Supporting Statement A for

Cancer Therapy Evaluation Program (CTEP)

Branch and Support Contracts Forms and Surveys (NCI)

OMB# 0925-0753 Expiration Date 03/31/2026

This is a revision to the original submission and all changes are highlighted in yellow

March 13, 2024

Check off which applies:

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

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A. JUSTIFICATION

This is a request for OMB to approve the revised information collection, Cancer Therapy Evaluation Program (CTEP) Support Contracts Forms and Survey (OMB control number #0925-0753, expiration 3/31/2026), for three years. This revision removes one form, adds seven new forms, and revises five forms. The National Cancer Institute (NCI) 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 are termed the Clinical Oncology Research Enterprise (CORE) and represent an integrated set of information systems and processes that 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 (Food and Drug Administration (FDA) regulations pertaining to the sponsor of clinical trials and the selection of qualified investigators under 21 CRF 312.53). Survey collections assess satisfaction and provide feedback to guide improvements with processes and technology.

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 in CTEP and DCP-supported studies and to institute programs that minimize redundancy among grant and contract holders, thereby reducing the overall cost of maintaining a robust treatment trials program.

The Public Health Service Act, Section 411 (42 USC *§* 285a) authorizes the NCI to collect information to develop a National Cancer Program that 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 are significant information system and process integrations between the branches and contractors represented in this submission. For example, the foundation of the person and institution roster information in the CTSU’s Roster Maintenance application is via the Pharmaceutical Management Branch’s (PMB) investigator and clinical site staff registration. 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 NCI established the CTSU 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 documents, data management, and patient enrollment services. In addition, the CTSU develops and maintains systems to support each of the above-listed activities and integrates with several other CTEP systems. CTEP oversees the CTSU contract but does not utilize expertise or staffing outside of contractor or subcontract staff.

The CIRB is operated through the 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 who are representative of the oncology community outside of the NCI. The NCI provides funding as well as logistical and operational support to the CIRB. 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.

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 the National Clinical Trials Network (NCTN) Groups and the NCORP Research bases. The scheduling, results, and follow-up of each audit are tracked 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. Inclusion is for the automation of the investigator registration process and the use of the electronic system to enhance the registration of key staff at the clinical sites.

Capital Technology Information Systems (CTIS), Inc. is the CTEP contractor responsible for the development and maintenance of the CTEP Enterprise system including the AIS, AURORA (agent tracking system), 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 the responsibilities of the NCI. It includes modifications to OMB-approved forms for the CTSU and CIRB and the addition of new forms for the CTSU, CIRB, and CTEP. The use of electronic forms and submissions 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 next section provides a detailed description of each form/survey.

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 the processing of information and to guarantee the quality of the information collected,

CTSU has instituted standard forms to facilitate many activities. These activities are critical to project functions such as the collection of participating site and Lead Protocol Organization (LPO) regulatory information, Delegation of Tasks Log (DTL), patient accrual, site supplies, and LPO system setup information for the Oncology Patient Enrollment Network (OPEN) and the Compliance, Learning, and Standard Operating Procedures Solutions (CLASS) Learning Management System (LMS) setup.
CTSU Forms: The CTSU standard forms fall into six categories: Regulatory, Membership, Patient Enrollment, Data Management, 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.

- Attachment A01 – CTSU IRB/Regulatory Approval Transmittal Process
- Attachment A02 – CTSU IRB Certification Form
- Attachment A03 – Optional Form 1 – Withdrawal from Protocol Participation Form
- Attachment A04 – Site Addition Form
- Attachment A23 – CTSU LPO Approval of Early Closure Form

Based upon the processing metrics from August 2022 – August 2023, the CTSU processes approximately 6,763 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 networks. Regulatory packets are a mix of IRB approvals, protocol-specific requirements (PSRs), or both. Packet submission may occur via an automated link between the CIRB and CTSU, or the local site may submit the packet via the Regulatory Submission Portal on the CTSU website. Form, A01, CTSU IRB/Regulatory Approval Transmittal Form/Process has been modified to reflect the current electronic submission process. 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 IRB Manager System, which pushes IRB approval data for participating sites to the Regulatory application, thereby eliminating the need for sites to submit a separate approval to the CTSU Regulatory Office. CIRB IRB approvals average 97% of the total IRB approvals processed each month. Local IRB approvals and other 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 the required information.

Form A04, Site Addition form, documents additional sites under their IRB review.

The new form, A23, LPO Approval of Early Closure Form is designed to work with form A03, Withdrawal from Protocol Participation Form, to appropriately document local site closure of a protocol and ensure the site has verified with the LPO that all outstanding data or data queries have been resolved prior to closing the study.

CTSU Supply Request Forms (Attachments A06-A07)

CTSU Supply Request Forms support ordering of Investigational Brochures (IBs) and study supplies such as Quality of Life booklets or laboratory kits.

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 the collection of information on the investigator to perform checks ensuring they are eligible to receive the brochure.

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 site information to ensure the site is eligible to receive supplies and provides shipping information.

CTSU Data Management Forms (Attachment A10)

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 remove data management forms as studies close to data collection or data collection is transferred back the Lead Protocol Organization (LPO).

