



Division of Responsibilities Between the Central IRB and Participating Local Institutions

The following division of responsibilities is based on the premise that the Central IRB's (CIRB) primary function is initial and continuing review of Adult and Pediatric research protocols and that the local institution's primary function is consideration of local context and oversight of local performance for these protocols. The local institution, through its own local IRB, will decide on a protocol-by-protocol basis whether to accept the review of the CIRB or to conduct its own review of the protocol.

The responsibilities of the CIRB are to:

- 1) Perform initial reviews of new research protocols, discuss any issues with the lead organization and Study Chair, and make a final decision of approval or disapproval of the protocol;
- 2) Maintain and make accessible to a designated local IRB at the local institution the CIRB application, protocol reviews, letters to Study Chairs, approvals and disapprovals, and minutes of the CIRB meetings;
- 3) Carry out Continuing Reviews, reviews of Serious Adverse Events, reviews of protocol amendments, reviews of DSMB reports, and reviews of any other documents submitted by the lead organization or Study Chair;
- 4) Notify each local institution that has accepted the CIRB review of any new materials that have been reviewed for an active protocol and any changes in the protocol approval status;
- 5) Maintain a Board membership that satisfies the requirements of 45 CFR 46, 21 CFR 56 and provide special expertise as needed from Board members or consultants to adequately assess all aspects of each protocol;
- 6) Make available to the local institution the roster of CIRB membership and the CIRB Standard Operating Procedures and policies;
- 7) Ensure that CIRB members receive proper initial and continuing education on topics relevant to human subjects protections;
- 8) Notify the local institution immediately if there is ever a suspension or restriction of the CIRB's authorization to review protocols; and
- 9) Notify the local institution of any CIRB policy decisions or regulatory matters that might affect the institution's reliance on CIRB reviews or performance of the research at the local institution.

The responsibilities of the local institution are to:

- 1) Ensure the safe and appropriate performance of the research at its institution. This includes, but is not limited to, monitoring protocol compliance, any major protocol violations, and any serious adverse events occurring at the institution, and providing a mechanism by which complaints about the research can be made by local study participants or others. Any actions taken as a result of problems that are identified in these areas should be shared with the CIRB and reported as required by the procedures established by the protocol's lead organization;
- 2) Ensure that the investigators and other staff at the local institution who are conducting the research are appropriately qualified and meet the institution's standards for eligibility to conduct research;
- 3) Notify the CIRB immediately if there is a suspension or restriction of a local investigator;
- 4) Provide to the CIRB and keep current the names and addresses of local contact persons who have authority to communicate for the local IRB, such as the local IRB administrator;
- 5) Establish a written procedure by which the local IRB will receive and review the CIRB materials for protocols to be performed at the local institution. For each CIRB reviewed protocol (approval or disapproval) that is submitted to the local IRB by a local investigator:
 - Review the CIRB's materials;
 - Determine if there are any local context issues that must be addressed by the local IRB;
 - Determine if the CIRB review is acceptable to the local IRB; and
 - Decide whether to accept the CIRB review or conduct a separate local full board IRB review.Report to the CIRB the decision about local acceptance/rejection of the CIRB review. Notify the CIRB if there is ever a change in the acceptance/rejection of the CIRB review;
- 6) As appropriate, add local restrictions, stipulations, or substitutions to CIRB approved informed consents. Deletion of CIRB approved requirements in the protocol and Informed Consent Form is not allowed, and substantive changes that affect the meaning of CIRB approved requirements are not allowed;
- 7) If the local IRB accepts the CIRB approval of a protocol, maintain in the local IRB records documentation of the decision and evidence that it has received and considered all CIRB material relevant to the protocol;
- 8) Maintain an OHRP approved Assurance for human subjects research;
- 9) Maintain a local IRB whose membership satisfies the requirements of 45 CFR 46 and 21 CFR 56;
- 10) Maintain a human subjects protection program, as required by the DHHS OHRP;
- 11) Ensure that local IRB members and local investigators receive proper initial and continuing education on the requirements related to human subjects protections;
- 12) Notify the CIRB immediately if there is ever a suspension or restriction of the local IRB's authorization to review protocols; and
- 13) Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.