Supporting Statement B:

NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI) OMB No. 0925-0625, Expiry Date: 1/31/2014

November 2013

Revisions from the 2011 approved submission are highlighted in yellow.

Submitted by:

CAPT Michael Montello, Pharm. D., MBA National Institutes of Health National Cancer Institute Cancer Therapy Evaluation Program (CTEP) Operations and Informatics Branch (OIB)

> BG 9609 RM 5W344 9609 Medical Center Drive Rockville, MD 20850 (240) 276-6080 E-mail: mike.montello@nih.gov

Table of Contents

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

LIST OF ATTACHMENTS

Attachment 1: CIRB Customer Satisfaction Survey Attachment 1A: Email Invitation to Participate in Survey Attachment 1B: Survey Attachment 2: NCI CIRB Institution Enrollment Worksheet Attachment 2A: Request for 30 Day NCI CIRB Website Access Form Authorization Agreement / Division of Responsibilities between Attachment 2B: the NCI CIRB and the Signatory Institution Attachment 2C: NCI CIRB Signatory Enrollment Form IRB Staff at Signatory Institution's IRB Attachment 2D: Attachment 2E: Investigator at Signatory Institution Attachment 2F: **Research Staff at Signatory Institution** Investigator at Affiliate Institution with an IRB Attachment 2G: Research Staff at Affiliate Institution with an IRB Attachment 2H: Attachment 2I: Investigator at Affiliate Institution without an IRB Research Staff at Affiliate Institution without an IRB Attachment 2J: Institutional Contact for Signatory Institution Attachment 2K: Attachment 2L: **IRB** at Signatory Institution Attachment 2M: Component Institution at Signatory Institution **IRB** at Affiliate Institution Attachment 2N: Attachment 20: Affiliate Institution without an IRB Attachment 2P: Facilitated Review Acceptance Form Study Review Responsibility Transfer Form Attachment 2Q: Attachment 2R: Annual Institution Worksheet About Local Context Attachment 2S: Annual Principal Investigator Worksheet About Local Context Attachment 2T: Study-Specific Worksheet About Local Context Attachment 2U: Study Closure or Transfer of Study Review Responsibility Form Attachment 2V: Potential Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form Add or Remove Signatory and/or Component Institution Attachment 2W: Personnel Attachment 2X: Add or Remove Affiliate Institution Personnel Attachment 2Y: Add or Remove Component Institution Add or Remove Affiliate institution Attachment 2Z: Attachment 2ZA: One Time Study Roll Over Worksheet Attachment 2ZB: Change of Signatory Institution PI Form Attachment 3: CIRB New Board Member Orientation

Attachment 3A: CIRB New Board Member Welcome Letter Attachment 3B: CIRB Board Member Biographical Sketch Form **CIRB Board Member Contact Information Form** Attachment 3C: Attachment 3D: **CIRB Board Member W-9** CIRB Board Member Non-Disclosure Agreement (NDA) Attachment 3E: Attachment 3F: **CIRB Board Member Orientation Steps**

Attachment 3G:	NCI's Privacy Policy		
Attachment 3H:	CIRB Adult Query of Candidate Interest		
Attachment 3I:	CIRB Pediatric Query of Candidate Interest		
Attachment 3J:	Confirming Candidate Qualifications and Conflict of		
	Interest (COI) Statement		
Attachment 3K:	CIRB Notification of Selection to Serve on NCI CIRB		
Attachment 3L:	CIRB Notice of Rotation Off		
Attachment 3M:	CIRB Thank you to Retiring Members and Acknowledgement		
	of Resignation		
Attachment 3N:	CIRB Internal Plaque Order Form		
Attachment 3O:	CIRB Operations New Member Checklist		
Attachment 3P:	CIRB Educational Checklist for Member File		
Attachment 3Q:	CIRB Operations Checklist for Retiring Board Members		
Attachment 4: CIRB	Direct Deposit Form		
Attachment 5: CIRB	Application Forms:		
Attachment 5A: Attachment 5B: Attachment 5C:	NCI Adult/Pediatric CIRB Application for Treatment Studies NCI Adult/Pediatric CIRB Application for Ancillary Studies NCI Adult/Pediatric CIRB Application for Continuing Review		

Attachment 5D:Summary of CIRB Application RevisionsAttachment 5E:Locally-Developed Material Submission FormAttachment 5F:Application Request to Review Translated Documents

