

# Supporting Statement A for

## CTEP Support Contracts Forms and Surveys

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Check off which applies:

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

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## **A. JUSTIFICATION**

This is a new information collection seeking approval for three years. The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP and DCP oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The information collected for both programs is for the purposes of membership, enrollment, opening of Institutional Review Board (IRB) approved studies, documenting IRB review, regulatory approval (for sites not using the CIRB), patient enrollment, and routing of case report forms. Information will also be collected through surveys to assess satisfaction and provide feedback to guide improvements with processes and technology as well as assessing health professional's interests in clinical trials.

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

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

The Public Health Service Act, Section 411 (42 USC § 285a) authorizes the National Cancer Institute (NCI) to collect information in order to develop a National Cancer Program which consists of “an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute,” as well as “ other programs and activities of the Institute.” This scope of work calls for the establishment of the NCI CIRB which was created to reduce the administrative burden on local Institutional Review Boards (IRBs) and investigators while protecting human research participants. This scope also supports the mission of the CTSU which provides administrative and systems support to clinical trials networks and participating sites; while instituting programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program.

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

Both programs support the National Clinical Trials Network (NCTN), Experimental Therapeutics Clinical Trials Network (ETCTN), and NCI Community Oncology Research Program (NCORP) programs

in conducting NCI-funded research. In addition, the CTSU supports several smaller networks, such as the Cancer Immunotherapy Trials Network (CITN).

## **A.2 Purpose and Use of the Information Collection**

This information collection is proposed to fulfill responsibilities of the National Cancer Institute which consists of coordinated cancer research program enveloping both the NCI CIRB and CTSU. The NCI CIRB was previously approved under OMB 0925-0625, which expires 12/31/2016. The CTSU program was previously approved under OMB 0925-0624 which expires 1/31/2017. The proposed information collection is the combining of these two projects to decrease administrative burden.

The NCI CIRB reduces administrative burden on local IRBs and investigators while protecting human research participants and the CTSU provides administrative systems support to clinical trials networks and participating sites while instituting programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program.

Broadly the information collected supports IRB review of NCI-supported studies, documentation of clinical site acceptance of IRB review, management of institutions and persons participating on NCI-supported trials, verification of participation and regulatory requirements, patient enrollment, and clinical data collection. The combined infrastructure of the NCI CIRB and CTSU allows investigators to streamline study startup activities, study review and approval, conduct research, reach conclusions faster, and offer patients studies that incorporate precision medicine at over 3,000 clinical sites and to approximately 34,000 patients per year.

### **NCI CIRB**

The benefits to research participants include study review by individuals who represent oncology experts, as well as specialized expertise such as pediatric oncology, early drug development, and prevention. The benefits to investigators and research staff include: easier to open trials; eliminates preparation of study submissions to local IRBs, including completion of IRB application, duplication of IRB packets, subsequent submissions for amendments, continuing reviews; eliminates back-and-forth with IRB to gain study approval. Efficiencies for IRB members and IRB staff include: elimination of full board review of NCI-sponsored trials, and reduction of administrative burden. Benefits to study participants include: having dedicated review of NCI-sponsored trials for study participant protections, access to more trials more quickly, and access to trials for rare diseases. Additionally, more trials may be opened at more institutions more quickly, accrual to trials may begin more rapidly, trials may obtain accrual goals sooner, and trial questions may be answered more quickly. The NCI uses various information collection tools to support CIRB activities. Information collection tools include: worksheets and/or forms requiring completion by an institution conducting a clinical trial eligible for review by the CIRB, as well as worksheets and/or forms requiring completion by the CIRB members themselves. CIRB forms fall into four categories: Enrollment, Board Membership, Board Review, and Local Context. These forms were developed to ensure data is collected in a consistent manner for specific project needs. All forms are described below.

## CTSU

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

### Surveys

Surveys have been developed to gauge satisfaction, providing valuable end user information on services provided to participating clinical sites; surveys have been developed to assess aspects of administrative functions at CTEP, assess barriers to opening clinical trials, and new network initiatives. Additionally, surveys have been developed to assess opening a clinical trial, accruing to a clinical trial, and determining reasons for low accrual. A new survey with this submission polls Principal Investigator's (PIs) participating in the ETCTN program that are oncologists and researchers at organizations that have received grants and are responsible for developing and running clinical trials; another new survey collects information from the organization's clinical research staff (i.e. grant and site administrators, clinical research associates and registrars) and inquiries about satisfaction with processes and resources involved to submit and administer protocols.

CTSU Forms: The CTSU standard forms fall into five categories: Regulatory, Membership, Data Management, Patient Enrollment and Administrative.

#### CTSU Regulatory Forms (Attachments A1-A4)

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 A1: CTSU IRB/Regulatory Approval Transmittal Form -
- Attachment A2: CTSU IRB Certification Form
- Attachment A3: Optional Form 1 - Withdrawal from Protocol Participation Form
- Attachment A4: Site Addition form

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



with CTEP, other CTSU systems such as OPEN, and the NCTN Groups in near real time to support patient enrollments, drug shipment, and data management.

The CTSU processes on average 18,000 IRB approvals a month. Processing is facilitated by systems integration with CIRB's IRBManager system, which pushes IRB approval data for participating sites to the RSS, thereby eliminating the need for sites to submit a separate approval to the CTSU Regulatory Office. CIRB IRB approvals are averaging 60% of the total IRB approvals processed each month. Local IRB approvals and other protocol specific requirements (PSRs) are submitted by the site to the CTSU Regulatory Office as noted above. Local IRB approvals are accepted in the form of IRB approval letters, *Protection of Human Subjects Assurance Identification/Certification/Declaration*, and the CTSU IRB Certification form, or a mix of forms such as a signed IRB approval letter and the CTSU IRB Certification form. Information collected on the CTSU IRB Certification form includes, CTEP site code identifiers; FWA Assurance information; IRB number information required to meet the Food and Drug Administration Amendment Act (FDAAA) regulations; and more detailed information on the review process such as the level of review and approval dates. Use of the form is not mandatory, but is strongly encouraged as it reduces processing time and site follow up time to collect required information.

