**Supporting Statement B for**

CTEP Branch and Support Contracts Forms and Surveys (NCI)

**OMB No., 0925-0753 Expiration Date: 03/31/2026**

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
	+ 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

A23 – LPO Approval of Early Study Closure

* + Supply Request Forms

A06 – CTSU Request for Clinical Brochure

A07 – CTSU Supply Request Form

* + Data Management

A10 – RTOG 0834 CTSU Data Transmittal Form

* + Patient Enrollment

A15 – CTSU Patient Enrollment Transmittal Form

A16 – CTSU Patient Transfer Form

* + Administrative

A18 – CTSU OPEN Rave Request Form

A22 – Compliance, Learning, and SOP Solutions (CLASS) Course Setup Request Form

* + Delegation of Task Log

A19 – LPO Form Creation (

A20 – Site Form Creation and PDF

A21 – PDF Signature Form

A24 – DTL International Signature Form

* Attachment B – List of NCI CIRB Forms / Documents
	+ 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

* + NCI CIRB Board Member Documents

B03 – CIRB Board Member Application (NEW)

B08 – CIRB Member COI Screening Worksheet

B09 – CIRB COI Screening for CIRB meetings

* + 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

* + 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

B50 – Final Video Submission Posting Form

B52 – Unanticipated Problem or Serious or Continuing Noncompliance Application

* Attachment C – List of Surveys
	+ CIRB Surveys

C04 – CIRB Customer Satisfaction Survey

C05 – CIRB Follow-up Survey (Communication Audit)

C07 – CIRB Board Members Annual Assessment Survey

* + CTEP Survey

C08 – Protocol and Information Office (PIO) External Customer Satisfaction Survey

* Attachment D – Audit Information System Forms

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)

E05 – Non-IND/Non-Treatment Investigator Registration Form

E06 – International Investigator Statement (IIS) Form

* Attachment F – CTEP form for central database submissions

F01 – NCI dbGaP Initial Study Registration Information

* Attachment G – List of Additional Attachments
	+ CTSU

G01 – CTSU - Privacy Impact Assessment (PIA)

G02 – CTSU - Westat IRB Letter

G03 – Privacy Act Memo

* + CIRB

G04 – CIRB- FIPS Assessment

G05 – CIRB - OHSR Determination

G06 – CIRB - Emmes IRB Letter

* + CTEP-ESYS (CTIS)

G09 – CTEP-ESYS- Privacy Impact Assessment (PIA)

G10 – 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 Central Institutional Review Board (CIRB). These surveys provide valuable information on the use of services or applications and feedback from the users on improvements. In all cases, simple descriptive statistics are used for analysis of data.

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 CIRB, services or 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 a 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 if 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, and the Cancer Prevention and Control (CPC) board. A new CIRB Board Members Annual Assessment Survey (Attachment C07) has been developed to inquire annually of the 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.

## B.2 Procedures for the Collection of Information

1. **Survey Procedures**.

**CIRB Surveys**: For the CIRB Customer Satisfaction Survey (Attachment C04), all CIRB participants that contact to the Helpdesk via email or phone with inquiries 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.

Survey Analysis: All information collected is related to user experience with the CIRB services and applications. For the CIRB 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 CIRB 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.

1. **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.

1. **Quality Control.**

For the 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.

## 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 a 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 the 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 a 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

The 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 the targeted 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.

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

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 purpose of the surveys. The survey team is led by the CIRB Co-PIs, Claudine Valmonte 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 purpose of the form. The PIO management team monitors the feedback responses.