SUPPORTING STATEMENT A:

NIH NCI CENTRAL INSTITUTIONAL REVIEW BOARD (CIRB) INITIATIVE (NCI)

OMB No. 0925-0625, Expiry Date: 1/31/2014

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Revisions from the 2011 approved submission are highlighted in yellow.

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The National Cancer Institute (NCI) Central Institutional Review Board (CIRB) provides a centralized approach to human subject protection and provides a cost efficient approach avoiding duplication of effort at each institution. The CIRB provides the services of a fully constituted IRB and provides a comprehensive and efficient mechanism to meet regulatory requirements pertaining to human subject protections including: initial reviews, continuing reviews, review of amendments, and adverse events. The Initiative consists of three central IRBs: Adult CIRB – late phase emphasis, Adult CIRB – early phase emphasis, and Pediatric CIRB. CIRB membership includes oncology physicians, surgeons, nurses, patient advocates, ethicists, statisticians, pharmacists, attorneys and other health professionals. The benefits of the CIRB Initiative reaches research participants, investigators and research staff, Institutional Review Boards (IRB), and Institutions. Benefits include: study participants having dedicated review of NCI-sponsored trials for participant protections, access to more trials more quickly and access to trials for rare diseases, accrual to trials begin more rapidly, ease of opening trials, elimination of need to submit study materials to local IRBs, and elimination of the need for a full board review. The benefits to the National Clinical Trials Network and Experimental Therapy-Clinical Trials Network include a cost efficient approach that avoids duplication of efforts at each institution. A variety of information collection tools to support NCI's CIRB activities which include: worksheets, forms and a survey that is provided to all customers contacting the CIRB helpdesk.

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 NCI Central Institutional Review Board Initiative (CIRB, 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 Operations and Informatics Branch (OIB). The CIRB is an NCI

initiative utilizing the time and expertise of board members that are representative of the oncology community outside the NCI. The NCI provides funding as well as logistical and operational support to the CIRB. This support is provided by CTEP and its contractors. While the CIRB reviews CTEP sponsored studies, neither the CIRB members nor reviewers are affiliated with CTEP. This is a request for OMB to approve the revision to the NCI CIRB submission which includes implementing a new, independent operating model, revised forms with more direct questions, and board specific forms/worksheets. Although it appears there is an increase in the number of forms due in part to the new model and adding of new board, the estimate of burden hours and respondents costs has not increased due in part by implemented efficiencies.

Beginning in January 2001, the Adult CIRB has been meeting twice monthly to review phase 3 and select phase 2 Cooperative Group studies. The Pediatric CIRB was constituted in June 2004 and began reviewing NCI-approved Children's Oncology Group (COG) phase 2, 3 and pilot studies in November 2004. The Adult CIRB – Early Phase Emphasis (EPE) will begin reviewing studies in June 2013. The new Adult CIRB - EPE will meet twice monthly to review select phase 1 and select phase 2 NCI funded studies. CIRB membership is composed of individuals who represent a broad range of oncology scientific and nonscientific disciplines. Board members may include: oncology physicians, surgeons, nurses, patient advocates, pharmacists, ethicists, statisticians, attorneys, and other health professionals. NCI employees cannot sit on the CIRB and therefore, the CIRB is collectively made up of public members.

The NCI CIRB provides a centralized approach to human subject protections that streamlines local IRB review of adult and pediatric national multicenter cancer treatment

trials. The benefits to research participants include study review by individuals who represent a broad range of oncology expertise, as well as specialized expertise such as pediatric oncology and early drug development. The benefits to investigators and research staff includes: easier to open trials; eliminates preparation of study submissions to local IRBs, including completion of IRB application, duplication of IRB packets, subsequent submissions for amendments, continuing reviews; eliminates back-and-forth with IRB to gain study approval. Efficiencies for IRB members and IRB staff include: eliminates full board review of NCI-sponsored trials, and administrative burden. Benefits to study participants includes: having dedicated review of NCI-sponsored trials for study participant protections, access to more trials more quickly, and access to trials for rare diseases. Additionally, more trials may be opened at more institutions more quickly, accrual to trials may begin more rapidly, trials may obtain accrual goals sooner, and trial questions may be answered more quickly. The benefits to the National Clinical Trials Network (NCTN) and Experimental Therapy-Clinical Trials Network (ET-CTN) include a cost efficient approach that avoids duplication of efforts at each institution. The CIRB provides the services of a fully constituted IRB and provides comprehensive and efficient mechanism to meet regulatory requirements pertaining to human subject protections including: initial reviews, continuing reviews, review of amendments, and adverse events.

