AGENDA

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

- **CIRB Website** ([https://ncicirb.org](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
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
Ensure that CIRB is aware of DCP templates, and processes.
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

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IDENTIFY YOU ARE ASKING ABOUT A CONSORTIA SITE