USING THE CIRB TO REVIEW SOUTHWEST ONCOLOGY GROUP TREATMENT STUDIES
October 2003

Web site: http://www.ncicirb.org/
CIRB Quick Guide: http://www.ncicirb.org/CIRB_Users_Guide.PDF
Phone: 1-888-657-3711
E-mail: cirbcontact@westat.com

The Central Institutional Review Board (CIRB) Initiative is a project sponsored by the National Cancer Institute (NCI), in consultation with the DHHS Office of Human Subjects Protections (OHRP) created to develop an innovative approach to human subjects protection. The unique feature of the CIRB is its "facilitated review" process that can streamline the protocol activation process at local sites for national multi-center NCI-sponsored Phase III cancer treatment trials.

Facilitated review is only used when your IRB of record is the NCI's Central Institutional Review Board (CIRB).

Applications and procedures for entering into this agreement with the CIRB can be found on the Web site www.ncicirb.org.

Once the CIRB has approved a Phase III study and your site has arranged with the CIRB to be the "IRB of Record," a local investigator or staff member is responsible for downloading the protocol, informed consent document, and the CIRB application from the participant side of this Web site and submits these documents to his/her local IRB.

Each local IRB designates at least one voting member of the local IRB to conduct the "facilitated review" of the study that the investigator submitted. The designated person decides whether a particular protocol and informed consent document are acceptable and whether they are appropriate in their local context.

Local IRBs have the option to 1) accept the CIRB approval "as is," 2) accept it with minimal modifications, or 3) decide not to accept the CIRB review and require that the investigator submit the protocol for full board review at the local site. If the designated person does not accept the CIRB review, they may still utilize the CIRB written materials as resources for their local process.

As part of this "facilitated review," the local IRB may add stipulations or local requirements to protocols, particularly to increase subjects' safety, to clarify procedures, etc., but may not delete or contradict any protocol contents. Local boilerplate additions or deletions to the informed consent dealing with state and local law, institutional requirements, or IRB policies may be considered. 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. Per current OHRP and NCI guidances, any informed consent changes must be justified in the IRB minutes and sent to the Cooperative Group administering that protocol. Changes do NOT need to be sent to the CIRB.

The local IRB must notify the CIRB Administrative Office each time it accepts the initial CIRB review of a protocol. This can be done by clicking on the "Protocol Acceptance" button/link within the main menu for each protocol and following the directions for completing the Protocol Acceptance Form. 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 to the CIRB. A separate form must be submitted for each initial protocol review that is accepted.

The CIRB will notify the local IRB when there are any actions taken on the protocol, i.e., a Serious Adverse Event (SAE) report resulting in a change in the consent form, an approved protocol amendment, a change in the protocol/informed consent resulting from the continuing review, etc.

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Submission of IRB approval to the CTSU is the responsibility of the local site. The site should write in "facilitated" review on the CTSU Transmittal Form (*until the box has been added by the CTSU on the next revision of the form*). The CIRB should also be noted as the IRB of Record. The CIRB date of approval should be used, not the local site's date of facilitated review. Completion of these documents takes into consideration that necessary assurances are in place with the different parties involved. Study coordinators must use the IRB Registration Number of the "IRB of Record" (the CIRB).

If a site wants to join the CIRB after the site has already opened a study, and the site would like the CIRB to become the IRB of record for that protocol, the site must close the study with their local IRB and reopen the study through the CIRB.

For local site review of amendments, SAEs, continuing reviews, etc., the local IRB no longer has to perform these reviews for a study when they are using the CIRB, but they can if they elect to. The CIRB posts these reviews on their Web site and it is up to the local IRB to retrieve and make note of the reviews and approvals. There is also no requirement by the CIRB that a site notify the CIRB that a facilitated review of an amendment has taken place. In certain cases, if the cooperative group requires documents to be submitted to the CTSU, then the local site is still responsible for this submission. Again, the CIRB is the IRB of Record, and thus, it is the date of the CIRB approval that should be used as the date of amendment approval.

For further information about the division of responsibilities for the CIRB and the local IRB, go to http://www.ncicirb.org/Div_Responsibilities1.PDF.