The NCI uses various information collection tools to support CIRB activities. Information collection tools include: worksheets and/or forms requiring completion by an institution conducting a clinical trial eligible for review by the CIRB, as well as worksheets and/or forms requiring completion by the CIRB members themselves, all

described below. Additionally, the CIRB Operations Office developed a survey that is provided to all customers contacting the CIRB helpdesk. Approximately 335 helpdesk inquiries are received per month. The survey responses are anonymous and the response rate is approximately 20% (see Section A.2 CIRB Customer Satisfaction Survey). Customer Satisfaction Surveys are conducted through an online provider of web-based surveys (SurveyMonkey.com), no identifiable information on the customer is requested.

A.2 Purpose and Use of the Information Collection

There are six general areas in which worksheets and/or forms are requested for completion. The areas include: CIRB Customer Satisfaction Survey, CIRB Enrollment, CIRB Membership, CIRB Direct Deposit, CIRB Applications, and CIRB Reviewer Worksheets. Detail is provided below on each worksheets and/or form, how completed, responsible party for completing, and purpose and use of the collected information. The CIRB Customer Satisfaction 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 CIRB Initiative. The remaining forms and/or worksheets are necessary to facilitate a complete review of protocols by the CIRB with the absence of conflict of interest in place.

NCI CIRB Customer Satisfaction Survey[1] (Attachment 1)

The customer satisfaction survey was developed to collect customer feedback pertaining to the use of the CIRB Helpdesk. Any customer (local institution, member

[1] In the 2010 submission, the Customer Satisfaction Survey was referred to as the CIRB Helpdesk Survey. Though the name has changed for this submission, contents of this survey remain unchanged since 2011.

of Cooperative Group, NCTN, ET-CTN, 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 (Attachment 1A). We receive approximately 335 helpdesk inquiries per month and since this is a voluntary survey, we receive approximately 55-65 completed surveys a month. The surveys are completed online through SurveyMonkey.com (Attachment 1B).

NCI CIRB Enrollment Forms (Attachment 2)

The NCI CIRB Enrollment documents collect information on institutions interested in enrolling or that have already enrolled in the CIRB Initiative. The CIRB currently has 341 institutions enrolled in the NCI Central IRB Initiative. Forms in this category collect information that includes: request for website access, enrollment and contact information, and acceptance and transfer forms. Some of the available enrollment forms have changed or are new forms since the last submission. Those that have changes or are new are mentioned below, along with a description of the information that is being collected:

Attachment 2B: Authorization Agreement and Division of Responsibilities between NCI CIRB and Signatory Institution – this is a new form that documents the arrangement for the IRB of an institution with an FWA to rely on the CIRB for review of studies on the CIRB menu. Two original documents are completed, signed and submitted to the CIRB Operations Office where they are signed by NCI Official. This form is retrievable via the CIRB website.

Attachment 2I: Investigator at Affiliate Institution without an IRB – this is a new form developed to update contact information for Investigators at each affiliated institution without an IRB so that each may receive

study-related correspondence from the CIRB with the new independent model. This form also confirms the contact information of Investigators that should no longer receive study-related correspondence. This form is retrievable via the CIRB website.

Attachment 2J: Research Staff at Affiliate Institution without an IRB – this is a new form developed to update Research personnel contact information at Affiliate Institution without an IRB to assure receipt of study-related correspondence from the CIRB with the new independent model. This form also confirms the contact information of research staff that should no longer receive study-related correspondence. This form is retrievable via the CIRB website.

Attachment 2K: Institutional Contact for Signatory Institution – this is a new form developed to update information for Institutional contact information at Signatory Institution to assure they receive study-related correspondence from the CIRB with the new independent model. This person is CIRB primary point of contact with the institution and must be a senior institutional official that has the authority to commit institution named on FWA form, as well as institutional components to a legal binding agreement. This form also confirms the contact information of Institutional contacts that should no longer receive study-related correspondence. This form is retrievable via the CIRB website.

Attachment 2R: Annual Institution Worksheet about Local Context – this is a new worksheet developed to collect information during enrollment with the new independent model. This worksheet is completed by the Institutions Primary Contact using IRBManager and submitted to the CIRB for review. This form is updated electronically online.

Attachment 2S: Annual Principal Investigator Worksheet about Local Context – this is a new worksheet developed to collect information during enrollment with the new independent model. This worksheet is completed by each Principal Investigator who will open a CIRB-approved study. Worksheet is completed in IRBManager and is submitted to the CIRB for review. This form is updated electronically online.

Attachment 2T: Study-Specific Worksheet About Local Context – this is a new worksheet developed to collect information during enrollment with the new independent model. This worksheet is completed by the Principal Investigator to open a new study with the CIRB. This worksheet is completed in IRBManager, submitted to the CIRB for review. This form is updated electronically online.

