

Supporting Statement A For:

**NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)**

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## **A. JUSTIFICATION**

### **A.1 Circumstances Making the Collection of Information Necessary**

The Public Health Service Act, Section 411 (42 USC § 285a) authorizes the National Cancer Institute (NCI) to collect information in order to develop a National Cancer Program which consists of “an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute,” as well as “...other programs and activities of the Institute.” This scope of work calls for the establishment of the Central Institutional Review Board Initiative (CIRB, [www.ncicirb.org](http://www.ncicirb.org)) which was created to reduce the administrative burden on local Institutional Review Boards (IRBs) and investigators while protecting human research participants. The CIRB is operated through the Cancer Therapy Evaluation Program (CTEP), within the Division of Cancer Treatment and Diagnosis at NCI. The CIRB is an NCI initiative utilizing the time and expertise of Board members that are representative of the oncology community outside of the NCI. The NCI provides funding as well as logistical and operational support to the CIRB. This support is handled by CTEP and its contractors. While the CIRB reviews CTEP sponsored studies, none of the CIRB Board members or reviewers are affiliated with CTEP, nor does CTEP’s support of the CIRB influence CIRB Member decision making.

Beginning in January 2001, the Adult CIRB has been meeting twice monthly to review Phase 3 Cooperative Group trials. The Pediatric CIRB began reviewing all NCI-approved COG Phase 2, 3 and Pilot protocols beginning in November 2004. Both Boards are composed of individuals who represent a broad range of oncology scientific and nonscientific disciplines. These may include oncology physicians, nurses, patient

representatives, pharmacists, ethicists, and attorneys. As none of the Board members are NCI employees, the Board collectively is made up of public members.

The NCI uses various information collection tools to support CIRB activities. These include forms requiring completion by a site conducting a clinical trial eligible for review by the CIRB, as well as forms requiring completion by the CIRB members themselves which will be described below. Additionally, the CIRB developed a survey that is provided to any customer which contacts the CIRB helpdesk. Approximately 125 helpdesk inquiries are received per month. The responses are anonymous and the response rate is approximately 23% (see Section A.2 Helpdesk Survey). Surveys are conducted through SurveyMonkey.com and no identifiable information on the customer is collected.

## **A.2 Purpose and Use of the Information**

There are 6 general areas in which forms are completed. These include CIRB: helpdesk, enrollment, membership, direct deposit, application, and reviewer forms. The detail below for each of the forms describes how, by whom and for what purpose the information is used.

### CIRB Helpdesk Survey (Attachment 1)

The survey was developed to collect customer feedback pertaining to the use of the CIRB Helpdesk. Any customer (local site, member of Cooperative Group, 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). We receive approximately 140 helpdesk inquiries per

month and since this is a voluntary survey, we receive approximately 30-35 completed surveys a month. The surveys are anonymous. They are completed online through SurveyMonkey.com. We do not collect any identifiable information on the customer completing the survey.

NCI CIRB Institution Enrollment Forms (Attachment 2)

The Enrollment documents were created to collect information on those institutions interested in enrolling or have already enrolled in the CIRB Initiative. The CIRB currently has 297 institutions enrolled in the CIRB. The package of information includes:

- Attachment 2A: CIRB Institution Enrollment Worksheet – form developed to collect information for any new sites that are interested in enrolling into the CIRB Initiative. The data from this form are automatically uploaded into the CIRB enrollment system with quality checks implemented pre and post upload
- Attachment 2B: CONTACT FORM: IRB Staff at Signatory Institutions IRB – form developed to update new IRB Staff at an IRB from signatory institution that reviews Cooperative Group studies approved by the CIRB and should receive study-related correspondence. This form also confirms the contact information of IRB Staff that should no longer receive study-related correspondence
- Attachment 2C: CONTACT FORM: Investigator at Signatory Institution – form developed to update contact information for Investigators at signatory institution so that they may receive study-related correspondence from the CIRB. This form also confirms the contact information of Investigators that should no longer receive study-related correspondence
- Attachment 2D: CONTACT FORM: Research Staff at Signatory Institution – form developed to update contact information for Research Staff from signatory institution who should receive study-related correspondence from the CIRB. This form also confirms the contact information of research staff that should no longer receive study-related correspondence