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

#### CTSU Membership Forms (Attachments A5 A7)

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

Attachment A5: CTSU Roster Update Form – mandatory form primarily used to designate the primary points of contact at each site and is used to assign primary contact roles to the CTSU roster. Persons assuming these contact roles must sign that they agree to act as a central point of contact for their institution.

Attachment A6: CTSU Request for Clinical Brochure - Clinical Brochures are essential to the investigator's understanding of the mechanism of action for the study agent, and are required documentation to the IRB to support the review process. As the clinical brochures are proprietary, the form allows for collection of information on the investigator to perform checks ensuring they are eligible to receive the brochure. The form is submitted via fax or email by clinical sites to order study-related supplies.

Attachment A7: CTSU Supply Request Form - A subset of the studies supported by the CTSU require the clinical sites to obtain supplies to conduct the study. The CTSU Supply Request Form facilitates site requests for supplies that CTSU distributes by providing information on the site to ensure they are approved for the study and eligible to receive supplies, and providing shipping information. The form is submitted via fax or email by clinical sites to order study-related supplies.

CTSU Data Management Forms (Attachments A8-A14)

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

Attachment A8: Site Initiated Data Update Form – Support data management activities and is based upon a common header template with modifications per protocol that outline each study’s Case Report Form (CRF) submission requirements and/or study specific instructions.

Attachment A9: Data Clarification Form - Support data management activities and is based upon a common header template with modifications per protocol that outline each study’s Case Report Form (CRF) submission requirements and/or study specific instructions.

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

Attachment A11: MC0845 (8233) CTSU Data Transmittal Form - Support data management activities and is based upon a common header template with modifications per protocol that outline each study’s Case Report Form (CRF) submission requirements and/or study specific instructions.

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

Attachment A13: TAILORx\_PACCT1\_Data Transmittal Form - Support data management activities and is based upon a common header template with modifications per protocol that outline each study’s Case Report Form (CRF) submission requirements and/or study specific instructions.

Attachment A14: Unsolicited Data Modification Form (UDM); Protocol: TAILORx/PACCT-1 – serves as a transmittal form to facilitate processing of modifications to previously submitted case report forms on the Tailorx/PACCT-1 study when the data modifications were not requested by the CTSU data management staff.

### CTSU Patient Enrollment Forms (Attachments A15-A16)

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

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

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

### CTSU Administrative Form (Attachment A17)

CTSU Administrative Forms have been created to facilitate account requests to the Regulatory Support System (RSS) and manage administrative information.

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

### NCI CIRB Forms/Documents:

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

### NCI CIRB Enrollment Forms (Attachments B01 – B02)

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

Attachment B1: 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 B2: NCI CIRB Signatory Enrollment Form  
The CIRB Signatory Enrollment Form is used to capture essential information on the Signatory Institution (SI) enrolling in the NCI CIRB, component and affiliate institutions relying on the SI, as well as information used to establish presence within the CIRB's IT systems. In addition to SI, component and affiliate institution details, information requested includes the CTEP Site Code for the SI and contact(s) for CIRB communications.

#### CIRB Board Member Documents (Attachments B03 - B09)

NCI CIRB Board Member documents collect information on members and potential members of the CIRB. The NCI CIRB consists of four Boards: Adult - Late Phase Emphasis (LPE), Adult - Early Phase Emphasis (EPE), Pediatric and Cancer Prevention and Control (CPC). Recruited members are invited to serve on the CIRB; information is shared regarding meeting dates, responsibilities, etc. If the candidate accepts the candidacy opportunity, and is approved by NCI, a formal invitation for membership is released and a packet of information is sent to the candidate. The board member packet includes documents collecting biographical information, contact information, tax information, and direct deposit information (optional), a non-disclosure agreement, and conflict of interest document. Once a board member is recruited, each member is expected to serve a two-year term, although may be asked to serve multiple terms.

Attachment B03: CIRB Board Member Biographical Sketch Form  
Attachment B04: CIRB Board Member Contact Information Form  
Attachment B05: CIRB Board Member W-9  
Attachment B06: CIRB Board Member Non-Disclosure Agreement (NDA)  
Attachment B07: CIRB Direct Deposit Form  
Attachment B08: CIRB Member Conflict of Interest (COI) Screening Worksheet  
Attachment B09: CIRB COI Screening for CIRB Meetings

#### NCI CIRB Board Reviewer Documents (Attachments B10-B39)

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

Attachment B10	CIRB Initial Review Application
Attachment B11:	CIRB Initial Review Application for Exempt Studies
Attachment B12:	CIRB Amendment Review Application
Attachment B13:	CIRB Ancillary Studies Application for Adult / Pediatric
Attachment B14:	CIRB Continuing Review Application for Adult / Pediatric
Attachment B15:	Adult Initial Review of Cooperative Group Protocol
Attachment B16:	Pediatric Initial Review of Cooperative Group Protocol
Attachment B17:	Adult Continuing Review of Cooperative group Protocol
Attachment B18:	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:	Adult & Ped Pharmacist's Review of a Cooperative Group Study
Attachment B22:	CPC Pharmacist's Review of a Cooperative Group Study
Attachment B23:	Adult Expedited Amendment Review
Attachment B24:	Pediatric Expedited Amendment Review used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to an adult protocol by a NCTN Group or ETCTN Lead Academic Organization (LAO) submitted to the CIRB for expedited amendment review.
Attachment B25:	Adult Expedited Continuing Review
Attachment B26:	Pediatric Expedited Continuing Review used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to an adult protocol by a NCTN Group submitted to the CIRB for continuing review.
Attachment B27:	Adult Cooperative Group Response to CIRB Review
Attachment B28:	Pediatric Cooperative Group Response to CIRB Review used by the reviewer and provides questions to answer in regards to the response. The form is completed by the CIRB member and captures their comments, questions, and determination regarding the response.
Attachment B29:	Adult Expedited Study Chair Response to Required Modifications
Attachment B30:	Pediatric Expedited Study Chair Response to Required Modifications used by study chair to expedite review of a NCTN or ETCTN LAO response submitted in reference to CIRB-required modifications for Adult protocol review.
Attachment B31:	Reviewer Worksheet - Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN) - used by reviewer to assess whether a reported event is an unanticipated problem and/or serious or continuing noncompliance issue, or neither.