Attachment 2U: Study Closure or Transfer of Study Review Responsibility Form – this is a new form developed to collect information as it relates to study closure or transferring study review responsibility with the new independent model. This form is completed by the Principal Investigator to close a study or transfer review responsibility for the study from the CIRB to another IRB. This form is completed in IRBManager and is submitted to the CIRB for review. This form is updated electronically online.

Attachment 2V: Potential Unanticipated Problem or Serious or Continuing Noncompliance (UP and/or SCN) Reporting Form – this is a new form developed to collect potential unanticipated problem and/or serious or continuing noncompliance to the CIRB with the new independent model. This form is completed by the Principal Investigator to report a potential unanticipated problem and/or serious or continuing noncompliance to the CIRB. The form is completed in IRBManager and is submitted to the CIRB for review. This form is updated electronically online.

Attachment 2W: Add or Remove Signatory and/or Component Institution Personnel – this is a new form developed to update Signatory and/or Component Institution personnel that review NCI-sponsored studies approved by the CIRB and should receive study-related correspondence with the new independent model. This form also confirms the contact information of Signatory and/or Component Institution Personnel that should no longer receive study-related correspondence. This form is updated electronically online.

Attachment 2X: Add or Remove Affiliate Institution Personnel – this is a new form developed to update Affiliate Institution personnel that review NCI-sponsored studies approved by the CIRB and should receive study-related correspondence with the new independent model. This form also confirms the contact information of Affiliate Institution Personnel that should no longer receive study-related correspondence. This form is updated electronically online.

Attachment 2Y: Add or Remove Component Institution – this is a new form developed to update Component Institutions that conduct NCI-sponsored studies approved by the CIRB and should receive study-related correspondence with the new independent model. This form also confirms the contact information of Component Institution that should no longer conduct or receive study-related correspondence. This form is updated electronically online.

Attachment 2Z: Add or Remove Affiliate institution – this is a new form developed to update Affiliate Institutions that conduct NCI-sponsored studies

approved by the CIRB and should receive study-related correspondence with the new independent model. This form also confirms the contact information of Affiliate Institution that should no longer conduct or receive study-related correspondence. This form is updated electronically online.

Attachment 2ZA: One Time Study Rollover Worksheet – this is a new worksheet developed to provide information for each study open under the facilitated review model that is being rolled over to the new independent model. This worksheet is completed by the IRB staff in Participant's Area of the CIRB website at time of transition. Once completed, the worksheet is submitted to CIRB for review.

Attachment 2ZB: Change of Signatory Institution PI Form – this is a new form developed to update Signatory Institution Principal Investigator information that conducts NCI-sponsored studies approved by the CIRB and should receive study-related correspondence with the new independent model. This form also confirms the contact information of Signatory Institution Principal Investigator that should no longer receive study-related correspondence. This form is updated electronically online.

NCI CIRB Membership Information (Attachment 3)

Membership documents were created to collect information on all members and potential members of the CIRB. We currently have three Boards (Adult – late phase emphasis (LPE), Adult – early phase emphasis (EPE), and Pediatric CIRB). Once recruited, each Board Member is expected to serve a two-year term, although may be asked to serve up to four years. Prospective 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 NCI, a formal invitation for membership and packet of information is sent to the candidate. There have been no changes to the membership documents since the 2011 submission. The variety of forms in Attachment 3 collect contact and biographical information, tax forms, non-disclosure

agreement, qualifications, and a conflict of interest statement.

Direct Deposit Form (Attachment 4)

This is an optional form for CIRB Members to complete should they choose to receive government honoraria via direct deposit. We currently recruit for three Boards (as listed directly above) with a combined membership of 45 people. We anticipate the need for these forms to be completed by 25 people in the next two years, on an ongoing basis as each member rotates off and new members rotate on.

NCI CIRB Application Forms (Attachment 5).

The NCI CIRB Application forms are submitted by participants and are required in order to complete a submission for review. The CIRB maintains six application forms in total. Two new forms have been added with the new independent model, these include:

Attachment 5E: Locally-Developed Material Submission Form – provided by CIRB operations staff to an institution to collect information on locally developed, participant-directed materials to be used for recruitment or educational purposes for either adult or pediatric trials. This form is retrievable via CIRB website and once completed, is submitted to the CIRB for review.

Attachment 5F: Application Request to Review Translated Documents - provided by CIRB operations staff to an institution using translated materials to be used for recruitment or educational purposes for either adult or pediatric trials. This form is retrievable via CIRB website and once completed, is submitted to the CIRB for review.

