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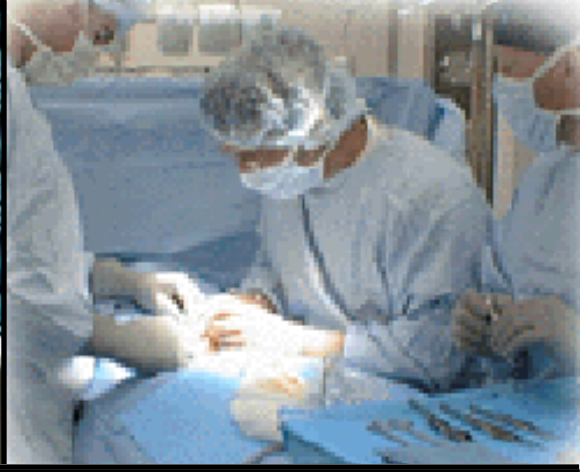

The NCI CIRB Initiative: Change and Growth

Jacquelyn L. Goldberg, JD
Head, CIRB Initiative

CTTI June 12, 2014

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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

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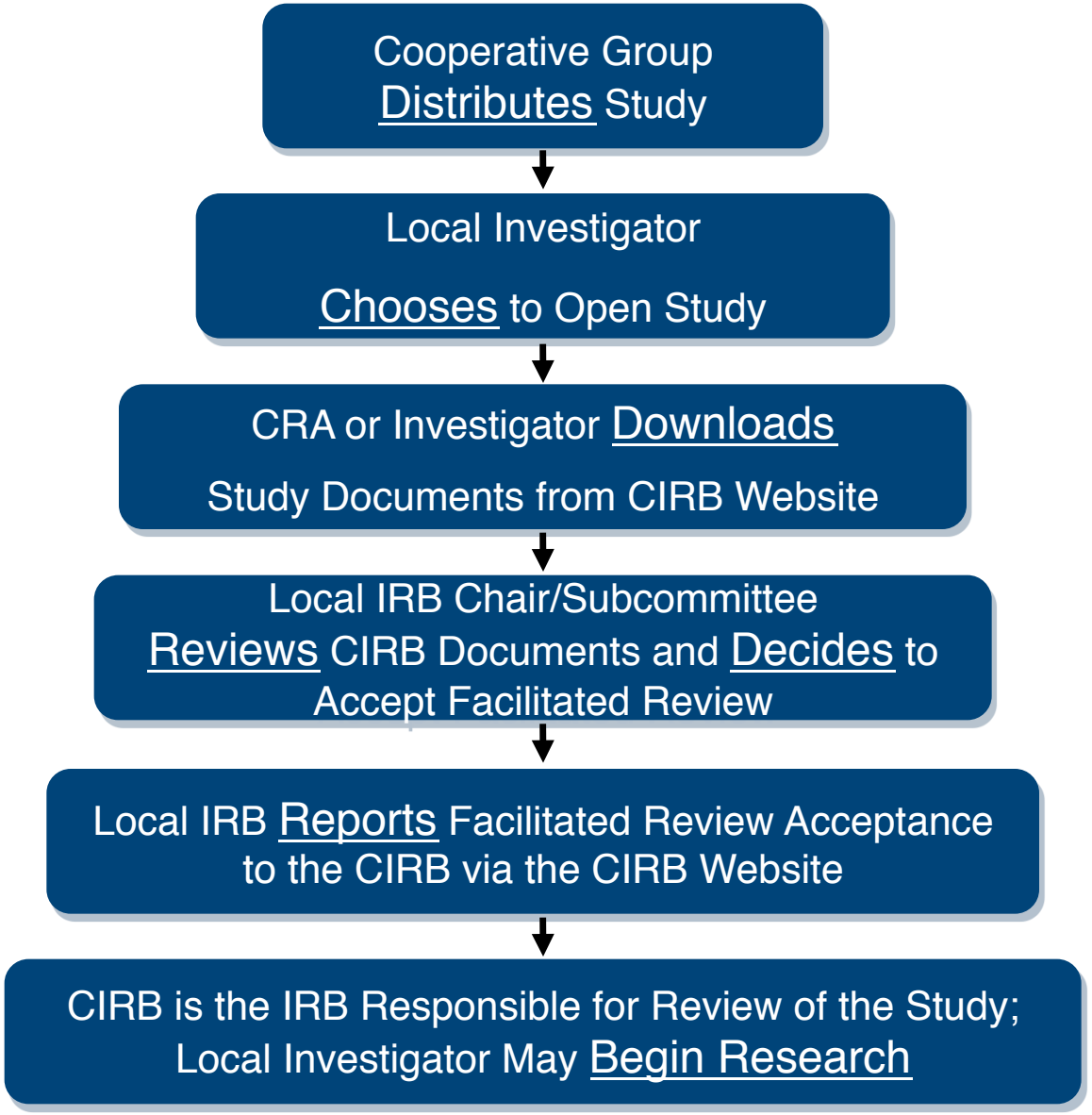
Facilitated Review



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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

Independent Model

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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NCI CIRB Website: http://www.ncicirb.org

Helpdesk Email: ncicirbcontact@emmes.com

Helpdesk Toll-free Number: 1-888-657-3711

May request a specific staff member when calling

Fax Number: 1-301-560-6538