- Attachment B32: Reviewer Worksheet - CIRB Statistical Reviewer Form used by subcommittee member to review a NCTN Group submission of statistical considerations for CIRB approval.
- Attachment B33: CIRB Application for Translated Documents  
Attachment B34: Reviewer Worksheet of Translated Documents used by subcommittee member to review, document and provide comments for a NCTN Group submission of translated materials for CIRB approval.
- Attachment B35: Reviewer Worksheet of Recruitment Material used by subcommittee member to review a NCTN Group or ETCTN LAO submission of locally developed material for CIRB approval.
- Attachment B36: Reviewer Worksheet Expedited Study Closure Review used by subcommittee member to review a NCTN Group or ETCTN LAO submission of study closure.
- Attachment B37: Reviewer Worksheet of Expedited Review of Study Chair Response to CIRB-Required Modifications - used by the reviewer to indicate documents reviewed and expedited review specifics regarding Study Chair response by a NCTN Group or ETCTN Lead Academic Organization (LAO) submitted to the CIRB for expedited amendment review.
- Attachment B38: Reviewer Worksheet of Expedited Initial Review used by the reviewer to indicate documents reviewed and expedited review specifics about an adult protocol by a NCTN Group or ETCTN Lead Academic Organization (LAO) submitted to the CIRB for expedited Initial Review.
- Attachment B39: Reviewer Worksheet – CPC - Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN) used by reviewer to assess whether a reported event is an unanticipated problem and/or serious or continuing noncompliance issue, or neither for CPC.

CIRB Local Context Forms (Attachments B40-B45):

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

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

- Attachment B41: Annual Principal Investigator Worksheet about Local Context - this Worksheet is completed by PI who will open a CIRB approved study and captures information specifically related to the local context of the PI. The information includes the number of support staff, any financial conflicts of interest, recruitment processes, consent process, and consent for those that don't speak English. This form is completed via IRBManager and submitted to the CIRB for review. This worksheet is completed and updated online.
- Attachment B42: Study-Specific Worksheet about Local Context – this worksheet collects information regarding the local site acceptance of the CIRB review on a per protocol basis. This worksheet is completed by the PI to open a new study with the CIRB. This worksheet is completed online via IRBManager and is submitted to the CIRB for review. This worksheet is completed and updated online.
- Attachment B43: Study Closure or Transfer of Study Review Responsibility Form – this form collects information as it relates to study closure or transferring study review responsibility. This form is completed by the PI to close a study or transfer review responsibility for the study from the CIRB to another IRB. This form is completed in IRBManager and is submitted to the CIRB for review. This form is completed and updated online.
- Attachment B44: Unanticipated Problem or Serious or Continuing Noncompliance (UP and/or SCN) Reporting Form – this form collects potential unanticipated problem and/or serious or continuing noncompliance to the CIRB. This form is completed by the PI to report a potential unanticipated problem and/or serious or continuing noncompliance to the CIRB. The form is completed in IRBManager and is submitted to the CIRB for review. This form is completed and updated online.
- Attachment B45: Change of Signatory Institution PI Form – this form collects Signatory Institution PI information that conducts NCI-sponsored studies approved by the CIRB and should receive study-related correspondence. This form also confirms the contact information of Signatory Institution PI that should no longer receive study-related correspondence. This form is completed and updated online.

#### Surveys:

Surveys are used to objectively measure customer satisfaction and provide data needed to continually improve services. Customer satisfaction surveys assess perceptions of our customers, as opposed to our perceptions of how well services are delivered (attachments C1-13). The methodology for sending CTSU, CIRB and CTEP surveys is similar. CTSU frequently assists CTEP with clinical trial-related surveys by providing the pool of potential participants based upon site registration and enrollment data, coordination of the survey distribution, data collection, and survey analysis. In general, the surveys are distributed by e-mail and conducted on-line using common tools such as Survey Monkey. Selected participants are generally sent reminder e-mails midway through the collection process. All surveys are voluntary and efforts are made to keep the time needed to complete the survey to a

minimum. A reminder email is sent out after one week, and the survey closed after two weeks. Data are compiled from an Excel spreadsheet print out and put into a standard report and shared with CTEP and the study team to review.

- Attachment C01: CTSU Website Customer Satisfaction Survey – this survey has not been conducted since 2012. We will continue to include the survey as it may be conducted again at some point in the future. The survey is submitted to approximately 1,000 persons who have used the CTSU website in the last year.
- Attachment C02: CTSU Help Desk-Customer Service Satisfaction Survey – this survey has not been conducted since 2012. Similar to the website survey it may be conducted at some point in the future. The Help Desk survey is submitted to users from a pool of approximately 1,000 persons that have used Help Desk services in the last month.
- Attachment C03: CTSU Oncology Patient Enrollment Network (OPEN) Survey – this survey is posted to the OPEN website and is available upon a user completing a patient enrollment. No changes requested at this time.
- Attachment C04: CIRB Customer Satisfaction Survey - the customer satisfaction survey was developed to collect customer feedback pertaining to the use of the CIRB Help Desk. Any customer (local institution, member of Cooperative Group, NCTN, ETCTN, public inquiry, etc.) submitting a request to the Help Desk (via email or phone) can randomly receive an email request to complete the survey if they provide an email address during the discussion via phone, or have submitted an email inquiry with valid email address. CIRB receives approximately 500 Help Desk inquiries per month. The surveys are completed online via SurveyMonkey.com.
- Attachment C05: CIRB Follow-up Survey (Communication Audit) – this survey is used to inquire to CIRB stakeholders regarding their use of CIRB instruments, processes, and online presence.
- Attachment C06: CIRB Website Focus Groups(s) (Communication Project)  
A – CIRB Members; B – Local Institutions; C – Network Groups; D – Website Usability testing. Focus groups surveyed key CIRB participants regarding their use of CIRB instruments, processes and online presence during an independent consultation of the CIRB.
- Attachment C07: CIRB Board Members Annual Assessment Survey – this survey is used to inquire to Board Members regarding their experience as a CIRB member and open channels for receiving valuable feedback.

