase clinician interest in the trial's objectives.

Attachment C10: Prospective Clinical Trial Template Survey – this survey will be used for trials that are in protocol development phase of a clinical trial (i.e., after the concept has been approved but before the trial is activated). This survey is designed to identify the greatest challenges to sites to both open the trial and to accrue patients. Information from this survey helps study teams learn the trial's greatest challenges and then plan ahead to prepare information for clinicians and patients to ensure equipoise and informed decision making.

Attachment C11: Low Accruing Clinical Trial Template Survey – this survey will be used for trials that have already been activated in the field but are considered at risk for closure due to slow accrual. This survey is designed to identify if scientific interest remains in the trial, the greatest accrual challenges to sites, and areas for improvement to increase accrual. Information from this survey will help both CTEP and study teams determine if the trial should remain open and if so, what additional resources are needed to help sites accrue to the trial.

CTMB AIS

As a sponsor and funding agency for cancer clinical trials, FDA regulations require DCTD/CTEP to maintain a monitoring program. CTMB provides oversight of the monitoring programs for NCI-supported trials and includes an auditing component for Network Group trials to verify data accuracy, and investigator compliance with the protocol and regulatory requirements. Information on audit scheduling, conduct, and results is entered into the AIS. Specific information collected and the parties responsible for entry are outlined below.

CTMB Audit Specific Forms (Attachments D01 D07)

CTMB audit specific forms have been created to maintain the audit schedule, audit finding and follow-up information for a site participating on the clinical trial within the NCTN or under the Clinical Trials Monitoring Service (CTMS) which supports audits on phase I, II, Cancer Center and Children's Oncology Group (COG) Phase I consortium trials. The CTMB conducts approximately 800 audits a year, which are managed by approximately 190 active LPO and CTMS users for the sites that are aligned with the NCTN, ETCTN and other CTEP-supported networks. CTMB has identified the primary points of contacts from each LPO and CTMS staff who are responsible for planning and conducting audits and supporting data management.

Attachment D01: Audit Scheduling Form – This form is used by the LPO and CTMS users to schedule an audit. The users select the tier to be audited and provide the audit date, audit type, audit duration, audit location, contact person, auditors, protocol, site and/or children sites and the patients being audited.

Attachment D02: Preliminary Audit Finding Form – Preliminary audit finding form is an essential form that auditor will submit to CTMB electronically within 24 hours after the audit completion. This form captures information on each component of the audit (Regulatory, Pharmacy, and Patient Case), institution name and address, critical and/or major deficiencies for the components that were audited. The form is submitted electronically or emailed by the auditor to CTMB.

Attachment D03:	Auditor Maintenance Form – LPOs and CTMS users maintain a list of auditors in AIS who can be assigned to an audit. Auditors are registered in the RCR and assigned a unique identifier as well as a CTEP Identity and Access Management (IAM) account. Audit-specific information of an auditor is managed by the group and CTMS users.
Attachment D04:	Final Audit Finding Form – Once an audit is conducted, the LPO and CTMS users are required to complete a final audit finding form for all the components audited. Audit components include regulatory, patient case and pharmacy review. The form provides a comprehensive list of deficiencies for each component category per the CTMB Audit Guidelines. Users select the deficiencies identified within each component category, and assign category rating for each protocol/site/patient combination. Users assign overall assessment rating and indicate whether follow up or re-audit is required for the component. The form also captures audit procedures used, exit interview and general comments. Time to complete the report varies substantially based on the number and type of findings, cases reviewed, and if CTMB has comments on the final report that require revisions to the final report. The completed form is submitted to CTMB for review. The form is due to CTMB within 60 days from audit completion date.
Attachment D05:	Follow-up Form – If an audit mandates a follow-up, then the LPO and CTMS users work with the sites/PI to prepare a Corrective and Preventive Action (CAPA) plan to overcome the identified deficiencies. This documentation is submitted to CTMB for review.
Attachment D06:	Roster Maintenance Form – CTMS users maintain the audit roster for CTMS Phase I Phase II studies. Users can submit a roster add or update request to CTMB for review and approval. Once approved, the roster will be used to schedule an audit.
Attachment D07:	Final Report and CAPA Request Form – For audits conducted by CTMS, if the audit requires a follow up, then the CTMS user is required to send the final audit finding report and the standard CAPA templates for each component to the sites to capture the CAPA plan. The sites will complete the component specific CAPA templates and send it back to CTMS for submission to CTMB for review.

PMB

As a sponsor and funding agency for cancer clinical trials, FDA regulations require the DCTD/CTEP to specifically ensure the following:

- Selection of investigators qualified by training and experience as appropriate experts to investigate the agent; and
- Investigators appropriately designate clinical research tasks to individuals qualified by training and experience.

Several programs within the NCI including the NCTN, ETCTN, and DCP NCI Community Oncology Research Program (NCORP) use the RCR system to electronically collect data to meet the needs of annual registration. RCR serves as a repository of registration information for all clinical research personnel participating on NCI-sponsored clinical trials. The RCR system, in combination with other CORE applications, ensures real-time updates to control trial activities and system access. The RCR supports an annual registration submission lifecycle to allow investigators and clinical site staff to quickly participate on research trials, increase efficiency, and lower the cost of conducting clinical trials.

The RCR is replacing the current paper-based investigator registration process, and supports FDA requirements for submission of electronic data to support the IND and any future New Drug Applications (NDAs) or Biologic License Applications (BLAs). Form completion burden is heavily weighed to the initial completion of the registration profile, but as the data is saved year-to-year, subsequent annual registrations will only require verification of information and updates as appropriate. Specific documents collected include:

Attachment E01:	Statement of Investigator (Form FDA 1572), electronically signed by investigator – A mandatory registration document that identifies the primary organization, practice sites, labs, and institutional review boards (IRBs) to which an investigator is associated when participating on NCI-funded research studies.
Attachment E02:	NCI Biosketch – A mandatory registration document that satisfies Box 2 of the Form FDA 1572 as an “Other Statement of Qualifications” and the professional information requirements previously obtained from the Curriculum Vitae (CV).
Attachment E03:	Financial Disclosure Form (FDF) for Investigator Registration – An electronic capture of confidential financial disclosure information for investigators.
Attachment E04:	Agent Shipment Form – An electronic capture of the names and contact information for responsible persons who will serve as the site’s shipping

designee(s) (who oversees receipt and proper handling of drug orders) and as the person responsible to accurately order drugs through the Online Agent Order Processing (OAOP) system.