- Attachment 2E: CONTACT FORM: Investigator at Affiliate Institution – form developed to update contact information for Investigators at each affiliated institution so that each may receive study-related correspondence from the CIRB. This form also confirms the contact information of Investigators that should no longer receive study-related correspondence
- Attachment 2F: CONTACT FORM: Research Staff at Affiliate Institution – form developed to update Research personnel contact information at Affiliate Institution to assure receipt of study-related correspondence from the CIRB. This form also confirms the contact information of research staff that should no longer receive study-related correspondence
- Attachment 2G: CONTACT FORM: IRB at Signatory Institution – form developed to update IRB information at Signatory Institution that currently review Pediatric and/or Adult Cooperative Group cancer treatment studies. This form also confirms the contact information of IRB(s) that should no longer receive study-related correspondence
- Attachment 2H: CONTACT FORM: Component Institution at Signatory Institution – form developed to update information for each new component institution for which the signatory institution has legal authority to operate under a different name and participate in Cooperative Group trials approved by the CIRB. This form also confirms the contact information of components that should no longer receive study-related correspondence
- Attachment 2I: CONTACT FORM: IRB at Affiliate Institution – form developed to update information for each new IRB relying on an IRB from the signatory institution for review of Cooperative Group studies approved by the CIRB. This form also confirms the contact information of IRB(s) that should no longer receive study-related correspondence
- Attachment 2J: CONTACT FORM: Affiliate Institution without an IRB – form developed to update information for each new institution without an IRB that is relying on an IRB from signatory institution for review of Cooperative Group studies approved by the CIRB. This form also confirms the contact information of Institution(s) that should no longer receive study-related correspondence
- Attachment 2K: Request for 30 Day Access Form – form developed for IRBs to obtain 30-day access to the Participant’s Area of the CIRB website for those IRBs interested in joining the Initiative

Attachment 2L: Facilitated Review Acceptance Form – form developed for Signatory Institution IRB's to approve the acceptance of CIRB Facilitated Review for study indicated

Attachment 2M: Study Review Responsibility Transfer Form – form developed for Signatory Institution IRB's to transfer responsibility of study review from CIRB back to local IRB for study indicated

### CIRB Membership Information (Attachment 3)

These membership documents were created to collect information on the members of the CIRB. We currently have two Boards (Adult and Pediatric), with 18 members on the Adult Board and 15 members on the Pediatric Board. Each Board Member serves a two year term. Perspective Board Members are invited to serve on the CIRB and information is shared with them regarding meeting dates, responsibilities, etc. If the candidate expresses interest and is approved by CTEP, a formal invitation for membership and packet of information is sent to the candidate. The package of information includes:

Attachment 3A: CIRB New Board Member Welcome Letter – provided one time to a new Board member when they join the CIRB

Attachment 3B: CIRB Board Member Biographical Sketch Form – provided one time to a Board Member in order to provide background information as a way of introducing the new member of the Board

Attachment 3C: CIRB Board Member Contact Information Form – provided one time to collect contact information

Attachment 3D: CIRB Board Member W-9 – provided one time to a new Board member in order to receive annual W-9 forms

Attachment 3E: CIRB Board Member Non-Disclosure Agreement (NDA) – provided when a new Board member joins the CIRB for the purposes of identifying all affiliations that would require recusal of the Board member

- Attachment 3F: CIRB Board Member Orientation Steps – provided one time to serve as a guiding document to ensure the new Board member has gone through all appropriate orientation steps
- Attachment 3G: NCI's Privacy Policy – provided one time as a “for your information” for the new Board member
- Attachment 3H: TEMPLATE LETTER: CIRB Adult Query of Candidate Interest – personalized letter/email sent to candidate inquiring interest in joining Adult CIRB Board
- Attachment 3I: TEMPLATE LETTER: CIRB Pediatric Query of Candidate Interest – same as above, only for Pediatric CIRB Board
- Attachment 3J: TEMPLATE LETTER: Confirming Candidate Qualifications and Conflict of Interest (COI) Statement – personalized letter/email sent to candidate confirming qualifications
- Attachment 3K: TEMPLATE LETTER: CIRB Notification of Selection to Serve on NCI CIRB – personalized letter/email notifying of appointment
- Attachment 3L: TEMPLATE LETTER: CIRB Notice of Rotation Off – personalized letter/email notifying of rotation off CIRB Board
- Attachment 3M: TEMPLATE LETTER: CIRB Thank you to Retiring Members and Acknowledgement of Resignation – personalized letter/email thanking and acknowledging retiring member
- Attachment 3N: INTERNAL OPERATIONS: CIRB Internal Plaque Order Form – Internal administrative form used to order plaque for retiring Board Members
- Attachment 3O: INTERNAL OPERATIONS: CIRB Operations New Member Checklist – Internal administrative form used to track and record documents sent and received to/from new Board Members
- Attachment 3P: INTERNAL OPERATIONS: CIRB Educational Checklist for Member File – Internal administrative form used to track and record educational steps of Board Members
- Attachment 3Q: INTERNAL OPERATIONS: CIRB Operations Checklist for Retiring Board Members – Internal administrative form used to track and record steps of Retiring Board members

