The NCI CIRB Initiative:
Change and Growth

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• **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

**CIRB**
- Initial Review
- Continuing Review
- Amendment Review
- Conducts reviews for local context concerns
- Reviews/determines Unanticipated Problems both locally-occurring and trial-wide impact

**Signatory**
- Ensures safe and appropriate performance of research at the site
- Maintains records for CIRB-approved studies per Network Group guidelines
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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