NCI CIRB Reviewer Worksheets (Attachment 6)

The NCI CIRB Reviewer Worksheets are completed and submitted by Board Members once review of protocol has been assigned and completed. Additionally, there are documents completed and submitted by NCI-sponsored institutions, cooperative groups when responding to CIRB review. New Reviewer Forms have been added in accordance with requirements pertaining with the new independent model. The new

reviewer worksheets and NCI-sponsored institutions, cooperative group response documents include:

Attachment 6L:	Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN) – used by reviewer to assess whether a reported event is an unanticipated problem and/or serious or continuing noncompliance issue, or neither.
Attachment 6M:	Adult Expedited Amendment Review – used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to an adult protocol by a Cooperative Group submitted to the CIRB for expedited amendment review.
Attachment 6N:	Pediatric Expedited Amendment Review - used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to a pediatric protocol by a Cooperative Group submitted to the CIRB for expedited amendment review.
Attachment 6O:	Adult Expedited Continuing Review - used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to an adult protocol by a Cooperative Group submitted to the CIRB for continuing review.
Attachment 6P:	Pediatric Expedited Continuing Review - used by the reviewer to indicate documents reviewed and expedited review specifics about the type of changes made to a pediatric protocol by a Cooperative Group submitted to the CIRB for continuing review.
Attachment 6Q:	Adult Expedited Study Review - used by the reviewer to indicate documents reviewed and verifying study status of an adult protocol submitted by a Cooperative Group to the CIRB for expedited study closure.
Attachment 6R:	Pediatric Expedited Study Review - used by the reviewer to indicate documents reviewed and verifying study status of an pediatric protocol submitted by a Cooperative Group to the CIRB for expedited study closure.
Attachment 6S:	Adult Expedited Study Chair Response to Required Modifications – used by study chair to expedite review of Cooperative Group response submitted in reference to CIRB-required modifications for Adult protocol review.
Attachment 6T:	Pediatric Expedited Study Chair Response to Required Modifications – used by study chair to expedite review of

Cooperative Group response submitted in reference to CIRB-required modifications for Pediatric protocol review.

Attachment 6U: Reviewer Worksheet of Translated Documents - used by subcommittee member to review Cooperative Group submission of translated materials for CIRB approval.

Attachment 6V: Reviewer Advertisement Checklist - used by subcommittee member to review Cooperative Group submission of locally developed material for CIRB approval.

It is anticipated that worksheets/forms may be revised or included in this information collection because of the changing nature of the CIRB 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: NCI CIRB Institution Enrollment Worksheets, CIRB New Board Member Orientation packet, Non-Disclosure Agreement, W-9, CIRB Application Forms, and CIRB Reviewer Worksheets. While currently enrolled institutions are transitioning from the Facilitated Review Model to the new CIRB Independent Model, the IT system in use identifies and pre-populates forms with current institutional information for maximum efficiency. This pre-population reduces time to complete forms. In addition, the CIRB Customer Satisfaction Survey an online tool and results are reviewed and stored electronically.

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)” and published on 9/28/2012 (Attachment 9). A revision to the CIRB PIA is currently underway due to changes in the Informatic Support network.

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. Currently, the CIRB is working closely with CTEP and CTSU on identifying requirements for integration of CIRB systems with CTEP and CTSU/RSS where there is overlap of information being collected. Variables under consideration include: NCI Institution Code, Institution name, Institution location, Institution enrollment, principal Investigator name, research staff name, email address; protocol title, protocol review date, and date of study activation.

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 335 inquires 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 equal opportunity to respond.

The NCI CIRB Institution Enrollment Forms (Attachment 2A-2ZB) are electronically generated forms completed by institutions at enrollment, and when there is an update to personnel or institution contact status. A subset of the initial enrollment form is sent on an annual basis, via email, to the enrolled institution for confirmation of information. This frequency is needed to ensure current, correct data; that appropriate users have access to the CIRB website, appropriate contact information is available for communications, and appropriate relationships are established and maintained with affiliates, components, and Institutions. The Contact Forms are available via the NCI CIRB website and are completed electronically. The frequency is at the discretion of the institution, since completion is dependent upon when there is a personnel update or status change at the institution.

CIRB Membership Documents (Attachments 3A-3Q) are electronically generated template letters and forms either reviewed or completed by the Board member during orientation and rotation of service; (Attachments 3N – 3Q) are electronically generated checklists used by internal operations to order and track board member activity.

The Direct Deposit Form (Attachment 4) is completed by a board member if they decide to use direct deposit for an honorarium. Using direct deposit is encouraged.

The CIRB Application Forms (Attachment 5A – 5F) are electronically generated forms completed per submission to the CIRB. This frequency is necessary as it details information specific to each submission.