We anticipate the need for these forms to be completed by 33 people in the next two years, on an ongoing basis as each member is rotated off and a new member comes on.

Direct Deposit Form (Attachment 4)

This is an optional form for CIRB Members to complete should they choose to receive their government honoraria via direct deposit. We currently have two Boards (as listed directly above) with a combined membership of 33 people. We anticipate the need for these forms to be completed by 33 people in the next two years, on an ongoing basis as each member is rotated off and a new one comes on.

CIRB Application Forms (Attachment 5).

The Application Forms are required to be submitted to the CIRB in order to complete a submission for review. We have five application forms in total. These forms include:

- Attachment 5A: Adult CIRB Application – provided by CIRB operations staff to a clinical trial site that is requesting CIRB review for adult studies, retrievable via CIRB web site
- Attachment 5B: Pediatric CIRB Application – same as above except specific for pediatric studies
- Attachment 5C: Adult/Pediatric CIRB Application - Ancillary Studies: provided by CIRB operations staff to a clinical trial site that is requesting CIRB review of an ancillary study
- Attachment 5D: Summary of CIRB Application Revisions - a summary of revisions made to the application at time of an amendment, provided by clinical trial site to the CIRB
- Attachment 5E: Adult/Pediatric CIRB Application for Continuing Review – provided by CIRB operations staff to a clinical trial site to provide information in advance of the annual continuing review process. This form is retrievable via CIRB web site and is used for both adult and

pediatric studies

CIRB Reviewer Forms (Attachment 6)

These forms are completed by the Board Members when they submit their reviews:

- Attachment 6A: Adult CIRB Reviewer Findings – Initial Review of Cooperative Group Protocol – forms are provided to a reviewer upon assignment of an adult protocol for review
- Attachment 6B: Pediatric CIRB Reviewer Findings - Initial Review of Cooperative Group Protocol – same as above except specific for pediatric studies
- Attachment 6C: Adult CIRB Reviewer Findings Cooperative Group Response to CIRB Review – used by the reviewer to assess the response to CIRB review submitted by the Cooperative Group for an adult protocol
- Attachment 6D: Pediatric CIRB Reviewer Findings Cooperative Group Response to CIRB Review – same as above but specific for pediatric studies
- Attachment 6E: Adult CIRB Reviewer Findings Amendment to Cooperative Group Protocol – used by the reviewer to document specifics about the type of changes made to an adult protocol by a Cooperative Group that is resubmitted to the CIRB
- Attachment 6F: Pediatric CIRB Reviewer Findings Amendment to Cooperative Group Protocol – same as above but specific for pediatric studies
- Attachment 6G: Adult CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol – used by the reviewer to assess the magnitude of changes made to or those that need to be made to the adult protocol as discovered during the continuing review process, occurring annually
- Attachment 6H: Pediatric CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol – same as above but specific for pediatric studies
- Attachment 6I: CIRB Pharmacy Reviewer Form – used by a pharmacist reviewer to provide specialized feedback to a protocol submitted for CIRB review

- Attachment 6J: CIRB Statistical Reviewer Form – used by a statistician reviewer to provide specialized feedback to protocol submitted for CIRB review
- Attachment 6K: CIRB SAE Reviewer Worksheet – used by subcommittee member to provide rationale and recommendation regarding SAE and then forwarded to board for final voting. After board review, available on the CIRB website

The CIRB Helpdesk Survey seeks to collect information that can be used by the CIRB in a systematic fashion to improve operations and enhance reviewer satisfaction with the initiative. The remainder of the forms are necessary in order to facilitate a complete review of protocols by the CIRB with the absence of conflict of interest in place.