The clinical trial surveys (attachments C08-C13)



- Attachment C08: Protocol and Information Office (PIO) External Customer Satisfaction Survey– CTEP PIO serves to improve the protocol development and conduct processes through the use of efficient business practices and informatics tools. The CTEP PIO manages all protocol related materials and coordinating major aspects of the scientific review process. CTEP PIO staff interacts directly with multiple personnel from each of the clinical trial site locations involved in the development and management of CTEP sponsored clinical trials. The PIO Survey helps verify areas of high quality performance and areas for improvement as identified by the external stakeholders. An email is sent to the clinical trial personnel listed in the CTEP Enterprise database that includes a link to complete this on-line, annual survey. This survey was originally piloted in 2011 (OMB No. 0925-0046, Expiration Date 2/28/2013).
- Attachment C09: Concept Clinical Trial Template Survey - this survey will be used to understand clinician interest in a trial while the concept is still under development and before the trial is approved by NCI. This survey is designed to identify scientific interest in the trial's research questions, the study design, and accrual challenges given the patient population. Information from this survey can help study teams learn if changes need to be made to the design or concept in order to increase clinician interest in the trial's objectives.
- Attachment C10: Prospective Clinical Trial Template Survey - this survey will be used for trials that are in protocol development phase of a clinical trial (i.e., after the concept has been approved but before the trial is activated). This survey is designed to identify the greatest challenges to sites to both open the trial and to accrue patients. Information from this survey helps study teams learn the trial's greatest challenges and then plan ahead to prepare information for clinicians and patients to ensure equipoise and informed decision making.
- Attachment C11: Low Accruing Clinical Trial Template Survey - this survey will be used for trials that have already been activated in the field but are considered at risk for closure due to slow accrual. This survey is designed to identify if scientific interest remains in the trial, the greatest accrual challenges to sites, and areas for improvement to increase accrual. Information from this survey will help both CTEP and study teams determine if the trial should remain open and if so, what additional resources are needed to help sites accrue to the trial.
- Attachment C12: ETCTN PI Survey - information is collected from PIs who are oncologists and researchers at organizations that have received ETCTN grants and are responsible for developing and running the program's clinical trials. The PI survey serves to collect information about their satisfaction with the ETCTN's implementation and processes; their perceived quality of scientific protocols developed; their reactions and experiences to the team-science approach; and their belief on how the program has affected their level of collaboration with peers.

Attachment C13: ETCTN RS Survey - information is collected for the organizations' clinical research staff (i.e., grant and site administrators, clinical research associates and registrars) asked about their satisfaction with ETCTN processes and resources available to submit and administer ETCTN protocols.

Additional attachments to this submission

For the CTSU the following attachments are included:

Attachment D01: Privacy Impact Assessment (PIA). Contact information collected from the forms is added to the CTSU-ESYS, and data security is maintained as outlined in the Privacy Impact Assessment (PIA). The PIA was re-approved by HHS on 8/24/2012. The last revised submission was provided in July 2015 under the IT system name "NIH NCI Cancer Trials Support Unit (CTSU)" for the CTSU-ESYS inclusive of the website, RSS, and other related modules.

Attachment D02: Westat IRB Letter. The CTSU project and its forms and surveys have been reviewed by the Westat IRB and given approval.

Attachment D03: Privacy Act Memo. In this June 4, 2010 memo to Michael Montello, Pharm.D., the NIH Privacy Act Officer determined that the NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" covers the CTSU data collection, which involves collection of personally identifiable information such as name, date of birth, social security number, mailing address, telephone number, medical record number and mailing address.

For the CIRB the following attachments are included:

Attachment D04: The Federal Information Processing Standard 199 (FIPS-199) Categorization (Security Categorization) report is a key document including the determination of the security impact level for the cloud environment that hosts the CIRB Web System. Security controls are implemented per the applicable environment. The Privacy Impact Assessment (PIA) is not a contractual requirement. The FIPS 199 was submitted September 2014 and annual update on 09/2015 for the CIRB Web System.

Attachment D05: OHSR Determination. On October, 10, 2010, the Office of Human Subject Research (OHSR) found the CIRB project data being collected is for the sole purpose of fulfilling the mission of the Central Institutional Review Board (CIRB). The data available is not intended for any use other than to conduct IRB review of studies. Therefore, OHSR found that data are not being collected on human subject participants as part of the CIRB Initiative.

Attachment D06: Emmes IRB Letter. In September 2016, the Emmes IRB found the NCI CIRB project and its forms and surveys to be exempt.

Attachment D07: Privacy Act Memo. In a memo to Steve Friedman, dated December 28, 2009, the NIH Privacy Act Officer determined that the NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" covers the CIRB data collection, which includes the collection of personally identifiable information (PII) such as name, address, home telephone number, cell phone number, gender, ethnicity, social security number, financial information, educational level, etc.

### **A.3 Use of Information Technology and Burden Reduction**

The CIRB and CTSU are continuously seeking ways to reduce burden through advances in information technology. Utilization of computerized records management has reduced the need to compile, arrange, and update documentation. Upgrades to internal systems and integration efforts between the two projects, and with other NCI Applications have resulted in operational efficiencies such as support for SSO macros multiple systems, eliminating the need to collect contact information on members across multiple systems, and reducing the burden of regulatory collection.

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

Both Emmes and Westat have completed a Security Testing and Evaluation (ST&E) of their systems as per the guidelines set forth in the Federal Information Security Management Act (FISMA) and specifically in NIST Special Publication 800-53A Rev 3 and in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist. The ST&E on the CTSU Enterprise **system** was **successfully** completed by an independent third party auditor to ensure the security controls are in place and working as intended. Based on this, CTSU maintains an active Authorization to Operate (ATO) issued by the NCI's authorizing official. In addition to the Security certification, CTSU enterprise system is managed according to the Westat's Enterprise Systems Development Group (ESDG) processes and procedures. ESDG is a Capability Maturity Model Integration (CMMI) Maturity Level 2 certified organization. The NCI CIRB Project FIPS assessment is included with OMB SSA (attachment D04).