For the PMB, the Statement of Investigator (Form FDA 1572) is a modified version of the FDA paper form with responses specific to investigator participation on NCI sponsored studies. Other versions of Financial Disclosure forms are also in use within the government but are not specific to CTEP requirements, and there is no mechanism for data exchange without incurring additional costs and burden to the government and participating investigators. In addition, all forms within the RCR are electronic which is unique for investigator registration to clinical trials.

Completion of the electronic registration profile in the RCR ensures compliance with NCI/DCTD/CTEP and DCP's responsibilities as IND sponsors. The FDA can request copies of these forms at any time for audit and review. Record keeping of investigator registration and financial disclosure data in a standard format is required to track compliance. NCI/DCTD/CTEP does not establish a standardized format for submission of the Curriculum Vitae (CV). However, the RCR system captures professional information requirements (as stated in the CV) in the Biosketch (Attachment E02) and allows investigators to upload a CV document as an option. The record-keeping retention period is specified by FDA regulation, and the NCI does not deviate from that requirement.

Additional attachments to this submission

Below is a list of additional attachments supporting this OMB revision.

For the CTSU the following attachments are included:

Attachment F01: Privacy Impact Assessment (PIA). Contact information collected from the forms is added to the CTSU-ESYS, and data security is maintained as outlined in the Privacy Impact Assessment (PIA). The PIA was re-approved by HHS on 8/24/2012. The last revised submission was provided in July 2015 under the IT system name "NIH NCI Cancer Trials Support Unit (CTSU)" for the CTSU-ESYS inclusive of the website, RSS, and other related modules.

Attachment F02: Westat IRB Letter. The CTSU project and its forms and surveys have been reviewed by the Westat IRB and given approval.

Attachment F03: Privacy Act Memo. In this June 4, 2010 memo to Michael Montello, Pharm.D., the NIH Privacy Act Officer determined that the NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" covers the CTSU data collection, which involves collection of personally identifiable information (PII) such as name, date

of birth, social security number, mailing address, telephone number, medical record number and mailing address.

For the CIRB the following attachments are included:

Attachment F04: The Federal Information Processing Standard 199 (FIPS-199) Categorization (Security Categorization) report is a key document including the determination of the security impact level for the cloud environment that hosts the CIRB Web System. Security controls are implemented per the applicable environment. The Privacy Impact Assessment (PIA) is not a contractual requirement. The FIPS 199 was submitted September 2014 and annual update on 09/2015 for the CIRB Web System.

Attachment F05: OHSR Determination. On October 10, 2010, the Office of Human Subject Research (OHSR) found the CIRB project data being collected is for the sole purpose of fulfilling the mission of the Central Institutional Review Board (CIRB). The data available is not intended for any use other than to conduct IRB review of studies. Therefore, OHSR found that data are not being collected on human subject participants as part of the CIRB Initiative.

Attachment F06: Emmes IRB Letter. In September 2016, the Emmes IRB found the NCI CIRB project and its forms and surveys to be exempt.

Attachment F07: Privacy Act Memo. In a memo to Steve Friedman, dated December 28, 2009, the NIH Privacy Act Officer determined that the NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" covers the CIRB data collection, which includes the collection of PII such as name, address, home telephone number, cell phone number, gender, ethnicity, social security number, financial information, educational level, etc.

A.3 Use of Information Technology and Burden Reduction

The NCI, DCTD, CTEP continuously seeks mechanisms to reduce burden through advances in information technology. Utilization of computerized records management has reduced the need to compile, arrange, and update documentation. Upgrades to internal systems and integration efforts between the CTEP CORE systems, and other NCI Applications have resulted in operational efficiencies such as support for Single Sign-On (SSO), eliminating the need to collect contact information on members across multiple systems.

When paper forms are used, the forms are in PDF writable formats, and Word formats are available upon request. Paper forms are accepted via fax, fax server or email. The surveys are distributed electronically using commercial software products. All surveys are voluntary and the survey applications are easy to use with no user training or requirements for additional software.

Both Emmes and Westat have completed a Security Testing and Evaluation (ST&E) of their systems as per the guidelines set forth in the Federal Information Security Management Act (FISMA) and specifically in NIST Special Publication 800-53A Rev 3 and in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist. The ST&E on the CTSU Enterprise system was successfully completed by an independent third party auditor to ensure the security controls are in place and working as intended. Based on this, CTSU maintains an active Authorization to Operate (ATO) issued by the NCI's authorizing official. In addition to the Security certification, CTSU enterprise system is managed according to the Westat's Enterprise Systems Development Group (ESDG) processes and procedures. ESDG is a Capability Maturity Model Integration (CMMI) Maturity Level 2 certified organization.

The CTMB AIS and RCR systems, part of the CTEP-ESYS and managed by CTIS, Inc. The CTEP-ESYS has been FISMA compliant system for the last 14 years and maintains an Active Authorization to Operate (ATO) since 2004. The PIA for CTEP-ESYS is completed. **(Attachment F08)** The CTEP-ESYS FIPS assessment is included with OMB SSA (**Attachment F09**).

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

Information collected for the CTSU, CIRB, CTMB and PMB components of the CORE is unique to the NCI programs and is not found elsewhere in the government. The integration of systems and processes allows for data to be collected in a single application and shared throughout the CORE to support the conduct of clinical trials using a federated approach. Investigators and staff key to the conduct of trials register in the PMB RCR application. Individuals are assigned unique identifiers and user names and passwords for accessing other applications in the CORE. Institution and person information is shared with all other downstream organizations including the CTSU, CIRB, CTMB, and the organizations responsible for clinical trial development such as the NCTN and ETCTN. As an example, the CIRB, NCTN, and ETCTN maintain institution and person rosters in the CTSU-supported RSS based upon the unique identifiers, registration types and statuses assigned in RCR. Additional information is added to define the institutions and individuals responsibilities within each organization and to allow access to other systems within the CORE. For example, a Clinical Research Associate (CRA) must be registered with RCR with a specific registration type, added to a roster in RSS and assigned user roles to access the common data management system using their CTEP user name and password. Use of a federated system minimizes duplication of data and processes across CTEP branches and programs, and allows for more efficient sharing of information.

A.5 Impact on Small Businesses or Other Small Entities

Small business and other small entities are not impacted.

A.6 Consequences of Collecting the Information Less Frequently

NCI/DCTD/CTEP forms are designed to support real time business processes. Information collection supports distinct processes within the CORE. RCR registration data is collected per individual and reviewed annually, membership data is collected per institution and individual, regulatory data is collected per study, and enrollment data per protocol. Reduction in the frequency of form collection would cause the loss of required data, increase processing times, and reduce data quality. For example, less frequent collection of regulatory data would impact CTEP's ability to verify that institutions have appropriate IRB approval for trial participation.

