

Supporting Statement B for

CTEP Branch and Support Contracts Forms and Surveys (NCI)

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This is an extension to the original submission and all changes are highlighted in yellow

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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 Supply Request Forms
 - A06 – CTSU Request for Clinical Brochure
 - A07 – CTSU Supply Request Form
 - o Data Management
 - A10 – RTOG 0834 CTSU 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
 - A18 – CTSU OPEN Rave Request Form
 - o Delegation of Task Log
 - A19 – LPO Form Creation
 - A20 – Site Form Creation and PDF
 - A21 – PDF Signature Form
- Attachment B – List of NCI 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 Application for Adult / Pediatric
 - B14 – CIRB Continuing Review Application 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 of Cooperative Group Protocol
B20 – Pediatric Amendment of Cooperative Group Protocol
B21 – NCI CIRB Reviewer Worksheet Pharmacist Review of 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 Modifications
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
B38 – Reviewer Worksheet of Expedited Initial Review

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 PI

B46 – Request Waiver of Assent Worksheet

B47 – CIRB Waiver of consent Request Supplemental Form

B48 – Reviewer Worksheet CIRB Review for Inclusion of Incarcerated Participants

B49 – Notification of Incarcerated Participant Form

• Attachment C – List of Surveys

o CTSU Survey

C03 – CTSU Oncology Patient Enrollment Network (OPEN) Feedback Form

- o CIRB Surveys
 - C04 – CIRB Customer Satisfaction Survey
 - C05 – CIRB Follow-up Survey (Communication Audit)
 - C07 – CIRB Board Members Annual Assessment Survey
- o CTEP Survey
 - C08 – Protocol and Information Office (PIO) External Customer Satisfaction 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 – Privacy Act Memo
 - o CIRB
 - F04 – CIRB- FIPS Assessment
 - F05 – CIRB - OHSR Determination
 - F06 – CIRB - Emmes IRB Letter
 - 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 customer satisfaction surveys to assess the services or applications of the Cancer Therapy Support Unit (CTSU), Central Institutional Review Board (CIRB), Protocol and Information Office (PIO). 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) Feedback Form.

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

B.1 Respondent Universe and Sampling Methods

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

For the CTSU, the Oncology Patient Enrollment Network (OPEN) Feedback Form (Attachment C03), all users of the OPEN application are eligible to complete a feedback form. 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 Helpdesk (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 **Survey Monkey™** 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.

B.2 Procedures for the Collection of Information

a. Survey Procedures.

CTSU Survey: The CTSU Oncology Patient Enrollment Network (OPEN) Feedback Form is an ongoing and 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 Survey: 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. Feedback is tabulated from the survey for internal use and process improvement.

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.

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 **the following areas are described**: survey objectives, methodology, results, important findings, conclusions and recommendations.

b. Rationale for Sample Size.

The CTSU OPEN Feedback form is available to all users of the application.

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 survey, the sample size is based upon the current list of PIO contacts at the organizations responsible for developing protocols.

c. Quality Control.

For the OPEN Feedback form, CTSU staff monitor responses and communicate comments during routine project communication.

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

No testing is done for the CTSU OPEN Feedback form as it is ongoing.

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

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

For the CTSU OPEN Feedback form, no consultations with persons outside of the CTEP contracting team or the contractor have been made for the purposes of the form. The OPEN team monitor the feedback responses.

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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For the PIO survey form, no consultations with persons outside of the CTEP contracting team or the contractor have been made for the purposes of the form. The PIO management team monitor the feedback responses.