

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 008
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103,109, 115

SUBJECT: Initial Application Materials to be Reviewed at Full Committee

1. The IRB Committee must obtain information in sufficient detail to make the determinations required under federal regulations, when conducting the initial or full Committee review of proposed research.
2. Materials to be provided to the IRB Committee.
 - a) The following materials should be provided to the primary reviewer:
 1. A completed IRB application with a signature page.
 2. Full investigator's or sponsor's protocol.
 3. Proposed informed consent document(s) and/or script as appropriate.
 4. Copies of surveys, questionnaires, or videotapes.
 5. Copies of letters of assurance or cooperation with research sites.
 6. Relevant and complete grant applications.
 7. Investigator's brochure.
 8. Advertising/recruitment flyers intended to be seen or heard by potential subjects, including email solicitations.
 - b) Materials to be provided to non-primary reviewers: All IRB Committee members shall receive copies of the above mentioned materials with the exception of the grant application. However, all materials and complete documentation shall be available to all members for review at the convened meeting, or prior to the meeting upon request.
 - c) These materials should be received by members via courier or mail sufficiently in advance of the meeting date to allow for review of this material.
3. Grant Application. The primary reviewer shall review the grant application, if any, to ensure that the research described in the IRB proposal is consistent with the grant application. A copy of the grant application or proposal shall be retained by the IRB Office and made available to any IRB member who may wish to review it. The IRB may require the investigator(s) to summarize and cross-reference materials, identify

any IRB approved protocols that describe the proposed research, and either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies.

4. IRB Review of NIH Approved Informed Consent documents for NIH supported Multi-center Clinical Trials. The IRB Committee must receive and review a copy of the NIH approved sample informed consent document and the full NIH approved Investigator's protocol as a condition for review and approval of the local informed consent document. Any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the investigator, approved by the IRB Committee, and reflected in the IRB Committee minutes.
5. Inclusion of Women, Children, Minorities, and other vulnerable populations in Research. NIH supported investigators must provide details of the proposed involvement of humans in the research, including the characteristics of the subject population, anticipated numbers, age ranges, and health statuses. The proposed research should specify the gender and racial/ethnic composition of the subject population, as well as criteria for inclusion or exclusion of any sub-population.