

## Supporting Statement A For:

Cancer Trials Support Unit (CTSU) (NCI)

**OMB No. 0925-0624, Expiration Date: 12/31/2013**

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**Revisions to the original submission are in yellow throughout this document.**

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The Cancer Therapy Evaluation Program (CTEP) establishes and supports programs to facilitate the participation of qualified investigators on CTEP-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. Currently guided by the efforts of the Clinical Trials Working Group (CTWG) and the Institute of Medicine (IOM) recommendations to revitalize the Cooperative Group program, CTEP has funded the Cancer Trials Support Unit (CTSU). The CTSU collects standardized forms to process site regulatory information, changes to membership, patient enrollment data, and routing information for case report forms. In addition, CTSU collects seven surveys used for customer satisfaction or related to clinical trials. The customer satisfaction surveys assess different areas of service delivery at CTSU including: the CTSU Help Desk, the CTSU web site, the Protocol and Information Office (PIO), and the Oncology Patient Enrollment Network (OPEN). User satisfaction surveys are compiled as part of the project quality assurance activities and are used to direct improvements to processes and technology. Additionally, there are three surveys collect information about health professional's interests in clinical trial, potential issues with opening and accruing to a clinical trial and reasons for low accrual.

## **A. JUSTIFICATION**

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

The Cancer Trials Support Unit (CTSU) is a contractor operated service offered by the National Cancer Institute - Cancer Therapy Evaluation Program (CTEP) - to enhance and facilitate access to cancer clinical trials in the United States and Canada. The CTSU maintains a broad menu of trials developed by the cancer Cooperative Groups and other research consortia and works with these organizations to offer patient enrollment, data collection, data quality management, and enrollment reimbursement services to clinical sites entering patients in these trials. In addition, the CTSU offers a regulatory support service to all CTEP-funded Cooperative Group cancer clinical trials and selected networks by collection of regulatory documents and maintenance of a national database of investigators and sites. The CTSU also provides education and training for clinical site staff and clinical trials promotion services to help increase enrollment in cancer trials. A large and complex information technology infrastructure has been developed to support CTSU operations and exchange data with other data centers involved in cancer research. Westat is the prime contractor for this project.

The Public Health Service Act, and Section 413 (42 USC § 285a-2) authorizes CTEP to establish and support programs to facilitate the participation of qualified investigators on CTEP-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. Based upon the

recommendations of the Armitage report in the late 1990's and currently guided by the efforts of the Clinical Trials Working Group (CTWG) and recommendations by the Institute of Medicine (IOM) to revitalize the Cooperative Group program, CTEP has funded the CTSU.

As part of this program the CTSU has established services for providing protocol and program information through a password protected web site to participating institutions. To ensure consistency in processing of information and to guarantee the quality of the information collected CTSU has instituted numerous standard forms. Standard CTSU forms are collected to facilitate many of the activities described above (**attachment 1a-1t**). CTSU forms fall into six categories including regulatory, membership, drug shipment, data management, patient enrollment, and administrative. The forms were developed to ensure that data is collected in a consistent manner for specific project tasks. These tasks are critical to key project functions such as the collection of participating site regulatory information, patient accrual, and data collection.

The CTSU conducts three customer satisfaction surveys for quality assurance purposes: one for the CTSU web site (**attachment 2**) and one for the help desk service (**attachment 3**). Additionally, a web based survey is also available to assess user satisfaction with the Oncology Patient Enrollment Network (OPEN) (**attachment 4**). This system was released in October 2009 the survey provides valuable end user information on a new system that is critical for standardizing the enrollment process across the CTEP-support trials. A fourth customer satisfaction survey specifically targets customers who interact with the Protocol and Information Office (PIO) (**attachment 5**).

Three additional surveys are conducted to assess the ideas of opening a clinical trial (**attachment 6**), accruing to a trial (**attachment 7**), and reasons for low accrual (**attachment 8**). These surveys were previously pilot tested (OMB No. 0925-0046-21) with clinical trials that were considered challenging by CTEP. The three surveys are templates that can be tailored to a specific clinical trial and then sent out via an email to clinicians to gather their feedback electronically. Survey data were able to assist CTEP and trial study teams to identify which elements of a trial posed the greatest barriers, clinicians' interest in a trial (i.e., was the trial

worth opening at their sites?), and ways a trial could be better supported to increase patient accrual. For example, a survey was conducted for RTOG-0848, a trial with two research questions addressing pancreatic cancer; from the survey data the study team learned that clinicians were no longer as interested in one of the research questions and they (erroneously) believed that the science had already been answered (so they believed it was not necessary for them to put patients on the trial). Working with CTEP, the study team used the findings to develop trial-specific materials to clearly explain the importance of the trial to clinicians. The Principle Investigator also used the data to determine if the trial should be amended to drop the uninteresting research question. Since the survey and the follow up activities, the trial has accrued an additional 166 patients and the accrual rate has increased from 5 patients a month (prior to the survey) to 9.3 patients a month.