Contact information collected from the forms is added to the CTSU enterprise systems and data security is maintained as outlined in the Privacy Impact Assessment (PIA). The CTSU PIA was re-approved by HHS on 8/24/2012 and the IT system name is "NIH NCI Cancer Trials Support Unit (CTSUS)" for the CTSU Enterprise system inclusive of the website, RSS, and other related modules (attachment D01) and is updated as changes are made.

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

The information collected is unique to this program and is not found elsewhere in the government.

## **A.5 Impact on Small Businesses or Other Small Entities**

Small business and other small entities are not impacted.

## **A.6 Consequences of Collecting the Information Less Frequently**

CTSU and CIRB forms are designed to support real time business processes. Reduction in the frequency of form collection would cause the loss of required data, increase processing times, and reduce data quality. For example, less frequent collection of regulatory data would impact CTEP's ability to verify that institutions had appropriate IRB approval for trial participation.

Surveys fall into three categories dependent on their release schedule, a) routine surveys that follow a standard release cycle, b) ongoing assessments that are available as part of an application, and c) ad hoc surveys released to evaluate a clinical trial, service, or application. Information on the anticipated releases, number of potential respondents, and burden of response is captured in the A12 burden tables.

Surveys released on a routine schedule include:

- CTSU Website Customer Satisfaction Survey (Attachment C01)
- CTSU Help Desk Customer Satisfaction Survey (Attachment C02)
- CIRB Customer Satisfaction Survey (Attachment C04)
- CIRB Board Members Annual Assessment (Attachment C07)
- PIO External Customer Satisfaction Survey (Attachment C08)

The CTSU website and Help Desk surveys are currently not being collected, but may be used again in the future. If collection resumes, the surveys will not be distributed at a frequency of greater than annually.

Ongoing survey linked to an application:

- CTSU OPEN Survey (attachment C03)

Ad Hoc surveys to evaluate a clinical trial, application, or service:

- CIRB Follow-up Survey (attachment C05)
- CIRB Website Focus Group (attachment C06a-d)
- CTEP Concept Clinical Trial Survey (attachment C08)
- CTEP Prospective Clinical Trial Survey (attachment C09)
- CTEP Low Accruing Clinical Trial Survey (attachment C10)
- ETCTN PI Survey (attachment C11)
- ETCTN RS Survey (attachment C12)

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

The NCI CIRB project complies with 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 December, 13, 2016, Vol. 81, and p. 89955. There have been no public comments received.

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

NCI contracts with Westat and Emmes to provide services to administer the CTSU and CIRB programs respectively. Subcontractors may also be used with NCI approval, and under the direction of the primary contractors to administer the CTSU and CIRB programs.

### **A.9 Explanation of Any Payment of Gift to Respondents**

Both CTSU and CIRB do not employ any form of payment of gift to respondents.

### **A.10 Assurance of Confidentiality Provided to Respondents**

All information will be kept secure to the extent allowable under the law. Data collected is entered either into the CTSU Enterprise System or into the CIRB Web System. All contractor staff is required to have human subject protections training, and participate in security awareness training on an annual basis. Both programs collect personally identifiable information (PII) in the form of names, addresses and contact information. 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. In addition, data is maintained for an indefinite period of time. Data backups are maintained per organizational policies specific to each contractor. Limited information is available to users via the CTSU members' website.

Both CTSU and CIRB systems are secured through the use of the CTEP-Identify and Access Management (CTEP-IAM) user name and password. User authentication is based on roster data in the RSS. All nonpublic parts of the resource are maintained in accordance with appropriate privacy and security access controls pursuant to applicable policies. CTSU forms and surveys are submitted to the Westat IRB for review and were determined exempt from human subject research. 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. The CIRB project has also been reviewed by Emmes IRB and found to be exempt from human subject research.

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

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

The need to collect PII occurs sporadically and is stored electronically with frequent backups to ensure information is recoverable, as needed. CIRB members are made aware of this collection and the need for the collection through the CIRB privacy statement. The NCI Privacy Policy is available electronically and it is shared during the enrollment application process. The need for the collection of this information is relevant and justified to ensure that no CIRB member can unduly influence the approval of a study when there is an appearance of conflict due to professional or personal relationships such as financial gain or professional growth. The types of data used are both scientific and administrative, and used to inform board members concerning the studies under review, manage the operations and communications of Adult and Pediatric Central Institutional Review Boards, and convey information to sites concerning studies reviewed by the CIRB and decisions made by the CIRB. The NIH Privacy Act Officer has reviewed this data collection and deemed the Privacy Act is applicable, and is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" (Attachment D07). 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 D05).

#### **A.11 Justification for Sensitive Questions**

For the CTSU and CTEP surveys, PII is not collected. For the CTSU forms, a minimal amount of personally identifiable information (PII) is collected and is related to specific tasks and immediate contact information. The CTSU, CTEP, nor CIRB survey collection requests information about the user's race, ethnicity, sex, and religion or habits that would be considered sensitive.

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

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 D03).

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 D07). 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 D05).

#### **A.12.1 Estimated Annualized Burden Hours**

The estimated annualized burden hours for this information collection are 15,524 from an estimated 24,100 respondents.

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

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

- CTSU IRB/Regulatory Approval and IRB Certification Form (attachments A1 and A2) – clinical sites participate on multiple protocols per year averaging one submission per month.
- Site Addition Form (Attachment A4) – a percentage of the clinical sites submitting regulatory forms do so for multi-site networks. The Site Addition Form allows for documentation of multiple sites covered under a single IRB approval.
- CTSU Supply Request Form (Attachment A7) – as noted above, clinical sites participate on multiple protocols throughout the year and use the form to request initial and resupply of items such as laboratory kits. Supplies vary and are ordered per protocol.
- Site Initiated Data Update Form (Attachment 8) – this form is used by the clinical sites when submitting unsolicited data updates and supports routing of the update to the correct processing team.
- Data Clarification Form (Attachment 9) – this form is used by the CTSU team to request a data clarification on case report form data submitted by the clinical site. A separate form is used for each clarification, and sites may have multiple clarifications during the year.
- RTOG 0834 CTSU Data Transmittal Form – 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.
- MC0845 (8233) CTSU Data Transmittal Form (Attachment A10) – this form is submitted by the clinical sites with their clinical data for the 8233 study to support processing. There are multiple sites submitting the form, on multiple patients, and at multiple patient visits.
- CTSU Generic Data Transmittal Form – this form is submitted for any study for which CTSU has

data management responsibilities but does not have a study-specific transmittal form. Again, clinical sites will submit this form with their per visit patient case report forms to support processing. The form is used by multiple sites, for multiple patients and at multiple patient visits.

