

Supporting Statement A For:

Cancer Trials Support Unit (CTSU) (NCI)

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LIST OF ATTACHMENTS

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 - 1c – CTSU Acknowledgment Form
 - 1d – Optional Form 1 – Withdrawal from Protocol Participation Form
 - o Membership Forms
 - 1e – CTSU Roster Update Form
 - 1f – CTSU Radiation Therapy Facilities Inventory Form
 - o Drug Shipment
 - 1g – CTSU IBCSG Drug Accountability Form
 - 1h – CTSU IBCSG Transfer of Investigational Agent Form
 - o Data Management
 - 1i – Site Initiated Data Update Form
 - 1j – N0147 CTSU Data Transmittal Form
 - 1k – Site Initiated Data Update Form (DUF), Protocol NCCTG N0147
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 - o Patient Enrollment
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 - 1bb – CTSU P2C Enrollment Transmittal Form
 - 1cc - CTSU Transfer Form
 - o Administrative
 - 1dd – CTSU System Account Request Form
 - 1ee – CTSU Request for Clinical Brochure
 - 1ff – CTSU Supply Request Form
 - 1gg – CTSU Generic Data Transmittal Form

- Attachment 2 – Web Site Survey
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- Attachment 4 – Oncology Patient Enrollment Network (OPEN) Survey
- Attachment 5 – Privacy Impact Assessment
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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 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), 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 in the introductory paragraph. A complete listing of CTSU forms is found in **Attachment 1**. CTSU forms fall into six categories including regulatory, roster, 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 two customer satisfaction surveys to meet deliverable requirements of the contract: one for the CTSU web site and one for the help desk service. Additionally, a web based survey is also available to assess user satisfaction with the Oncology Patient Enrollment Network (OPEN). This system was released in October 2009, and while this survey is not a contract deliverable, it provides valuable end user information on a new system that is critical for standardizing the enrollment process across the CTEP-support trials.

A.2 Purpose and Use of the Information

CTSU Forms:

As stated in Section A.1, standard forms fall into six categories, regulatory, roster, drug shipment, data management, patient enrollment, and administrative. **Attachment 1** lists all CTSU standard forms by category.

CTSU regulatory forms (**attachments 1a-1d**) 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; 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 followup 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.

Roster forms (**attachments 1e and 1f**) are designed to maintain the CTSU person roster 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 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 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.

The CTSU Radiation Facilities Inventory Form (**attachment 1f**) 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.

Forms to support site tracking of study agents on the IBCSG studies (**attachment 1g and 1h**) 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. CTSU followed the format used by the Pharmaceutical Management Branch (PMB) at CTEP in the development of the forms.

To support data management activities, the data transmittal, data clarification, and data update forms (**attachments 1i-1z**) 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. CTSU processes approximately 3735 Case Report Form (CRF) packets per month on 11 studies for which CTSU is responsible for all or part of the data management activities.

It is anticipated that CTSU will provide data management support for additional protocols in the future requiring the activation of new protocol specific data transmittal forms. New data management forms will be developed for the same purpose and following the same template as existing forms, and CTSU will submit a change request for this application to OMB prior to the release of any additional data management forms.

Form/Attachment 1gg 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 year. 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 request.

The CTSU Patient Enrollment Transmittal form 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 600 patient registrations per month. The 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. The CTSU Patient Transfer, CTSU Patient Enrollment Transmittal, and the CTSU P2C Enrollment Transmittal Forms are mandatory for processing. (See **attachments 1aa-1cc**)

Administrative forms (**attachment 1dd-1ff**) 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 200 requests each month. The supply and IB request forms are not mandatory but are the preferred method of requesting supplies.

All CTSU forms are designed to collect the minimum necessary information to maintain CTSU processes. Most forms are available in PDF writable formats, and Word formats are available upon request. Submission of all forms is accepted by fax and/or e-mail.

Surveys:

Survey questionnaires 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 two annual surveys (help desk and web site) have a core set of questions used to assess overall customer satisfaction over time and may include additional questions or rewording of questions needed to assess new or changed service offerings. A change request to this submission will be sent if the survey questions or modified.