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 on this study prior to initial submission to OMB was published on (February 21, 2018, Vol. 83, and p. 7483). No public comments were received.

A.8.2 Efforts to Consult Outside Agency

No outside consultation was made.

A.9 Explanation of Any Payment of Gift to Respondents

No form of payments or gifts will be given to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

All information will be kept secure to the extent allowable under the law. The aggregate CORE systems of CTEP, CTSU and CIRB are required by NCI as the sponsor for the initiation, conduct, and monitoring of clinical trials is shared across systems. All NCI and contractor staff are required to have Human Subjects Training (HST) and participate in NIH Security Awareness and Privacy training on an annual basis. PII in the form of names, addresses and contact information is collected and shared across CORE systems. Financial Information collected on the RCR FDF or for the CIRB is not shared with other CORE systems. Participants are aware of the use of the data, and the NIH privacy statement appears upon login to all integrated systems including the CTSU members' website. Data is maintained at minimum per federal requirements and frequently longer due to the ongoing nature of research. Data backups are maintained per organizational policies specific to each contractor. Limited information is available to users via the CTSU members' website.

All systems use SSO authorization based upon the CTEP-IAM user name and password. User authentication is a combination of CTEP-IAM authorization and roster data in the RSS. All nonpublic parts of the resource are maintained in accordance with appropriate privacy and security access controls pursuant to applicable policies. CTSU forms and surveys are submitted to the Westat IRB for review and were determined exempt from human subject research. Contact information collected on CTSU forms is added to the CTSU enterprise systems and data security is maintained as outlined in the Privacy Impact Assessment (PIA). The CTSU PIA was re-approved by HHS on 8/24/2012 and the IT system name is "NIH NCI Cancer Trials Support Unit (CTSU)" for the CTSU Enterprise system inclusive of the website, RSS, and other related modules (**Attachment F01**) and is updated as changes are made

The CIRB project has been reviewed by the Office of Human Subjects Research (OHSR) and determined to be "Not Human Subjects Research" based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" and guidance on Engagement of Institutions in Human Subjects Research.

Surveys are circulated via email and use standard survey processing tools. Identifying information based upon the user email is not used in the analysis of the data, nor are any efforts made to link respondents to their email. The CIRB maintains information to ensure that no CIRB member can unduly influence the approval of a study when there is an appearance of conflict due to professional or personal relationships such as financial gain or professional growth. Data used in the CIRB process include scientific and administrative data. Data is used to inform board members concerning the studies under review, manage the operations and communications of the CIRB, and conveys information to Institutions concerning studies reviewed by the CIRB and decisions made by the CIRB.

The CIRB collects PII from Board members and local sites in the form of name, address, telephone numbers, email address, social security number, employment information, financial information, educational level, etc. This information may be completed as hard or electronic copies and mailed or emailed to the Operations Office for data entry. Board members and site representatives provide information voluntarily and are aware of the purposes for which their contact information will be used. Data stored in CIRB information systems is not purged or deleted and is maintained to support CIRB current operations. The electronic information is stored within the system indefinitely as legacy data for review and analysis of CIRB activities. Hard copies are shredded once data have been entered.

The need to collect PII occurs sporadically and is stored electronically with frequent backups to ensure information is recoverable, as needed. CIRB members are made aware of this collection and the need for the collection through the CIRB privacy statement. The NCI Privacy Policy is available electronically and it is shared during the enrollment application process. The need for the collection

of this information is relevant and justified to ensure that no CIRB member can unduly influence the approval of a study when there is an appearance of conflict due to professional or personal relationships such as financial gain or professional growth. The types of data used are both scientific and administrative, and used to inform board members concerning the studies under review, manage the operations and communications of Adult and Pediatric Central Institutional Review Boards, and convey information to sites concerning studies reviewed by the CIRB and decisions made by the CIRB. The NIH Privacy Act Officer has reviewed this data collection and deemed the Privacy Act is applicable, and is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" (Attachment F07). Additionally, the Office of Human Subjects Research (OHSR) has reviewed this information collection and has deemed that "Federal regulations for the protection of human subjects do not apply" (**Attachment F05**).

For the CTMB AIS, a standard privacy and securing warning banner is on the bottom of each form. This warning alerts users that information within the forms is monitored and recorded by the government, and against improper usage of the information. The forms provide a role based access and each user can only view the forms based on their role and group affiliation. The forms does not collect any PII information.

For the PMB RCR, all information is kept private to the extent permitted by law. Information collected during the investigator registration process is made available to the IND sponsor and to the FDA to meet regulatory requirements as outlined in 21 CRF 312.64(d). Investigators are made aware of their legal requirements when they complete the FDA 1572 form. Data collection is covered by the NIH Privacy Act Systems of Record, 09-25-0200, "Clinical Basic and Population-based Research Studies of the NIH/HHS/OD. A Privacy Impact Assessment (PIA) was approved by HHS on November 22, 2016. An update was submitted at the end of 2017. (**Attachment F08)**.

A.11 Justification for Sensitive Questions

For the CTSU forms, a minimal amount of PII is collected and is related to specific tasks and immediate contact information.

For the CIRB, sensitive information collected includes the Board Members social security number, home address, phone number and bank information if the direct deposit mechanism is used. Such sensitive information will be kept private under the Privacy Act. PII collected, includes name, mailing address, telephone number, and email address.

Information identifying the auditors and clinical site staff is collected to identify individuals involved in the conduct of the audit. Audit findings which are indicative of clinical site performance are kept

confidential and access is limited to the, NCTN and Research bases, contractor conducting the audit, and NCI staff. Audit findings indicative of fraud or indicating significant risk to human subjects may be shared with other federal agencies as required by federal regulations including the Office of Human Research Protections (OHRP). The results of the audit are shared with the audited site in the standard format with only audit specific information. The Forms do not collect PII information.

For the RCR, PII for investigators and sub-investigators is being collected in the form of name, CTEP Person ID, email address, mailing address, phone numbers, certificates, education records, employment status, publications, honors, employment history, medical licenses, HSP/GCP trainings, FDA Form 1572 and potential pharma conflicts as reported on the Financial Disclosure Form. The collection and evaluation of this information is necessary to meet FDA regulatory requirements for investigators, sub-investigators and research participants who are responsible for conducting clinical trials. Additionally, the PII is gathered:

- To ensure that investigators, sub-investigators and research participants are qualified and the site is an appropriate location at which to conduct the study.
- To inform investigators, sub-investigators and research participants of their obligations and to obtain necessary commitments to follow pertinent FDA regulations.
- To communicate with investigators, sub-investigators, and research participants with respect to clinical research trial activities.