- TailorX\_PACCT1 Data Transmittal Form (Attachment A13) – this form is submitted with case report forms for the TailorX/PACCT1 study. This was a large 10,000 patient study. Clinical sites submit the form for multiple patients at multiple time points.
- Unsolicited Data Modification Form Protocol TAILORx/PACCT-1 (Attachment 14) – this form is submitted by the clinical sites when submitting site initiated case report form updates. Again, this is a large study with multiple patients at each site and multiple clinical 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 I generally enroll multiple patients per year.

**A.12-2 Estimated Annualized Burden Hours**

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A1)	Health Care Practitioner	2444	12	2/60	978
CTSU IRB Certification Form (Attachment A2)	Health Care Practitioner	2444	12	10/60	4,888
Withdrawal from Protocol Participation Form (Attachment A3)	Health Care Practitioner	279	1	10/60	47
Site Addition Form (Attachment A4)	Health Care Practitioner	80	12	10/60	160
CTSU Roster Update Form (Attachment A5)	Health Care Practitioner	600	1	5/60	50
CTSU Request for Clinical Brochure (Attachment A6)	Health Care Practitioner	360	1	10/60	60
CTSU Supply Request Form (Attachment A7)	Health Care Practitioner	90	12	10/60	180



<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
Site Initiated Data Update Form (Attachment A8)	Health Care Practitioner	2	12	10/60	4
Data Clarification Form (Attachment A9)	Health Care Practitioner	150	24	10/60	600
RTOG 0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	12	76	10/60	152
MC0845(8233) CTSU Data Transmittal (Attachment A11)	Health Care Practitioner	5	12	10/60	10
CTSU Generic Data Transmittal Form (Attachment A12)	Health Care Practitioner	5	12	10/60	10
TAILORx_PACCT1_Data Transmittal Form (Attachment A13)	Health Care Practitioner	161	96	10/60	2576
Unsolicited Data Modification Form: Protocol: TAILORx/PACCT-1 (Attachment 14)	Health Care Practitioner	30	12	10/60	60
CTSU Patient Enrollment Transmittal Form (Attachment A15)	Health Care Practitioner	12	12	10/60	24
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	360	2	10/60	120
CTSU System Access Request Form (Attachment A17)	Health Care Practitioner	180	1	20/60	60

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B1)	Participants	50	1	15/60	13
NCI CIRB Signatory Enrollment Form (Attachment B2)	Participants	50	1	15/60	13
CIRB Board Member Biographical Sketch Form (Attachment B3)	Board Member	25	1	15/60	6
CIRB Board Member Contact Information Form (Attachment B4)	Board Member	25	1	10/60	4
CIRB Board Member NDA (Attachment B6)	Board Member	25	1	10/60	4
CIRB Direct Deposit Form (Attachment B7)	Board Member	25	1	15/60	6
CIRB Member COI Screening Worksheet (Attachment B8)	Board Members	12	1	30/60	6
CIRB COI Screening for CIRB meetings (Attachment B9)	Board Members	72	1	15/60	18
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	1	60/60	80

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
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	30/60	200
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) Protocol	Board Members	275	1	60/60	275
Pediatric Continuing Review of Cooperative Group Protocol (Attachment B18)	Board Members	130	1	60/60	130

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
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	10	1	120/60	20
CPC Pharmacist's Review of Cooperative Group Study (Attachment B22)	Board Members	20	1	120/60	40
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

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
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 Mod (Attachment B29)	Board Members	40	1	15/60	10
Pediatric Expedited Study Chair Response to Required Mod (Attachment B30)	Board Members	40	1	15/60	10
Reviewer Worksheet - Determination of UP or SCN (Attachment B31)	Board Members	360	1	10/60	60
Reviewer Worksheet - CIRB Statistical Reviewer Form (Attachment B32)	Board Members	100	1	60/60	100
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

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
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 Expedited Review of Study Chair Response to CIRB-Required Modifications (Attachment B37)	Board Members	5	1	30/60	3
Reviewer Worksheet of Expedited IR (Attachment B38)	Board Members	5	1	30/60	3
Reviewer Worksheet -CPC - Determination of UP or SCN (Attachment B39)	Board Members	40	1	15/60	10
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

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Annual Burden Hours</b>
Study-Specific Worksheet About Local Context (Attachment B42)	Health Care Practitioner	4800	1	20/60	1600
Study Closure or Transfer of Study Review Responsibility Form (Attachment B43)	Health Care Practitioner	1680	1	15/60	420
UP or SCN Reporting Form (Attachment B44)	Health Care Practitioner	360	1	20/60	120
Change of SI PI Form (Attachment B45)	Health Care Practitioner	120	1	15/60	30
CTSU Website Customer Satisfaction Survey (Attachment C1)	Health Care Practitioner	275	1	15/60	69
CTSU Help Desk Customer Satisfaction Survey (Attachment C2)	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey (Attachment C3)	Health Care Practitioner	60	1	15/60	15
CIRB Customer Satisfaction Survey (Attachment C4)	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit) (Attachment C5)	Participants/ Board Members	300	1	15/60	75

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Website Focus Groups, Communication Project (Attachment C6 A-D)	Participants/ Board Members	18	1	60/60	18
CIRB Board Member Annual Assessment Survey (Attachment C7)	Board Members	60	1	20/60	20
PIO Customer Satisfaction Survey (Attachment C8)	Health Care Practitioner	60	1	5/60	5
Concept Clinical Trial Survey (Attachment C9)	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey (Attachment C10)	Health Care Practitioner	1000	1	1/60	17
Low Accrual Clinical Trial Survey (Attachment C11)	Health Care Practitioner	1000	1	1/60	17
ETCTN PI Survey (Attachment C12)	Physician	75	1	15/60	19
ETCTN RS Survey (Attachment C13)	Health Care Practitioner	175	1	15/60	44
<b>Totals</b>		<b>24,100</b>	<b>100,337</b>		<b>15,524</b>

The total annualized cost to respondents is \$666,027. Wage estimates are based upon a generic category of Health Care Practitioner at a median hourly wage rate of \$37.40 per hour for allied health professionals and \$95.05 per hour for collections limited to physicians. Information is provided by the Bureau of Labor Statistics website at <http://www.bls.gov/oes/current/oes290000.htm>.



