

## **Supporting Statement B for**

### CTEP Support Contracts Forms and Surveys

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## Table of Contents

B.	COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS.....	1
B.1	RESPONDENT UNIVERSE AND SAMPLING METHODS.....	1
B.2	PROCEDURES FOR THE COLLECTION OF INFORMATION.....	4
B.3	METHODS TO MAXIMIZE RESPONSE RATES AND DEAL WITH NONRESPONSE.....	7
B.4	TEST OF PROCEDURES OR METHODS TO BE UNDERTAKEN.....	7
B.5	INDIVIDUALS CONSULTED ON STATISTICAL ASPECTS AND INDIVIDUALS COLLECTING AND/OR ANALYZING DATA.....	8

## **LIST OF ATTACHMENTS**

- Attachment A – List of CTSU Forms
  - o Regulatory Forms
    - A01 – CTSU IRB/Regulatory Approval Transmittal Form
    - A02 – CTSU IRB Certification Form
    - A03 – Optional Form 1 – Withdrawal from Protocol Participation Form
    - A04 – Site Addition Form
  - o Membership Forms
    - A05 – CTSU Roster Update Form
    - A06 – CTSU Request for Clinical Brochure
    - A07 – CTSU Supply Request Form
  - o Data Management
    - A08 – Site Initiated Data Update Form
    - A09 – Data Clarification Form
    - A10 – RTOG 0834 CTSU Data Transmittal Form
    - A11 – MC0845 (8233) CTSU Data Transmittal Form
    - A12 – CTSU Generic Data Transmittal Form
    - A13 – TAILORx\_PACCT1\_Data Transmittal Form
    - A14 – TAILORx Unsolicited Data Modification Form
  - o Patient Enrollment
    - A15 – CTSU Patient Enrollment Transmittal Form
    - A16 – CTSU Patient Transfer Form
  - o Administrative
    - A17 – CTSU System Access Request Form
  
- Attachment B – List of CIRB Forms / Documents
  - o NCI CIRB Enrollment Forms
    - B01 – NCI CIRB Authorization Agreement and Division of Responsibilities  
between the NCI CIRB and Signatory Institution
    - B02 – NCI CIRB Signatory Enrollment Form
  
  - o NCI CIRB Board Member Documents
    - B03 – CIRB Board Member Biographical Sketch Form
    - B04 – CIRB Board Member Contact Information Form
    - B05 – CIRB Board Member W-9
    - B06 – CIRB Board Member Non-Disclosure Agreement (NDA)
    - B07 – CIRB Direct Deposit Form
    - B08 – CIRB Member COI Screening Worksheet
    - B09 – CIRB COI Screening for CIRB meetings
  
  - o NCI CIRB Board Reviewer Documents
    - B10 – CIRB Initial Review Application
    - B11 – CIRB Initial Review Application for Exempt Studies
    - B12 – CIRB Amendment Review Application
    - B13 – CIRB Ancillary Studies App for Adult / Pediatric

- B14 – CIRB Continuing Review App for Adult / Pediatric
- B15 – Adult Initial Review of Cooperative Group Protocol
- B16 – Pediatric Initial Review of Cooperative Group Protocol
- B17 – Adult Continuing Review of Cooperative group Protocol
- B18 – Pediatric Continuing Review of Cooperative Group Protocol
- B19 – Adult Amendment Review of Cooperative Group Protocol
- B20 – Pediatric Amendment Review of Cooperative Group Protocol
- B21 – Adult & Ped Pharmacist's Review of a Cooperative Group Study
- B22 – CPC Pharmacist's Review of a Cooperative Group Study
- B23 – Adult Expedited Amendment Review
- B24 – Pediatric Expedited Amendment Review
- B25 – Adult Expedited Continuing Review
- B26 – Pediatric Expedited Continuing Review
- B27 – Adult Cooperative Group Response to CIRB Review
- B28 – Pediatric Cooperative Group Response to CIRB Review
- B29 – Adult Expedited Study Chair Response to Required Mod
- B30 – Pediatric Expedited Study Chair Response to Required Mod
- B31 – Reviewer Worksheet - Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN)
- B32 – Reviewer Worksheet CIRB Statistical Reviewer Form
- B33 – CIRB Application for Translated Documents
- B34 – Reviewer Worksheet of Translated Documents
- B35 – Reviewer Worksheet of Recruitment Material
- B36 – Reviewer Worksheet Expedited Study Closure Review
- B37 – Reviewer Worksheet Expedited Review of Study Chair Response to CIRB-Required Modifications
- B38 – Reviewer Worksheet of Expedited Initial Review
- B39 – Reviewer Worksheet – CPC - Determination of Unanticipated Problem (UP) and/or Serious Continuing Noncompliance (SCN)