Survey questions fall into three general categories, frequency of use, general satisfaction, and specific questions on a new service or application. Examples of survey questions are included; please see **attachments 2-4**. As the web site and help desk surveys have been on-hold for greater than a year, screen shots are not available, but the attachment for the OPEN survey (**attachment 4**) is an excellent example of the Zoomerang™ tool that is used for all CTSU surveys.

- 1) CTSU Web Site Customer Satisfaction Survey (see **attachment 2**) – has been conducted since 2007. The survey is submitted to approximately 1,000 persons who have used the CTSU web site in the last year.

- 2) CTSU Help Desk-Customer Service Satisfaction Survey (see **attachment 3**) – was also first conducted in 2007. 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.
- 3) CTSU Oncology Patient Enrollment Network (OPEN) Survey (see **attachment 4**) – this survey is posted to the OPEN web site and is available upon a user completing a patient enrollment. The report of the results is not a contract deliverable, but is very useful in assessment of a new service offering of the CTSU.

A.3 Use of Improved Information Technology and Burden Reduction

Forms are submitted to CTSU via fax, fax server, or e-mail dependent upon the form and process.

The surveys are distributed using Zoomerang™ a commercial product that can be used to send survey request via e-mail. Users click a link within the e-mail to access the survey. Surveys results are answered by clicking on radio buttons or by typing in free text.

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.

User burden for the forms is minimal. Instructions are self explanatory and generally located on the form. Forms include a PDF instructions cover page and infrequently a more detailed instruction sheet. Completion of the form is not anticipated to take longer than drafting of an e-mail with similar information, and reduces the need for follow up with the submitter as all required processing fields are collected.

For the two annual surveys, requests to participants are submitted via e-mail with a follow up reminder e-mail submitted after 7 to 10 days. The OPEN survey may be accessed upon completion of a patient enrollment in OPEN. Estimated time to complete the survey is 10 to 15 minutes per user.

CTSU is actively pursuing the Certification and Accreditation (C&A) of its enterprise computer system infrastructure. Document preparation per National Institute of Standards and Technology (NIST) templates as well as preparing boundary agreements between the CTSU and Cooperative Groups is ongoing. Completion of the C&A is scheduled for the fourth quarter of 2010.

For the CTSU forms minimal submitter contact information is collected. Contact information collected is added to the CTSU enterprise systems and data security is maintained as outlined in the Privacy Impact Assessment (PIA). A PIA was promoted to HHS on 8/11/2009 and the IT system name is “NIH NCI Cancer Trials Support Unit (CTSU)” for the CTSU Enterprise system inclusive of the web site, RSS, and other related modules (see **attachment 5**).

For the surveys, the e-mail address of survey participants is collected and stored, but its distribution is limited to the quality assurance team and the project director. Questions are related to the system or services of the CTSU and are not sensitive in nature.

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.

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 intuitions. 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.

A.6 Consequences of Collecting the Information Less Frequently

CTSU forms are designed to support real time CTSU 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 and help desk surveys are currently collected annually. Previously these surveys were collected bi-annually but have been reduced to yearly for budgetary reasons. 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 the OPEN application has only recently been moved to site production use (Oct. 2009) 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

Federal Register:

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on July 13, 2010, Vol. 75, p. 39950. There have been no public comments.

Consults:

No persons outside the CTSU were consulted on the development of the surveys. The forms and surveys are directed to the users of the CTSU generally within the last calendar year if not more immediately.

A.9 Explanation of Any Payment or Gift to Respondents

Customer satisfaction survey respondents are given the opportunity to participate in a drawing for a \$25.00 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 \$25 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 SPARCSS. Additionally, incentives were used successfully in 2002, 2004, and 2006 to obtain response rates above 70 percent for three physician surveys (OMB No. 0930-0246 and 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. The system PIA outlines system security and confidentiality measures (see **attachment 5**). 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.

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.

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 (see **attachment 6**).

A.11 Justification for Sensitive Questions

Forms and surveys are related to CTSU systems and services. Information collected 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.

There is no personally identifiable information (PII) collected for the surveys; however PII is collected on some forms that are used in this submission. The PII collected includes name, date of birth, social security number, mailing address, telephone number, medical record 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” (see **attachment 7**).

A.12 Estimates of Annualized Burden Hours and Costs

Estimates are based upon annual cumulative response rate to forms and surveys. **Attachment 1** and Table A.12 includes estimated burden by form. 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. Please also note estimates are subject to rounding.

