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# NCI CIRB Initiative

NRG Oncology Semiannual Meeting
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## Agenda

- Overview of the CIRB
- Key definitions
  - *Signatory Institution*
  - *Component Institution*
  - *Affiliate Institutions*
  - *Local Context Considerations*
- Steps for enrolling in the CIRB
- Frequently Asked Questions
- Benefits of the CIRB

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1

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## Overview of the CIRB

- Goal
  - *Reduce the significant local administrative burdens of multi-site trials while maintaining a high level of human subjects protection*
- Three CIRBs
  - *Adult CIRB – Late Phase Emphasis*
    - Began reviews of Cooperative Group Phase 3 treatment trials in 2001
  - *Adult CIRB – Early Phase Emphasis*
    - Began reviews of phase 0, 1, 2 trials late 2013
  - *Pediatric CIRB*
    - Began reviews of COG phase 2, 3 and pilot trials in 2004

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2

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## Overview of the CIRB Model

- As of January 1, 2013 the CIRB operates under an independent model for review of NCI-sponsored research
- What is the "independent model"?
  - *CIRB continues to review studies as before*
  - *CIRB becomes IRB of Record for investigators*
    - Local IRB has no review responsibilities
  - *CIRB reviews institution's local context considerations before approving new study at institution*
  - *CIRB reviews locally-developed recruitment/educational materials; locally-occurring unanticipated problems or serious or continuing non-compliance; responds to investigator/institution questions*
  - *Institution is responsible for monitoring conduct of research*
    - Includes reporting concerns to CIRB

3

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## Signatory Institution

- The Signatory Institution in the CIRB Initiative is the institution whose Institutional Official signs the Authorization Agreement and Division of Responsibilities document
- The Signatory Institution's responsibilities are outlined in the Division of Responsibilities
- The Signatory Institution must have a Federalwide Assurance (FWA)
- The Signatory Institution must have independent oversight of the research

4

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## Signatory Institution's Component Institution(s)

- The Signatory Institution's Component Institution operates under a different name than the Signatory Institution but the Signatory Institution has legal authority for the Component Institution
- The following information for a Component Institution must be the same as the Signatory Institution:
  - *FWA number*
  - *Local context considerations*
    - If the local context considerations are not the same, the institution cannot be a Component Institution
  - *Boilerplate language and institutional requirements*
  - *The office that monitors the conduct of research*

5

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## Signatory Institution's Affiliate Institution(s)

- The following information for an Affiliate Institution must be the same as the Signatory Institution:
  - *Local context considerations*
    - If the local context considerations are not the same, the institution cannot be an Affiliate Institution
  - *Boilerplate language and institutional requirements*
  - *The office that monitors the conduct of research*

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6

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## Local Context Considerations

- What constitutes the CIRB's review of local context?
  - *Consideration of local population for any unique requirements*
  - *Confirmation that any institutional requirements, local and state laws are appropriately addressed*
  - *Consideration if investigator has sufficient time to conduct research safely*
  - *Consideration if investigator has an adequate number of qualified supporting research staff*
  - *Consideration if facilities are adequate to conduct research and protect study participants*
  - *Confirmation that boilerplate language for the consent form complies with Federal regulations*

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7

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## Division of Responsibilities under CIRB Model

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

Signatory Institution

- *Ensures safe and appropriate conduct of research at the institution*
- *Maintains records for CIRB-approved studies per network/program guidelines*

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8

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## Institutional Considerations Prior to Enrollment

- Identify the Signatory Institution
- Verify that any institutions relying on the Signatory Institution's IRB meet the CIRB's definition of a Component Institution or an Affiliate Institution
- Identify the individual(s) who will be the Signatory Institution Primary Contact(s)
- Review the information required by the CIRB to assess your institution's local context considerations
- If you have any questions, contact the CIRB Helpdesk before you begin the steps for Enrollment

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9

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## 6 Easy Steps – Summary of Enrollment

1. Complete and submit the NCI CIRB Signatory Institution Enrollment Form
   - *Located on the CIRB website (https://www.ncicirb.org) using the "Enrollment Packet" link under the heading "How to Join"*
   - *Provides general information about your Signatory Institution and any Component or Affiliate Institution as well as contact information for key personnel*
   - *Submit via email to the CIRB Helpdesk at ncicirbcontact@emmes.com*
2. Complete and submit signed Authorization Agreement and Division of Responsibilities document (requires signature of Signatory Official)
   - *Located on the CIRB website (https://www.ncicirb.org) using the "Enrollment Packet" link under the heading "How to Join"*
   - *Submit hardcopy signatures via mail to the CIRB Operations Office*

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10

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## 6 Easy Steps – Summary of Enrollment (cont.)

3. Modify your Institution's Federalwide Assurance (FWA), if applicable
4. Complete and submit the Annual Signatory Institution Worksheet About Local Context via IRBManager
   - *Contains descriptions of state and local laws, including required boilerplate language*
   - *A Word version of the Worksheet can be accessed on the CIRB website to view the questions prior to completion in IRBManager*
5. Complete and submit the Annual Principal Investigator Worksheet About Local Context via IRBManager
   - *A Word version of the Worksheet can be accessed on the CIRB website to view the questions prior to completion in IRBManager*
   - *Provides research activity descriptions*
6. Receive letter from the CIRB confirming that enrollment is complete and may begin to open studies

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11

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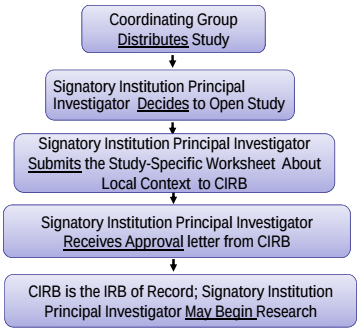
## After Enrollment: Opening a New Study

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12

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## Frequently Asked Questions

- CIRB Review of the Consent Form
  - *CIRB reviews and approves the model consent form as supplied by the Study Chair for each study*
  - *CIRB reviews and approves the institution's boilerplate language as supplied in the Annual Signatory Institution Worksheet*
  - *Principal Investigators have the responsibility to insert the CIRB-approved boilerplate language into the CIRB-approved model consent form*
- Possible unanticipated problems and/or serious or continuing noncompliance reported directly to CIRB
  - *PI/Institution submits form and management plan, when applicable*
  - *CIRB makes determination and does reporting, when applicable*
- Who will review a translated consent form?
  - *CIRB will review and approve; submit the Locally-Developed Material Submission Form, the translated document, and a copy of translator's certificate of accuracy*

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13

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## Benefits of Using the CIRB

- Benefits patients and research participants
  - *Oncology-specific, multidisciplinary Boards*
  - *Dedicated review for study participant protections*
  - *Opens trials faster, supports completing 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 submissions to IRB for amendments, continuing reviews, adverse events, etc.*
  - *Eliminates completing IRB application and duplicating IRB submission packets*
- Benefits for IRB members
  - *Saves IRB members' time and effort by eliminating full board review of network/program trials*

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14

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## Contacting the CIRB

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

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

15