- o NCI CIRB Local Context Forms

- B40 – Annual Signatory Institution Worksheet about Local Context
- B41 – Annual Principal Investigator Worksheet about Local Context
- B42 – Study-Specific Worksheet about Local Context
- B43 – Study Closure or Transfer of Study Review Responsibility
- B44 – Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form
- B45 – Change of Signatory Institution Principal Investigator Form

- Attachment C – List of Surveys

- o CTSU Surveys

- C01 – CTSU Website Customer Satisfaction Survey
- C02 – CTSU Help Desk Customer Satisfaction Survey
- C03 – CTSU Oncology Patient Enrollment Network (OPEN) Survey

- o CIRB Surveys
  - C04 – CIRB Customer Satisfaction Survey
  - C05 – CIRB Follow-up Survey (Communication Audit)
  - C06 A – CIRB Website Focus Group – CIRB Members
  - C06 B – CIRB Website Focus Group – Local Institutions
  - C06 C – CIRB Website Focus Group – Network Group
  - C06 D – CIRB Website Focus Group – Website Usability testing
  - C07 – CIRB Board Members Annual Assessment Survey
  
- o CTEP Surveys
  - C08 – Protocol and Information Office (PIO) External Customer Satisfaction Survey
  - C09 – Concept Clinical Trial Survey
  - C10 – Prospective Clinical Trial Survey
  - C11 – Low Accruing Clinical Trial Survey
  - C12 – ETCTN PI Survey
  - C13 – ETCTN RS Survey
  
- Attachment D – List of Additional Attachments
  - o CTSU
    - D01 – Privacy Impact Assessment (PIA)
    - D02 – Westat IRB Letter
    - D03 – Privacy Act Memo
  
  - o CIRB
    - D04 – CIRB- FIPS Assessment
    - D05 – CIRB - OHSR Determination
    - D06 – CIRB - Emmes IRB Letter
    - D07 – CIRB - Privacy Act Memo

## **B. Collection of Information Employing Statistical Methods**

The NCI collects several customer satisfaction and protocol interest surveys to assess the services of the Cancer Therapy Support Unit (CTSU), Central Institutional Review Board (CIRB), Protocol and Information Office (PIO), and physician interest in study participation including feedback on the Experimental Therapeutics Clinical Trials Network (ETCTN). These surveys provide valuable information on the use of services and feedback from the users on improvements. In all cases, simple descriptive statistics are used for analysis of data.

The CTSU surveys include:

- Help Desk Customer Satisfaction Survey (currently on hold)
- Website Satisfaction Survey (currently on hold)
- OPEN Survey.

The CIRB conducts several surveys:

- C04 – CIRB Customer Satisfaction Survey
- C05 – CIRB Follow-up Survey (Communication Audit)
- C06 – CIRB Website Focus Group (A, B, C, D)
- C07 – CIRB Board Members Annual Assessment Survey

CTEP conducts several surveys to assess programs and investigator interest in protocols:

- PIO Satisfaction Survey
- Concept Survey
- Prospective CT Survey
- ETCTN Site Satisfaction
- ETCTN PI Survey.

### **B.1 Respondent Universe and Sampling Methods**

The surveys target users of CTSU, CIRB, CTEP services and ETCTN clinical site staff.