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, when manual enrollment is required because of technical issues, or the 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 and A22)

CTSU Administrative Forms have been created to facilitate OPEN and CLASS setup.

Attachment A18: CTSU-OPEN Rave Request Form – This administrative form supports the setup and testing of studies in OPEN. Information on this form is critical to ensuring eligible patients are enrolled in NCI-sponsored studies, and to supporting integrations with several other systems including the clinical data management system, Medidata Rave®. Additional instructions were added, and one question was added back from the previous version of the form.

Attachment A22: CLASS Course Setup Request Form – This administrative form supports the setup of LPO or NCI requested training in the CLASS application and if these trainings need to be linked to other applications to allow access.

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 the 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/site-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 is verified during site audits and may be 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 Form – Documents the Clinical Investigator's (CI) agreement to conduct the study per applicable NCI policies and federal regulations and oversee staff assignments. The CI has the option of signing per site-protocol DTL or signing several DTLs using a bulk-signing feature. The signing process is electronic for both the bulk and individual signing processes. The full per DTL form is available to view and print in PDF format. The attestation viewed when signing will depend upon the CI's location. CIs in the U.S. will sign an attestation reflecting requirements outlined by the Food and Drug Administration (FDA), and CIs outside of the U.S., who are not obligated to follow U.S. requirements, will attest to statements reflecting ICH E6 requirements.

Attachment A24: Electronic Signature Form – International – This is a new form and documents the CI agreement to conduct the study per applicable NCI policies and Good Clinical Practice (GCP). This serves the same purpose as Attachment A21, but the language was modified for international investigators. The DTL application has internal checks to verify that the CI is at an international site.

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 consistently 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; and eliminates back-

and-forth with the local IRB to gain study approval. Efficiencies for IRB members and IRB staff include the elimination of full board review of NCI-sponsored trials and the reduction of administrative burden. Benefits to study participants include having a 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:

Forms are collected in four general areas including 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 619 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 a presence within the CIRB's IT systems. In addition to SI, component, and affiliate institution details, the 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 NCI approves the candidate, CIRB sends a formal invitation for membership and additional information 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

NCI CIRB Board Reviewer Documents (Attachments B10-B38 and B50 and B52)

Board Members use CIRB Reviewer Worksheets when reviewing information submitted to the NCI CIRB. The LPOs submit review application forms at the 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 the trial; amendment applications highlight the changes to the trial. There are also forms for the Study Chair to document responses to the CIRB review. Board Members complete and submit the NCI CIRB Reviewer Worksheets once the review of a protocol is assigned and completed. Additionally, there are documents completed and submitted by NCI-sponsored institutions when responding to CIRB reviews.

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 an 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 an 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 regarding the response. The CIRB member completes this form, which 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 the 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 members to review an NCTN Group submission of statistical considerations for CIRB approval.
Attachment B33:	CIRB Application for Translated Documents – This form collects information on participant-facing translated materials.
Attachment B34:	Reviewer Worksheet of Translated Documents – Used by subcommittee members to review, document, and provide comments for an NCTN Group submission of translated materials for CIRB approval.
Attachment B35:	Reviewer Worksheet of Recruitment Material – Used by subcommittee members to review an NCTN Group or ETCTN LAO submission of locally developed material for CIRB approval.
Attachment B36:	Reviewer Worksheet Expedited Study Closure Review – Used by subcommittee members to review an 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 an NCTN Group or ETCTN Lead Academic Organization (LAO) submitted to the CIRB for expedited Initial Review.
Attachment B50:	Recruitment Material Video Review Submission – This is a new form and documents the final approved Recruitment Material Video that will be posted for study participants.
Attachment B52:	This is a new form and the application collects information on a reported study-wide unanticipated problem and/or serious or continuing noncompliance event for review by the CIRB.

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 institution's Primary Contact online via IRB Manager 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 the PI who will open a CIRB-approved study and capture 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 who do not speak English. This form is completed via IRB Manager and submitted to the CIRB for review. This worksheet is completed and updated online. The form is being amended to refine the question text and add permissible values instead of free-text fields. The addition of the permissible values does not increase the burden on the respondents as it only provides prompts to information that was previously collected in the free-text fields providing more direction and supporting analysis.

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 IRB Manager 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 or transfer of study review responsibility. This form is completed by the PI to close a study with the CIRB or to transfer study review responsibility to another IRB. This form is completed in IRB Manager 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 and/or serious or continuing noncompliance issues to the CIRB. This form is completed by the PI to report a potential unanticipated problem to the CIRB. The form is completed

in IRB Manager 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 the 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.

Attachment B47: CIRB Waiver of Consent Request Supplemental Form – This form collects a request for the waiver of consent from the Study Chair as part of the Initial Review, Amendment Review, or Continuing Review application process. This form is completed and submitted as a Word document. The form is being amended to meet the regulatory requirements and was updated to include the specific items that the sites must address to qualify for a waiver of consent. While these requirements were already in place, they are now clearly spelled out to ensure that the sites have considered the applicable requirements. The checkboxes are to assist the site with verifying they have met all federal regulations and acts as a worksheet for the sites. It also consolidates all instructions and regulation references into a single location to assist the site.