The CIRB Reviewer Forms (Attachment 6A – 6V) are electronically generated forms completed per review submission by board members. This frequency is necessary as it provides the reviewer's comments to formulate determination when reviewing each submission. There are no technical or legal obstacles; no consequence for less use. Reviewer forms are 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 22, 2013, Vol. 78, P. 52204. There were no public comments 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 non-government CIRB Board Member volunteers receive 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 Chair receives $1000 and the Vice Chair receives $600 for contributing service daily to the CIRB. Should they choose to receive honoraria, it is available in the form of a check or direct deposit. The CIRB Board Members consists of nationally renowned experts in their field that may relinquish upward of $75 - $450 /hour 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 the membership documents to be completed by 25 people in the next three years, on an ongoing basis as members rotate off and new members rotate on. The membership documents include: CIRB Board Member Biographical Sketch Form, CIRB Board Member Contact Information Form, CIRB Board Member W-9, CIRB Board Non-Disclosure Agreement, and CIRB Direct Deposit Form.

A.10 Assurance of Confidentiality Provided to Respondents

The CIRB collects personally identifiable information (PII) from board members and institutions. This information may be completed in hard or electronic format and mailed or emailed to the CIRB Operations Office for data entry. Board members and institution 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 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 Act (Attachment 7) is available electronically and it is shared during the enrollment application process and is available on the CIRB website. 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 the CIRB, and conveys information to Institutions concerning studies reviewed by the CIRB and decisions made by the CIRB. .

The NIH Privacy Act Officer has reviewed this information collection and deemed the Privacy Act is applicable to this collection of information (Attachment 7). The information collected 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". This was published in the Federal Register on September 26, 2002, Vol. 67, p. 60776. Additionally, the Office of Human Subjects Research (OHSR) has reviewed this information collection and has deemed that "federal regulation for the protection of human subjects does not apply" (Attachment 8).

A.11 Justification for Sensitive Questions

PII is collected from board members and institutions in the form of name, address, telephone numbers, email address, social security number, employment information, financial information, educational level, etc. Personally identifiable information is collected for the Customer Satisfaction Survey. Additionally, sensitive information collected includes Board Members' social security number, home address, phone number and bank information if the direct deposit mechanism is used. Beyond the PII, there is no sensitive information collected, as defined by salary, medical history, religious preference, or related information.

A.12 Estimates of Annualized Burden Hours and Costs

Table A.12-1 indicates the annual burden of hours for all 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 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, NCI-sponsored institutions interacting with CIRB, enrolling into the CIRB, submitting Facilitated Review with the CIRB, or submitting protocol for review. The annualized burden is estimated to be 2,199 hours, which amounts to a total burden of 6,598 hours over a 3 year collecting period.

Table A.12-1. Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
CIRB Customer Satisfaction Survey (Attach 1)	Participants/ Board Members	1500	1	10/60	250
Request for 30 Day Website Access Form (Attach 2A)	Participants	25	1	10/60	4
Authorization Agreement and Division of Responsibilities between the NCI CIRB and Signatory Institution (Attach 2B)	Participants	340	1	30/60	170
NCI CIRB Signatory Enrollment Form (Attach 2C)	Participants	40	1	4	160
IRB Staff at Signatory Institution's IRB (Attach 2D)	Participants	25	1	10/60	4
Investigator at Signatory Institution (Attach 2E)	Participants	65	1	10/60	11
Research Staff at Signatory Institution (Attach 2F)	Participants	65	1	10/60	11
Investigator at Affiliate Institution with an IRB (Attach 2G)	Participants	25	1	10/60	4
Research Staff at Affiliate Institution with an IRB (Attach 2H)	Participants	25	1	10/60	4
Investigator at Affiliate Institution without an IRB (Attach 2I)	Participants	25	1	10/60	4
Research Staff at Affiliate Institution without an IRB (Attach 2J)	Participants	25	1	10/60	4
Institutional Contact for Signatory Institution (Attach 2K)	Participants	65	1	10/60	11
IRB at Signatory Institution (Attach 2L)	Participants	25	1	10/60	4

Component Institution at Signatory Institution (Attach 2M)	Participants	65	1	10/60	11
IRB at Affiliate Institution (Attach 2N)	Participants	25	1	10/60	4
Affiliate Institution without an IRB (Attach 2O)	Participants	25	1	10/60	4
Facilitated Review Acceptance Form (Attach 2P)	Participants	300	1	10/60	50
Study Review Responsibility Transfer Form (Attach 2Q)	Participants	80	1	10/60	13
Annual Institution Worksheet About Local Context (Attach 2R)	Participants	120	1	20/60	40
Annual Principal Investigator Worksheet About Local Context (Attach 2S)	Participants	120	1	20/60	40
Study-Specific Worksheet About Local Context (Attach 2T)	Participants	220	1	20/60	73
Study Closure or Transfer of Study Review Responsibility Form (Attach 2U)	Participants	120	1	10/60	20
Potential Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attach 2V)	Participants	120	1	15/60	30
Add or Remove Signatory and/or Component Institution Personnel (Attach 2W)	Participants	120	1	10/60	20
Add or Remove Affiliate Institution Personnel (Attach 2X)	Participants	120	1	10/60	20
Add or Remove Component Institution (Attach 2Y)	Participants	120	1	10/60	20
Add or Remove Affiliate Institution (Attach 2Z)	Participants	120	1	10/60	20
One Time Study Roll Over Worksheet (Attach 2ZA)	Participants	120	1	10/60	20
Change of Signatory Institution PI Form (Attach 2ZB)	Participants	120	1	10/60	20
CIRB Board Member Biographical Sketch Form (Attach 3B)	Board Members	25	1	15/60	6

