
NCI CIRB PROCESS

JULY 26, 2017

CONSORTIA WEBINAR

LAURA COVINGTON

JOHN HORIGAN

AGENDA

- New CIRB website
- Think Tank Questions
- More Questions since March

NEW CIRB WEBSITE

- CIRB Website (<https://ncicirb.org>)
 - Created to improve navigation
 - Refine the content and make it shorter and easier to read
 - Add a search capability
 - Ensure that spreadsheets and documents are easily downloaded
 - Update the website

THINK TANK QUESTIONS

Education: CIRB Submission Process

- Introduces a page for the Networks (NCTN, ETCTN, NCORP, and Consortia) representatives
- Currently three Quickguides addressing submitting documents to the CIRB
 - Consortia processes for study submission to the CIRB are the same
- Submitting a Study for Initial Review
- More are in development

THINK TANK QUESTIONS

Education: Addressing CIRB Stipulations

- CIRB typically issues determination within 7 days of CIRB meeting
 - Letter is addressed to Study Chair (Protocol PI) and copied to DCP program staff
 - Review stipulations carefully
 - If concerns exist regarding specific stipulations, contact CIRB Operations Office with concerns; CIRB Ops Staff will clarify stipulation with CIRB members, or arrange a conference call for follow-up
 - If declining a stipulation, give a strong rationale for why, and indicate how the CIRB's concern is otherwise addressed

THINK TANK QUESTIONS

Education: CLO Site Coordinators would like to be copied on correspondence between CIRB and PIO

- **CIRB communicates its determinations to the Study Chair (Protocol PI) copying DCP program staff**
 - **CIRB Ops notifies DCP PIO of final CIRB approval**
- **Study Chair is responsible for communicating determinations and changes in protocol/consent form to CLO and other organizations**

THINK TANK QUESTIONS

Ensure that CIRB is aware of DCP templates, and processes.

THINK TANK QUESTIONS

Education: CIRB Local Context Submission

- Navigating the CIRB as a Consortia Site
- 30+ Quickguides for Institutions on the CIRB website
- Quickguides related to:
 - Managing a Site
 - Managing a Study
 - Special Considerations
 - IRBManager Basics

THINKS TANK QUESTIONS

Education: Using IRBManager

- Quickguides for navigating IRBManager
- Finding Approval Letters and Approved Boilerplate Language

CLO Site Coordinators reported having difficulty searching for protocols in IRB Manager and finding that protocol documentation is occasionally not updated in a timely manner.

MONITORING VISITS WHEN RELYING ON THE CIRB

- Studies open under the CIRB are now being monitored
- Questions are coming in on what is expected at monitoring visits for studies open under the CIRB
- POs will need to provide additional information to the monitors, including:
 - Annual Signatory Institution Worksheet content and approval letter
 - Boilerplate language included in the Annual Signatory Institution Worksheet approval letter
 - Annual Principal Investigator Worksheet content and approval letter
 - Study-Specific Worksheet approval letter
- Monitors verify that everything approved by the CIRB is happening at the institution
- Reporting Audit Findings

CIRB HELPDESK CONTACT

PHONE: 888.657.3711

NCICIRBCONTACT@EMMES.COM

IDENTIFY YOU ARE ASKING ABOUT A CONSORTIA SITE