OMB approval pursuant to the Paperwork Reduction Act is currently requested for this revised information collection to extend the expiry date three years.

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

### **CTSU Forms:**

As stated in Section A.1, standard forms fall into six categories, regulatory, membership, drug shipment, data management, patient enrollment, and administrative. CTSU regulatory forms (**attachments 1a-1e**) are required to maintain benefits of the program by ensuring that institutions participating in CTEP-supported clinical trials have received Institutional Review Board (IRB) approval. The CTSU processes approximately 10,000 IRB approvals per month for all NCI-supported phase I, II and III Cooperative Group trials and select Phase 2 Contractor and network studies. The regulatory data is shared with CTEP and the Cooperative Groups in near real time to support patient enrollments. While there are other methodologies to submit IRB approval information such as local IRB letters and the *Protection of Human Subjects Assurance Identification/Certification/Declaration*, the CTSU IRB Certification form collects additional information needed to ensure local site compliance with regulatory and protocol specific requirements. Additional information collected includes, CTEP site code identifiers; facilitated review information unique to clinical sites participating in the NCI Central IRB (CIRB) program; **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. Use of the form is not mandatory, but is strongly encouraged as it reduces processing 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 CIRB continuing participation.

Minor changes and the rationale behind these changes to the Regulatory forms are listed below.

**Attachment 1a** CTSU IRB/Regulatory Approval Transmittal Form: Changes were made to better reflect the information needed when processing IRB/Regulatory documents and replace the fields previously listed under the Packet Type area. The following fields were added: Normal and Urgent packet type, Attn:, and lines for applicable sites, protocols and Institutional PI.

**Attachment 1b** CTSU IRB Certification Form: No changes.

**Attachment 1c** CTSU Acknowledgement Form: In box 9 of the form, the IRB numbers for the adult CIRB, pediatric CIRB, and early phase emphasis boards were added. With the expansion of sites utilizing the NCI CIRB as the IRB record we anticipate a need to have the IRB numbers readily available on the form to minimize site burden.

**Attachment 1d** Optional Form 1 - Withdrawal from Protocol Participation Form: No changes.

**Attachment 1e** Site Addition Form: Federal Wide Assurance numbers for parent and child sites were added. The rationale behind this is to continue to track FWA information when additional sites are added to existing IRB approvals collected by the CTSU.

Membership forms (**attachments 1f and 1g**) are designed to maintain the CTSU person membership and site radiation facilities information. The CTSU roster is comprised of approximately 20,000 active investigators and associates that are aligned with the Cooperative Groups and other CTEP-supported networks. The CTSU processes approximately 1000 roster transactions per month. This information is shared with the Cooperative Groups or **Lead Protocol Organization** sponsoring the protocol and CTEP. Accurate and current information is critical to ensure that the responsible persons at the clinical sites are contacted with protocol related queries and updates. The CTSU Roster Update Form (**attachment 1f**) is mandatory 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. Aside from the OMB approval of the change request in November 2012, no other changes have been made.

The CTSU Radiation Facilities Inventory Form (**attachment 1g**) is submitted by sites to verify credentialing with the Radiological Physics Center (RPC). Credentialing with RPC is a CTEP requirement for sites participating on protocols with a radiation component. This form is collected once per facility. RT Facilities already participating in the RPC monitoring program only complete the first two pages of the form which is primarily contact information. For RT facilities that have not participated in the RPC monitoring program, the entire form and supporting documents must be submitted. CTSU submits copies of these forms to RPC to assist in maintaining up-to-date information in their database. Updates to these forms are requested when facility contact information changes. **Changes to submission instructions were made so that users may now fax or email the form to the CTSU Regulatory Office fax/email address.**

Forms to support site tracking of study agents on the IBCSG studies (**attachment 1h and 1i**) were developed by CTSU. Study agents for these internationally led trials (IBCSG 24-02 and 25-02) are distributed through Pfizer's subcontractor, and CTSU supports the distribution process by supplying patient enrollment (enrollment date, patient ID, and treatment arm) and drug shipment information. The accountability and transfer form do not need to be submitted to the CTSU, but may be reviewed at the time of site audit. No changes are requested at this time.