Attachment B48: Reviewer Worksheet CIRB Review for the Inclusion of Incarcerated Participants: This form is used by subcommittee members to review, document, and provide comments for the determination regarding the inclusion of incarcerated participants on a covered study submitted for CIRB approval.

Attachment B49: Notification of Incarcerated Participant Form – This form collects information as it related to enrolled participants who become incarcerated during the course of the study and the PI has determined it is in the best interest of the participant to remain on study. This form is completed by the PI or designee to notify the CIRB of a participant's incarceration. This form is completed in IRB Manager and submitted to the CIRB for review. This form is completed and updated online.

SURVEYS

Surveys are used to objectively measure customer satisfaction and provide data needed to improve services. Customer satisfaction surveys assess perceptions of our customers, as opposed to our perceptions of how well services are delivered. In general, the surveys are distributed by email or conducted online with common tools such as Survey Monkey. Selected participants are generally sent reminder emails 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. Generally, a reminder email is sent out after one week, and the survey is closed after two weeks. Data are compiled and shared with the contractors and CTEP for review.

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 an 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 a 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 asks Board Members about their experience as a CIRB member and open channels for receiving valuable feedback.

Attachment C08 : Protocol and Information Office (PIO) External Customer Satisfaction Survey – CTEP PIO serves to improve the protocol development and conduct processes with 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.

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, and document audit findings and follow-up information for a site participating in 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 contact 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, and 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 ratings for each protocol/site/patient combination. Users assign overall assessment ratings and indicate follow-up or re-audit is required for the component. The form also captures audit procedures used, exit interviews, and general comments. The 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 the 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 ensure specifically 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's NCI Community Oncology Research Program (NCORP) use the RCR system to collect electronic data to meet the needs of annual registration. RCR serves as a repository of registration information for all clinical research personnel participating in 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 participate in research trials, increase efficiency, and lower the cost of conducting clinical trials.

The RCR replaced the paper-based investigator registration process and supports FDA requirements for the 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 in 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 the receipt and proper handling of drug orders) and as the person responsible to accurately order drugs through the Online Agent Order Processing (OAOP) system.

Attachment E05: Non-Investigator/Non-Treatment (NINT) Registration Form – This is a new form. It is an electronic form that captures information on investigators who do not participate in IND/treatment studies including limited contact information, practice sites, IRBs, education, licensure, and training. The purpose of this form is to minimize data collection for investigators who do not participate in IND/treatment studies to facilitate their participation by minimizing the burden of unnecessary data collection. In the RCR application, investigators will be able to select the registration type that is appropriate for the type of studies in which they participate.

Attachment E06: International Investigator Statement (IIS) – This form supplements the sponsor investigator qualifications. It was originally part of the OMB submission for the Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer (OMB No. 0925-0613). With an increase in international participation on CTEP studies, a mechanism to ensure investigator compliance under the International Council for Harmonization of Technical Requirements for

Pharmaceuticals for Human Use (ICH) E6 regulations and Good Clinical Practice (GCP), was needed. Collection of ICH/GCP attestation as part of the IIS form for non-United States (U.S.) investigators is managed in the Registration and Credential Repository (RCR) dependent on the investigator's selection of a primary practice site. The signed attestation ensures that non-U.S. investigators agree to conduct research under applicable ICH/GCP guidance and country-specific regulations. The IIS will be used for non-U.S. investigators who are unable to sign Form FDA 1572[1] due to applicable country-specific regulations. Many European Union and other non-U.S. participants are not able to sign the FDA 1572 per their countries' regulations.

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 in NCI-sponsored studies. Variations of this form to accommodate international investigators and investigators not participating in IND/Treatment studies are available to document compliance with GCP when appropriate (e.g., IIS and NINT).

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.

CTEP

The NCI Database of Genotypes and Phenotypes (dbGaP) Initial Study Registration Information form (Attachment F01) was created to assist the study teams in registering their studies in the dbGaP system. dbGaP is a central National Institutes of Health (NIH) repository for sharing data on studies that measure the association between genotype and phenotype in humans. Data submitted from multiple studies is available to investigators for further research purposes.

Additional attachments to this submission

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

[1] OMB No. 0925-0753, Expiration 7/30/2021; has been submitted for revision.

For the CTSU the following attachments are included: Previously labeled as "F", all moved to "G" to accommodate a new category

Attachment G01: Privacy Impact Assessment (PIA). Contact information collected from the forms is added to the CTSU-Enterprise (ESYS), and data security is maintained as outlined in the Privacy Impact Assessment (PIA). The date of the last Security Authorization was (8.31.2022) under the IT system name "NCI Cancer Trials Support Unit Enterprise Information System (CTSU-EIS)" for the CTSU-ESYS inclusive of the website, Roster Maintenance, Regulatory, Protocol, OPEN, and other related modules.

Attachment G02: Westat IRB Letter. The CTSU project and its forms and surveys have been reviewed by the Westat IRB and approved.

Attachment G03: Privacy Act Memo. Dated August 5, 2020, 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 data collection.