It is anticipated that forms may be revised or included in this information collection because of the changing nature of this initiative and the challenge to streamline process and improve efficiency. At that time, we will seek further OMB approval.

### **A.3 Use of Improved Information Technology and Burden Reduction**

CIRB is continuously seeking ways to reduce burden through advances in information technology. Utilization of computer equipment and computerized records management has reduced the need to compile, arrange, and update documentation maintained by the CIRB. Internal operations have expanded the capability to review and respond electronically to protocols submissions requiring CIRB review. Forms that are generated, used and stored electronically include the CIRB New Board Member Orientation packet, Non-Disclosure Agreement, W-9, CIRB Institution Enrollment Worksheet, Board Membership Information, Direct Deposit Form, CIRB Application

Forms, and CIRB Reviewer Forms. In addition, the CIRB Helpdesk Survey is an online tool and results are reviewed electronically.

Additionally, the NCI CIRB Institution Enrollment Worksheet (Attachment 2) is an electronically generated form that is pre-populated with current Institutional information, and sent via email to the enrolled institution for confirmation.

A Privacy Impact Assessment (PIA) has been conducted on the NIH NCI Central Institutional Review Board (CIRB) and IT System name is “NIH NCI Central Institutional Review Board (CIRB)”.

#### **A.4 Efforts to Identify Duplication and Use of Similar Information**

The information collected by the CIRB is not collected in the same manner for the same purposes that similar information is collected by other organizations within the NCI. The CIRB is required to collect information that helps to specifically identify financial transaction location, conflict of interest related to a specific protocol under review, and scheduling ability for a particular CIRB meeting. There is, to the knowledge of the CIRB, no unnecessary redundancies occurring.

#### **A.5 Impact on Small Businesses or Other Small Entities**

The CIRB uses IT tools to automate the collection of recurring information. The CIRB attempts to minimize the burden on small businesses by limiting requests for information to those elements that are specific to a particular protocol under review by the CIRB or to information that may change in between protocol review periods.

Additionally, some requests include pre-populated responses to further reduce the time to complete the forms.

#### **A.6 Consequences of Collecting the Information Less Frequently**

The CIRB Helpdesk Survey (Attachment 1) is an electronic generated survey sent via email in response to CIRB Helpdesk inquiries. The CIRB receives approximately 140 inquiries per month, and each inquiry may be sent this electronic survey. This frequency is necessary to ensure that every person that has contacted the Helpdesk has an opportunity to respond.

The NCI CIRB Institution Enrollment Forms (Attachment 2A-2M) are electronically generated forms completed by sites at enrollment and when there is an update to personnel or institution contact status. The initial enrollment form is sent on an annual basis, via email, to the enrolled institution for confirmation. This frequency is needed to ensure current data, appropriate users have access to the CIRB website, appropriate contact information is available for communication, and appropriate relationships are established and maintained with affiliates, components, and IRBs. The Contact Forms are available via the website ([http://www.ncicirb.org/CIRB\\_Update\\_Person\\_Inst\\_Info.asp](http://www.ncicirb.org/CIRB_Update_Person_Inst_Info.asp)) and are completed electronically. The frequency is at the discretion of the site as it is completed when there is a personnel update or status change at the institution.

The CIRB New Board Member Orientation (Attachments 3A-3G) are electronically generated forms completed once by the Board member at time of orientation. \_\_\_\_\_

The CIRB Template Letters (Attachments 3H -3M) electronically generated emails/letters sent to each Board Member during rotation of service.

The CIRB Internal Operations (Attachments 3N – 3Q) electronically generated checklists used to order and track Board Member activity.

The Direct Deposit Form (Attachment 4) is completed once by the Board member if they decide to use direct deposit for honorarium payments.

Recordkeeping occurs with each convened meeting of the CIRB, and it is not considered feasible to conduct recordkeeping on a less frequent basis. The CIRB Application Forms (Attachment 5A-5E) are electronically generated forms that are completed per each initial submission to the CIRB. This frequency is necessary as it details information specific to the submission.

The CIRB Reviewer Forms (Attachment 6A – 6K) are electronically generated forms that are completed per each review submission to the CIRB. This frequency is necessary as it provides the reviewer’s comments by which the Board uses for determination when reviewing submission. There are no technical or legal obstacles; no consequences for less use and it is a “one-time” collection.

