

## **Supporting Statement B for**

**CTEP Branch** and Support Contracts Forms and Surveys

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## 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
    - A12 – CTSU Generic Data Transmittal Form
  - o Patient Enrollment
    - A15 – CTSU Patient Enrollment Transmittal Form
    - A16 – CTSU Patient Transfer Form
  - o Administrative
    - A17 – CTSU System Access Request Form
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  - o Delegation of Task Log
    - A19 – LPO Form Creation (NEW)
    - A20 – Site Form Creation and PDF (NEW)
    - A21 – PDF Signature Form (NEW)
- 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 Application (NEW)
    - 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/**Pediatric** Continuing Review of Cooperative group Protocol  
B19 – Adult Amendment Review of Cooperative Group Protocol  
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**B21 – NCI CIRB Reviewer Worksheet Pharmaxis Review of a Study**  
B23 – Adult Expedited Amendment Review  
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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  
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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  
**B46– Request Waiver of Assent Worksheet**

• Attachment C – List of Surveys

o CTSU Surveys

C03 – CTSU Oncology Patient Enrollment Network (OPEN) Survey

o CIRB Surveys

C04 – CIRB Customer Satisfaction Survey  
C05 – CIRB Follow-up Survey (Communication Audit)  
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
- Attachment D – Audit Information System Forms (NEW)
  - D01 – Audit Scheduling Form
  - D02 – Preliminary Audit Finding Form
  - D03 – Auditor Maintenance Form
  - D04 – Final Audit Finding Report Form
  - D05 – Follow-up Form
  - D06 – Roster Maintenance Form
  - D07 – Final Report and CAPA Request Form
- Attachment E – Pharmaceutical Management Branch Forms (NEW)
  - E01 – NCI/DCTD/CTEP FDA Form 1572 for Annual Submission
  - E02 – NCI/DCTD/CTEP Biosketch
  - E03 – NCI/DCTD/CTEP Financial Disclosure Form
  - E04 – NCI/DCTD/CTEP Agent Shipment Form (ASF)
- Attachment F – List of Additional Attachments
  - o CTSU
    - F01 – CTSU - Privacy Impact Assessment (PIA)
    - F02 – CTSU - Westat IRB Letter
    - F03 – CTSU - Privacy Act Memo
  - o CIRB
    - F04 – CIRB- FIPS Assessment
    - F05 – CIRB - OHSR Determination
    - F06 – CIRB - Emmes IRB Letter
    - F07 – CIRB - Privacy Act Memo
  - o CTEP-ESYS (CTIS)
    - F08 – CTEP-ESYS- Privacy Impact Assessment (PIA)
    - F09 – CTEP-ESYS- FIPS Assessment

## **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. 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:

- C03 – CTSU Oncology Patient Enrollment Network (OPEN) Survey.

The CIRB conducts several surveys:

- C04 – CIRB Customer Satisfaction Survey
- C05 – CIRB Follow-up Survey (Communication Audit)
- C07 – CIRB Board Members Annual Assessment Survey

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

- C08 – Protocol and Information Office (PIO) External Customer Satisfaction Survey
- C09 – Concept Clinical Trial Survey
- C10 – Prospective Clinical Trial Survey

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

The surveys target users of CTSU, CIRB, and CTEP services.

For the CTSU, 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.

The CIRB Customer Satisfaction Survey (Attachment C04) was developed to collect customer feedback pertaining to the use of the CIRB Hhelpdesk (Attachment C04). Any customer (local institution, member of a NCTN Group, ETCTN, public inquiry, etc.) submitting a request to the Helpdesk (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 500 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.

An email with the link to the PIO Survey (Attachment C08) 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 C09-11), 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.

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

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

**CTSU Surveys:** The CTSU Oncology Patient Enrollment Network (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.

**CIRB Surveys:** For the CIRB Customer Satisfaction Survey (Attachment C04), 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 Members Annual Assessment Survey (Attachment C07), 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.

**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 spreadsheet print out, placed into a standard report, and shared with CTEP and the study team to review.

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 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. Other 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 CIRB Customer Satisfaction Survey (Attachment C04), all people inquiring via Helpdesk have the potential to be surveyed. For the Board Members Annual Assessment Survey (Attachment C07), 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.

**c. Quality Control.**

For CIRB, the contractor follows an internal process developed for the NCI CIRB Helpdesk Survey 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. 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.

**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.

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 C07) 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 Awareness, Education and Training Manager, the CTSU website lead, and other CTSU staff members as assigned.

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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 and 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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