To support data management activities, the data transmittal, data clarification, and data update forms (**attachments 1j-1n**) are 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. Data Management forms are developed for the common purpose of efficiently managing and processing received data. No changes are requested at this time.

**Attachment 1n** represents a generic data transmittal form that will be implemented for future studies. Please note that over time, CTSU may also remove data management forms as studies close to data collection, or data collection is transferred back the lead protocol organization. At



present, we do not have a timeline for when this will occur on existing studies. A rough estimate of the timeframe for data collection through the CTSU is approximately five years. Changes to existing forms are expected due to protocol amendments. We anticipate that changes will be minimal and limited to the checklist portion of the form. Form updates will be submitted to OMB as change requests.

Several forms have been removed from the data management sections as they are no longer required for data collection purposes.<sup>1</sup> The corresponding protocols for the forms listed below are now closed to data collection or data management has transitioned back to the sponsoring organization and CTSU no longer collects data for the study. The following forms have been removed from this request:

- N0147 CTSU Data Transmittal Form
- Site Initiated Data Update Form (DUF), Protocol: NCCTG N0147
- Z4032 CTSU Data Transmittal Form
- Z1031 CTSU Data Transmittal Form
- Z1041 CTSU Data Transmittal Form
- CTSU 7868 Data Transmittal Form
- Site Initiated Data Update Form, protocol 7868
- TAILORX/PACCT1 CTSU Data Transmittal Form
- Unsolicited Data Modification Form (UDM), Protocol: TAILORx/PACCT1
- 8121 CTSU Data Transmittal Form
- Site Initiated Data Update Form, protocol 8121
- USMCI 8214/Z6091: CTSU Data Transmittal Form
- USMCI 8214/Z6091 Crossover Request/Checklist Transmittal Form

The CTSU Patient Transfer, CTSU Patient Enrollment Transmittal, and the CTSU P2C Enrollment Transmittal Forms are mandatory for processing (**attachments 1o-1q**). The CTSU Patient Enrollment Transmittal form (**attachment 1o**) collects required information for processing CTSU enrollments including CTEP site code, treating investigator identifiers, and information critical to site payment and audit responsibilities. The CTSU processes approximately 200 patient registrations per month. The CTSU Patient Transfer form (**attachment 1q**) 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. Aside from the OMB approval of the change request in November 2012, no other changes have been made to these forms.

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Administrative forms (**attachment 1r-1t**) are used to process account request for specific components of the CTSU Enterprise System and expedite processing of supplies and investigator brochures. CTSU processes approximately 150 requests each month. The supply and IB request forms are not mandatory but are the preferred method of requesting supplies. A minor change was made to the CTSU Request for Clinical Brochure (**attachment 1s**). An additional field was added to allow for the collection of the user's email address. Many clinical brochures are available in electronic format and may be distributed by email to the user.

### **Surveys:**

Surveys are used to objectively measure customer satisfaction and provide data needed to continually improve services. Customer satisfaction surveys assess perceptions of our customers, as opposed to our perceptions of how well services are delivered. The **three annual surveys (help desk, web site and PIO)** have a core set of questions used to assess overall customer satisfaction, frequency of use, and specific questions on a new service or application (**attachments 2, 3 and 5**). The OPEN survey (**attachment 4**) is a usability survey. **Attachment 5** is a simple customer satisfaction survey for customers that receive services and support from the Protocol and Information Office (PIO).

**Attachment 2** - CTSU Web Site Customer Satisfaction Survey – One question was removed (Please provide us with comments and/or suggestions about how to improve the usability of the Delinquent CRFs feature under the Clinical Data Tab) because it yielded a low number of responses. The question was added (Please provide us with comments and/or suggestions about the Document Search/DSN Search feature on the CTSU members' website home page) to collect user feedback on this recently added feature to the CTSU members' website.

**Attachment 3** - CTSU Help Desk-Customer Service Satisfaction Survey – In May 2012, the CTSU Help Desk hours were extended and frequency of use data for the extended hours will be collected for quality assurance purposes. For this reason, one question was added to assess the frequency of use during extended service hours (How often do you utilize the CTSU Help Desk between the hours of 5:30pm and 8:30pm?).