For the CTSU, the NIH Privacy Act Officer has reviewed this information collection and has determined that the Privacy Act will apply and this data collection is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" (**Attachment F03**).

For the CIRB, the NIH Privacy Act Officer has reviewed this data collection and deemed the Privacy Act is applicable, and is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" (**Attachment F07**). Additionally, the Office of Human Subjects Research (OHSR) has reviewed this information collection and has deemed that "Federal regulations for the protection of human subjects do not apply" (**Attachment F05**).

A.12.1 Estimated Annualized Burden Hours

The estimated annualized burden hours for this information collection are 112,798 from an estimated 136,487 respondents. Please note that the same respondents may submit multiple form types. For example, respondents will register in RCR and may also be responsible for submitting CIRB worksheets and CTSU IRB Certification forms. There is no current mechanism to determine the amount of overlap across respondents, but as participants in this program must register with CTEP, based on RCR numbers we anticipate approximately 33,000 users.

The estimates are based upon annual cumulative response rate to forms and surveys. Estimates on form usage are based upon processing metrics such as the number of regulatory packets or CRFs submitted; number of enrollment forms, board member documents, board reviewer documents and local context forms submitted. For more information, refer to Section A.2 in this document.

The number of responses per respondent varies dependent on the type and purpose of the collection. Many forms are collected only once per year as they are used for verification of participation. Other forms such as the regulatory forms, data transmittals, and patient enrollment forms may be submitted multiple times during the year as sites participate on multiple studies, enroll multiple patients, and submit clinical data on multiple patients at multiple time points. The repetitive nature of this collection is necessary to ensure that clinical sites are meeting federal regulations for review of studies prior to patient enrollment, enroll patients to trials in a timely manner, and submit clinical data in a timely manner to ensure patient safety is adequately monitored.

For CTMB, estimates are based upon annual cumulative response rate to forms. Estimates on form usage are based upon processing metrics such as the LPO and the CTMS users, number of audits conducted and the number of protocols, sites and patient cases audited. The burden estimate is based on a combination of collected forms and events on a yearly basis.

For the RCR, the estimate is based upon the results of personal experience of the CTEP staff and a small survey conducted to identify how institutions fulfill the requirement to complete the required forms. Although each institution does this differently the following estimates were developed. The investigational registration documents are completed as a result of combined efforts of the investigator and support staff (usually a clinical research assistant-CRA) the investigator does 40% of the work and the CRA performs 60% of the work.

For the RCR forms, the initial burden during the first year of the registration is anticipated to be significantly higher than in subsequent years. During the first year of the RCR, registrants will be creating their initial registration profiles, but in subsequent years they will only verify the previously entered information and make updates. Table A-12.2 reflects a combined rate averaged over three years. Estimate variations between year 1 and subsequent years are as follows:

- Attachment E01 – Statement of Investigator: estimated time for completion in year 1 is 15 minutes and in subsequent years it is 5 minutes, resulting in a burden change from 5,750 hours in year 1 to 1,917 hours in subsequent years;
- Attachment E02 – Biosketch: estimated time for completion in year 1 is 2 hours and in subsequent years 10 minutes, resulting in a reduction in burden change from 66,000 hours in year 1 to 5,500 hours in subsequent years;
- Attachment E03 – Financial Disclosure: no change

- Attachment E04 – Agent Shipment Form: estimated time for completion in year 1 is 10 minutes and in subsequent years 5 minutes, resulting in a burden change from 3,833 hours in year 1 to 1,917 hours in subsequent years.

In total, the reduction in burden from year 1 to subsequent years is 66,249 hours with a cost reduction of $4,280,055.

The rationale for more than one response per respondent is given below.

- CTSU IRB/Regulatory Approval and IRB Certification Form (attachments A01 and A02) – clinical sites participate on multiple protocols per year averaging one submission per month.
- Site Addition Form (Attachment A04) – a percentage of the clinical sites submitting regulatory forms do so for multi-site networks. The Site Addition Form allows for documentation of multiple sites covered under a single IRB approval.
- CTSU Supply Request Form (Attachment A07) – as noted above, clinical sites participate on multiple protocols throughout the year and use the form to request initial and resupply of items such as laboratory kits. Supplies are vary and are ordered per protocol.
- Site Initiated Data Update Form (Attachment A08) – this form is used by the clinical sites when submitting unsolicited data updates and supports routing of the update to the correct processing team.
- Data Clarification Form (Attachment A09) – this form is used by the CTSU team to request a data clarification on case report form data submitted by the clinical site. A separate form is used for each clarification, and sites may have multiple clarifications during the year.
- RTOG 0834 CTSU Data Transmittal Form (Attachment A10) – this form is submitted by the clinical sites with their clinical data for the RTOG 0834 study to support processing. There are multiple sites submitting the form, on multiple patients for multiple patient visits.
- CTSU Generic Data Transmittal Form (Attachment A12) – this form is submitted for any study for which CTSU has data management responsibilities but does not have a study-specific transmittal form. Again, clinical sites will submit this form with their per visit patient case report forms to support processing. The form is used by multiple sites, for multiple patients and at multiple patient visits.
- CTSU Patient Enrollment Transmittal Form (Attachment A15) – this is a processing form submitted for manual enrollments. Clinical sites submit one form per patient enrolled. Sites l generally enroll multiple patients per year.
- CTSU Transfer From (A16) – this is a processing form submitted to facilitate patient transfers between institutions and changes in the investigator overseeing patient care. On average clinical sites may have more than one patient transfer or investigator update per year.
- CTSU LPO Form (A19) – The LPOs are responsible for developing a template DTL for any study that may be used to support an FDA registration. At this time 10 studies have been identified as requiring DTLs, two for each domestic NCTN group.

