The NCI Central Institutional Review Board (CIRB) Initiative

- Designed to reduce the administrative burden on local IRBs and investigators while continuing a high level of protection for human research participants
- Enables investigators to enroll study participants into NCI-Sponsored clinical trials significantly faster than when using local IRB review
- Accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

The NCI Central Institutional Review Board (CIRB) Initiative

- Comprised of 2 CIRBs:
 - Adult CIRB established in 1999, reviews Adult Cooperative Group Phase 3 trials
 - Pediatric CIRB established in 2004, reviews Pediatric (COG)
 Pilot, Phase 1/2, and Phase 3 trials
- Currently developing a third CIRB for review of early phase trials

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How it Works: CIRB Review to Study Activation

Cooperative Group <u>Distributes</u> Study

Signatory Institution Principal Investigator <u>Decides</u> to Open Study

Signatory Institution Principal Investigator

<u>Submits</u> the Study-Specific Worksheet About

<u>Local Context</u>

Signatory Institution Principal Investigator Receives Approval letter from CIRB

CIRB is the IRB of Record; Signatory Institution Principal Investigator May Begin Research

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Benefits of Using the CIRB

- Benefits patients and research participants
 - Oncology-specific, multidisciplinary Boards
 - Open trials faster
 - Easier to open trials for rare diseases
- Benefits for Investigators and research staff
 - Eliminates back-and-forth with IRB to gain study approval
 - Eliminates frequent subsequent submissions for amendments, continuing reviews, adverse events, etc.
 - Eliminates or reduces redundancy
- Benefits for IRB members
 - Saves IRB members' time and effort
 - Eliminates local IRB review of Cooperative Group trials

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Typical CIRB Composition

One Chair and 14 Voting Members (15 total)

Patient Advocates 20% (3)

Physicians 47% (7)

Other Professionals 33% (5)

Nurses 1

Pharmacists 2

Statistician 1

Ethicist 1

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Status of the Early Phase CIRB

- Early Phase CIRB is expected to begin reviews in June 2013
- Meetings will be held twice per month (1st and 3rd Tuesday)
- Meetings are held using an internet-enhanced conference call
 - In-person meeting will be held yearly in combination with an Education Day
- Currently recruiting members
 - Interested candidates should contact the CIRB Administrator at jhorigan@emmes.com

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Contact the NCI CIRB

Email: ncicirbcontact@emmes.com

CIRB Toll-free Number: 888-657-3711

Fax Number: 301-560-6538

Website: http://www.ncicirb.org

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