#### **A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

Project complies with 5 CFR 1320.5. No special circumstances are anticipated.

#### **A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on August 16, 2010 (75 FR 49938). No public comments were received.

No efforts have been made to consult outside the agency in regards to this administrative information collection.

#### **A.9 Explanation of Any Payment or Gift to Respondents**

The only form of payment provided to the non-government CIRB Board Member volunteers is an honorarium based on role, attendance, and reviews completed. The honorarium is for review time estimated at 4 hours per review and meeting attendance estimated at 3-4 hours. This honorarium for CIRB Members provides \$200 for review and \$200 for meeting attendance. When a member is selected as Board Chair or Vice Chair, an additional modest stipend is provided for their additional service. The optional form of payment is available via check or direct deposit, should they choose to receive honoraria. The CIRB Board Members consists of nationally renowned experts in their field that may relinquish upward of \$75 - \$450 /hr providing professional service. The honorarium provides reimbursement for service and time of renowned experts, and supports the efforts of NCI CIRB to provide volunteers from a national pool of experts. We anticipate the need for these forms to be completed by 33 people in the next two years, on an ongoing basis as each member is rotated off and a new one comes on.

## **A.10 Assurance of Confidentiality Provided to Respondents**

The CIRB collects personally identifiable information (PII) from Board members and local sites in the form of name, address, telephone numbers, email address, social security number, employment information, financial information, educational level, etc. This information may be completed as hard or electronic copies and mailed or emailed to the Operations Office for data entry. Board members and site representatives provide information voluntarily and are aware of the purposes for which their contact information will be used. Data stored in CIRB information systems is not purged or deleted and is maintained to support CIRB current operations. The electronic information is stored within the system indefinitely as legacy data for review and analysis of CIRB activities. Hard copies are shredded once data have been entered.

The need to collect PII occurs sporadically and is stored electronically with frequent backups to ensure information is recoverable, as needed. CIRB members are made aware of this collection and the need for the collection through the CIRB privacy statement. The NCI Privacy Policy (Attachment 3G) is available electronically and it is shared during the enrollment application process. The need for the collection of this information is relevant and justified to ensure that no CIRB member can unduly influence the approval of a study when there is an appearance of conflict due to professional or personal relationships such as financial gain or professional growth.

The types of data used are both scientific and administrative and used to inform board members concerning the studies under review, manage the operations and communications of Adult and Pediatric Central Institutional Review Boards, and convey

information to sites concerning studies reviewed by the CIRB and decisions made by the CIRB. The material is kept private in accordance with the Privacy Act and 18 U.S.C. 1905, 21 U.S.C. 331(j), sections 301(j) and 520(c) of the Federal Food, Drug and Cosmetic Act.; CFR Title 45 Part 46 (Protection of Human Subjects), and CFR Title 21 Part 50 (Protection of Human Subjects), Part 56 (Institutional Review Boards); and, Legislation Authority is the Public Health Service Act (42 U.S.C. 241, 242, 248, 282, 284, 285a-j, 285l-q, 287, 287b, 287c, 289a, and 44 U.S.C 3101.).

The NIH Privacy Act Officer has reviewed this data collection and deemed the Privacy Act is applicable, and is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD" (Attachment 7). Additionally, the Office of Human Subjects Research (OHSR) has reviewed this information collection and has deemed that "Federal regulations for the protection of human subjects does not apply" (Attachment 8).

#### **A.11 Justification for Sensitive Questions**

Sensitive information collected includes the Board members social security number, home address, phone number and bank information if the direct deposit mechanism is used. Such sensitive information will be kept private under the Privacy Act.

## A.12 Estimates of Annualized Burden Hours and Costs

Table A.12-1 indicates the annual burden of hours for both CIRB Board Members and participants. “Board Members” refer to all volunteer committee members that have been formally designated to approve, monitor, and review Cancer research studies involving humans with the aim to protect the rights and welfare of the research subjects. The CIRB Board Members perform critical oversight functions for research conducted on human subjects that are scientific, ethical, and regulatory. “Participants” refer to all individuals, institutions, research personnel, IRBs, Cooperative Groups interacting with CIRB, enrolling into the CIRB, submitting Facilitated Review with the CIRB. The annualized burden is estimated to be 2209 hours, which amounts to a total burden of 6627 hours over a 3 year period.

