NCI Central IRB Initiative

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- **Began August 1999 in consultation with OHRP (OPRR)**
- **Goal:**
  - **To enhance the protection of research participants by providing consistent expert IRB review before protocols are distributed to local investigators**
  - **To eliminate the significant local administrative burdens for multi-site trials while maintaining a high level of human subjects protection**

Selecting a CIRB Model

- **OHRP (OPRR) allows for different centralized IRB models**
- **See Guidance of August 27,1998 (updated July 21, 2000) entitled "Knowledge of Local Research Context"**
  http://ohrp.osophs.dhhs.gov/humansubjects/guidance/local.htm

- **Model A**
  - **Appropriate where no local IRB**
  - **Understanding of local context obtained via site visits, audits, teleconferences**
- **Model B**
  - **More appropriate where local IRB already present**
  - **Can utilize LIRB for understanding of local context**
  - **No need for site visits, etc.**

- **NCI chose Model B for practical reasons**
  - **Unlike many other CIRBs, the NCI CIRB does not exist in lieu of a local IRB**
  - **Local IRBs already exist and NCI must interface with them**
  - **Local IRB chair/members understand local research context better than national entity**
  - **Refer to it as the “facilitated review” model**

How does the facilitated review model work?

- CIRB approves protocol
- Local investigator is notified of protocol via
  - Routine Group activation announcement
  - CIRB e-mail

- If the local investigator decides to open protocol, s/he downloads the completed application, protocol and consent from the CIRB website
- Investigator submits documents to local IRB

- **Local IRB office downloads all CIRB review materials: primary reviews, detailed minutes, correspondence, etc. (some LIRBs request that the PI download all documents)**
- **Local chair/subcommittee reviews for local concerns and decides whether to approve**

- If LIRB accepts, they notify CIRB.
- The CIRB becomes the IRB of record. It handles amendments, continuing reviews, adverse events etc.
- If it does not accept, LIRB can decide to review the protocol themselves as per their own local procedures.

Division of Responsibilities

- **The CIRB's primary function is *initial and continuing review* of protocols**
- **The local institution's primary function is *consideration of local context and oversight of local performance***

Structure of the Initiative

- NCI Director appoints Board members with expertise in respective fields (consumer advocates, ethicists, physicians, nurses, pharmacists, statisticians)
  - No NCI employees
  - 25% consumer advocates
- Registered with OHRP

- **Two Central IRBs have been established**
  - **Adult CIRB reviews all phase 3 adult Cooperative Group protocols (started January 2001)**
  - **Pediatric CIRB reviews pediatric phase 2, phase 3 and pilot protocols (started November 2004)**

- Each board meets via a web-based meeting tool called Epanel and also meets in person twice a year
- Each board meets every two weeks (except during the months of the in-person meeting when there may be only one meeting)

- **Enrollment of institutions**
  - **Modify institution's FWA to include the CIRB**
  - **Sign authorization agreement**
  - **Create a local IRB SOP for utilizing the CIRB**
  - **Notify local investigators of the new process; copy CIRB operations office and provide local contact information**

FAQs

- Indemnification
  - Federal govt cannot indemnify
  - Commericial IRBs do not indemnify
- AE reporting
  - AEs accessed from national system; local PI does not have extra reporting requirements

- **Informed Consent Changes**
  - **OK to add local boilerplate**
- **Cost**
  - **No fee for participation**

Profile

- **Enrolled institutions: 295**
  - **Adult only institutions: 177**
  - **Pediatric only institutions: 47**
  - **Both adult and pediatric: 71**
- **Active studies open to accrual: 130**
  - **Adult studies: 98**
  - **Pediatric studies: 32**

Evaluation of CIRB Initiative

- Components
  - Use
  - Satisfaction with processes
  - Quality and compliance
  - Cost

- **Measure local utilization of facilitated review (internal tracking of LIRB activity)**
- **Quantify CIRB effect on local site time frames**
- **Assess the CIRB experience (contract with RTI):**
  - **Local IRB Chair (survey)**
  - **LIRB Coordinator (survey)**
  - **Site Principal Investigator for protocol (survey)**
  - **CIRB members (focus group)**

- **Demonstrate compliance (accreditation)**
- **Economic assessment (contract with economist)**

Outreach/Accreditation

- Potential 1800 adult research sites; have actively solicited only 400 to build foundation of program
- Accreditation

Benefits of Central Review

- Research Participants
- Local IRBs
- Investigators/Scientific Research

Benefits to Research Participants

- CIRB review occurs BEFORE protocol distributed nationally;
- CIRB has authority to make changes while local IRBs can only approve/disapprove
- Extricates full Board review process from local institutional politics

- Sophisticated patient advocates and experts in oncology conduct the reviews
- AE review more comprehensive than at local level
  - SAE subcommittee has multi-site context
  - Subcommittee can access drug monitors at IDB
  - LIRB can consult website re local AE
- Ease of use at local level results enables LIRB members to focus on local investigator initiated trials, drug co trials, and other aspects of human subjects protection program (eg, education)

Benefits to LIRBs

- Office does not need to duplicate forms for entire Board
- Entire Board does not need to meet to review protocol at any stage
- Ease of use at local level results enables LIRB members to focus on local investigator-initiated trials, drug co trials, and other aspects of human subjects protection program (eg, education)

Benefits to Investigators/Research

- Administrative
  - No advance preparation for IRB review at the local site
  - No waiting for the next meeting of the full board; investigators can enroll patients in trials much faster potentially as quickly as 24-48 hours
  - No need to submit continuing reviews, amendments or AE reports (except for AEs at local site) to the LIRB or the CIRB - CIRB becomes IRB of record
- More trials open per site
- Trials in rare diseases become feasible

Welcome to the Central IRB Initiative

partnering with local IRBs

The Central IRB (CIRB) Initiative is designed to help reduce the administrative burden on local IRBs and investigators while continuing a high level of protection for human research participants.

A local IRB's use of the CIRB facilitated review mechanism enables an investigator to enroll patients into adult and pediatric Cooperative Group clinical trials significantly faster than when employing the traditional method of IRB review.

The CIRB Initiative is sponsored by NCI in consultation with the Department of Health and Human Services Office for Human research Protections (OHRP).

What's New

- NEW CIRB Protocol Activity Update (12/17/04)
- Adult Sites Participating in the CIRB Initiative (12/10/04)
- Pediatric Sites Participating in the CIRB Initiative (12/10/04)
- Agenda for 1/7/05 Adult CIRB Meeting
- For CTSU Users: RSS Update
- ANNOUNCEMENT: Expansion of the NCI's Central IRB Initiative: The Pediatric Central IRB's Formation
- Has Contact Information at your Institution Changed?
- NCI Informed Consent Template Revised

>> more what's new

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