
INCREASING AWARENESS OF THE LOCAL CIRB REVIEW/PROCESS/ CHALLENGES FOR CIRB APPROVED CONSORTIA STUDIES AND AMENDMENTS

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OBJECTIVES

- Understand the purpose of the Authorization Agreement and Division of Responsibilities document.
- Understand the institutional oversight responsibility for studies open with the CIRB.
- Discuss the limitations and challenges of the local process.

AUTHORIZATION AGREEMENT AND DIVISION OF RESPONSIBILITIES

AUTHORIZATION AGREEMENT AND DIVISION OF RESPONSIBILITIES

- Agreement between the Signatory Institutions and the CIRB
- Signed by the institutional official of the Signatory Institution's FWA – Signatory Institution Primary Contact should have a copy
- Lists the SI's Component and Affiliate Institutions
- Defines the responsibilities of the CIRB and the Signatory Institution
- Mirrored in Section 3.0 of the CIRB SOPs.

AUTHORIZATION AGREEMENT AND DIVISION OF RESPONSIBILITIES

CIRB Responsibilities

- Conduct initial, amendment, and continuing reviews of the study
- Review local context considerations as submitted to the CIRB via Worksheets by PO
- Review potential unanticipated problems and serious or continuing noncompliance for CLO and PO

AUTHORIZATION AGREEMENT AND DIVISION OF RESPONSIBILITIES

Signatory Institution Responsibilities

- Report the names of Component and Affiliate Institutions and any subsequent changes
- Notify the CIRB if PI changes for a study
- Notify the CIRB of regulatory deficiencies cited on an audit
- Incorporate CIRB-approved boilerplate language
- Maintain a regulatory file

AUTHORIZATION AGREEMENT AND DIVISION OF RESPONSIBILITIES

Signatory Institution Responsibilities: *Ensure the safe and appropriate performance of research at the Signatory Institution and its institutions*

- Ensure the initial and ongoing qualifications of investigators and research staff
- **Oversee the conduct of the research**
- **Monitor protocol compliance**
- Provide a way to receive and address concerns
- Investigate, manage, and notify the CIRB of study-specific incidents

OVERSEEING THE CONDUCT OF THE RESEARCH

- Institution is responsible for knowing the research that is being conducted at their institution
- Local IRBs have frequently been tasked with this responsibility in addition to serving as the IRB of record for research conducted at the institution
- Challenge: Relying on an external IRB, so no IRB regulatory review should be done by the local IRB, BUT they still have the oversight responsibilities

OVERSEEING THE CONDUCT OF THE RESEARCH

- How does an institution determine internal feasibility?
- Should the local IRB determine whether the institution has the resources (equipment, personnel, etc.) to do this study?
- How is the oversight implemented at the institution?
- Who is responsible for making sure all the requirements are met?

MONITORING PROTOCOL COMPLIANCE

- In some institutions, the local IRB is responsible for conducting compliance audits.
- Local IRB purview may also include review of SAEs, unanticipated problems, and serious or continuing noncompliance occurring at the institution.
 - Goal is to ensure that the institution is aware of what is happening on the research they conduct.

MONITORING PROTOCOL COMPLIANCE

- Institutional policy identifies responsibilities and expectations when relying on an external IRB.
- What needs to be monitored and who is the best group to do it?

QUESTIONS AND ANSWERS

QUESTIONS

What is the role of the Signatory Institution Primary Contact?

- Varies from institution to institution
- Multiple people can be assigned the role
- Receives all correspondence from the CIRB related to local context reviews
- Frequently responsible for updates to the Annual Signatory Institution Worksheet
- CIRB contact for questions that arise

QUESTIONS

What are some challenges of working with the Signatory Institution Primary Contact?

- Individual may be part of another department within the organization
- Individual may have developed local context with a specific investigator or department in mind
- Individual may not have time to coordinate with a new program

QUESTIONS

How to engage the Signatory Institution Primary Contact?

- CIRB Helpdesk will identify them for you
- If multiple, see if one is able to provide assistance
- If contact is overburdened, potentially identify a Signatory Institution Primary Contact for the Consortia program

QUESTIONS

Which short form consent should the PO use?

- The PO can use a short form consent approved for their institution
- The CIRB-approved short form consent is available for institutions to use after:
 - The institution's short form policy is submitted to the CIRB on either the Annual Signatory Institution Worksheet or the Annual PI Worksheet

QUESTIONS

What should an institution do if they have a study participant and the translated consent form is not available, but is being created?

- An approved short form consent should be used
- The translated consent form should be provided when available (not required if it is not a language usually translated)
- Boilerplate language can be translated by the institution and submitted on the Annual Signatory Institution Worksheet for all studies

QUESTIONS

What IRB documentation is reviewed at annual monitoring visits?

- The approval letter from the CIRB
- The institution's boilerplate language
- The study consent form to confirm that only the institution's boilerplate language has been added
- Study-specific modifications, if applicable, should be found in the approval letter

QUESTIONS

Do the Annual Signatory Institution Worksheet and Annual Principal Investigator Worksheet need to be submitted each year?

- Annual Signatory Institution Worksheet should be submitted whenever there is a change to boilerplate language or oversight
- Annual PI Worksheet should be submitted whenever there are substantive changes
- CIRB sends a reminder each year to review your Worksheet and update if there are changes
- If there are no changes, a submission is not required

CIRB HELPDESK CONTACT

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