For the CIRB the following attachments are included:

Attachment G04: 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 latest report for FIPS 199 was submitted in June 2023 for the CIRB Manager Information System.

Attachment G05: 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 an IRB review of studies. Therefore, OHSR found that data are not being collected on human subject participants as part of the CIRB Initiative.

Attachment G06: Emmes IRB Letter. In September 2016, the Emmes IRB found the NCI CIRB project and its forms and surveys to be exempt.

For CTEP attachments are included:

Attachment G09: Privacy Impact Assessment (PIA). Contact information collected from the forms is added to the CTEP-ESYS, and data security is maintained as outlined in the Privacy Impact Assessment (PIA). The last date signed was August 31, 2022 under the IT system name "Cancer Therapy Evaluation System".

Attachment G10: 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 environment that hosts the NCI CTEP Enterprise system. Security controls are implemented per the applicable environment. The latest report for FIPS 199 is dated June 7, 2023

A.3 Use of Information Technology and Burden Reduction

The NCI, DCTD, and CTEP continuously seeks mechanisms to reduce burden through advances in information technology. The 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 application upload 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 The Emmes Company and Westat have completed a Security Testing and Evaluation (ST&E) of their systems as per the guidelines outlined 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. An independent third-party auditor to ensure the security controls are in place and working as intended. CTSU successfully completed the ST&E on the CTSU Enterprise system. 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 a FISMA compliant system for the last 14 years and has maintained an Active Authorization to Operate (ATO) since 2004. Attached are the PIA Memo for the CTEP Branch and Support Contracts Forms and Surveys **(Attachment G03)**, the Privacy Act Form **(Attachment G09)**, and the CTEP-ESYS FIPS **(Attachment G10)**.

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 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 CTEP's RCR application. Individuals are assigned unique identifiers, usernames 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 Roster Maintenance application, which uses 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, to be added to a roster in the Roster Maintenance application, and assigned user roles to access the common data management system using their CTEP username and password. The 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 businesses 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 site and 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 affect 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 November 14, 2023, Vol, 88, No. 218, Page 78053. 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 Good Clinical Practice (GCP) 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 a 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-Identity and Access Management (IAM) username and password. User authentication is a combination of CTEP-IAM authorization and roster data in the Roster Maintenance application. All nonpublic parts of the resource are maintained in accordance with appropriate privacy and security access controls pursuant to applicable policies. CTSU forms 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 in August 2021 and the IT system name is "NIH NCI Cancer Trials Support Unit (CTSU)" for the CTSU-ESYS inclusive of the website, modernized applications, and other related modules (**Attachment G01**) 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 or available online and use standard survey processing tools. Identifying information based on 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 convey 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 is submitted on hard copy forms or electronic forms 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's 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 the CTEP Branch and Support Contracts Forms and Surveys (**Attachment G03**). 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 G05**).

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 do 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 signed by HHS on August 31, 2022. (**Attachment G09)**.

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 Member's 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 that are indicative of clinical site performance are kept confidential and access is limited to the NCTN Research Bases, the 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 the 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 pharmaceutical company conflicts as reported on the Financial Disclosure Form. The collection and evaluation of this information are 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 that 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 G03**).

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 G03**). 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 G05**).

A.12.1 Estimated Annualized Burden Hours

The estimated annualized burden hours for this information collection are 162,836 from an estimated 253,511 respondents. Please note that the same respondents may submit multiple form types. For

example, respondents will register in RCR and may 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 48,000 users.

The estimates are based on the 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 depending 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, DTL, and patient enrollment forms may be submitted multiple times during the year as sites participate in multiple studies and enroll multiple patients. The repetitive nature of this collection is necessary to ensure that clinical sites are meeting federal regulations for the review of studies prior to patient enrollment, enroll patients in 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 the annual cumulative response rate to forms. Estimates on form usage are based on processing metrics such as the LPO and the CTMS users, the 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 the 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 investigational registration documents are completed with the combined efforts of the investigator and support staff (usually a clinical research assistant-CRA). The investigator does about 40% of the work and the CRA performs about 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 the initial completion burden per OMB instruction. Burden changes between the initial registration submission and subsequent years are as follows:

- Attachment E01 – Statement of Investigator: estimated time for initial completion is 15 minutes and in subsequent years it is 5 minutes.
- Attachment E02 – Biosketch: estimated time for initial completion is 2 hours and in subsequent years 10 minutes.
- Attachment E03 – Financial Disclosure: no change.
- Attachment E04 – Agent Shipment Form: The estimated time for initial completion is 10

minutes and in subsequent years 5 minutes.

Per RCR registrants, the burden change for investigators and non-physician investigators is from 160 minutes for the initial submission, to 35 minutes in subsequent registration years. For the registration type of Associate Plus, it is from 135 minutes for their initial registration and 25 minutes in subsequent years. If 75% of the registrants are renewals, this results in a reduction of 68,775 burden hours from the initial year to subsequent years.

There is no difference in time between a U.S.-based investigator completing and signing the Statement of Investigator and an international investigator signing the IIS Form as the difference in the forms is the attestation.