**Attachment 4** - CTSU Oncology Patient Enrollment Network (OPEN) Survey – this survey is posted to the OPEN web site and is available upon a user completing a patient enrollment. No changes requested at this time.

**Attachment 5** - Protocol and Information Office (PIO) External Customer Satisfaction Survey– the Cancer Therapy Evaluation Program’s Protocol and Information Office (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 6** – 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 7** – 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 8** – 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.

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

Most forms are available in PDF writable formats, and Word formats are available upon request. Forms are submitted to CTSU via fax, fax server, or e-mail dependent upon the form and process. The surveys are distributed using Survey Monkey™ a commercial product that can be used to send survey request via e-mail (**attachments 2, 3, 4 and 5**). Users click a link within the e-mail to access the survey. For the surveys, the technology was selected due to the ease of use. It incorporates already existing e-mail contact information, requires no end user training, or loading of programs to the user's computer. The ease of use improves user compliance with the survey.

The clinical trial surveys (**attachments 6, 7, and 8**) are tailored based on information in the trial's concept or protocol. Once reviewed by CTEP and the study team, an invitational email is sent via CTSU to the PIs and site administrators at those CTSU sites identified as relevant recipients (e.g., those sites that have opened the trial, are listed as pending to open the trial, or have opened/accrued to a previous trial related to the one listed in the survey). The email invitation has a description of the request and a link to the online survey. A reminder email is sent out after one week, and the survey closed after two weeks. Data are compiled from an excel sheet print out and put into a standard report and shared with CTEP and the study team to review.

Westat completed security assessment of the CTSU enterprise system as per the guidelines set forth in the Federal Information Security Management Act (FISMA) and specifically in NIST Special Publication 800-53 Rev 3 and in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist. The assessment was completed by an independent third party assessor to ensure the security controls are in place and working as intended. Based on this, CTSU maintains an active Authorization to Operate (ATO) that was 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.

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). A 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 web site, RSS, and other related modules (**attachment 9**). An annual PIA is submitted to the NCI Privacy Act Officer for review.

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

Forms and survey information collected are specific to the services and applications managed by the CTSU. No similar services are available within the CTEP-supported mechanism. When alternative forms do exist, as is the case with the CTSU IRB Certification Form, the form is optional but preferred, as the existing forms and letters do not collect the extent of information required for processing.

For the surveys, there are no other similar information collections for these respondents.

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

Surveys and data collection forms are used by individuals who already participate in the CTSU activities, without distinction as to whether they work at large or small institutions. There is no requirement for institutional participation or reporting. We do not track the size of the institutions that utilize CTSU services, but multiple types of institutions including university based medical centers, NCI-designated cancer centers, community hospitals, and physician practices participate and thus it can be assumed that some may be small businesses. All CTSU forms are designed to collect the minimum necessary information to maintain CTSU processes.

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

CTSUS forms are designed to support real time CTSUS 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.

The web site, help desk, and **PIO surveys are currently collected annually**. Annual surveys are the minimum needed to provide adequate information on CTSU services. The OPEN survey is posted to the OPEN application and is ongoing. As more studies utilize the OPEN application for patient enrollment, ongoing feedback is useful for quickly determining system upgrades that make the application more efficient.

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

For the purposes of this information collection, there may be times when special circumstances arise during the collection of CTSU forms. This would include estimating that the average user of a given CTSU service (site regulatory coordinator, site patient registrar) report information on a monthly basis. Estimates on form usage are based upon processing metrics such as the number of regulatory packets or CRFs submitted. As the majority of CTSU forms act as transmittal and routing sheets, and are not universally required for processing, metrics on the exact number of CTSU forms received are often not available. For example, a data transmittal form may accompany three to five CRFs. Metrics on the number of CRFs received are kept, but not necessarily if the transmittal form was submitted. In addition, metrics are not available on the frequency that individual users of CTSU services submit a given form, as tasks are assigned at the site level, and not all institutions and CTSU members take part in all services and protocols.

#### **A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

**The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on August 30, 2013, Vol. 78, p. 53763. There have been no public comments.**

No persons outside the CTSU were consulted on the development of the surveys.