CIRB Board Member Contact Information Form (Attach 3C)	Board Members	25	1	10	4
CIRB Board Member W-9 (Attach 3D)	Board Members	25	1	15	6
CIRB Board Member Non-Disclosure Agreement (NDA) (Attach 3E)	Board Members	25	1	10	4
CIRB Direct Deposit Form (Attach 4)	Board Members	25	1	15	6
NCI Adult/Pediatric CIRB Application for Treatment Studies (Attach 5A)	Participants	25	1	2	50
NCI Adult/Pediatric CIRB Application for Ancillary Studies (Attach 5B)	Participants	10	1	2	20
NCI Adult/Pediatric CIRB Application for Continuing Review (Attach 5C)	Participants	80	1	1	80
Summary of CIRB Application Revisions (Attach 5D)	Participants	20	1	30	10
Locally-Developed Material Submission Form (Attach 5E)	Participants	15	1	15/60	4
Application Request to Review Translated Documents (Attach 5F)	Participants	15	1	15/60	4
Adult Initial Review of Cooperative Group Protocol (Attach 6A)	Board Members	15	1	4	60
Pediatric Initial Review of Cooperative Group Protocol (Attach 6B)	Board Members	15	1	4	60
Adult Continuing Review of Cooperative Group Protocol (Attach 6C)	Board Members	130	1	1	130
Pediatric Continuing Review of Cooperative Group Protocol (Attach 6D)	Board Members	70	1	1	70
Adult Amendment of Cooperative Group Protocol (Attach 6E)	Board Members	10	1	2	20
Pediatric Amendment of Cooperative Group Protocol (Attach 6F)	Board Members	10	1	2	20

Adult Cooperative Group Response to CIRB Review (Attach 6G)	Participants	15	1	1	15
Pediatric Cooperative Group Response to CIRB Review (Attach 6H)	Participants	10	1	1	10
Adult Pharmacist's Review of a Cooperative Group Study (Attach 6I)	Board Members	10	1	2	20
Pediatric Pharmacist's Review of a Cooperative Group Study (Attach 6J)	Board Members	20	1	2	40
CIRB Statistical Reviewer Form (Attach 6K)	Board Members	30	1	30	15
Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN) (Attach 6L)	Board Members	40	1	10	7
Adult Expedited Amendment Review (Attach 6M)	Board Members	350	1	30	175
Ped Expedited Amendment Review (Attach 6N)	Board Members	150	1	30	75
Adult Expedited Continuing Review (Attach 6O)	Board Members	120	1	30	60
Ped Expedited Continuing Review (Attach 6P)	Board Members	70	1	30	35
Adult Expedited Study Closure (Attach 6Q)	Board Members	20	1	20	7
Ped Expedited Study Closure (Attach 6R)	Board Members	20	1	20	7
Adult Expedited Study Chair Response to Required Mod (Attach 6S)	Board Members	350	1	15/60	88
Ped Expedited Study Chair Response to Required Mod (Attach 6T)	Board Members	150	1	15/60	38
Reviewer Worksheet of Translated Documents (Attach 6U)	Board Members	15	1	15/60	4
Reviewer Advertisement Checklist (Attach 6V)	Board Members	10	1	20/60	3
Total		6,085			2,199

Table A.12-2 indicates the Annualized Cost to Respondents for all CIRB Board Members and participants. The total annualized cost to respondents is estimated to be $66,146, which amounts to a total annualized cost to respondents of $198,437.76 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 board members composition consists of individuals who represent a broad range of oncology scientific and nonscientific disciplines. Board members may include: oncology physicians, surgeons, nurses, patient advocates, pharmacists, ethicists, statisticians, attorneys, and other health professionals. According to the U.S. Department of Labor, Bureau of Labor Statistics (http://www.bls.gov/), the mean hourly earnings of production by major industry sector during May, 2012 are as follows: Healthcare Practitioners and Technical Occupations, $35.35; Life, Physical, and Social Science Occupations, $32.87; All Occupations, $22.01. Using these estimates we averaged the wage rate to be $30.08.