For the CTSU, the most recent help desk survey (**attachment C01**), 1,800 (49%) e-mail addresses were randomly selected from the population of 3,679 CTSU users who had contacted the CTSU help desk over a 12-month period. Of the 1,800 users, there were approximately 325 respondents. This represents an 18% response rate for the survey, or a sample of approximately 10% of the currently active user community. No other filtering or selection criteria were applied to selection of the names or e-mail addresses. As noted, this survey is currently on-hold but may be reinstated at a later date.

For the annual website survey (**attachment C02**), 1,000 names (15%) were randomly selected from the population of approximately 7,241 registered CTSU users who had visited the CTSU ‘members’ website (<http://members.ctsu.org>) over a 12-month period. Then users who had invalid e-mail addresses or no current experience with the website were filtered out, leaving 275 respondents. Since this is an annual survey, it is estimated that there will be 275 respondents surveyed over a one-year time frame. This represents a 28% response rate for the survey or a sample of approximately 5% of the currently active user community. No other filtering or selection criteria were applied to selection of the

names or e-mail addresses. This survey is also on-hold but may be reinstated at a later date.

For the Oncology Patient Enrollment Network (OPEN) survey (**attachment C03**), all users of the OPEN application are eligible to complete a survey. There is no consideration of other characteristics beyond use of the services/applications.

All CTSU surveys are voluntary and conducted via commercially available electronic survey software such as SurveyMonkey™.

The CIRB Customer Satisfaction Survey (attachment C04) was developed to collect customer feedback pertaining to the use of the CIRB help desk (Attachment C04). Any customer (local institution, member of a NCTN Group, 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. The CIRB receives approximately 540 helpdesk inquiries per month. This average is based on the total per month for one year (total received inquiries in one year: 6460) and dividing the total by the number of associated months ( $6460/12 = 540$ ). No sampling is performed. One hundred percent of the people inquiring to the CIRB Operations helpdesk have the potential to be surveyed as long as a valid email address is provided. There is no consideration of other characteristics beyond inquiry and use of the services. Since this is a voluntary survey, the CIRB receives approximately 55-65 completed surveys a month.

The CIRB has approximately 65 Board Members combined that comprise the NCI CIRB four Boards: Adult Early Phase Emphasis (EPE), Adult Late Phase Emphasis (LPE), Pediatric CIRB, the Cancer Prevention and Control (CPC) board. A new CIRB Board Members Annual Assessment survey (Attachment C07) has been developed to inquire annually to Board Members regarding their experience as a CIRB member and to open channels for receiving valuable feedback. The survey will be generated via SurveyMonkey™ and sent to all Board Members requesting a response.

As a result of the NCI CIRB growth, an independent communications audit has been underway. As a result of this audit, focus groups (Attachment C06a - d) and a follow-up survey (Attachment C05) have been and/or are being conducted. Although the follow-up survey was sent to all participating members of the CIRB, the response rate was approximately 17%. The focus groups were comprised of key stakeholders from four groups: CIRB members, Local Institutions, Network Groups, and a focus group to test usability of website. The focus groups used a sampling of people from each group to obtain valuable feedback from the selected groups. Each focus group was comprised of 10 people and lasted approximated 60 minutes.

An email with the link to the PIO Survey (**attachment C07**) will be sent out by CTEP PIO once per year to approximately 200 staff responsible for the development of clinical trials. It is anticipated that up to 100 personnel will respond.

For the CTEP clinical trial surveys (**attachments C08-10**), participants will be the Principle Investigators (PIs) and site administrators listed on the CTSU roster at sites that are either approved or pending for the trial of interest. Participants also will include those PIs and site administrators from sites that actively accrued patients to previous but similar trials (and who are not listed as approved or pending). Each participant will be sent an invitational email describing the request as well as a survey link to an online survey.