- CTSU Site From and PDF Signature Form (A20 and A 21)– For clinical trials that may support FDA registrations, a DTL is required per site and study to document clinical site staff designated by the investigator to conduct specific study-related responsibilities.
- CTSU OPEN Rave Request Form (A18) – The form is required to facilitate setup of eligibility checklist (ECs). A form is required for new, amended and revised EC forms. The LPO staff may submit multiple forms over the study life-cycle and for each study that they are responsible for setup.
- Audit Scheduling From, Preliminary Findings, and Maintenance Forms (D01-D03) – auditors at the NCTNs and the auditing contract may be responsible for coordinating and reporting on multiple audits per year. Each organization retains multiple audit staff that must access the AIS to schedule and report on site audits per the CTMB guidelines. CTMB conducts approximately 800 audits per year and has approximately 152 authorized users. Tasks assigned to auditors may vary depending on the organization they represent.
- Final Audit Finding Report (D04) – each audit scheduled is coordinated by a lead auditor who is responsible for submission of the final audit report. Lead auditors may submit multiple audits per year. The final report addresses all components of the audit (regulatory, patient case and pharmacy) and the time to completion may vary dependent on the size of the audit, findings, and if CTMB requires revisions to the report.
- Follow-up Form (D05)
- Final Report and CAPA Request Form (D07)

Table 1 - A.12-2 Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A01)	Health Care Practitioner	2444	12	2/60	978
CTSU IRB Certification Form (Attachment A02)	Health Care Practitioner	2444	12	10/60	4888
Withdrawal from Protocol Participation Form (Attachment A03)	Health Care Practitioner	279	1	10/60	47
Site Addition Form (Attachment A04)	Health Care Practitioner	80	12	10/60	160
CTSU Roster Update Form (Attachment A05)	Health Care Practitioner	600	1	5/60	50

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CTSU Request for Clinical Brochure (Attachment A06)	Health Care Practitioner	360	1	10/60	60
CTSU Supply Request Form (Attachment A07)	Health Care Practitioner	90	12	10/60	180
Site Initiated Data Update Form (Attachment A08)	Health Care Practitioner	2	12	10/60	4
Data Clarification Form (Attachment A09)	Health Care Practitioner	150	24	10/60	600
RTOG 0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	12	76	10/60	152
CTSU Generic Data Transmittal Form (Attachment A12)	Health Care Practitioner	5	12	10/60	10
CTSU Patient Enrollment Transmittal Form (Attachment A15)	Health Care Practitioner	12	12	10/60	24
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	360	2	10/60	120
CTSU System Access Request Form (Attachment A17)	Health Care Practitioner	180	1	20/60	60
CTSU OPEN Rave Request Form (Attachment A18)	Health Care Practitioner	30	21	10/60	105
CTSU LPO Form Creation (Attachment A19)	Health Care Practitioner	5	2	120/60	20
CTSU Site Form Creation and PDF (Attachment A20)	Health Care Practitioner	400	10	30/60	2000
CTSU PDF Signature Form (Attachment A21)	Health Care Practitioner	400	10	10/60	667

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B01)	Participants	50	1	15/60	13
NCI CIRB Signatory Enrollment Form (Attachment B02)	Participants	50	1	15/60	13
CIRB Board Member Application (Attachment B03)	Board Member	100	1	30/60	50
CIRB Member COI Screening Worksheet (Attachment B08)	Board Members	100	1	15/60	25
CIRB COI Screening for CIRB meetings (Attachment B09)	Board Members	72	1	15/60	18
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	1	60/60	80
CIRB IR Application for Exempt Studies (Attachment B11)	Health Care Practitioner	4	1	30/60	2
CIRB Amendment Review Application (Attachment B12)	Health Care Practitioner	400	1	15/60	100
CIRB Ancillary Studies Application (Attachment B13)	Health Care Practitioner	1	1	60/60	1
CIRB Continuing Review Application (Attachment B14)	Health Care Practitioner	400	1	15/60	100
Adult IR of Cooperative Group Protocol (Attachment B15)	Board Members	65	1	180/60	195
Pediatric IR of Cooperative Group Protocol (Attachment B16)	Board Members	15	1	180/60	45

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
NCI Adult/Pediatric Continuing Review of Cooperative Group Protocol (Attachment B17)	Board Members	275	1	60/60	275
Adult Amendment of Cooperative Group Protocol (Attachment B19)	Board Members	40	1	120/60	80
Pediatric Amendment of Cooperative Group Protocol (Attachment B20)	Board Members	25	1	120/60	50
Pharmacist's Review of a Cooperative Group Study (Attachment B21)	Board Members	50	1	120/60	100
Adult Expedited Amendment Review (Attachment B23)	Board Members	348	1	30/60	174
Pediatric Expedited Amendment Review (Attachment B24)	Board Members	140	1	30/60	70
Adult Expedited Continuing Review (Attachment B25)	Board Members	140	1	30/60	70
Pediatric Expedited Continuing Review (Attachment B26)	Board Members	36	1	30/60	18
Adult Cooperative Group Response to CIRB Review (Attachment B27)	Health Care Practitioner	30	1	60/60	30
Pediatric Cooperative Group Response to CIRB Review (Attachment B28)	Health Care Practitioner	5	1	60/60	5

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Adult Expedited Study Chair Response to Required Modifications (Attachment B29)	Board Members	40	1	30/60	20
Reviewer Worksheet-Determination of UP or SCN (Attachment B31)	Board Members	400	1	10/60	67
Reviewer Worksheet - CIRB Statistical Reviewer Form (Attachment B32)	Board Members	100	1	15/60	25
CIRB Application for Translated Documents (Attachment B33)	Health Care Practitioner	100	1	30/60	50
Reviewer Worksheet of Translated Documents (Attachment B34)	Board Members	100	1	15/60	25
Reviewer Worksheet of Recruitment Material (Attachment B35)	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Study Closure Review (Attachment B36)	Board Members	20	1	15/60	5
Reviewer Worksheet of Expedited IR (Attachment B38)	Board Members	5	1	30/60	3
Annual Signatory Institution Worksheet About Local Context (Attachment B40)	Health Care Practitioner	400	1	40/60	267
Annual Principal Investigator Worksheet About Local Context (Attachment B41)	Health Care Practitioner	1800	1	20/60	600
Study-Specific Worksheet About Local Context (Attachment B42)	Health Care Practitioner	4800	1	20/60	1600

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Study Closure or Transfer of Study Review Responsibility (Attachment B43)	Health Care Practitioner	1680	1	20/60	560
Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attachment (B44)	Health Care Practitioner	360	1	20/60	120
Change of Signatory Institution PI Form (Attachment B45)	Health Care Practitioner	120	1	20/60	40
Request Waiver of Assent Form (Attachment B46)	Health Care Practitioner	60	1	20/60	20
CTSU OPEN Survey (Attachment C03)	Health Care Practitioner	60	1	15/60	15
CIRB Customer Satisfaction Survey (Attachment C04)	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit) (Attachment C05)	Participants/ Board Members	300	1	15/60	75
CIRB Board Member Annual Assessment Survey (Attachment C07)	Board Members	60	1	15/60	15
PIO Customer Satisfaction Survey (Attachment C08)	Health Care Practitioner	60	1	5/60	5
Concept Clinical Trial Survey (Attachment C09)	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey (Attachment C10)	Health Care Practitioner	1000	1	1/60	17
Low Accrual Clinical Trial Survey (Attachment	Health Care Practitioner	1000	1	1/60	17