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

For forms listed under **attachments 1a-1t**: no gifts will be given to respondents, nor any such expectations set. The customer satisfaction surveys (**attachments 2-3**) provide respondents with the opportunity to participate in a drawing for a \$50.00 Visa gift card. Participation is based upon a “yes” response to the question, “Would you like to enter a drawing for a chance to win a \$50.00 Visa gift card?” Negative responses are not considered for the gift card. Responses to the gift card collection are not calculated in the survey analysis. Gift card winners are randomly selected. Employees of the contractors are not eligible. We believe that use of this incentive has improved the response rate to surveys distributed to health care professionals and physicians. The modest amount has been used recently in other OMB-approved NCI studies involving a similar sample (OMB #0925-0595, Expiration Date: 12/31/2010). Additionally, incentives were used successfully in 2002, 2004, and 2006 to obtain response rates above 70 percent for three physician surveys (OMB Nos. #0930-0246, #0930-0262, and #0925-0562).

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

Forms are submitted via fax or e-mail dependent on the process supported. Data collected from the forms is entered into the CTSU Enterprise system. All contractor staff is required to have human subjects training, sign a “Certificate of Confidentiality”, and participate in security awareness training on an annual basis. The portions of the CTSU data collection that pertain to maintenance of site rosters and the collection of information for IRB/Regulatory compliance will be accessible on the CTSU members’ website and in the CTSU enterprise system. All nonpublic parts of the resource will be maintained private in accordance with appropriate security access controls pursuant to applicable policies.

Surveys are circulated via e-mail or upon completion of an enrollment in OPEN. Identifying information based upon the user e-mail is not used in the analysis of the data, nor are any efforts made to link respondents to their e-mail. Contact information that is collected is added to the CTSU enterprise systems and data security is maintained

The forms and surveys were submitted to the Westat IRB for review and expedited approval has been granted for their use. In addition, the CTSU project has been reviewed by the CTSU IRB and given approval (**attachment 10**).

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

For the surveys, there is no PII collected. For the forms, a minimal amount of personally identifiable information (PII) is collected and is related to specific tasks and immediate contact information. No information is collected about the user's race, ethnicity, sex, religion or habits that would be considered sensitive. The PII collected includes name, mailing address, telephone number, and email address. 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 11**).

#### **A.12 Estimates of Annualized Burden Hours and Costs**

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. For more information refer to Section A.7 in this document. It is estimated that the average user of a given CTSU service (site regulatory coordinator, site patient registrar) would submit a given CTSU form once per month. The burden estimate is based on responses for forms at a site level, and not all institutions and CTSU members take part in all services and protocols; and thus tracking the number of respondents and their frequency of response for each form or survey may not be accurate. Estimates are subject to rounding.

The annual burden is estimated to be 25,205 hours which amounts to a total of 75,614 hours over the course of three years (see Table A.12-1). The estimated burden over three years has decreased by approximately 10,000 hours when compared to the previous approval estimates submitted in 2010. This is due to the decrease in Data Management activities and forms no longer required on the contract.



**Table A.12-1: Estimated Annualized Burden Hours**

Form Name (Attachment #)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
CTSU IRB/Regulatory Approval Transmittal Form (Attachment 1a)	Health Care Practitioner	9,000	12	2/60	3,600
CTSU IRB Certification Form (Attachment 1b)	Health Care Practitioner	8,500	12	10/60	17,000
CTSU Acknowledgement Form (Attachment 1c)	Health Care Practitioner	500	12	5/60	500
Withdrawal from Protocol Participation Form (Attachment 1d)	Health Care Practitioner	50	12	5/60	50
Site Addition (Attachment 1e)	Health Care Practitioner	25	12	5/60	25
CTSU Roster Update Form (Attachment 1f)	Health Care Practitioner	50	12	4/60	40
CTSU Radiation Therapy Facilities Inventory Form (Attachment 1g)	Health Care Practitioner	20	12	30/60	120
CTSU IBCSG Drug Accountability Form (Attachment 1h)	Health Care Practitioner	11	12	10/60	22
CTSU IBCSG Transfer of Investigational Agent Form (Attachment 1i)	Health Care Practitioner	3	12	20/60	12
Site Initiated Data Update Form (Attachment 1j)	Health Care Practitioner	10	12	10/60	20
Data Clarification Form (Attachment 1k)	Health Care Practitioner	341	12	20/60	1,364
RTOG 0834 CTSU Data Transmittal Form (Attachment 1l)	Health Care Practitioner	60	12	10/60	120
MC0845(8233) CTSU Data Transmittal (Attachment 1m)	Health Care Practitioner	50	12	10/60	100
CTSU Generic Data Transmittal Form (Attachment 1n)	Health Care Practitioner	500	12	10/60	1,000
CTSU Patient Enrollment Transmittal Form (Attachment 1o)	Health Care Practitioner	200	12	10/60	400
CTSU P2C Enrollment Transmittal Form (Attachment 1p)	Health Care Practitioner	15	12	10/60	30