For the purposes of clarity and brevity for this section, Table A.12-1 and A.12-2 have been combined into one table. The annual site burden is estimated to be 27,861 hours which amounts to a total of 85,583 hours over the course of three years. The estimated annualized cost to respondents is \$757,828.00 (see Table A.12). This amounts to a total cost of \$2,273,484.00 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 \$27.20 per hour. Information is provided by the Bureau of Labor Statistics web site at <http://www.bls.gov/oes/2008/may/oes290000.htm>.

Table A.12-1 & A.12-2: Estimates of Annual Burden Hours and Annualized Cost to Respondents

Attach No.	Section/Form or Survey Title	Use Metrics/ month - # Respond	Estimated Time for site to complete	Estimated burden (minutes/ hours)	Frequency of Response	Total Annual Usage/Annual Burden Hours	Annual Cost/Item (\$27.20)
Regulatory/Roster							
1a	CTSU IRB/Regulatory Approval Transmittal Form	9,000	2 minutes	0.03	12.00	3,600	97,920.00
1b	CTSU IRB Certification Form	8,500	10 minutes	0.17	12.00	17,000	462,400.00
1c	CTSU Acknowledgement Form	500	5 minutes	0.08	12.00	500	13,600.00
1d	Optional Form 1 - Withdrawal from Protocol Participation Form	50	5 minutes	0.08	12.00	50	1,360.00
Roster Forms							
1e	CTSU Roster Update Form	50	2-4 minutes	0.07	12.00	40	1,088.00

1f	CTSU Radiation Therapy Facilities Inventory Form	20	30 minutes	0.50	12.00	120	3,264.00
Drug shipment							
1g	CTSU IBCSG Drug Accountability Form	11	5-10 minutes	0.17	12.00	22	598.40
1h	CTSU IBCSG Transfer of Investigational Agent Form	3	20 minutes	0.33	12.00	12	326.40
Data Management							
1i	Site Initiated Data Update Form (generic)	100	5-10 minutes	0.17	12.00	200	5,440.00
1j	N0147 CTSU Data Transmittal Form	1000	5-10 minutes	0.17	12.00	2,000	54,400.00
1k	Site Initiated Data Update Form (DUF), Protocol: NCCTG N0147*	75	5-10 minutes	0.17	12.00	150	4,080.00
1l	TAILORX/PACCT 1 CTSU Data Transmittal Form	2100	5-10 minutes	0.17	12.00	4,200	114,240.00
1m	Data Clarification Form	650	15-20 minutes	0.33	12.00	2,600	70,720.00
1n	Unsolicited Data Modification Form (UDM), Protocol:TAILORx/PACCT1	75	5-10 minutes	0.17	12.00	150	4,080.00
1o	Z4032 CTSU Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00
1p	Z1031 CTSU Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00
1q	Z1041 CTSU Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00
1r	Z6051 CTSU Data Transmittal Form	75	5-10 minutes	0.17	12.00	150	4,080.00
1s	RTOG 0834 CTSU Data Transmittal Form*	60	5-10 minutes	0.17	12.00	120	3,264.00
1t	CTSU 7868 Data Transmittal Form	50	5-10 minutes	0.17	12.00	100	2,720.00
1u	Site Initiated Data Update Form, protocol 7868	10	5-10 minutes	0.17	12.00	20	544.00
1v	MC0845(8233) CTSU Data Transmittal*	50	5-10 minutes	0.17	12.00	100	2,720.00