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
C11)					
Audit Scheduling Form (Attachment D01)	Group/CTMS Users	152	5	21/60	266
Preliminary Audit Findings Form (Attachment D02)	Auditor	152	5	10/60	127
Audit Maintenance Form (Attachment D03)	Group/CTMS Users	152	5	9/60	114
Final Audit Finding Report Form (Attachment D04)	Group/CTMS Users	75	11	1098/60	15098
Follow-up Form (Attachment D05)	Group/CTMS Users	75	7	27/60	236
Roster Maintenance Form (Attachment D06)	CTMS Users	5	1	18/60	2
Final Report and CAPA Request Form (Attachment D07)	CTMS Users	12	9	1800/60	3240
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01)	Physician	23,000	1	15/60	5750
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care Practitioner	33,000	1	120/60	66,000
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03)	Physician; Health Care Practitioner	33,000	1	5/60	2750
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04)	Physician	23,000	1	10/60	3833
Totals		**136,487**	**207,989**		**112,898**

The total annualized cost to respondents is $6,529,394. Wage estimates are based upon a generic category of Health Care Practitioner at a median hourly wage rate of $35.83 per hour for allied health professionals (code 29-1199) and $99.48 per hour for Physicians and Surgeons, All Other (code 29-0169) for collections limited to physicians. Information is provided by the Bureau of Labor Statistics at http://www.bls.gov/oes/current/oes290000.htm.

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Table A.12-2a - Annualized Costs to Respondents

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A01)	Health Care Practitioner	978	$ 35.83	$ 35,027
CTSU IRB Certification Form (Attachment A02)	Health Care Practitioner	4888	$ 35.83	$ 175,137
Withdrawal from Protocol Participation Form (Attachment A03)	Health Care Practitioner	47	$ 35.83	$ 1,666
Site Addition Form (Attachment A04)	Health Care Practitioner	160	$ 35.83	$ 5,733
CTSU Roster Update Form (Attachment A05)	Health Care Practitioner	50	$ 35.83	$ 1,792
CTSU Request for Clinical Brochure (Attachment A06)	Health Care Practitioner	60	$ 35.83	$ 2,150

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
CTSU Supply Request Form (Attachment A07)	Health Care Practitioner	180	$ 35.83	$ 6,449
Site Initiated Data Update Form (Attachment A08)	Health Care Practitioner	4	$ 35.83	$ 143
Data Clarification Form (Attachment A09)	Health Care Practitioner	600	$ 35.83	$ 21,498
RTOG 0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	152	$ 35.83	$ 5,446
CTSU Generic Data Transmittal Form (Attachment A12)	Health Care Practitioner	10	$ 35.83	$ 358
CTSU Patient Enrollment Transmittal Form (Attachment A15)	Health Care Practitioner	24	$ 35.83	$ 860
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	120	$ 35.83	$ 4,300
CTSU System Access Request Form (Attachment A17)	Health Care Practitioner	60	$ 35.83	$ 2,150
CTSU OPEN Rave Request Form (Attachment A18)	Health Care Practitioner	105	$ 35.83	$ 3,762

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
CTSU LPO Form Creation (Attachment A19)	Health Care Practitioner	20	$ 35.83	$ 717
CTSU Site Form Creation and PDF (Attachment A20)	Health Care Practitioner	2000	$ 35.83	$ 71,660
CTSU PDF Signature Form (Attachment A21)	Health Care Practitioner	667	$ 99.48	$ 66,320
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B01)	Participants	13	$ 35.83	$ 448
NCI CIRB Signatory Enrollment Form (Attachment B02)	Participants	13	$ 35.83	$ 448
CIRB Board Member Application (Attachment B03)	Board Member	50	$ 99.48	$ 4,974
CIRB Member COI Screening Worksheet (Attachment B08)	Board Members	25	$ 99.48	$ 2,487
CIRB COI Screening for CIRB meetings (Attachment B09)	Board Members	18	$ 99.48	$ 1,791

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	$ 35.83	$ 2,866
CIRB IR Application for Exempt Studies (Attachment B11)	Health Care Practitioner	2	$ 35.83	$ 72
CIRB Amendment Review Application (Attachment B12)	Health Care Practitioner	100	$ 37.40	$ 3,740
CIRB Ancillary Studies Application (Attachment B13)	Health Care Practitioner	1	$ 37.40	$ 37
CIRB Continuing Review Application (Attachment B14)	Health Care Practitioner	100	$ 37.40	$ 3,740
Adult IR of Cooperative Group Protocol (Attachment B15)	Board Members	195	$ 99.48	$ 19,399
Pediatric IR of Cooperative Group Protocol (Attachment B16)	Board Members	45	$ 99.48	$ 4,477

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
Adult/Pediatric Continuing Review of Cooperative Group Protocol (Attachment B17) Protocol	Board Members	275	$ 99.48	$ 27,357
Adult Amendment of Cooperative Group Protocol (Attachment B19)	Board Members	80	$ 99.48	$ 7,958
Pediatric Amendment of Cooperative Group Protocol (Attachment B20)	Board Members	50	$ 99.48	$ 4,974
Pharmacist's Review of a Cooperative Group Study (Attachment B21)	Board Members	100	$ 99.48	$ 9,948
Adult Expedited Amendment Review (Attachment B23)	Board Members	174	$ 99.48	$ 17,310
Pediatric Expedited Amendment Review (Attachment B24)	Board Members	70	$ 99.48	$ 6,964

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
Adult Expedited Continuing Review (Attachment B25)	Board Members	70	$ 99.48	$ 6,964
Pediatric Expedited Continuing Review (Attachment B26)	Board Members	18	$ 99.48	$ 1,791
Adult Cooperative Group Response to CIRB Review (Attachment B27)	Health Care Practitioner	30	$ 35.83	$ 1,075
Pediatric Cooperative Group Response to CIRB Review (Attachment B28)	Health Care Practitioner	5	$ 35.83	$ 179
Adult Expedited Study Chair Response to Required Mod (Attachment B29)	Board Members	20	$ 99.48	$ 1,990
Reviewer Worksheet-Determination of UP or SCN (Attachment B31)	Board Members	67	$ 99.48	$ 6,632