CTSU Transfer Form (Attachment 1q)	Health Care Practitioner	20	12	10/60	40
CTSU System Account Request Form (Attachment 1r)	Health Care Practitioner	20	12	20/60	80
CTSU Request for Clinical Brochure (Attachment 1s)	Health Care Practitioner	75	12	10/60	150
CTSU Supply Request Form (Attachment 1t)	Health Care Practitioner	75	12	10/60	150
CTSU Web Site Customer Satisfaction Survey (Attachment 2)	Health Care Practitioner	275	1	15/60	69
CTSU Helpdesk Customer Satisfaction Survey (Attachment 3)	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey (Attachment 4)	Health Care Practitioner	60	1	15/60	15
PIO Customer Satisfaction Survey (Attachment 5)	Health Care Practitioner	100	1	5/60	8
Concept Clinical Trial Survey (Attachment 6)	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey (Attachment 7)	Health Care Practitioner	1000	1	5/60	83
Low Accrual Clinical Trial Survey (Attachment 8)	Health Care Practitioner	1000	1	5/60	83
ANNUALIZED TOTALS					25,205

The estimated annualized cost to respondents is \$729,404 (see Table A.12-2). This amounts to a total cost of \$2,188,211 over a three year period of information collection. Wage estimates are based upon a generic category of Health Care Practitioner at a median hourly wage rate of \$28.94 per hour. Information is provided by the Bureau of Labor Statistics web site at <http://www.bls.gov/oes/current/oes290000.htm>.

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

Form Name (Attachment #)	Type of Respondent	Number of Respondents	Total Annual Burden Hour	Hourly Wage Rate	Total Annual Cost
CTSU IRB/Regulatory Approval Transmittal Form (Attachment 1a)	Health Care Practitioner	9,000	3,600	\$28.94	\$104,184.00
CTSU IRB Certification Form (Attachment 1b)	Health Care Practitioner	8,500	17,000	\$28.94	\$491,980.00
CTSU Acknowledgement Form (Attachment 1c)	Health Care Practitioner	500	500	\$28.94	\$14,470.00

Withdrawal from Protocol Participation Form (Attachment 1d)	Health Care Practitioner	50	50	\$28.94	\$1,447.00
Site Addition (Attachment 1e)	Health Care Practitioner	25	25	\$28.94	\$723.50
CTSU Roster Update Form (Attachment 1f)	Health Care Practitioner	50	40	\$28.94	\$1,157.60
CTSU Radiation Therapy Facilities Inventory Form (Attachment 1g)	Health Care Practitioner	20	120	\$28.94	\$3,472.80
CTSU IBCSG Drug Accountability Form (Attachment 1h)	Health Care Practitioner	11	22	\$28.94	\$636.68
CTSU IBCSG Transfer of Investigational Agent Form (Attachment 1i)	Health Care Practitioner	3	12	\$28.94	\$347.28
Site Initiated Data Update Form (Attachment 1j)	Health Care Practitioner	10	20	\$28.94	\$578.80
Data Clarification Form (Attachment 1k)	Health Care Practitioner	341	1,364	\$28.94	\$39,474.16
RTOG 0834 CTSU Data Transmittal Form (Attachment 1l)	Health Care Practitioner	60	120	\$28.94	\$3,472.80
MC0845(8233) CTSU Data Transmittal (Attachment 1m)	Health Care Practitioner	50	100	\$28.94	\$2,894.00
CTSU Generic Data Transmittal Form (Attachment 1n)	Health Care Practitioner	500	1,000	\$28.94	\$28,940.00
CTSU Patient Enrollment Transmittal Form (Attachment 1o)	Health Care Practitioner	200	400	\$28.94	\$11,576.00
CTSU P2C Enrollment Transmittal Form (Attachment 1p)	Health Care Practitioner	15	30	\$28.94	\$868.20
CTSU Transfer Form (Attachment 1q)	Health Care Practitioner	20	40	\$28.94	\$1,157.60
CTSU System Account Request Form (Attachment 1r)	Health Care Practitioner	20	80	\$28.94	\$2,315.20
CTSU Request for Clinical Brochure (Attachment 1s)	Health Care Practitioner	75	150	\$28.94	\$4,341.00
CTSU Supply Request Form (Attachment 1t)	Health Care Practitioner	75	150	\$28.94	\$4,341.00
CTSU Web Site Customer Satisfaction Survey (Attachment 2)	Health Care Practitioner	275	69	\$28.94	\$1,996.86
CTSU Helpdesk Customer	Health Care	325	81	\$28.94	\$2,344.14