Table A.12 - 1 Estimates of Annual Burden Hours					
Type of Respondents	Survey Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Min/Hr)	Annual Burden Hours
Participants/ Board Members	CIRB Helpdesk Survey (Attachment 1)	1500	1	10/60	250
				(.17 hour)	
Participants	NCI CIRB Institution Enrollment Worksheet (Attachment 2A)	30	1	3.5 hours	105
Participants	IRB Staff at Signatory Institution's IRB (Attachment 2B)	65	1	10/60	11
				(.17 hour)	
Participants	Investigator at Signatory Institution (Attachment 2C)	65	1	10/60	11
				(.17 hour)	
Participants	Research Staff at Signatory Institution (Attachment 2D)	65	1	10/60	11
				(.17 hour)	
Participants	Investigator at Affiliate Institution (Attachment 2E)	65	1	10/60	11
				(.17 hour)	
Participants	Research Staff at Affiliate Institution (Attachment 2F)	65	1	10/60	11
				(.17 hour)	
Participants	IRB at Signatory Institution (Attachment 2G)	65	1	10/60	11
				(.17 hour)	
Participants	Component Institution at Signatory Institution (Attachment 2H)	65	1	10/60	11
				(.17 hour)	
Participants	IRB at Affiliate Institution (Attachment 2I)	65	1	10/60	11
				(.17 hour)	
Participants	Institution Affiliate Institution without an IRB (Attachment 2J)	65	1	10/60	11
				(.17 hour)	

Participants	Request for 30-Day Access Form (Attachment 2K)	50	1	10/60	8
				(.17 hour)	
Participants	Facilitated Review (FR) Acceptance Form (Attachment 2L)	1450	1	10/60	242
				(.17 hour)	
Participants	Study Review Responsibility Transfer Form (Attachment 2M)	120	1	10/60	20
				(.17 hour)	
Board Members	CIRB New Board Member Biographical Sketch Form (Attachment 3B)	16	1	30/60	8
				(.5 hour)	
Board Members	CIRB New Board Member Contact Information Form (Attachment 3C)	16	1	15/60	4
				(.25 hour)	
Board Members	CIRB New Board Member W-9 (Attachment 3D)	16	1	15/60	4
				(.25 hour)	
Board Members	CIRB New Board Member Non-Disclosure Agreement (NDA) (Attachment 3E)	16	1	15/60	4
				(.25 hour)	
Board Members	Direct Deposit Form (Attachment 4)	16	1	15/60	4
				(.25 hour)	
Participants	NCI Adult CIRB Application (Attachment 5A)	150	1	2 hours	300
Participants	NCI Pediatric CIRB Application (Attachment 5B)	62	1	2 hours	124
Participants	Adult/Pediatric CIRB Application - Ancillary Studies (Attachment 5C)	10	1	2 hours	20
Participants	Summary of CIRB Application Revisions (Attachment 5D)	20	1	30/60	10
				(.5 hour)	
Participants	Adult/Pediatric CIRB Application for Continuing Review (Attachment 5E)	230	1	1 hour	230
Board Members	Adult CIRB Reviewer Findings – Initial Review of Cooperative Group Protocol (Attachment 6A)	20	1	4 hours	80
Board Members	Pediatric CIRB Reviewer Findings – Initial Review of Cooperative Group Protocol (Attachment 6B)	12	1	4 hours	48
Board Members	Adult CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6C)	25	1	1 hour	25
Board Members	Pediatric CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6D)	70	1	1 hour	70
Board Members	Adult CIRB Reviewer Findings Amendment Cooperative Group Protocol (Attachment 6E)	130	1	1.5 hours	195
Board Members	Pediatric CIRB Reviewer Findings Amendment to Cooperative Group Protocol (Attachment 6F)	50	1	1.5 hours	75
Board Members	Adult CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6G)	150	1	.5 hour	75

Board Members	Pediatric CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6H)	110	1	.5 hour	55
Board Members	CIRB Reviewer Form (Attachment 6I)	20	1	2 hours	40
Board Members	CIRB Statistical Reviewer Form (Attachment 6J)	20	1	2 hours	40
Board Members	CIRB SAE Reviewer Worksheet (Attachment 6K)	10	15	30/60	75
				(.5 hour)	
<b>Total:</b>		<b>4904</b>			<b>2209</b>

Table A.12-2 indicates the Annualized Cost to Respondents for both CIRB board members and participants. The total annualized cost to respondents is estimated to be \$ 45,324, which amounts to a total annualized cost to respondents of \$135,972 over a 3 year period.