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
Reviewer Worksheet-CIRB Statistical Reviewer Form (Attachment B32)	Board Members	25	$ 99.48	$ 2,487
CIRB Application for Translated Documents (Attachment B33)	Health Care Practitioner	50	$ 35.83	$ 1,792
Reviewer Worksheet of Translated Documents (Attachment B34)	Board Members	25	$ 99.48	$ 2,487
Reviewer Worksheet of Recruitment Material (Attachment B35)	Board Members	5	$ 99.48	$ 497
Reviewer Worksheet Expedited Study Closure Review (Attachment B36)	Board Members	5	$ 99.48	$ 497
Reviewer Worksheet of Expedited IR (Attachment B38)	Board Members	3	$ 99.48	$ 249

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
Annual Signatory Institution Worksheet About Local Context (Attachment B40)	Health Care Practitioner	267	$ 35.83	$ 9,555
Annual Principal Investigator Worksheet About Local Context (Attachment B41)	Health Care Practitioner	600	$ 35.83	$ 21,498
Study-Specific Worksheet About Local Context (Attachment B42)	Health Care Practitioner	1600	$ 35.83	$ 57,328
Study Closure or Transfer of Study Review Responsibility Form (Attachment B43)	Health Care Practitioner	560	$ 35.83	$ 20,065
Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attachment (B44)	Health Care Practitioner	120	$ 35.83	$ 4,300
Change of SI PI Form (Attachment B45)	Health Care Practitioner	40	$ 35.83	$ 1,433

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
Request Waiver of Assent Form (Attachment B46)	Health Care Practitioner	20	$ 35.83	$ 717
CTSU OPEN Survey (Attachment C03)	Health Care Practitioner	15	$ 35.83	$ 537
CIRB Customer Satisfaction Survey (Attachment C04)	Participants	150	$ 35.83	$ 5,375
Follow-up Survey (Communication Audit) (Attachment C05)	Participants/ Board Members	75	$ 35.83	$ 2,687
CIRB Board Member Annual Assessment Survey (Attachment C07)	Board Members	15	$ 99.48	$ 1,492
PIO Customer Satisfaction Survey (Attachment C08)	Health Care Practitioner	5	$ 35.83	$ 179
Concept Clinical Trial Survey (Attachment C09)	Health Care Practitioner	42	$ 35.83	$ 1,493
Prospective Clinical Trial Survey (Attachment C10)	Health Care Practitioner	17	$ 35.83	$ 597

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
Low Accrual Clinical Trial Survey (Attachment C11)	Health Care Practitioner	17	$ 35.83	$ 597
Audit Scheduling Form (Attachment D01)	Health Care Practitioner	266	$ 35.83	$ 9,531
Preliminary Audit Finding Form (Attachment D02)	Health Care Practitioner	127	$ 35.83	$4,538
Audit Maintenance Form (Attachment D03)	Health Care Practitioner	114	$ 35.83	$ 4,085
Final Audit Finding Report Form (Attachment D04)	Health Care Practitioner	15098	$ 35.83	$ 540,943
Follow-up Form (Attachment D05)	Health Care Practitioner	236	$ 35.83	$ 8,465
Roster Maintenance Form (Attachment D06)	Health Care Practitioner	2	$ 35.83	$ 54
Final Report and CAPA Request Form (Attachment D07)	Health Care Practitioner	3240	$ 35.83	$ 116,089

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Costs
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01)	Physician	5750	$ 99.48	$ 572,010
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care Practitioner	66000	$ 61.29	$ 4,045,140
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03)	Physician; Health Care Practitioner	2750	$ 61.29	$ 168,548
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04)	Physician	3833	$ 99.48	$ 381,340
Totals		**112,798**		**$ 6,529,394**

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

There are no additional costs or capital costs to respondents.

A.14 Annualized Cost to the Federal Government

The total annualized cost to the federal government is $1,613,105. Table A.14 provides an estimate of labor/processing cost at the task level inclusive of form and packet processing, site follow up, and all related processing activities. Estimates are based on federal oversight for each contract. An explanation of activities by contractor is given below.

Table A.14: Total Annualized Cost to the Federal Government

Staff	Grade/ Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					**$205,000**
Associate Branch Chief, CTOIB	Grade 14/Step 9	$140,000	50%		$70,000
Chief, CTOIB	Grade 15/Step 10	$150,000	50%		$75,000
Head CIRB	Grade 14/Step 10	$150,000	5%		$7,500
Nurse Consultant, DCP CIRB Liaison	Grade 14/Step 10	$150,000	5%		$7,500
CTMB, Branch Chief	Grade 14/Step 10	$150,000	25%		$37,500
PMB, Branch Chief	Grade 14/Step 10	$150,000	5%		$7,500
Contractor Cost					**$1,408,105**
CTSU and CIRB Forms Processing		$68,000	30%		$466,735
Survey Generation, Conduct, and Analysis		$68,000	10%		$62,300
PMB Contractor Costs		$65,116	1350%		$879,070
Travel					$0
Other Cost					$0
Total Costs					**$1,613,105**

Federal personnel provide contract oversight. Oversight activities include monitoring of the contract budget, ensuring compliance with the contract statement of work, and working with the contractors to ensure timely and efficient implementation of the contracts.

Emmes Corporation, as the primary contractor for the NCI CIRB Operations Office, is responsible for developing, maintaining, and processing information gathered on the CIRB forms and CIRB surveys to support the mission of the CIRB. Information obtained from CIRB data collection is critical in ensuring compliance with federal regulations regarding the protection of human subjects in clinical trials. Cost given above are those related to processing of CIRB-related forms.

Westat, as the primary contractor for the CTSU, is responsible for developing, maintaining, and processing information gathered on the CTSU forms and surveys to support administrative, regulatory, and clinical data collection for NCI sponsored trials. Information obtained from the CTSU data collections is critical in ensuring compliance with federal regulations regarding the protection of human subjects, ensuring appropriate documentation of regulatory document processing, and the collection of clinical trials data. Cost provided above are directly related to processing of regulatory, data management, membership and patient enrollment forms.

EDJ, Associates is the contractor responsible for processing of PMB registration forms. The level of effort is approximately 13.5 full time equivalent (FTE).

CTIS, as the primary CTEP information system contractor is responsible for developing and maintaining the AIS and RCR systems. Processing of information is completed by CTEP staff and other contracting staff. Information obtained from the data collections is critical to ensuring compliance with federal regulations regarding the protection of human subjects and the distribution of investigational agents.

A.15 Explanation for Program Changes or Adjustments

This revision adds data collection for the CTMB AIS and for the PMB RCR as well as form changes for the CTSU and CIRB.