The new NINT registration type was designed to minimize the time and burden of registration for investigators and other healthcare personnel to participate on non-IND/non-treatment studies. For initial completion, this represents a decrease of approximately 90 minutes. As with other registration types, re-registration in subsequent years will require the verification of existing information and any appropriate updates, and is estimated to take about 15 minutes.

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 and Clinical Brochure Request Forms (Attachment A06 and A07) – as noted above, clinical sites participate on multiple protocols throughout the year and use these forms to request initial and resupply of items such as IBs and laboratory kits.
- 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 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 OPEN Rave Request Form (A18) – The form is required to facilitate the setup the of eligibility checklist (ECs). A form is required for new, amended and revised EC forms. The LPO staff submit multiple forms over the study life cycle and for each study that they are responsible for setup.
- 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 Form and PDF Signature Form (A20, A21, and A24)– 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 CLASS Course Setup Request Form (A22) – this form documents the LPO or NCI request for setting up a training course in CLASS. As the nature of trainings may vary (e.g., protocol-specific, application-specific, or general) a separate form is required for each request. CIRB Review Process – (B10-B38) – The study PI working under the auspices of the NCI-funded LPOs, may request review of more than one study in a year. While not all forms are required, each study will require initial submission to the CIRB, reviewer comments, and tracking of the review process as required by federal regulation. As appropriate, additional information on translations, review of study recruitment materials, or request for expedited review may be submitted.
- CIRB Site Review Process (B40–B45) – Signatory institutions will participate in multiple studies in a given year. Forms are study specific.
- CIRB Special Processing Forms (B46-B49, B50, and B52) – In some instances, studies reviewed by the CIRB will include vulnerable populations including children and incarcerated participants, require approval of patient-facing materials, or the reporting of study-wide events. As appropriate, the study PI and participating sites will request approval for such inclusions.
- 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.
- Audit Finding Documentation (D04–D07) – each audit scheduled is coordinated by a lead auditor who is responsible for the 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 depending on the size of the audit, findings, and if CTMB requires revisions to the report.

Table 12-1 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	Health Care Practitioner	279	1	10/60	47

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Participation Form (Attachment A03)					
Site Addition Form (Attachment A04)	Health Care Practitioner	80	12	10/60	160
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
RTOG-0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	30	2	5/60	5
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 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 DTL Site Form Creation (Attachment A20)	Health Care Practitioner	400	10	30/60	2000
CTSU DTL Electronic Signature Form (Attachment A21)	Health Care Practitioner	400	10	10/60	667
CTSU CLASS Course Setup Form (Attachment A22)	Health Care Practitioner	10	2	20/60	7
CTSU LPO Approval for Early Closure Form (Attachment A23)	Health Care Practitioner	2444	6	20/60	4888
International DTL Signing (Attachment A24)	Health Care Practitioner	29	1	0.1667	5
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

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
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
Adult 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
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	15/60	1200
Study Closure or Transfer of Study Review Responsibility (Attachment B43)	Health Care Practitioner	1680	1	15/60	420
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	35	1	20/60	12
CIRB Waiver of Consent Request Supplemental Form (Attachment B47)	Health Care Practitioner	20	1	15/60	5
Review Worksheet CIRB Review for Inclusion of Incarcerated Participants (Attachment B48)	Board Members	20	1	60/60	20
Notification of Incarcerated Participant Form (B49)	Health Care Practitioner	20	1	20/60	7
Final Video Submission Posting Form (Attachment B50)	Health Care Practitioner	80	1	15/60	20
Unanticipated Problem or Serious or Continuing Noncompliance Application (Attachment B52)	Health Care Practitioner	20	1	30/60	10
CIRB Customer Satisfaction Survey (Attachment C04)	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit)	Participants/ Board Members	300	1	15/60	75

(Attachment C05)					
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
Audit Scheduling Form (Attachment D01)	Health Care Practitioner	229	5	21/60	401
Preliminary Audit Finding Form (Attachment D02)	Health Care Practitioner	229	5	10/60	191
Audit Maintenance Form (Attachment D03)	Health Care Practitioner	158	5	9/60	119
Final Audit Finding Report Form (Attachment D04)	Health Care Practitioner	110	11	1098/60	22143
Follow-up Form (Attachment D05)	Health Care Practitioner	44	7	27/60	139
Roster Maintenance Form (Attachment D06)	Health Care Practitioner	7	1	18/60	2
Final Report and CAPA Request Form (Attachment D07)	Health Care Practitioner	3	9	1800/60	810
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01)	Physician	26,500	1	15/60	6625
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care Practitioner	48,000	1	120/60	96000
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03)	Physician; Health Care Practitioner	48,000	1	15/60	12000
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04)	Physician	24,000	1	10/60	4000
Non-IND/Non-Treatment Registration Form (Attachment E05)	Physician	1,000	1	60/60	1000
International Investigator Statement (Attachment E06)	Physician	2,100	1	15/60	525
Basic Study Information Form (Attachment F01)	Health Care Practitioner	140	1	20/60	47
Totals		**173,523**	**253,570**		**162,836**