The Annual Burden Hours was reported in Table A.12-1 and reported into Table A.12-2 to calculate respondent cost. The CIRB Board Members composition consists of patient advocates, physicians, ethicist, nurses, pharmacists and statisticians. The participants consist of “Education, Health, and Business service professionals.” According to the U.S. Department of Labor, Bureau of Labor Statistics (<http://stats.bls.gov/>), the average hourly earnings of production by major industry sector during 2009 are as follows: “Professional and business services”, \$22.40; “Education and health services”, \$19.42; “Private service”, \$18.27. We used these estimates to approximate hourly wage rates and calculate cost to respondent. “Participants” approximate hourly wage is an average of education, health, professional and business services: \$20.91; “Board Members” approximate hourly wage rate is an average of the three major industry categories: \$20.03.

**A.12 - 2 Annualized Cost to Respondents**

Type of Respondents	Survey Instrument	Number of Respondents	Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Participants/ Board Members	CIRB Helpdesk Survey (Attachment 1)	1500	250	20.47	\$ 5,118
Board Members	NCI CIRB Institution Enrollment Worksheet (Attachment 2A)	30	105	20.03	\$2,103
Participants	IRB Staff at Signatory Institution's IRB (Attachment 2B)	65	11	20.91	\$227
Participants	Investigator at Signatory Institution (Attachment 2C)	65	11	20.91	\$227
Participants	Research Staff at Signatory Institution (Attachment 2D)	65	11	20.91	\$227
Participants	Investigator at Affiliate Institution (Attachment 2E)	65	11	20.91	\$227
Participants	Research Staff at Affiliate Institution (Attachment 2F)	65	11	20.91	\$227
Participants	IRB at Signatory Institution (Attachment 2G)	65	11	20.91	\$231
Participants	Component Institution at Signatory Institution (Attachment 2H)	65	11	20.91	\$231
Participants	IRB at Affiliate Institution (Attachment 2I)	65	11	20.91	\$231
Participants	Institution Affiliate Institution without an IRB (Attachment 2J)	65	11	20.91	\$231
Participants	Request for 30-Day Access Form (Attachment 2K)	50	8	20.91	\$174
Participants	Facilitated Review (FR) Acceptance Form (Attachment 2L)	1450	242	20.91	\$5053
Participants	Study Review Responsibility Transfer Form (Attachment 2M)	120	20	20.91	\$418
Board Members	CIRB New Board Member Biographical Sketch Form (Attachment 3B)	16	8	20.03	\$160
Board Members	CIRB New Board Member Contact Information Form (Attachment 3C)	16	4	20.03	\$80
Participants	CIRB New Board Member W-9 (Attachment 3D)	16	4	20.91	\$84
Board Members	CIRB New Board Member Non- Disclosure Agreement (NDA) (Attachment 3E)	16	4	20.03	\$80
Board Members	Direct Deposit Form (Attachment 4)	16	4	20.03	\$80
Participants	NCI Adult CIRB Application (Attachment 5A)	150	300	20.91	\$6,273

Participants	NCI Pediatric CIRB Application (Attachment 5B)	62	124	20.91	\$2,593
Participants	Adult/Pediatric CIRB Application - Ancillary Studies (Attachment 5C)	10	20	20.91	\$418
Participants	Summary of CIRB Application Revisions (Attachment 5D)	20	10	20.91	\$209
Participants	Adult/Pediatric CIRB Application for Continuing Review (Attachment 5E)	230	230	20.91	\$4,809
Board Members	Adult CIRB Reviewer Findings – Initial Review of Cooperative Group Protocol (Attachment 6A)	20	80	20.03	\$1,602
Board Members	Pediatric CIRB Reviewer Findings – Initial Review of Cooperative Group Protocol (Attachment 6B)	12	48	20.03	\$961
Board Members	Adult CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6C)	25	25	20.03	\$501
Board Members	Pediatric CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6D)	70	70	20.47	\$1,433
Board Members	Adult CIRB Reviewer Findings Amendment Cooperative Group Protocol (Attachment 6E)	130	195	20.03	\$3,906
Board Members	Pediatric CIRB Reviewer Findings Amendment to Cooperative Group Protocol (Attachment 6F)	50	75	20.03	\$1,502
Board Members	Adult CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6G)	150	75	20.03	\$1,502
Board Members	Pediatric CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6H)	110	55	20.03	\$1,102
Board Members	CIRB Reviewer Form (Attachment 6I)	20	40	20.03	\$801
Board Members	CIRB Statistical Reviewer Form (Attachment 6J)	20	40	20.03	\$801
Board Members	CIRB SAE Reviewer Worksheet (Attachment 6K)	10	75	20.03	\$1,502
	Total:		2699		\$ 45,324