Table A.12-2 indicates the Annualized Cost to Respondents. The estimated burden hours are 15,524 with an annualized cost of \$666,643.

**Table A.12-2a: CTSU Annualized Cost to Respondents**

Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Cost
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A1)	Health Care Practitioner	978	\$37.40	\$ 36,577
CTSU IRB Certification Form (Attachment A2)	Health Care Practitioner	4,888	\$37.40	\$ 182,811
Withdrawal from Protocol Participation Form (Attachment A3)	Health Care Practitioner	47	\$37.40	\$ 1,758
Site Addition Form (Attachment A4)	Health Care Practitioner	160	\$37.40	\$ 5,984
CTSU Roster Update Form (Attachment A5)	Health Care Practitioner	50	\$37.40	\$ 1,870
CTSU Request for Clinical Brochure (Attachment A6)	Health Care Practitioner	60	\$37.40	\$ 2,244
CTSU Supply Request Form (Attachment A7)	Health Care Practitioner	180	\$37.40	\$ 6,732
Site Initiated Data Update Form (Attachment A8)	Health Care Practitioner	4	\$37.40	\$ 150
Data Clarification Form (Attachment A9)	Health Care Practitioner	600	\$37.40	\$ 22,440
RTOG 0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	152	\$37.40	\$ 5,685

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Total Annual Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Annual Cost</b>
MC0845(8233) CTSU Data Transmittal (Attachment A11)	Health Care Practitioner	10	\$37.40	\$ 374
CTSU Generic Data Transmittal Form (Attachment A12)	Health Care Practitioner	10	\$37.40	\$ 374
TAILORx_PACCT1_Data Transmittal Form (Attachment A13)	Health Care Practitioner	2576	\$37.40	\$ 96,342
Unsolicited Data Modification Form: Protocol: TAILORx/PACCT-1 (Attachment 14)	Health Care Practitioner	60	\$37.40	\$ 2,244
CTSU Patient Enrollment Transmittal Form (Attachment A15)	Health Care Practitioner	24	\$37.40	\$ 898
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	120	\$37.40	\$ 4,488
CTSU System Access Request Form (Attachment A17)	Health Care Practitioner	60	\$37.40	\$ 2,244
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B1)	Participants	13	\$37.40	\$ 486
NCI CIRB Signatory Enrollment Form (Attachment B2)	Participants	13	\$37.40	\$ 486

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Total Annual Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Annual Cost</b>
CIRB Board Member Biographical Sketch Form (Attachment B3)	Board Member	6	\$95.05	\$ 570
CIRB Board Member Contact Information Form (Attachment B4)	Board Member	4	\$95.05	\$ 380
CIRB Board Member NDA (Attachment B6)	Board Member	4	\$95.05	\$ 380
CIRB Direct Deposit Form (Attachment B7)	Board Member	6	\$95.05	\$ 570
CIRB Member COI Screening Worksheet (Attachment B8)	Board Members	6	\$95.05	\$ 570
CIRB COI Screening for CIRB meetings (Attachment B9)	Board Members	18	\$95.05	\$ 1,711
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	\$37.40	\$ 2,992
CIRB IR Application for Exempt Studies (Attachment B11)	Health Care Practitioner	2	\$37.40	\$ 75
CIRB Amendment Review Application (Attachment B12)	Health Care Practitioner	100	\$37.40	\$ 3,740
CIRB Ancillary Studies Application (Attachment B13)	Health Care Practitioner	1	\$37.40	\$ 37

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Total Annual Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Annual Cost</b>
CIRB Continuing Review Application (Attachment B14)	Health Care Practitioner	200	\$37.40	\$ 7,480
Adult IR of Cooperative Group Protocol (Attachment B15)	Board Members	195	\$95.05	\$ 18,535
Pediatric IR of Cooperative Group Protocol (Attachment B16)	Board Members	45	\$95.05	\$ 4,277
Adult Continuing Review of Cooperative Group Protocol (Attachment B17) Protocol	Board Members	275	\$95.05	\$ 26,139
Pediatric Continuing Review of Cooperative Group Protocol (Attachment B18)	Board Members	130	\$95.05	\$ 12,357
Adult Amendment of Cooperative Group Protocol (Attachment B19)	Board Members	80	\$95.05	\$ 7,604
Pediatric Amendment of Cooperative Group Protocol (Attachment B20)	Board Members	50	\$95.05	\$ 4,753
Pharmacist's Review of a Cooperative Group Study (Attachment B21)	Board Members	20	\$95.05	\$ 1,901

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Total Annual Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Annual Cost</b>
CPC Pharmacist's Review of Cooperative Group Study (Attachment B22)	Board Members	40	\$95.05	\$ 3,802
Adult Expedited Amendment Review (Attachment B23)	Board Members	174	\$95.05	\$ 16,539
Pediatric Expedited Amendment Review (Attachment B24)	Board Members	70	\$95.05	\$ 6,654
Adult Expedited Continuing Review (Attachment B25)	Board Members	70	\$95.05	\$ 6,654
Pediatric Expedited Continuing Review (Attachment B26)	Board Members	18	\$95.05	\$ 1,711
Adult Cooperative Group Response to CIRB Review (Attachment B27)	Health Care Practitioner	30	\$37.40	\$ 1,122
Pediatric Cooperative Group Response to CIRB Review (Attachment B28)	Health Care Practitioner	5	\$37.40	\$ 187
Adult Expedited Study Chair Response to Required Mod (Attachment B29)	Board Members	10	\$95.05	\$ 951