Table A. 12-2 Annualized Cost to Respondents

Form Name	Type of Respondent	Annual Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Cost
CIRB Customer Satisfaction Survey (Attachment 1)	Participants / Board Members	250	$30.08	$7,520.00

Request for 30 Day Website Access Form (Attachment 2A)	Participants	4	$30.08	$120.32
Authorization Agreement and Division of Responsibilities between the NCI CIRB and Signatory Institution (Attachment 2B)	Participants	170	$30.08	$5,113.60
NCI CIRB Signatory Enrollment Form (Attachment 2C)	Participants	160	$30.08	$4,812.80
IRB Staff at Signatory Institution's IRB (Attachment 2D)	Participants	4	$30.08	$120.32
Investigator at Signatory Institution (Attachment 2E)	Participants	11	$30.08	$330.88
Research Staff at Signatory Institution (Attachment 2F)	Participants	11	$30.08	$330.88
Investigator at Affiliate Institution with an IRB (Attachment 2G)	Participants	4	$30.08	$120.32
Research Staff at Affiliate Institution with an IRB (Attachment 2H)	Participants	4	$30.08	$120.32
Investigator at Affiliate Institution without an IRB (Attachment 2I)	Participants	4	$30.08	$120.32
Research Staff at Affiliate Institution without an IRB (Attachment 2J)	Participants	4	$30.08	$120.32
Institutional Contact for Signatory Institution (Attachment 2K)	Participants	11	$30.08	$330.88
IRB at Signatory Institution (Attachment 2L)	Participants	4	$30.08	$120.32
Component Institution at Signatory Institution (Attachment 2M)	Participants	11	$30.08	$330.88
IRB at Affiliate Institution (Attachment 2N)	Participants	4	$30.08	$120.32
Affiliate Institution without an IRB (Attachment 2O)	Participants	4	$30.08	$120.32
Facilitated Review Acceptance Form (Attachment 2P)	Participants	50	$30.08	$1,504.00
Study Review Responsibility Transfer Form (Attachment 2Q)	Participants	13	$30.08	$391.04

Annual Signatory Institution Worksheet About Local Context (Attachment 2R)	Participants	40	$30.08	$1,203.20
Annual Principal Investigator Worksheet About Local Context (Attachment 2S)	Participants	40	$30.08	$1,203.20
Study-Specific Worksheet About Local Context (Attachment 2T)	Participants	73	$30.08	$2,195.84
Study Closure or Transfer of Study Review Responsibility Form (Attachment 2U)	Participants	20	$30.08	$601.60
Potential Unanticipated Problem or Serious or Continuing Noncompliance Reporting Form (Attachment 2V)	Participants	30	$30.08	$902.40
Add or Remove Signatory and/or Component Institution Personnel (Attachment 2W)	Participants	20	$30.08	$601.60
Add or Remove Affiliate Institution Personnel (Attachment 2X)	Participants	20	$30.08	$601.60
Add or Remove Component Institution (Attachment 2Y)	Participants	20	$30.08	$601.60
Add or Remove Affiliate Institution (Attachment 2Z)	Participants	20	$30.08	$601.60
One Time Study Roll Over Worksheet (Attachment 2ZA)	Participants	20	$30.08	$601.60
Change of Signatory Institution PI Form (Attachment 2ZB)	Participants	20	$30.08	$601.60
CIRB Board Member Biographical Sketch Form (Attachment 3B)	Board Members	6	$30.08	$180.48
CIRB Board Member Contact Information Form (Attachment 3C)	Board Members	4	$30.08	$120.32
CIRB Board Member W-9 (Attachment 3D)	Board Members	6	$30.08	$180.48
CIRB Board Member Non-Disclosure Agreement (NDA) (Attachment 3E)	Board Members	4	$30.08	$120.32
CIRB Direct Deposit Form (Attachment 4)	Board Members	6	$30.08	$180.48
NCI Adult/Pediatric CIRB Application for Treatment Studies (Attachment 5A)	Participants	50	$30.08	$1,504.00

NCI Adult/Pediatric CIRB Application for Ancillary Studies (Attachment 5B)	Participants	20	$30.08	$601.60
NCI Adult/Pediatric CIRB Application for Continuing Review (Attachment 5C)	Participants	80	$30.08	$2,406.40
Summary of CIRB Application Revisions (Attachment 5D)	Participants	10	$30.08	$300.80
Locally-Developed Material Submission Form (Attachment 5E)	Participants	4	$30.08	$120.32
Application Request to Review Translated Documents (Attachment 5F)	Participants	4	$30.08	$120.32
Adult Initial Review of Cooperative Group Protocol (Attachment 6A)	Board Members	60	$30.08	$1,804.80
Pediatric Initial Review of Cooperative Group Protocol (Attachment 6B)	Board Members	60	$30.08	$1,804.80
Adult Continuing Review of Cooperative Group Protocol (Attachment 6C)	Board Members	130	$30.08	$3,910.40
Pediatric Continuing Review of Cooperative Group Protocol (Attachment 6D)	Board Members	70	$30.08	$2,105.60
Adult Amendment of Cooperative Group Protocol (Attachment 6E)	Board Members	20	$30.08	$601.60
Pediatric Amendment of Cooperative Group Protocol (Attachment 6F)	Board Members	20	$30.08	$601.60
Adult Cooperative Group Response to CIRB Review (Attachment 6G)	Participants	15	$30.08	$451.20
Pediatric Cooperative Group Response to CIRB Review (Attachment 6H)	Participants	10	$30.08	$300.80
Adult Pharmacist's Review of a Cooperative Group Study (Attachment 6I)	Board Members	20	$30.08	$601.60
Pediatric Pharmacist's Review of a Cooperative Group Study (Attachment 6J)	Board Members	40	$30.08	$1,203.20
CIRB Statistical Reviewer Form (Attachment 6K)	Board Members	15	$30.08	$451.20