Satisfaction Survey (Attachment 3)	Practitioner				
CTSU OPEN Survey (Attachment 4)	Health Care Practitioner	60	15	\$28.94	\$434.10
PIO Customer Satisfaction Survey (Attachment 5)	Health Care Practitioner	100	8	\$28.94	\$231.52
Concept Clinical Trial Survey (Attachment 6)	Health Care Practitioner	500	42	\$28.94	\$1,215.48
Prospective Clinical Trial Survey (Attachment 7)	Health Care Practitioner	1000	83	\$28.94	\$2,402.02
Low Accrual Clinical Trial Survey (Attachment 8)	Health Care Practitioner	1000	83	\$28.94	\$2,402.02
ANNUALIZED TOTALS			25,205		\$729,403.76

**A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

There is no additional cost or capital cost to respondents for completion of the forms or surveys. Forms are available on the CTSU web site. No cost to the respondents is associated with obtaining a CTEP-IAM account to access the CTSU web site 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 annual cost to the Federal Government is estimated at \$1,953,405 and over a three-year time-frame, it is estimated to be \$5,860,215 (Table A.14-1). Costs to the Federal government would be incurred regardless of use of the forms as the tasks supported are essential to the functioning of the project. The cost to the Federal government is expected to decrease due to the removal of data management forms from collection and plans for increased automation.

Table A.14-1 provides an estimate of CTSU labor/processing cost at the task level inclusive of form and packet processing, site followup, and all related processing activities. Cost estimates are based upon cost account codes developed for the project and are given based upon the 2012 calendar year. The three year estimate for regulatory core processing, membership processing and patient enrollment processing is reduced by 20% from the 2012 totals over three years to account for reductions in processing cost because of planned automation.

**Table A.14-1: Project Cost for Forms and Surveys**

Forms/Surveys	Task Cost Per Year	Cost Estimate for 3 years
Regulatory Core Processing	\$1,437,501	\$4,312,503
Membership Processing	\$123,703	\$371,109
Patient Enrollment Processing	\$295,381	\$886,143
IBCSG Studies	\$26,725	\$80,175
RTOG 0834 –	\$4,211	\$12,633
8233 – Data Processing	\$3,152	\$9,456
Customer Satisfaction Surveys (Help, Web Site, OPEN, and PIO)	\$15,932	\$47,796
Clinical Trial Surveys	46,800	140,400
Totals	\$1,953,405	\$5,860,215

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

This program change is being submitted as a revised information collection and includes minor updates to forms and the customer satisfaction surveys. Additionally, several forms are no longer required for collection, which results in a decrease of 9,623 burden hours and about a 20% cost reduction associated with this project. The Protocol and Information Office Customer Satisfaction Survey has been added to this submission and it is anticipated that information collection will occur annually. Additionally, three surveys related to clinical trial ideas, opening and accrual, and low accruals have been added to this information collection.

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

A timeline is developed for review and analysis of the survey data. Data is solely for project use and not for publication. Survey results are reviewed internally for quality assurance.

<b>Timeline Project Tasks</b>	<b>Task Completion</b>	<b>Timeframe</b>
Forms	1 to 3 business days	Ongoing
Surveys		
Planning	2 to 4 weeks	Annual
Survey Period	10 days	Annual
Analysis and Report	4 weeks	Annual

The current contract was awarded in September 2006 for three years, with four optional one year extensions. The current extension runs through August 31, 2013. NCI-CTEP released a Request for Proposal (RFP) for the project on May 10, 2013. The contract period of performance is from September 1, 2013 to August 31, 2014 with six optional contract years. At this time the contract has not been awarded. As the primary contractor on the current contract, Westat will ensure documentation of the OMB submission package is transitioned to the next contract. The majority of forms and the surveys are expected to last the duration of the contract.

**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**

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