Based on a previous pilot study conducted by NCI (OMB No. 0925-0046-21) an average of 146 participants completed a survey. Given the new structure of the National Clinical Trial Network (NCTN) (fewer but more innovative clinical trials), NCI is expecting to conduct no more than 10 clinical trial surveys a year. Assuming 150 participants a trial with ten surveys a year, the assumption is 1,500 participants completing the surveys per year.

The ETCTN customer service surveys (**attachments C11-12**) will be completed on line. Respondents will be invited by email, and an on-line link will be available to link to the surveys. The ETCTN PI Survey collects information 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. This survey serves to gather 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. The ETCTN Research Staff (RS) Survey collects information for the organizations' clinical research staff (i.e., grant and site administrators, clinical research associates and registrars) who are asked about their satisfaction with ETCTN processes and resources involved to submit and administer protocols.

For the two ETCTN surveys, it is expected that 250 participants will be surveyed each year (total N=500). All ETCTN Grant Principal Investigators (N=30) and Grant Administrators will be surveyed (N=45). For all other roles where there are 75-150 persons per category (i.e., PIs and other research staff, including site administrators, clinical research associates and registrars) the level of involvement in the program will vary, we will use a purposive sample to survey only those who have participated in the ETCTN program processes of opening and/or accruing patients to an ETCTN trial over the previous grant year. Potential respondents will be identified based upon ETCTN site registration, enrollment and roster data in the CTSU Regulatory Support System (RSS). We expect the sample to be principal investigators who have been involved in opening a trial during the previous grant year (N=45) and other research staff (site administrators, clinical research associates, and registrars) who participated in the process over the past grant year (N=130).



## **B.2 Procedures for the Collection of Information**

### **a. Survey Procedures.**

CTSU Surveys: Survey questions fall into three general categories, frequency of use, general satisfaction, and specific questions on services or applications. The surveys are made up of 15 to 20 multiple choice questions with a free text field for additional comments at the end of the survey. The help desk and website surveys have 5 to 8 core questions used quantitatively demonstrate trends in user satisfaction over time (**attachments C01 and 02**). Other questions are used to measure user satisfaction with new features or services, and to determine the frequency of application/service use by the respondent. Questions are kept to a minimum to decrease the time necessary to complete the survey and encourage response.

The OPEN survey is an ongoing survey available to persons completing an enrollment in the OPEN application (**attachment C03**). A set of core questions were developed, but these may vary over time as new features are added to the system.

The CTSU survey populations for the help desk and website surveys are randomly selected from a pool of recent users of the help desk or website over the previous 12 months. To avoid bias there is no attempt to stratify users. Several methods are used to obtain objective results:

- To avoid sampling bias, surveys questionnaires are sent broadly to the customer base or randomly selected samples of the customers.
- Identification of individual respondents is withheld from the staff involved in the service being surveyed.
- To avoid over interpretation of single survey results, trends are measured over time.
- Whenever possible, a core set of satisfaction measures are used over time.
- Customers are provided opportunity for open-ended responses.

Survey notifications are sent by e-mail that includes instructions and a link. The survey is deployed using SurveyMonkey™, an online survey system. Reminder e-mails are sent to participants that have not yet responded encouraging participation approximately a week after the initial e-mail. The survey is closed approximately 10 business days after distribution.

**CIRB Surveys:** For the CIRB customer satisfaction survey, all CIRB participants that inquire to the Helpdesk (via email or phone) will receive an email request to complete the survey if a valid email address is provided. The surveys are anonymous and are completed online via SurveyMonkey.com. The customer completing the survey is not requested to provide any identifiable information.

For the CIRB Board Member Annual Assessment survey, all Board Members will receive an email request to complete the annual assessment survey. The surveys are anonymous and are completed online via SurveyMonkey.com. The board member completing the survey is not requested to provide any identifiable information.

For the CIRB Audit, the focus groups were comprised of key stakeholders from four groups: CIRB members, Local Institutions, Network Groups, and a focus group to test usability of website. The focus groups used a sampling of people from each group to obtain valuable feedback from the selected groups. The focus groups are conducted via conference call and led by a professional consultant. Each focus group was comprised of 10 people and lasted approximated 60 minutes.

