

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Review of New Applications	Date Effective 11/05/04	Supercedes P&P dated 6/16/04

Full Committee Review

Research that is more than minimal risk is reviewed at a convened meeting of the full Committee. In order to review the research, a majority of the voting members must be present, including at least one member whose primary concerns are in a non-scientific area. A physician must be present when reviewing FDA-regulated research. The Committee cannot review or approve research if a quorum fails during the meeting by recusal of members with conflicting interests, early departure, or absence of a non-scientist. A full Committee meeting may be cancelled for lack of quorum, lack of a non-scientific member, or other reasons determined by a Co-Chair.

Applications are placed on each Committee’s agenda in the order in which they are received in the CHR Office. The schedule of full Committee meetings is available on the CHR website.

Application materials are sent to CHR members at least one week before the meeting. Those attending the meeting receive the application, the consent documents, and other materials, such as advertisements, interview scripts or recruitment letters. The primary reviewer also receives the complete grant application, sponsor’s protocol, and questionnaires, and for an investigational drug or device study, the Investigator’s Brochure. At the discretion of the Co-Chair, the investigator may be invited to attend the meeting to clarify unresolved issues. The investigator must, however, leave during the discussion and vote.

During the review, the primary reviewer summarizes his or her review of the project and states his or her recommendations. The Committee determines whether the project and proposed study methods meet the criteria for approval or whether revisions are required. The consent document is reviewed for accuracy, clarity, and inclusion of required and optional elements. By a majority of those eligible to vote, a project is either: (1) approved as submitted; (2) conditionally approved pending receipt of required minor revisions; (3) deferred pending review of the revised proposal at a subsequent full Committee meeting, or (4) disapproved. Specific changes may be requested by the Committee as a condition for approval. In such cases, when only the agreement of the investigator to the requested changes is required, the Committee may delegate review and final approval of the changes to a Co-Chair or a single CHR reviewer under an expedited review procedure.

Written minutes of each full Committee meeting include: (1) attendance, (2) the number of votes to approve, defer, disapprove, or abstain, (3) the basis for requested changes or for

disapproving the research, and (5) a summary of controversial issues and their resolution. Minutes are reviewed, revised as required, and approved at a subsequent full Committee meeting.