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Central IRB Review of Oncology Trials: The NCI's Model

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Abstract: *The National Cancer Institute (NCI) has established a Central Institutional Review Board (CIRB) to eliminate redundant reviews and streamline the workload for IRBs and research staff participating in NCI-sponsored Cooperative Group trials. This article describes the way in which the NCI CIRB was developed, how it works, enrollment and utilization data, evaluations, and news. The NCI CIRB provides study participants protections by using a partnership between the local IRB and the NCI's CIRB.*

Introduction to IRB Responsibilities

An IRB has many responsibilities:

- Initial review by the full board
- Review of investigator responses to IRB requests
- Reviews after a study is open:
 - Full board review of amendments
 - Annual continuing reviews, usually by the full board
 - Review of adverse events distributed by the Cooperative Group
- Monitoring the conduct of the trial
- Review of locally-occurring adverse events as per the institution's standard operating procedures (SOPs).

Clinical research professionals spend a great deal of their time preparing IRB submissions and working with the IRB on the initial review. Once the study is open, clinical research professionals must submit amendments, continuing reviews, and serious adverse event reports.

The NCI CIRB can handle many of the responsibilities of local IRBs, reducing the workload of local IRBs and clinical research professionals at the institution. The CIRB conducts:

- Initial review by the full board
- Review of investigator responses to CIRB requests
- Reviews after the study is open.

The local IRB is left with monitoring the conduct of trials locally and reviewing locally-occurring adverse events as per the institution's SOPs.

Background of the NCI Central IRB

In August 1997, the *Armitage Report* tasked the NCI's Clinical Trials Program Review Group with helping the NCI to create a more efficient and effective clinical research effort by identifying redundant processes or procedures that could be either streamlined or eliminated. The review group quickly identified the Cooperative Group trials and the related required IRB review as a redundant process to be streamlined.

Cooperative Group trials require full board IRB review at every institution that wants to participate in a study. However, no institution can make any changes to the protocol. Review by every institution is a major redundant activity that is expensive for the local sites and wasteful of the time of both the IRBs and the clinical research teams.

The NCI responded with the Central IRB Initiative. The primary goal of the CIRB is to meet the demands of the *Armitage Report*: To reduce the significant local administrative burdens of multi-site trials while maintaining a high level of human subjects protection. There is also a positive secondary benefit that has come out of the CIRB. The CIRB has enhanced leverage compared to local IRBs, and it can positively influence human subjects protections. The CIRB can request that a Cooperative Group conducting a study respond to its questions, provide more information, or even make a change to the protocol. Previously, Cooperative Groups were not required and were unable

to respond to the requests of local IRBs. The Cancer Therapy Evaluation Program mandates that Cooperative Groups respond to the requests of the CIRB. This has positively influenced human subjects protections.

Table 1 describes the regulation (45 CFR 46.114) that provides the underpinnings of the NCI CIRB. It is a joint review arrangement. When the NCI decided to pursue this concept, staff perceived value in collaborating with the Office for Human Research Protections (OHRP). The NCI wanted to be sure to establish the CIRB in a manner acceptable with the OHRP and the FDA, since many sites could potentially be using the CIRB. It

was understood that the NCI wanted the sites to be compliant with the regulatory requirements and do well when audited.

The first decision was choosing which of the two review models for central IRBs that the OHRP allows to be used. The first model, the independent/standalone model, is generally what commercial IRBs follow. This is appropriate where there is no local IRB, if the local IRB does not want to be involved, or if the commercial IRB does not want to involve the local IRB. The central IRB using this model obtains an understanding of the local context through site visits, audits, teleconferences, and so forth.

Most institutions have some exposure to commercial models, through either having used one or at least being familiar with how they work.

The second model, shared responsibilities, more rare. This model is appropriate where a local IRB is already present. The central IRB can use the local IRB to understand the local context. There is no need for site visits, etc. An authorization agreement between the IRB that does the reviews and the IRB that accepts the review is required. The NCI chose the shared responsibilities model, which enables the NCI's CIRB to partner with local IRBs who are best positioned to

TABLE 1
The Regulatory Underpinnings of the NCI CIRB

- Frequent consultations with the Office for Human Research Protections (OHRP)
- 45 CFR 46.114: Cooperative research:
 - Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a *joint review arrangement, rely upon the review of another qualified IRB*, or make similar arrangements for avoiding duplication of effort.
 - Decision-making to determine the ‘review model:’
 - OHRP allows for different centralized IRB models to ensure the quality of human research protection (Guidance of August 27, 1998; updated July 21, 2000: *Knowledge of Local Research Context*) www.hhs.gov/ohrp/policy/local.html
 - Independent/standalone IRB model:
 - Appropriate where no local IRB exists
 - Understanding of local context obtained via site visits, audits, and teleconferences
 - Shared responsibilities model:
 - More appropriate where a local IRB is already present
 - Can utilize the local IRB for understanding of local context
 - No need for site visits, etc.
 - NCI chose a model where the CIRB and the local IRB share regulatory responsibilities – a partnership:
 - The CIRB’s primary function is initial and continuing review of studies, including amendments and adverse event review
 - The local institution’s primary function is consideration of local context, oversight of local performance, and review of locally occurring adverse events
 - Developed a new review term called “facilitated review,” during which the local IRB reviews the CIRB-approved study for local context considerations

understand local context issues. The CIRB offers its services at no cost.