The CIRB Audit follow-up survey is sent to all participating members of the CIRB. The surveys are anonymous and are completed online via SurveyMonkey.com. The CIRB enrolled participant completing the survey is not requested to provide any identifiable information.

CTEP Surveys: The decision to use clinical trial surveys was based on regular reviews of the CTEP NCTN trial portfolio. If a trial in its development process is considered to be challenging, or if an active trial is deemed slow accruing, CTEP will work with the study team to identify if a feedback survey can help with their decision making. Templates are tailored based on information in the trial's protocol. Once the survey is tailored, it is reviewed by CTEP and the study team. An invitation email list is developed based on 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 list includes the site PI and the site administrator. When ready, an invitational email is sent via CTSU to these individuals. The email invitation has a description of the request and a link to the online survey. A reminder email is sent out after approximately one week, and the survey closed after approximately 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.

ETCTN staff will receive an initial email invitation to participate in one of the two online ETCTN satisfaction surveys (**Attachments C11 and 12**). This invitation will describe the purpose of the survey, approximate burden time, and privacy details. A link to the survey will be included in the email, where the individual will be directed to the survey landing page. The landing page will reiterate the description of the survey, approximate burden time, and privacy details. Instructions are also provided for respondents to continue to the survey. The survey will be available for approximately 2 weeks. If the individual does not complete the survey within the first week, a follow-up reminder email will be distributed the following week.

Survey Analysis: All information collected is related to user experience with CTSU, CIRB or CTEP services and applications. For the CIRB and CTSU surveys, no identifying information is collected in the survey and no questions of a sensitive nature are asked in the survey. E-mail information is not used within the analysis. For the CIRB focus groups and CTEP participation surveys, no personally identifiable information (PII) is asked, though respondents may be asked to characterize their role at their institution, or provide information on the type of institution (i.e., academic medical center, community hospital, etc.).

The CTSU, CIRB, and CTEP surveys generally use a standard Likert scale that classifies responses as “satisfied”, “neutral” or “dissatisfied”. Following survey deployment, the project team reviews the survey data to identify recommendations for continuous improvement activities. This process includes identifying:

- A summary of strengths identified by the customer;
- A summary of weaknesses and customer concerns;
- Recommendations for leveraging strengths identified by the survey data; and
- Opportunities for improvement and priority recommendations.

Results may be compared across surveys to show general customer satisfaction trends. In addition, free text comments are reviewed and categorized.

With the CIRB survey, a monthly summary of survey results is included within a monthly status report and shared with NCI program group. For the CTSU and CTEP surveys, the project team drafts a survey findings report. Survey results are reported to CTEP and describe the following areas: survey objectives, methodology, results, important findings, conclusions and recommendations.

**b. Rationale for Sample Size.**

For the CTSU help desk and website surveys, a sample of approximately 1,400 participants was selected to avoid bias and achieve a significant number of respondents. Response rates are generally less than 25%.

For the CIRB Customer Satisfaction survey, all people inquiring via helpdesk have the potential to be surveyed. For the Board Member Annual Assessment Survey, all current board members will be polled annually. For the focus groups, the 10 per group was requested and recommended by the professional consultant.

For the CTEP surveys, sample size is based upon participation or interest in a protocol or disease area and varies across surveys. For the two ETCTN surveys, it is expected that 250 participants will be surveyed each year for two years (total N=500).

**c. Quality Control.**

For CTSU, the contractor will reinstate a standard operating procedure developed for the CTSU surveys at such time as the help desk and website surveys are reinstated

For CIRB, the contractor follows an internal process developed for the NCI CIRB Helpdesk Surveys and Board Member Annual Assessment Survey. This process includes monitoring survey responses, response rates, and completeness of acquired data. These processes are reviewed annually, and staff is trained on procedures in their work areas.

