

FULL BOARD DECISIONS

A majority vote of the quorum is required for decisions; questions from and hesitations of, all members are respected. Members with any financial interest in the study, representatives of the sponsor and the principal investigator may participate in discussion but are asked to leave during final deliberation and the vote.

Approval:

The IRB finds no regulatory or ethical reason to deny approval. An approval letter will be issued by the IRB to a specific investigator. Conditions, beyond the usual ones, may be attached to an approval.

Approval contingent: The IRB agrees in principle to approve the application but approval is not issued until specific modifications or clarifications are made. (*IRBs are urged to restrict this action to very objective questions and dictated consent form changes. We extend this to responses evaluable by an experienced IRB member.*) Negotiations will be carried out by the chair or vice-chair. Only when the reviewer agrees that the requirements have been met will the restrictions be removed and approval given. If the decision is by the full board review the approval period dates back to the date the full board made their decision.

Request for more information (tabling):

The IRB requires more information prior to making a decision. Another IRB meeting is necessary. This decision does not imply future approval or disapproval - only a lack of information.

Disapproval:

When the IRB cannot approve a protocol in its present form, the applicant will be given the opportunity to discuss the reasons for disapproval. Such discussion is intended to allow those modifications of the protocol needed to gain approval. Disapproval cannot be overturned at any other level.

EXPEDITED REVIEW DECISIONS The assigned reviewer may make one of two decisions:

Approve

The reviewer may grant approval on behalf of the IRB. The reviewer may ask clarifying questions and may ask for appropriate changes on behalf of the IRB prior to approval. Expedited decisions are listed for information on the following full agenda and the file is available for questions. This is to encourage consistency among reviewers and to keep everyone informed and is not intended to second-guess the reviewer. The study may start upon receipt of the approval letter.

Refer to full board.

The reviewer may refer to full board for any reason whatsoever. The reviewer cannot disapprove any application.

NON-SIGNIFICANT RISK DEVICES

The IRB agrees with the sponsor's contention that the investigational device, ***as the device is to be used within the context of the study***, does not pose a potential for serious risk of harm to the subjects in that study. This is a very separate decision, using a different risk definition from the risk within the protocol or as described on the consent form. This decision allows a study to proceed without first going to FDA. Business harms arising from a decision with which FDA disagrees are borne by the sponsor.