### A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

Descriptions of Methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, discount rate(s),

and time period over which costs will be incurred: The Total Capital/Start-up Cost are based on expense incurred during development for Central IRB, then annualized per year, considering purchase date, life expectancy of equipment, and contract period. The hardware has a life expectancy of 4 years with an increase in life expectancy extended to 7 years due to extended warranty. The extended warranty to increase life expectancy during contract period is expensed in the maintenance period at an annual rate based on years of increased life expectancy. The software purchased during development has not been upgraded. Updates to software are part of the original development expense and incurs no additional operational/maintenance expense. The annual average considers purchase of software and use during contract period.

The Operational/Maintenance and Purchase costs incurred covers three categories: subscription, warranty, and maintenance. The yearly Subscription expense incurred is multiplied by the number of years in the period. This provides us with the annual average and the total purchase cost for subscription. The Extended Warranty for hardware considers the increase in life years and the annual expense from the time of purchase and is calculated accordingly. The Generating, Maintaining, Disclosing or providing information is a percentage of the budget allocated to maintenance on a yearly basis. The annual cost is considered for each year with escalation increases considered; then, an average of the five maintenance period years is calculated to provide annual average. The total Estimate of Other Total Cost Burden for six year contract is \$150,640 (Table A.13-1). The Estimate of Other Total Annual Average Cost Burden is \$27,041 (Table A.13-1).

<b>A.13 - 1 Estimate of Other Total Annual Cost Burden to Respondents or (Record Keepers)</b>		
<b>Annualized Total Capital/Start-up Cost</b>	<b>Total for 6 yr. Contract</b>	<b>Annual Average</b>
Purchase of hardware	\$13,900	\$2,317/yr
Purchase of software program licenses	\$14,800	\$2,467/yr
<b>Annualized Operational/Maintenance and Purchase Costs</b>		
IRB Manager Subscription	\$79,920	\$13,320/yr
Extended Warranty for hardware	\$4,000	\$1,333/yr (for 3 yrs only)
Generating, Maintaining, Disclosing or providing information	\$38,020	\$ 7,604/yr (for 5 yrs only)
<b>Total</b>	<b>\$150,640</b>	<b>\$27,041</b>

#### **A.14 Annualized Cost to the Federal Government**

The overall government distribution is summarized in Table A.14-1.

<b>Table A.14-1 Government Cost Distribution</b>		
	<b>TOTAL</b> (3 base years, 3 award years = 6 year contract)	<b>ANNUAL AVERAGE</b> (1 year average based on 6 year contract)
CIRB Board Staff (1.15% FTE)	\$921,443	\$153,574
<b>Grand Total</b>	<b>\$921,443</b>	<b>\$153,574</b>

The average annual cost to the government over 12-month period is approximately \$153,574. This calculation is based on identifying staff members that contribute directly to the record keeping, determining percentage of FTE, calculating the accumulative total for 6-year contract (considering yearly escalation), then adding totals together and dividing by the contract period to determine annual average of CIRB staff members.

The Grand Total cost to the government over 6-year contract is approximately \$921,443, which amount to \$460,722 during the 3-year OMB approval collection time. This calculation is determined by identifying staff members that contribute directly to record keeping, determining percentage of FTE, calculating total for 6-year contract (considering escalation), then adding totals together for the Grand Total.

**A.15 Explanation for Program Changes or Adjustments**

This is an existing collection in use without an OMB number.

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

There are currently no plans to publish project information.

**A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

All instruments will display the OMB expiration date.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.