1w	8121 CTSU Data Transmittal Form*	100	5-10 minutes	0.17	12.00	200	5,440.00
1x	Site Initiated Data Update Form, Protocol 8121	10	5-10 minutes	0.17	12.00	20	544.00
1y	USMCI 8214/Z6091: CTSU Data Transmittal	50	5-10 minutes	0.17	12.00	100	2,720.00
	*In Development						
1z	USMCI 8214/Z6091 Crossover Request/Checklist Transmittal Form	5	5-10 minutes	0.17	12.00	10	272
Patient Enrollment							
1aa	CTSU Patient Enrollment Transmittal Form	600	5-10 minutes	0.17	12.00	1,200	32,640.00
1bb	CTSU P2C Enrollment Transmittal Form	30	5-10 minutes	0.17	12.00	60	1,632.00
1cc	CTSU Transfer Form	40	5-10 minutes	0.17	12.00	80	2,176.00
Administrative							
1dd	CTSU System Account Request Form	50	15-20 minutes	0.33	12.00	200	5,440.00
1ee	CTSU Request for Clinical Brochure	35	10 minutes	0.17	12.00	70	1,904.00
1ff	CTSU Supply Request Form	130	5-10 minutes	0.17	12.00	260	7,072.00
1gg	CTSU Generic Data Transmittal Form	500	5-10 minutes	0.17	12.00	1000.00	27200.00
Surveys/Web Forms							
2	CTSU Web Site Customer Satisfaction Survey	250	10-15 minutes	0.2500	1.00	63	1,700.00
3	CTSU Helpdesk Customer Satisfaction Survey	300	10-15 minutes	0.2500	1.00	75	2,040.00
4	CTSU OPEN Survey	120	10-15 minutes	0.2500	1.00	30	816.00
Annual Totals		21,770				34,802	946,600.80
Total for 3 year Approval Period						104,404.50	2,839,802.40

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

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. For example, cost for the receipt of the Patient Enrollment Form are not tracked, but total staff hours to process the enrollment, follow up with site staff, and complete quality control activities are tracked in aggregate. Cost estimates are based upon cost account codes developed for the project and are given based upon the 2009 calendar year.

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

Forms/Surveys	Task Hours per Year	Task Cost Per Year	Cost Estimate for 3 years
Regulatory Core Processing	27,075	\$1,505,647.00	\$4,516,941.00
Membership Processing	2,325	\$150,274.00	\$450,822.00
Patient Enrollment Processing	9,878	\$514,425.00	\$1,543,275.00
IBCSG Studies	405	\$32,324.00	\$96,972.00
7868 – Data Processing	255	\$11,319.00	\$33,957.00
N0147 – Data Processing	2,868	\$88,300.00	\$264,900.00
PACCT-1 – Data Processing	3,758	\$111,036.00	\$333,108.00
ACOSOG Z1031 – Data Processing	267	\$11,877.00	\$35,631.00
ACOSOG Z1041 – Data Processing	273	\$12,176.00	\$36,528.00

Forms/Surveys	Task Hours per Year	Task Cost Per Year	Cost Estimate for 3 years
ACOSOG Z6051 – Data Processing	113	\$5,355	\$16,605.00
RTOG 0834 –	176	\$15,015.00	\$45,045.00
ACOSOG Z4032 – Data Processing	304	\$13,467.00	\$40,401.00
8233 – Data Processing***	218	\$9,802.00	\$29,406.00
8121 – Data Processing***	218	\$9,802.00	\$29,406.00
USMCI 8214/Z6091 Processing***	218	\$9,802.00	29,406.00
Help Desk Survey*	164.5	\$12,987.00	\$38,961.00
Web Site Survey*	164.5	\$12,987.00	\$38,961.00
OPEN Survey**	49	\$3,550.00	\$10,60.00
Totals	48,729	\$2,530,145.00	\$7,590,435.00

*Estimate based upon percentage of time charged to the project quality assurance cost.

** Based on a percentage of time charged to OPEN production management cost.

*** Study is not yet or recently activated; estimates based upon ACOSOG study processing

The CTSU is an ongoing project. The current contract was awarded in September 2006 for three years, with four optional one year extensions. The current extension runs through August 31, 2010. All forms and surveys are expected to last the duration of the contract. The total annual cost to the Federal Government is estimated at \$2,530,145.00 and over a three-year time-frame, it is estimated to be \$7,590,435.00. 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. Arguably, without standardized forms the total cost would be higher due to follow up on incomplete and inconsistent information.

A.15 Explanation for Program Changes or Adjustments

This is a “Change due to Violation” and is being submitted as an “Existing Collection in Use Without an OMB number.” This information collection has not sought OMB clearance previously, but because of the nature of information, OMB has approved ongoing collection of information, while this submission is being processed.

As discussed with OMB on 10/7/2010, Form/Attachment 1gg represents a generic data transmittal form that will be implemented for future studies. 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 request.

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 distributed to CTEP for review.

Timeline Project Tasks	Task Completion	Timeframe
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

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.