A.12-2 Annualized Cost to Respondents

The total annualized cost to respondents is **$11,480,540.32.**

Table 12-2 Annualized Costs to Respondents

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A01)	Health Care Practitioner	978	$46.52	$45,496.56
CTSU IRB Certification Form (Attachment A02)	Health Care Practitioner	4888	$46.52	$227,389.76
Withdrawal from Protocol Participation Form (Attachment A03)	Health Care Practitioner	47	$46.52	$2,186.44
Site Addition Form (Attachment A04)	Health Care Practitioner	160	$46.52	$7,443.20
CTSU Request for Clinical Brochure (Attachment A06)	Health Care Practitioner	60	$46.52	$2,791.20
CTSU Supply Request Form (Attachment A07)	Health Care Practitioner	180	$46.52	$8,373.60
RTOG-0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	5	$46.52	$232.60
CTSU Patient Enrollment Transmittal Form (Attachment A15)	Health Care Practitioner	24	$46.52	$1,116.48
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	120	$46.52	$5,582.40
CTSU OPEN Rave Request Form (Attachment A18)	Health Care Practitioner	105	$46.52	$4,884.60
CTSU LPO DTL Form Creation (Attachment A19)	Health Care Practitioner	20	$46.52	$930.40
CTSU DTL Site Form Creation and PDF (Attachment A20)	Health Care Practitioner	2000	$46.52	$93,040.00
CTSU DTL Electronic Signature Form (Attachment A21)	Health Care Practitioner	667	$46.52	$31,028.84
CTSU CLASS Course Setup Form (Attachment A22)	Health Care Practitioner	7	$46.52	$325.64
CTSU LPO Approval for Early Closure Form (A23)	Health Care Practitioner	4888	$46.52	$227,389.76
International DTL Signing (A24)	Physician	5	$114.76	$573.80
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B01)	Participants	13	$46.52	$604.76
NCI CIRB Signatory Enrollment Form (Attachment B02)	Participants	13	$46.52	$ 604.76

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
CIRB Board Member Application (Attachment B03)	Board Member	50	$46.52	$2,326.00
CIRB Member COI Screening Worksheet (Attachment B08)	Board Members	25	$114.76	$2,869.00
CIRB COI Screening for CIRB meetings (Attachment B09)	Board Members	18	$114.76	$2,065.68
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	$46.52	$3,721.60
CIRB IR Application for Exempt Studies (Attachment B11)	Health Care Practitioner	2	$46.52	$93.04
CIRB Amendment Review Application (Attachment B12)	Health Care Practitioner	100	$46.52	$4,652.00
CIRB Ancillary Studies Application (Attachment B13)	Health Care Practitioner	1	$46.52	$46.52
CIRB Continuing Review Application (Attachment B14)	Health Care Practitioner	100	$46.52	$ 4,652.00
Adult IR of Cooperative Group Protocol (Attachment B15)	Board Members	195	$114.76	$22,378.20
Pediatric IR of Cooperative Group Protocol (Attachment B16)	Board Members	45	$114.76	$5,164.20
Adult Continuing Review of Cooperative Group Protocol (Attachment B17) Protocol	Board Members	275	$114.76	$31,559.00
Adult Amendment of Cooperative Group Protocol (Attachment B19)	Board Members	80	$114.76	$9,180.80
Pediatric Amendment of Cooperative Group Protocol (Attachment B20)	Board Members	50	$114.76	$5,738.00
Pharmacist's Review of a Cooperative Group Study (Attachment B21)	Board Members	100	$114.76	$11,476.00
Adult Expedited Amendment Review (Attachment B23)	Board Members	174	$114.76	$19,968.24
Pediatric Expedited Amendment Review (Attachment B24)	Board Members	70	$114.76	$8,033.20
Adult Expedited Continuing Review (Attachment B25)	Board Members	70	$114.76	$8,033.20
Pediatric Expedited Continuing Review (Attachment B26)	Board Members	18	$114.76	$2,065.68
Adult Cooperative Group Response to CIRB Review (Attachment B27)	Health Care Practitioner	30	$46.52	$1,395.60
Pediatric Cooperative Group Response to CIRB Review (Attachment B28)	Health Care Practitioner	5	$46.52	$232.60
Adult Expedited Study Chair Response to Required Modifications (Attachment B29)	Board Members	20	$114.76	$2,295.20

