The NCI CIRB Initiative: Change and Growth

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The CIRB Initiative in Context

- **What is the CIRB Initiative?**
  - 3 Boards (member bios at www.ncicirb.org)
    - Adult Late Phase Emphasis CIRB
    - Adult Early Phase Emphasis CIRB
    - Pediatric CIRB

- **Menu**
  - National Clinical Trials Network (NCTN; formerly the Cooperative Groups) extramural treatment trials phase 3 and selected phase 2; ETCTN phase 1 and 2; COG phase 1, 2, 3 and pilot

- **Participants (users)**
  - Institutions whose investigators conduct the above trials (estimated 2800 unique sites)
Overview of the CIRB Model

• Previous Model of Facilitated Review
  – From 1999 – December 31, 2013 operated under a “shared responsibilities” model where IRB review responsibilities were shared by the CIRB and the Local IRB
  – Institutions chose to enroll
Facilitated Review

Cooperative Group Distributes Study

Local Investigator Chooses to Open Study

CRA or Investigator Downloads Study Documents from CIRB Website

Local IRB Chair/Subcommittee Reviews CIRB Documents and Decides to Accept Facilitated Review

Local IRB Reports Facilitated Review Acceptance to the CIRB via the CIRB Website

CIRB is the IRB Responsible for Review of the Study; Local Investigator May Begin Research
Overview of the CIRB Model

- **Independent Model**
  - As of January 1, 2014 the CIRB operates an “Independent Model”
  - CIRB is “IRB of Record”
    - Local IRB has no IRB review responsibilities
  - CIRB reviews institution’s local context considerations before the local PI can open the study
  - CIRB reviews locally occurring unanticipated problems or serious or continuing non-compliance
  - Institution is responsible for monitoring conduct of research
    - Including reporting concerns to CIRB
  - Institutions in NCTN required to enroll; can request waiver only if it can prove turn around time as fast as CIRB (process for requesting a waiver not yet established)
Why a model change for the CIRB?

• **Rationale for change to Independent Model**
  - AAHRPP encouraged
  - NCI anticipated model change would increase CIRB enrollment and utilization

• **Need for Pilot Study**
  - Impact on local institutions already using the CIRB
  - Feasibility and best practices for the CIRB Operations Office
Pilot Study of Independent Model

**Pilot**
- 22 sites
  - 20 sites already using facilitated review; 2 sites volunteered who were not previously enrolled
- 12 month duration
- 189 (not unique) studies opened
- NCI’s Office of Market Research and Evaluation surveyed IRB and research staff
  - 78% “very satisfied” or “extremely satisfied”
  - 84% “extremely” or “very likely” to recommend to colleagues
National Study Chair Submits Study to CTEP/NCI
CTEP/NCI Issues “Approval On Hold”
CIRB Conducts Review
CTEP Issues Final Approval
NCTN Group Distributes Study
Institutional PI Submits Study-Specific Worksheet to CIRB
CIRB Conducts Local Context Review (w/in 72 hours)
PI receives CIRB Approval

Institutions can enroll in CIRB at any time
Key Features of the CIRB Independent Model

- Framework is the same as previously
  - Institutions must complete enrollment process
  - CIRB review of protocol entails interaction with Study Chair/Group at national level
- CIRB is the IRB of Record
  - Local context considerations are under the purview of the CIRB
    - Annual Institution Worksheet
    - Annual Principal Investigator Worksheet
    - Study-Specific Worksheet
  - There is no relationship with the local IRB per se; the relationship is between the CIRB and the institution which remains responsible for the conduct of the research; there is no facilitated review
Key Features (cont’d)

- Local context considerations include
  - Does investigator have sufficient time to conduct and complete studies
  - Does investigator have an adequate number of qualified staff
  - Are facilities adequate to conduct studies
  - Confirming that boilerplate language for the informed consent document complies with federal regulations
  - Confirming that any unique institutional requirements are appropriately addressed

- CIRB must review completed Worksheets describing local context considerations
  - Local Context Reviewers on the CIRB fulfill all CIRB membership functions and present any local context consideration reviews to the convened CIRB, when necessary
Key Features (cont’d)

- **CIRB Review of the ICD**
  - CIRB reviews and approves the model informed consent document (ICD) as supplied by the Study Chair for initial review and amendments
  - Principal Investigators have the responsibility to insert into the CIRB-approved model ICD the CIRB-approved boilerplate language

- **Unanticipated problems and/or serious or continuing noncompliance reported directly to CIRB**
  - PI/Institution submits management plan, when applicable
  - CIRB makes determination and does reporting, when applicable
### Division of Responsibilities under Independent Model

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<th>CIRB</th>
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<tr>
<td>• Initial Review</td>
<td>• Ensures safe and appropriate performance of research at the site</td>
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<td>• Continuing Review</td>
<td>• Maintains records for CIRB-approved studies per Network Group guidelines</td>
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<td>• Amendment Review</td>
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<td>• Conducts reviews for local context concerns</td>
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<td>• Reviews/determines Unanticipated Problems both locally-occurring and trial-wide impact</td>
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Goals

• **2014/2015**
  - Plan/conduct required enrollment of NCTN and ETCTN institutions
  - Obtain AAHRPP reaccreditation
  - Establish another Board for cancer prevention trials for 2015
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