For the CTEP surveys, CTEP staff follows internal procedures for monitoring and analyzing survey response.

### **B.3 Methods to Maximize Response Rates and Deal with Nonresponse**

For the majority of the surveys the expected response rates are approximately 15 to 25%. The number of questions is kept to a minimum to limit the time needed to complete the survey and encourage response. In addition, responses are multiple choice using a Likert scale of 1 to 5 which minimizes the time needed to complete the survey. Followup e-mails are sent to participants that have not responded, and a gift card giveaway is used for the CTSU surveys to encourage participation. No follow up is completed for non-respondents.

For CIRB, the purpose of the satisfaction survey and board member annual assessment is not statistical; rather an unobtrusive way to inquire regarding satisfaction with CIRB Operations and Board Members, and identify ways for improving service. Expected response rates are approximately 15 to 25%. The number of questions asked is kept to a minimum to limit the time needed to complete the survey and encourage response. In addition, most of the responses to questions are in multiple choice format; therefore, minimizing time needed to respond. No follow-up is completed for non-respondents. For the CIRB audit survey, this was a onetime survey and to ensure validity of results, was developed in collaboration with a professional communication expert, the survey was followed up with an email reminder encouraging participation. The focus groups were a onetime occurrence. A professional usability expert consultant conducted the focus groups and provided summary.

For the ETCTN surveys, the response rate estimate is 95% response rate, based on a similar survey that was administered to NCI grantees about the Central Institutional Review Board program (OMB No. 0925-0046-16, Expiration Date 2/28/2013). Thus, we expect 238 participants to provide data. Email reminders will be used to increase response rates. During the 2-week survey period, the initial invitation email will be sent the first week. If a participant does not complete the survey within the first week, a follow-up reminder email will be sent. This email reminder will provide a description of the survey, approximate burden time, privacy details, and a link to the survey.

### **B.4 Test of Procedures or Methods to be Undertaken**

For the CTSU no test surveys are completed, but proposed survey questions are reviewed internally prior to distribution.

CIRB satisfaction survey and CIRB board member annual assessment are distributed to staff for review prior to distribution to the target population. Previous contact with population indicates that they are willing to answer questions regarding customer satisfaction. The Short Questionnaire consists of a limited number of questions. No pre-test or sampling is completed for the surveys. For the CIRB Audit Survey and focus groups, a professional communication expert was consulted and statistician consulted on evaluation of audit survey results.

The previously approved surveys were distributed to a small number of staff for review prior to distribution to the target population. The PIO survey (**attachment C7**) was first piloted in 2011 (OMB No. 0925-0046, Expiration Date 2/28/2013) and a decision was

made to collect this information on an annual basis. Pilot tests of the clinical trial concepts, prospective and low accrual surveys were done in 2012-2013 (under OMB No. 0925-0046-21). All surveys listed above were re-approved as part of the last CTSU submission with an expiration date of 1/31/2017. These surveys are valuable and helpful in assisting 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.

**B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

For the CTSU surveys, no consultations with persons outside of the CTEP contracting team or the contractor have been made for the purposes of the surveys. The survey team is led by the CTSU Project Director, Karen Martier, and the CTSU Quality Assurance Associate, Susan Raitt. The implementation team consists of the CTSU Help Desk Supervisor, the CTSU Awareness, Education and Training Manager, the CTSU website lead, and other CTSU staff members as assigned.

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For the CIRB Audit survey, a communications expert was consulted and in house statistician for analyzing results. Regarding the CIRB Satisfaction Survey and Board Member survey, no consultations with persons outside of the NCI CIRB contracting team or the contractor have been made for the purposes of the surveys. The survey team is led by the CIRB PI, Claudine Valmonte; CIRB Project Manager, Jennifer Dugan; and CIRB Quality Assurance Manager, Laura Covington. The implementation team consists of the CIRB Outreach Coordinator, CIRB Outreach Specialist, the CIRB Helpdesk Coordinator, and other CIRB staff members as assigned.

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