The CIRB's primary function is the initial and continuing review of studies, including amendments and adverse event reviews. Anything that is related to conduct of the trial, oversight of local performance, local SOPs, and review of locally-occurring adverse events remains the responsibility of the local IRB.

A new review term was developed by the NCI and OHRP called "facilitated review." This is neither a full board review nor an expedited review by the local IRB. It is a facilitated review where the local IRB reviews the NCI CIRB-approved study for local context considerations. The local IRB Chair or a subcommittee reviews the documents that the CIRB has already approved plus the minutes of the CIRB meeting, the primary reviewers' comments, and the CIRB application. The local IRB Chair or a subcommittee determines if there are any local context issues that must be addressed. If there are not, the local IRB can decide to use the CIRB for this study.

How the NCI CIRB Works

After the Cooperative Group distributes a study to sites and a local investigator decides to open the study, the local IRB may use the NCI CIRB for the initial review (Table 2). The study documents are available on a password-protected section of the CIRB's Web site. When an institution enrolls in the CIRB, staffs of the IRB and the research team receive passwords to the restricted access section that contains the review documents.

The clinical research associate or the investigator downloads the study documents according to the local IRB's SOPs. The local IRB's Chair or a subcommittee reviews these documents and decides whether to accept facilitated review. If so, the IRB reports this through an NCI CIRB Web page that is only accessible to IRBs.

Institutions that are enrolled in the CIRB Initiative are under no obligation to use the NCI CIRB's review. The NCI is aware via anecdotes that some larger institutions do not want to use facilitated review

but they do use the CIRB's review documents to enhance and streamline their own reviews.

Once an institution's IRB reports acceptance of the facilitated review, the NCI CIRB becomes the reviewing IRB for that study and local investigators can begin the research. The "IRB of record" terminology is shared between the NCI CIRB and the local IRB.

There are a number of factors to consider when an institution is deciding whether or not to enroll in the NCI CIRB Initiative (Table 3). One is the speed of trial activation. When using facilitated review, the local IRB does not need to wait for its own IRB to conduct a full board review. The review documents are always on the CIRB Web site and available for downloading and submitting to the IRB chair or a subcommittee for review. A trial can usually be opened in under 14 days. It has been reported that trials have been opened within one day when a site had a potential study participant waiting in the clinic.

Other factors that should be considered when an institution is contemplating joining the NCI's CIRB Initiative include the time saved by the investigator, nurse, and/or clinical research associate because they do not have to complete an IRB application, compile and duplicate IRB submissions, or go back and forth with the IRB during the review process. The frequent submissions for continuing review, amendments, and adverse events are also eliminated. Using the NCI CIRB eliminates these reviews therefore is quite efficient for a site.

However, local IRBs differ in their willingness to use the NCI CIRB. Some institutions use the NCI CIRB but then require their investigators and clinical research associates to do redundant work to meet local

TABLE 2
The NCI CIRB's Facilitated Review Process: Initial Review

- The Cooperative Group distributes a study
- The local investigator decides to open the study
- The clinical research associate or the investigator downloads the CIRB-approved study documents from the CIRB Web site
- The local IRB chair or a subcommittee reviews the study documents and decides whether to accept facilitated review
- If the local IRB accepts facilitated review, the local IRB reports acceptance to the NCI CIRB through the NCI CIRB Web site
- The CIRB is the reviewing IRB for that study, and the local investigators can begin the research

TABLE 3
Factors to Consider When Deciding Whether to Join the NCI CIRB

- The NCI CIRB’s emphasis on speed of trial activation
- Investigator, nurse, and/or clinical research associate time, when using the NCI CIRB, eliminates:
 - Completing the IRB application
 - Compiling and duplicating IRB submissions
 - Back-and-forth with the IRB to gain study approval
 - Frequent subsequent submissions for amendments, continuing reviews, adverse events, etc.
- IRB members’ time and effort:
 - Using the NCI CIRB eliminates full board review of Cooperative Group trials
- The number of patients at a site with specific cancers:
 - Using the NCI CIRB makes it easier to open clinical trials for rare diseases

requirements. The NCI is trying to convince institutions to let the CIRB handle the review and not to require redundant work in order to maximize the efficiencies offered by using the CIRB. When institutions do fully use the NCI CIRB, IRB members save time and effort because they are not required to do a full board review for Cooperative Group trials. Also, using the NCI CIRB makes it easier to open trials for patients with rare cancers, where a site may have a small number of eligible patients.