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
Reviewer Worksheet- Determination of UP or SCN (Attachment B31)	Board Members	67	$114.76	$ 7,688.92
Reviewer Worksheet -CIRB Statistical Reviewer Form (Attachment B32)	Board Members	25	$114.76	$2,869.00
CIRB Application for Translated Documents (Attachment B33)	Health Care Practitioner	50	$46.52	$2,326.00
Reviewer Worksheet of Translated Documents (Attachment B34)	Board Members	25	$114.76	$2,869.00
Reviewer Worksheet of Recruitment Material (Attachment B35)	Board Members	5	$114.76	$573.80
Reviewer Worksheet Expedited Study Closure Review (Attachment B36)	Board Members	5	$114.76	$573.80
Reviewer Worksheet of Expedited IR (Attachment B38)	Board Members	3	$114.76	$ 344.28
Annual Signatory Institution Worksheet About Local Context (Attachment B40)	Health Care Practitioner	267	$46.52	$ 12,420.84
Annual Principal Investigator Worksheet About Local Context (Attachment B41)	Health Care Practitioner	600	$114.76	$68,856.00
Study-Specific Worksheet About Local Context (Attachment B42)	Health Care Practitioner	1200	$46.52	$55,824.00
Study Closure or Transfer of Study Review Responsibility (Attachment B43)	Health Care Practitioner	420	$46.52	$19,538.40
Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attachment (B44)	Health Care Practitioner	120	$46.52	$5,582.40
Change of Signatory Institution PI Form (Attachment B45)	Health Care Practitioner	40	$46.52	$1,860.80
Request Waiver of Assent Form (Attachment B46)	Health Care Practitioner	12	$46.52	$ 558.24
CIRB Waiver of Consent Request Supplemental Form (Attachment B47)	Health Care Practitioner	5	$46.52	$232.60
Review Worksheet CIRB Review for Inclusion of Incarcerated Participants (Attachment B48)	Board Members	20	$46.52	$930.40
Notification of Incarcerated Participant Form (B49)	Health Care Practitioner	7	$46.52	$ 325.64
Final Video Submission Posting Form (Attachment B50)	Health Care Practitioner	20	$46.52	$930.40
Unanticipated Problem or Serious or Continuing Noncompliance Application (Attachment B52)	Health Care Practitioner	10	$46.52	$465.20

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate*	Respondent Cost
CIRB Customer Satisfaction Survey (Attachment C04)	Participants	150	$46.52	$6,978.00
Follow-up Survey (Communication Audit) (Attachment C05)	Participants/ Board Members	75	$46.52	$3,489.00
CIRB Board Member Annual Assessment Survey (Attachment C07)	Board Members	15	$114.76	$1,721.40
PIO Customer Satisfaction Survey (C08)	Health Care Practitioner	5	$46.52	$232.51
Audit Scheduling Form (Attachment D01)	Health Care Practitioner	401	$46.52	$ 18,654.52
Preliminary Audit Finding Form (Attachment D02)	Health Care Practitioner	191	$46.52	$ 8,885.32
Audit Maintenance Form (Attachment D03)	Health Care Practitioner	119	$46.52	$ 5,535.88
Final Audit finding Report Form (Attachment D04)	Health Care Practitioner	22143	$46.52	$1,030,092.36
Follow-up Form (Attachment D05)	Health Care Practitioner	139	$46.52	$ 6,466.28
Roster Maintenance Form (Attachment D06)	Health Care Practitioner	2	$46.52	$ 93.04
Final Report and CAPA Request Form (Attachment D07)	Health Care Practitioner	810	$46.52	$37,681.20
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01)	Physician	6625	$114.76	$760,285.00
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care Practitioner	96000	$73.81	$7,085,760.00
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03)	Physician; Health Care Practitioner	12000	$73.81	$885,720.00
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04)	Physician	4000	$114.76	$459,040.00
Non-IND/Non-Treatment Registration Form (Attachment E05)	Physician	1000	$114.76	$114,760.00
International Investigator Statement (Attachment E06)	Physician	525	$114.76	$60,249.00
Basic Study Information Form (Attachment F01)	Health Care Practitioner	47	$46.52	$ 2,186.44
Totals		**162,836**		**$ 11,480,540.32**

*Wage estimates are based upon a generic category of Health Care Practitioner, at a mean hourly wage rate of $46.52 per hour for healthcare practitioners and technical occupations #29-0000 and $114.76 per hour for Physicians, All Other, #29-1229 (mean hourly rate) for collections limited to physicians. A blended rate of $73.81 is used for forms E02 – E03 as they are completed by both investigators and non-investigators. Information is provided by the Bureau of Labor Statistics at

http://www.bls.gov/oes/current/oes2No90000.htm.

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 $1,662,249.60. 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 the contractor is given below.

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

Cost Descriptions	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Associate Branch Chief, CTOIB	14/10	$181,216	50%		$90,608.00
Chief, CTOIB	15/10	$191,900	50%		$95,950.00
Head CIRB	14/10	$181,216	5%		$9,060.80
Nurse Consultant, DCP CIRB Liaison	14/10	$181,216	5%		$9,060.80
CTMB, Branch Chief	15/10	$191,900	25%		$47,975.00
PMB, Branch Chief	15/10	$191,900	5%		$9,595.00
Contractor Cost					**$1,400,000.00**
Travel					$0
Other Cost					$0
Total					**$1,662,249.60**

**The Salary in the table above is cited from: Office of Personnel Management https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB.pdf.

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.

The Emmes Company, 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 the 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 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. Costs provided above are directly related to processing of regulatory, data management, membership, and patient enrollment forms.

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

CTIS, Inc. 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 collection 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 removes C03 – OPEN Survey as it is no longer needed and adds or revises the following forms.

The burden from the previously approved submission was 151,769 hours and with these changes, it has increased to 162,836 hours. The net change is an increase of 11,067 hours. The addition of two new CIRB forms, two CTSU forms, and 3 CTEP form accounts for the overall increase.

The following revisions are being made to the previous submission:
For the CTSU

CTSU is adding a form to support the early withdraw of sites from study participation and to document the attestation of international investigators on the DTL. A description and purpose of the form are below.