Determination of Unanticipated Problem (UP) and/or Serious or Continuing Noncompliance (SCN) (Attachment 6L)	Board Members	7	$30.08	$210.56
Adult Expedited Amendment Review (Attachment 6M)	Board Members	175	$30.08	$5,264.00
Ped Expedited Amendment Review (Attachment 6N)	Board Members	75	$30.08	$2,256.00
Adult Expedited Continuing Review (Attachment 6O)	Board Members	60	$30.08	$1,804.80
Ped Expedited Continuing Review (Attachment 6P)	Board Members	35	$30.08	$1,052.80
Adult Expedited Study Closure (Attachment 6Q)	Board Members	7	$30.08	$210.56
Ped Expedited Study Closure (Attachment 6R)	Board Members	7	$30.08	$210.56
Adult Expedited Study Chair Response to Required Mod (Attachment 6S)	Board Members	88	$30.08	$2,647.04
Ped Expedited Study Chair Response to Required Mod (Attachment 6T)	Board Members	38	$30.08	$1,143.04
Reviewer Worksheet of Translated Documents (Attachment 6U)	Board Members	4	$30.08	$120.32
Reviewer Advertisement Checklist (Attachment 6V)	Board Members	3	$30.08	$90.24
Total		2,199		$66,145.92

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

NCI CIRB is not requesting any other additional burden or associated costs to respondents or recordkeepers for collection of information.

A.14 Annualized Cost to the Federal Government

The grand total cost to the government for one average year is $239,771. The cost to the government over 3-year OMB approval collection time period is $874,426.

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

Table A.14-1 Government Cost Distribution

Annualized Total Capital Costs;Operational/Maintenance and Purchase Costs	**Annual Average** (1 year average)	**3- year cost**
Purchase of hardware[2]	$2,317	$6,951
Purchase of software program licenses	$2,467	$7,401
IRB Manager Subscription	$39,316	$117,948
Generating, maintaining, disclosing or providing information	$7,604	$22,812
CIRB Board Staff (1.5 FTE 1 year, 2.5% FTE 2 years)	$239,771	$719,314
Grand Total	$239,771	$874,426

The total capital costs are based on expense incurred during NCI Central IRB Initiative contract and annualized per year to obtain the 3 year expense. The IRB Manager 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 of subscription for 3 years. 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 maintenance period is calculated to provide annual average to account for 3 years. The staff members that contribute directly to record keeping increases from 1.5 FTE to 2.5 FTE. This is due in part to the transition from the facilitated review model to the independent model. The totals are added together to calculate the total cost for a 3-year collection period.

[2] The purchase of hardware, software and the IRB Manager Subscriptions were inaccurately reported as a cost to the respondent (in Section A.13) in the 2011 submission. They are considered costs to the Federal Government.

A.15 Explanation for Program Changes or Adjustments

This is a request for a program change (i.e., considered a revision) that is the result of an agency's decision to make changes to the previously approved information collections. Initially, NCI CIRB review was conducted via a "facilitated review" process that streamlined local IRB review of adult and pediatric national multi-center cancer treatment trials. In 2012, the NCI conducted a pilot program to change the model for the NCI CIRBs to that of an independent model, which was well accepted. This pilot study was a generic sub-study under a separate OMB #: 0925-0046-16. This independent model is now the NCI CIRB operating model and all current members of the NCI CIRB will be transitioned over to the new model during 2013. In December 2012, the Association of the Accreditation of Human Research Protection Programs (AAHRPP) awarded the NCI CIRB with its independent model full accreditation.

With the evolving CIRB Initiative, project efficiencies have been implemented including revised forms with more direct questions and board specific forms/worksheets. Although there is an increase in the number of forms due in part to the new model and adding of a new board and the number of respondents (from 5,044 to 6,085 respondents; an increase of 1,181 respondents), the total burden has actually decreased by 121 hours (from 2,210 hours to 2,199 hours).

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.