The NCI has two oncology-specific CIRBs, the Adult CIRB and the Pediatric CIRB. Both CIRBs have a similar composition: One chair and 15 voting members. Generally, 20% to 25% of the members are patient advocates because their perspective is very important. About 44% of the members are physicians who are experts in oncology from the three main modalities as well as biomedicine. Other professionals — nurses, pharmacists, statisticians, and ethicists — account for about 37% of members. More information about the Adult CIRB and the Pediatric CIRB and their members is available on the NCI CIRB Web site (http://www.ncicirb.org/cirb_roster_brief.asp).

Utilization Data

There were 312 institutions enrolled in the NCI CIRB as signatory institutions (as of May 2010). Many of the signatory institutions have other IRBs that rely on their IRB for review. The NCI calls these institutions ‘affiliates.’ There were 712 signatory institutions and affiliates enrolled in the NCI CIRB (as of May 2010). An NCI audit at the end of August 2010 identified 881 enrolled signatory institutions and affiliates.

More than 11,000 facilitated reviews had been conducted for the adult and pediatric studies on the CIRB menu; more than 6,700 for the adult studies and more than 4,100 for the pediatric studies. The ten CTEP-sponsored Cooperative Groups — nine adult and one pediatric — participate in the NCI CIRB. The pediatric Cooperative Group, the Children’s Oncology Group, is very supportive of the NCI CIRB. Of the 2,109 Cancer Therapy Evaluation Program sites in the United States with open trials, 312 are CIRB-enrolled signatory institutions as of March 2010.

Some IRBs review adult Cooperative Group studies and have conducted 50 or more facilitated reviews. These

institutions have turned their entire Cooperative Group menu over to the NCI CIRB. There are 85 IRBs from that who have conducted 21 or more facilitated reviews of pediatric studies.

Evaluations

Local IRBs are interested in evaluations performed on the NCI CIRB. The NCI established an external evaluation panel with members from other divisions of the NCI and other non-NCI organizations to determine how to best evaluate the CIRB. The panel recommended maintaining the metrics on enrollment and utilization, which the NCI CIRB has done since its establishment in 2001. Table 4 provides an overview of this and other evaluations performed or underway: surveys, a cost analysis, and work on obtaining accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

In 2005, Research Triangle Inc. in Washington, D.C. conducted a satisfaction survey of local site IRB and research staff. Eighty percent of the respondents felt that participating in the CIRB saved them some or a great deal of time and effort. Sixty-five percent of the respondents rated their overall experience with the CIRB as good to very good.

Todd Wagner, PhD, an economist from Stanford University, conducted a cost/benefit analysis of the NCI CIRB (published in the *Journal of Clinical Oncology*, February 2010). This was an observational study comparing all sites using the NCI CIRB with sites using a local IRB. The results showed that the use of the CIRB resulted in faster reviews and reduced IRB and research staff time and effort, and that the total savings were higher when the CIRB was used as intended. Dr. Wagner quantified the results in cost. Now, the NCI has the science to prove that there is a savings when the CIRB is used, and even more so when used as intended.

TABLE 4
Evaluation of the NCI CIRB

- External review panel recommended maintaining metrics of enrollment and utilization:
 - Ongoing from beginning of the Initiative
- Satisfaction survey (of local site IRB and research staff):
 - Conducted by Research Triangle Inc. of Washington, DC in 2005:
 - 80% of respondents felt that participating in the CIRB saved them some or a lot of time and effort
 - 65% of respondents rated their overall experience as good to very good
- Cost analysis by Todd Wagner, PhD, Stanford University economist:

Published in the *Journal of Clinical Oncology*, February 2010 (<http://jco.ascopubs.org/cgi/content/full/28/4/662>)

- External review panel recommended obtaining AAHRPP accreditation:
 - In progress

a user name and password. The Web site has multiple search functions that may be used for finding trials, such as by Group, Study ID Number, Title, key word, etc. For each trial, there is a study-specific webpage with tabs for initial reviews, amendment reviews, continuing reviews, and adverse event reviews. The Web site was designed to parallel an institution's regulatory hard copy file.

To enroll in the NCI CIRB, the institution completes an enrollment form, which covers:

- Names of IRB(s) that review NCI Cooperative Group clinical trials
- Names of other institutions that rely on those IRBs for review of Cooperative Group trials, if any
- Contact information for the local investigator(s), research staff, and IRB.