Attachment 6: CIRB Reviewer Worksheets

Attachment 6A: Attachment 6B: Attachment 6C: Attachment 6D: Attachment 6E: Attachment 6F: Attachment 6G: Attachment 6H: Attachment 6I: Attachment 6J: Attachment 6J: Attachment 6K:	Adult Initial Review of Cooperative Group Protocol Pediatric Initial Review of Cooperative Group Protocol Adult Continuing Review of Cooperative Group Protocol Pediatric Continuing Review of Cooperative Group Protocol Adult Amendment of Cooperative Group Protocol Pediatric Amendment of Cooperative Group Protocol Adult Cooperative Group Response to CIRB Review Pediatric Cooperative Group Response to CIRB Review Adult Pharmacist's Review of a Cooperative Group Study Pediatric Pharmacist's Review of a Cooperative Group Study CIRB Statistical Reviewer Form
Attachment 6L:	Determination of Unanticipated Problem and/or Serious or
	Continuing Noncompliance
Attachment 6M:	Adult Expedited Amendment Review
Attachment 6N:	Ped Expedited Amendment Review
Attachment 60:	Adult Expedited Continuing Review
Attachment 6P:	Ped Expedited Continuing Review
Attachment 6Q:	Adult Expedited Closure
Attachment 6R:	Ped Expedited Closure
Attachment 6S:	Adult Expedited Study Chair Response to Required Mod

Attachment 6T:	Ped Expedited Study Chair Response to Required Mod
Attachment 6U:	Reviewer Worksheet of Translated Documents
Attachment 6V:	Reviewer Advertisement Checklist

- Attachment 7: Privacy Act Memo
- Attachment 8: Office of Human Subjects Research (OHSR) Determination
- Attachment 9: Privacy Impact Assessment (PIA)

B. STATISTICAL METHODS

The Central Institutional Review Board (CIRB) collects one survey. The purpose of this survey is not statistical but rather an in-obtrusive way to determine customer satisfaction with CIRB Operations and to identify ways for improving service. This survey provides valuable input on customer satisfaction of CIRB Operations. Simple descriptive statistics are used to interpret results of survey.

B.1 Respondent Universe and Sampling Methods

The CIRB satisfaction survey has not changed since the previous OMB submission. All customers: public inquiry, member of Cooperative Group, National Clinical Trials Network (NCTN), the Early Therapeutics Clinical Trials Network (ET-CTN) submitting a request to the Helpdesk (via email or phone) will receive an email request to complete the survey if a valid email address is provided (Attachment 1A).

We receive approximately 335 helpdesk inquiries per month. This average is based on the total per month for one year (total received inquiries in one year: 4020) and dividing the total by *#* of associated months (4020/12 = 335). No sampling is performed: 100% 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, we receive approximately 55-65 completed surveys a month. The surveys are anonymous. They are completed online through SurveyMonkey.com. We do not request any identifiable information on the customer completing the survey.

B.2 Procedures for the Collection of Information

The procedures for the collection of information with the CIRB Customer Satisfaction Survey (**Attachment 1B**) have not changed since the previous OMB Submission.

b. Rationale for Sample Size.

For the helpdesk surveys, an estimated 4020 people are polled on a yearly basis from the customer service base. These participants are selected because they contacted the CIRB Operations Helpdesk. Of the accumulative number of participants that contact the helpdesk annually, the response rates from the surveys generated is generally less 25%.

c. Quality Control.

The contractor follows an internal process developed for the NCI CIRB Helpdesk Surveys. This process includes monitoring the 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

The purpose of this survey is not statistical but rather an in-obtrusive way to determine customer satisfaction with CIRB Operations 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.

2

B.4 Test of Procedures or Methods to be Undertaken

Surveys 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.

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

No consultations with persons outside of the NCI CIRB contracting team or the

contractor have been made for the purposes of the survey. The survey team is lead by

the CIRB PI, Claudine Valmonte; CIRB Project Manager, Jennifer Dugan; and CIRB

Quality Assurance Manager. The implementation team consists of the CIRB Outreach

Coordinator, CIRB Outreach Specialist, the CIRB Helpdesk Coordinator, and other

CIRB staff members as assigned.

Claudine Valmonte	Jennifer Dugan
CIRB Principal Investigator	CIRB Project Manager
EMMES Corporation	EMMES Corporation
Telephone: 301-251-1161 x214	Telephone: 301-251-1161 x2827
Email: <u>cvalmonte@emmes.com</u>	Email: jdugan@emmes.com
Laura Covington	Allison Peel
CIRB Quality Assurance Manager	CIRB Outreach Coordinator
EMMES Corporation	EMMES Corporation
Telephone: 301-251-1161 x2742	Telephone: 301-251-1161 x17411
Email: Icovington@emmes.com	Email: apeel@emmes.com
Diana Orr CIRB Outreach Specialist EMMES Corporation Telephone: 301-251-1161 x129 Email: dorr@emmes.com	