



The Central Institutional Review Board Initiative

in consultation with OHRP

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How does the CIRB process work? (Detailed Version)

Here is a more detailed review of the steps involved in the review process for the Central IRB and the local IRB:

CIRB Procedures

1. As outlined in the NCI CIRB Operations Office Standard Operating Procedures, the CIRB receives the protocol, the informed consent document(s), a completed CIRB application and, when appropriate, an investigator drug brochure from the Cooperative Group via the Protocol Information Office at NCI. The CIRB staff clarifies any initial issues with the Study Chair of the Cooperative Group, designates the next meeting date for review, and assigns primary reviewers (two for the Adult CIRB and three for the Pediatric CIRB). The CIRB Chair decides if additional expertise (e.g., a consultant) needs to be brought into the review process.
2. The CIRB members meet at least once a month. At the meetings the Board members discuss the protocol and may consult by telephone with the Study Chair to explore any concerns they may have.
3. Per the NCI CIRB Board Standard Operating Procedures, the Board takes one of the following actions for each protocol: approve, approve pending modification, table, or disapprove. Any non-approval is followed up with communication with the Study Chair to resolve, wherever possible, outstanding issues identified by the Board.
4. After approval or disapproval, the Study Chair of the Cooperative Group is formally notified.
5. For each protocol, the CIRB's primary reviews, minutes, notification letters, and any other correspondence are posted in a separate section of this web site for participating institutions to access.
6. In addition to conducting initial reviews, the CIRB conducts Continuing Reviews and reviews of Serious Adverse Events (SAEs), Data Safety Monitoring Board (DSMB) reports, protocol amendments, national subject recruiting materials, etc. These actions are also posted on the web site for prompt access by participating institutions.

LOCAL INSTITUTION PROCEDURES

1. A local investigator at a participating institution who wishes to enroll subjects in a CIRB-approved protocol downloads the Local IRB Facilitated Review Packet and any other documents as desired by their local IRB, from the Participant side of this website and submits these documents to his/her local IRB. Alternately, local IRB Office Staff can download these same materials for submission to the IRB.
2. Each local IRB designates at least one voting member of the IRB to conduct the "facilitated review" of the study that the investigator submitted. The role of the person(s) is to determine whether there are local concerns that need to be addressed and whether to accept the CIRB Review. Local IRBs need to comply with OHRP guidance that, "...an institution relying upon another institution's IRB has a responsibility to ensure that the particular characteristics of its local research context are considered through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other members of its local IRB."
3. The designated person(s) examines the materials available on the CIRB web site, and/or such other information as they may seek, so they can decide whether a particular protocol and informed consent documents are acceptable and whether they are appropriate in their local context. We have created the Quick Guide and the Procedures Checklist for your use.
4. Local IRB policies should specify if that person(s) has more than a "yea or nea" authority, whether they (or other IRB members) can propose/approve additions to the protocol or word substitutions in the informed consent (see next paragraph). Local IRBs have the option to accept the CIRB approval "as is", accept it with de minimus modifications (see below), or they may decide not to accept the CIRB review and require that the investigator submit the protocol for full Board review at their site. If the designated person(s) do not

accept the CIRB review they may still utilize CIRB written materials as resources for their local process.

5. Local boilerplate additions to the informed consent dealing with state and local law, institutional requirements, or IRB policies may be added to the local consent form. No CIRB approved information may be deleted from the informed consent document. Local IRBs may also make minor word substitutions or additions in the informed consent document, particularly to facilitate better comprehension by the local population, as long as the proposed changes do not alter the meaning of the CIRB approved contents. Additional risks may be added to the informed consent document. Revisions/changes to the local consent form other than those described above require full board review at the local level, facilitated review may not be used, and the CIRB cannot serve as the IRB of record for the protocol at the local site.
6. The local IRB must notify the Central IRB Operation's Office each time it accepts the CIRB review of a protocol. Clicking on the "Facilitated Review Acceptance" button/link within the main menu for each protocol and completing the Facilitated Review Acceptance Form does this. In order for the CIRB to become the Official IRB of Record for the site for a particular study, this form needs to be completed and submitted. A separate form must be submitted for each protocol review that is accepted.

The CIRB will use this reply to set up a database both for record keeping and notification purposes. The CIRB will notify the local IRB when there are any actions taken on the protocol, e.g., an SAE report provoking a change in the consent form, an approved protocol amendment, a change in the protocol/informed consent resulting from the Continuing Review, etc.

DIVISION OF CIRB AND LOCAL RESPONSIBILITIES - DRAWING THE LINE

What exactly will the CIRB do for the participating local IRBs, and what do the local IRBs have to do in this shared arrangement? It is important that the combined efforts results in a complete program of human subjects protection. For more details please refer to the following document which clarifies the respective responsibilities of the parties; "Division of Responsibilities between NCI's Central IRB and Local Institutions".

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