Another survey, of sites that do not use the CIRB conducted by the Science and Technology Policy Institute in Washington, D.C., covered barriers to using the CIRB. Results of this survey recommended pursuing AAHRPP accreditation as an indicator of quality and encouraged the development of a model SOP for local IRBs to use in incorporating the CIRB into their IRB processes. Both recommendations have been accepted. The model SOP is available on the CIRB Web site and the NCI is working toward obtaining AAHRPP accreditation.

Kimberly Hahn published an article in the *SOCRA Source*, unbeknownst to the NCI, on "Measuring IRB Efficiency: Comparing the Use of the National Cancer Institute Central IRB to Local IRB Methods" (May 2009). The article was a retrospective analysis based on experiences at her institution. She demonstrated an increase in productivity for herself with fewer staff hours required after initiation of the CIRB. She also

said that: "The IRB process is most efficient and provides increased benefits in terms of time, costs, and patient safety, as well as other measures, when the central IRB is utilized."

From the investigator's perspective, Alan Keller, MD, made a presentation at the Institute of Medicine's National Cancer Policy Forum: Multi-Center Phase 3 Clinical Trials and NCI Cooperative Groups (July 2008) about "Multi-site Clinical Trials in the Community: Models and Methods: What Works, What Doesn't and Why." Dr. Keller was also very supportive of the CIRB as the key to reducing redundancy, cost, variability, and time, and the key to increasing oversight and safety. In fact, he encouraged the NCI to mandate the use of the CIRB.

The NCI CIRB Web Site

The NCI CIRB Web site has a participant's area where the restricted access information is located. Participants enter this area through

The institution must also complete an authorization agreement in which the institution agrees to partner with the CIRB as outlined in the division of responsibilities document. IRBs that are relying on the institution's IRB must be named on the authorization agreement.

NCI CIRB News

The NCI CIRB recently developed its own version of the informed consent document that must be used for adult trials. The CIRB's version is based on the Cooperative Group's model informed consent document and changes made by the CIRB that have been approved by the coordinating Cooperative Group. The NCI has also published a *NCI CIRB Handbook for Local Sites* (http://www.ncicirb.org/CIRB_Handbook.pdf) and rewrote its SOPs (http://www.ncicirb.org/CIRB_SOPs.pdf).

The Cancer Trials Support Unit posts Spanish translations of the informed consent document for most studies on

TABLE 5
Benefits of Participating in the NCI CIRB

- Benefits to research participants:
 - Oncology-specific multidisciplinary board
 - Dedicated review for study participant protections
 - Facilitated review allows local sites to open studies within days
 - Encourages sites to consider opening studies in rare diseases for those patients
- Benefits to investigators, research staff, and IRBs:
 - Streamlined processes:
 - Reduced workload: Fewer submissions and reviews
 - Completed IRB application provided
 - Elimination of full board review:
 - Reduced workload on local IRB members
 - Decreased local IRB time and costs:
 - CIRB becomes the reviewing IRB for the complete life-cycle of the protocol; advantages are cumulative over the many years of a phase 3 study

its website. The NCI CIRB will have approval of the Spanish translations available soon for participating sites to use.

Conclusion

Table 5 outlines the benefits of the NCI CIRB for research participants, investigators, research staff, and local IRBs. For research participants, the NCI CIRB provides an oncology-specific multidisciplinary board that is dedicated to conducting reviews to protect human subjects. Facilitative review allows sites to open a study in just a few days, which is especially helpful for studies in rare diseases. Some institutions using the CIRB open all new NCI Cooperative Group studies because it requires minimal additional work for them to do this. Others wait until they have an eligible subject before opening the study because facilitated review can be done quickly.

For investigators, research staff, and IRBs, using the NCI CIRB streamlines processes and reduces the workload. It eliminates full board review and decreases the time and costs for local IRBs. In adult trials, the CIRB only

reviews Phase 3 trials. Over the many years that a Phase 3 trial lasts, the advantages of using the CIRB review become cumulative. The Pediatric Central IRB reviews Pilot, Phase 2, and Phase 3 trials.

There are six easy steps to enrolling in the NCI CIRB:

1. Complete the CIRB enrollment form
2. Modify the institution's federal-wide assurance to include the CIRB
3. Sign the authorization agreement

4. Return the enrollment form/ authorization agreement to the CIRB
5. Create a local IRB SOP for utilizing the CIRB
6. Notify local investigators of the new process.

Table 6 provides contact information for the NCI CIRB, which encourages clinical research professionals and IRB members to contact them with any questions about the NCI CIRB.

TABLE 6
Contact Information for the NCI CIRB

- Website: www.ncicirb.org
- Email: ncicirbcontact@emmes.com
- Toll-free number: 888-657-3711
- Fax number: 301-560-6538
- Mailing address:
 - NCI CIRB
 - C/O The EMMES Corporation
 - 401 N. Washington Street, Suite 700
 - Rockville, MD 20850