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Total Annual Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Annual Cost</b>
Pediatric Expedited Study Chair Response to Required Mod (Attachment B30)	Board Members	10	\$95.05	\$ 951
Reviewer Worksheet - Determination of UP or SCN (Attachment B31)	Board Members	60	\$95.05	\$ 5,798
Reviewer Worksheet - CIRB Statistical Reviewer Form (Attachment B32)	Board Members	100	\$95.05	\$ 9,505
CIRB Application for Translated Documents (Attachment B33)	Health Care Practitioner	50	\$37.40	\$ 1,870
Reviewer Worksheet of Translated Documents (Attachment B34)	Board Members	25	\$95.05	\$ 2,376
Reviewer Worksheet of Recruitment Material (Attachment B35)	Board Members	5	\$95.05	\$ 475
Reviewer Worksheet Expedited Study Closure Review (Attachment B36)	Board Members	5	\$95.05	\$ 475

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Total Annual Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Annual Cost</b>
Reviewer Worksheet Expedited Review of Study Chair Response to CIRB-Required Modifications (Attachment B37)	Board Members	3	\$95.05	\$ 285
Reviewer Worksheet of Expedited IR (Attachment B38)	Board Members	3	\$95.05	\$ 285
Reviewer Worksheet - CPC - Determination of UP or SCN (Attachment B39)	Board Members	10	\$95.05	\$ 951
Annual Signatory Institution Worksheet About Local Context (Attachment B40)	Health Care Practitioner	267	\$37.40	\$ 9,986
Annual Principal Investigator Worksheet About Local Context (Attachment B41)	Health Care Practitioner	600	\$37.40	\$ 22,440
Study-Specific Worksheet About Local Context (Attachment B42)	Health Care Practitioner	1600	\$37.40	\$ 59,840
Study Closure or Transfer of Study Review Responsibility Form (Attachment B43)	Health Care Practitioner	420	\$37.40	\$ 15,708
UP or SCN Reporting Form (Attachment B44)	Health Care Practitioner	120	\$37.40	\$ 4,488

<b>Form Name</b>	<b>Type of Respondent</b>	<b>Total Annual Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Annual Cost</b>
Change of SI PI Form (Attachment B45)	Health Care Practitioner	30	\$37.40	\$ 1,122
CTSU Website Customer Satisfaction Survey (Attachment C1)	Health Care Practitioner	69	\$37.40	\$ 2,581
CTSU Help Desk Customer Satisfaction Survey (Attachment C2)	Health Care Practitioner	81	\$37.40	\$ 3,029
CTSU OPEN Survey (Attachment C3)	Health Care Practitioner	15	\$37.40	\$ 561
CIRB Customer Satisfaction Survey (Attachment C4) Satisfaction Survey (Attachment C4)	Participants	150	\$37.40	\$ 5,610
Follow-up Survey (Communication Audit) (Attachment C5)	Participants/ Board Members	75	\$37.40	\$ 2,805
Website Focus Groups, Communication Project (Attachment C6 A-D)	Participants/ Board Members	18	\$37.40	\$ 673
CIRB Board Member Annual Assessment Survey (Attachment C7)	Board Members	20	\$95.05	\$ 1,901
PIO Customer Satisfaction Survey (Attachment C8)	Health Care Practitioner	5	\$37.40	\$ 187



Form Name	Type of Respondent	Total Annual Burden Hours	Hourly Wage Rate	Total Annual Cost
Concept Clinical Trial Survey (Attachment C9)	Health Care Practitioner	42	\$37.40	\$ 1,571
Prospective Clinical Trial Survey (Attachment C10)	Health Care Practitioner	17	\$37.40	\$ 636
Low Accrual Clinical Trial Survey (Attachment C11)	Health Care Practitioner	17	\$37.40	\$ 636
ETCTN PI Survey (Attachment 12)	Physician	19	\$95.05	\$ 1,806
ETCTN RS Survey (Attachment 13)	Health Care Practitioner	44	\$37.40	\$ 1,646
<b>Totals</b>		<b>15,524</b>		<b>\$ 666,072</b>

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

There are no additional costs or capital costs to respondents for completion of the forms or surveys. Forms are available on the CTSU and CIRB websites. No cost to the respondents is associated with obtaining a CTEP-IAM account to access the CTSU website or completion of the forms and surveys beyond the time needed to complete the materials.

**A.14 Annualized Cost to the Federal Government**

The total annualized cost to the federal government is \$689,035. Table A.14 provides an estimate of CTSU and CIRB labor/processing cost at the task level inclusive of form and packet processing, site follow up, and all related processing activities.

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

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>					
Associate Branch Chief, CTOIB	Grade 14/Step 9	\$140,000	50%	N/A	\$70,000

Chief, CTOIB	Grade 15/Step 10	\$150,000	50%	N/A	\$75,000
Head CIRB	Grade 14/Step 10	\$150,000	5%	N/A	\$7,500
Nurse Consultant, DCP CIRB Liaison	Grade 14/Step 10	\$150,000	5%	N/A	\$7,500
<b>Contractor Cost</b>					
CTSU and CIRB Forms Processing	N/A	\$68,000	30%	N/A	\$466,735
Survey Generation, Conduct, and Analysis	N/A	\$68,000	10%	N/A	\$62,300
<b>Total Costs</b>					<b>\$689,035</b>

CTEP's role on the CIRB and CTSU programs is to provide contract oversight. Oversight activities include monitoring of the contract budget, ensuring compliance with the contract statement of work, and working with the contractors to ensure timely and efficient implementation of the contracts.

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

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

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

This is a new information collection. It is the combination of CIRB OMB# 0925-0625, expiry 12/31/2016 and CTSU OMB# 0925-0624, expiry 1/31/2017.

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

There are no plans for publication of form or survey information. Forms are processed generally within 1 to 3 business days of receipt dependent on the form type. CTSU and CIRB forms collection is

for ongoing activities to support NCI operations and regulatory requirements. There is no expected end date at this time.

**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.