A01, CTSU IRB/Regulatory Approval Transmittal Form/Process has been modified to reflect the current electronic submission process.

A22 CLASS Course Setup Request Form was updated to consolidate some questions (e.g., self-enrollment and auto-enrollment). Questions were added regarding unique tags/keys (question 1.7) and if the training is associated with a DTL (question 2.4). Other questions were reordered.

A23 CTSU LPO Approval of Early Closure Form
The form will document the LPO's approval for a site to proceed with the early closure of a trial by providing documentation to the CTSU that all data entry is complete and all queries are resolved. This will prevent the scenario of a site withdrawing prematurely and needing to reactivate the study with the IRB of record, recreate their DTL, and regain access to the clinical data management system, which is a time-consuming process and requires the CTSU to make several backend system updates.

A24 International DTL Signing

This is a new form and serves the same purpose as Attachment A21, CTSU PDF Signature Form, but the attestation reflects GCP requirements.

For the CIRB

CIRB modified forms to clarify wording, update instructions, remove questions that are no longer relevant, and added questions to capture data required for oversight of the institutions. Form revisions out outlined below.

B10 CIRB IR Application

The form is being amended to add language to request a waiver of informed consent when applicable to the study. This does not represent a new process or additional burden, but formalizes the responses required from the study team if a waiver or alternation of the elements of informed consent is requested.

B12 CIRB Amendment Review Application

The form is being amended to meet the regulatory requirements and was updated to include the specific items regarding financial conflict of interest disclosure of the Study Chair or any persons listed on the protocol who are involved in the development or coordination of the protocol. In addition, waiver of informed consent or elements of informed consent was added to this form.

B33 CIRB Application for Translated Documents

The CIRB Application for Translated Documents has undergone a complete overhaul to better reflect the current process and capture additional information on the nature of the request. It now has separate sections for a translation completed by the CTSU and those by the study team. It also has a section for review of translations of already approved materials, and translations for materials provided by an outside source.

B50 Final Video Submission Posting Form

This new form documents the final approved recruitment Material Video that will be posted for study participants.

B52 Unanticipated Problem or Serious or Continuing Noncompliance Application

This new application collects information on a reported study-wide unanticipated problem and/or serious or continuing noncompliance event for review by the CIRB.

For the PMB

E05 Non-IND/Non-Treatment Registration Form
This form streamlines the registration process for investigators who will not participate in IND or treatment studies while still allowing NCI to capture information required to meet federal regulations. It reduces the burden on investigators who do not participate in IND studies and possibly expands the pool of investigators willing to participate in non-IND/treatment studies.

E06 International Investigator Statement
This form supplements the sponsor investigator qualifications. It was originally part of the OMB submission for the Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer (OMB No. 0925-0613). With an increase in international participation on CTEP studies, a mechanism to ensure investigator compliance under the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 regulations and Good Clinical Practice (GCP), was needed. Collection of ICH/GCP attestation as part of the IIS form for non-U.S. investigators is managed in the Registration and Credential Repository (RCR) dependent on the investigator's selection of a primary site. The signed attestation ensures that non-U.S. investigators agree to conduct research under applicable ICH/GCP guidance and country-specific regulations. The IIS will be used for non-United States (U.S.) investigators who are unable to sign Form FDA 1572[2] due to applicable country-specific regulations. Many European Union and other non-U.S. participants are not able to sign Form FDA 1572 per their countries' regulations.

For CTEP

F01 Basic Study Information Form
This form supports study registration to the NCI dbGaP database. dbGaP is a central National Institutes of Health (NIH) repository for sharing data on studies that measure the association between genotype and phenotype in humans. Data submitted from multiple studies is available to investigators for further research purposes.

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

There are no plans for publication. Processing of data collection is dependent on the activity. CTSU forms are processed generally within one to three business days of receipt dependent on the form type. CIRB forms are generally processed within a week. RCR forms are generally processed within 2 weeks, and audits within 70 days of audit completion. All collections are ongoing activities to support NCI operations and regulatory requirements. There is no expected end date at this time.

[2] OMB No. 0925-0753, Expiration 7/30/2021; has been submitted for revision.

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 requests 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 are processed within 2 hours and transfers within 3 business days of form receipt.
CTSU Administrative Forms (A18 and A22)	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.
CIRB Board Member Forms (B03-B09)	Ongoing processing, updates are made in real time.
CIRB Reviewer Documents (B10-B38 and 50 and 52)	Ongoing processing, updates are made in real time.
CIRB Local Context Forms (B40-B45)	Ongoing processing, annual collection for the site investigator and per protocol for acceptance of CIRB review.
CIRB Special Population Forms (B46-B49)	Ongoing processing as needed.
CTMB AIS Forms (D01&D03)	Ongoing processing, and updates are made in real-time.
CTMB AIS Forms (D02)	Ongoing processing, and updates are made in real-time.
CTMB AIS Forms (D04, D05, & D07)	Ongoing processing, within 5-7 business days of receipt.
RCR Forms (E01-E06)	Ongoing processing, dependent on the registrant processing may take 1 to 5 business days.
CTEP Form	TBD

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.