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)
• 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
How it Works: CIRB Review to Study Activation

1. Cooperative Group Distributes Study
2. Signatory Institution Principal Investigator Decides to Open Study
3. Signatory Institution Principal Investigator Submits the Study-Specific Worksheet About Local Context
4. Signatory Institution Principal Investigator Receives Approval letter from CIRB
5. CIRB is the IRB of Record; Signatory Institution Principal Investigator May Begin Research
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
## Typical CIRB Composition

- One Chair and 14 Voting Members (15 total)

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Advocates</td>
<td>20%</td>
<td>3</td>
</tr>
<tr>
<td>Physicians</td>
<td>47%</td>
<td>7</td>
</tr>
<tr>
<td>Other Professionals</td>
<td>33%</td>
<td>5</td>
</tr>
<tr>
<td>Nurses</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Pharmacists</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Statistician</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Ethicist</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
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
Email: ncicirbcontact@emmes.com

CIRB Toll-free Number: 888-657-3711

Fax Number: 301-560-6538

Website: [http://www.ncicirb.org](http://www.ncicirb.org)