The burden from the previously approved submission was 15,524 and with these changes it has increased to 112,838. The net change is an increase of 97,314 hours. The CTMB AIS forms accounts for an additional 19,082 hours, and the PMB RCR forms for an additional 78,333 hours. The burden hours for the CTSU, CIRB and surveys slightly decreased to 15,524 hours.

The following revisions are being made to the original submission:

For the CTSU

- Removal of data tracking forms for completed studies:
  - A11 – MC0845 (8233) CTSU Data Transmittal

- A13 – TAILORx_PACCT1_Data Transmittal Form
- A14 – Unsolicited Data Modification Form: Protocol TAILORx/PACCT-1

- Addition of the form, A18 – CTSU OPEN Rave Request Form – an administrative form completed by the lead protocol organization (LPO) to support setup of the Oncology Patient Enrollment Network (OPEN) patient enrollment system.
- Addition of the Delegation of Task Log forms required to document research assignments at the clinical sites as follows:
  - A19 – LPO Form Creation
  - A20 – Site Form Creation and PDF
  - A21 – PDF Signature Form

Please note that forms were not re-numbered in this submission. New forms were given the next sequential number.

For the CIRB

CIRB documents related to board members (**Attachments B03-B07**) were consolidated into a single CIRB Board Member Document: CIRB Board Member Application (**Attachment B03**). The detailed list of forms consolidated into the new Membership Application is given below.

The CPC Pharmacist's Review of Cooperative Group Study (**Attachment B22**) and Reviewer Worksheet – CPC – Determination of UP or SCN (**Attachment 39**) documents have been merged into the Pharmacist's Review of a Cooperative Group Study (**Attachment B21**).

In addition, Pediatric Continuing Review of Cooperative Group Protocol (**Attachment B18**), Pediatric Expedited Study Chair Response to Required Modification (**Attachment B30**), and Reviewer Worksheet Expedited Review of Study Chair Response to CIRB-Required Modification (**Attachment B37**) were removed as they were duplicative of other collections.

List of removed/consolidated forms:

- Attachment B03 – CIRB Board Member Biographical Sketch Form
- Attachment B04 – CIRB Board Member Contact Information Form
- Attachment B05 – CIRB Board Member W-9
- Attachment B06 – CIRB Board Member NDA
- Attachment B07 – CIRB Direct Deposit Form
- Attachment B18 – - Pediatric Continuing Review of Cooperative Group Protocol
- Attachment B22 – CPC Pharmacist's Review of Cooperative Group Study
- Attachment B30 – Pediatric Expedited Study Chair Response to Required Modification

- Attachment B37 – Reviewer Worksheet Expedited Review of Study Chair Response to CIRB-Required Modification
- Attachment B39 – Reviewer Worksheet – CPC – Determination of UP or SCN
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Newly added forms: :

- Attachment B46 – Request Waiver of Assent Form

  This attachment was added to the collection to document the study investigator's request to waive assent.

The remaining CIRB forms were not re-numbered with the removal of these two forms and the consolidation of the membership forms noted above.

Renaming of form:

- Attachment B17, Adult Continuing Review of Cooperative Group Protocol, was renamed Adult/Pediatric Continuing Review of Cooperative Group Protocol.

For the Surveys

The following surveys are no longer used and are being removed.

- Attachment C01- CTSU Website Customer Satisfaction Survey
- Attachment C02- CTSU Help Desk Customer Satisfaction Survey
- Attachment C06 A-D - Website Focus Groups
- Attachment C12 -ETCTN PI Survey
- Attachment C13 - ETCTN RS Survey

For the CTMB

The Clinical Trials Monitoring Branch (CTMB) forms are a new form category. These forms are required to document NCI as the sponsor and funding agency for cancer and ensure compliance of FDA regulations for the oversight program. The following forms have been added:

- Attachment D01 – Audit Scheduling Form
- Attachment D02 – Preliminary Audit Finding Form
- Attachment D03 – Auditor Maintenance Form
- Attachment D04 – Final Audit Finding Form
- Attachment D05 – Follow-up Form
- Attachment D06 – Roster Maintenance Form

- Attachment D07 – Final Report and CAPA Request Form.

For the PMB

Addition of Pharmaceutical Management Branch (PMB), Registration and Credential Repository (RCR) application forms under a new forms category include:

- Attachment E01 – NCI/DCTD/CTEP FDA Form 1572 for Annual Submission
- Attachment E02 – NCI/DCTD/CTEP Biosketch
- Attachment E03 – NCI/DCTD/CTEP Financial Disclosure Form
- Attachment E04 – NCI/DCTD/CTEP Agent Shipment Form (ASF)

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

There are no plans for publication. Processing of data collections is dependent on the activity. CTSU and CIRB forms are processed generally within one to three business days of receipt dependent on the form type. RCR forms are generally processed within two weeks, and audits within 70 days of audit completion. All collections are ongoing activity to support NCI operations and regulatory requirements. There is no expected end date at this time.

A.16 Table

A.16 - 1 Project Time Schedule

Activity	Time Schedule
CTSU Regulatory Forms (A01-A04)	Ongoing processing, one form per site/study, processing generally takes 3 to 5 business days of form receipt.
CTSU Membership Forms (A05-A07)	Ongoing processing, roster requests are per site and supply request per study, processing is within 3 business days of form receipt.
CTSU Data Management Forms (A08-A12)	Ongoing processing, processing is within 3 business days of form receipt.
CTSU Patient Enrollment Forms (A15-A16)	Ongoing processing, enrollments processed within 2 hours and transfers within 3 business days of form receipt.
CTSU Administrative Forms (A17-A18)	Ongoing processing, within one business day of receipt.
CTSU DTL Application (A19-A21)	Ongoing processing, updates are made in real-time
CIRB Enrollment Forms (B01-B02)	Ongoing processing, initial collection for the site investigator and research staff

A.16 Table **A.16 - 1 Project Time Schedule**	
Activity	**Time Schedule**
CIRB Board Member Forms (B03-B09)	Ongoing processing, updates are made in real-time
CIRB Reviewer Documents (B10-B38)	Ongoing processing, updates are made in real-time
CIRB Local Context Forms (B40-B46)	Ongoing processing, annual collection for the site investigator and per protocol for acceptance of CIRB review,
CTMB AIS Forms (D01&D03)	Ongoing processing, updates are made in real-time.
CTMB AIS Forms (D02)	Ongoing processing, updates are made in real-time.
CTBM AIS Forms (D04, D05, & D07)	Ongoing processing, within 5-7 business days of receipt.
RCR/DARTS Forms	Ongoing processing, dependent on the registrant processing may take

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: None

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