

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 043
SECTION: RECORDS AND DOCUMENTATION
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: August 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.115

SUBJECT: IRB Committee Meeting Agenda – Contents

1. New IRB proposals submitted for review. At convened meetings, the IRB shall review all newly proposed human subject research. This excludes those projects that either meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) or one or more of the expedited categories as authorized in 45 CFR 46.110.
2. Continuing review applications. At a convened meeting, the IRB shall review all continuing human subjects research at intervals appropriate to the degree of risk, but not less than once per year. This excludes those projects that either meet one or more of the exemption categories as provided by 45 CFR 46.101(b) or one or more of the expedited categories as authorized by 45 CFR 46.101(b)(8) or (9).
3. Expedited review determinations. When a determination regarding a review conducted utilizing expedited review procedures has been made, this must be documented in the agenda provided to the full Committee for the next possible convened meeting as authorized in 45 CFR 46.110. The documentation must include a citation to the specific permissible category justifying the expedited review, and must advise all committee members of research proposals that have been approved under the expedited review procedure.
4. Major amendments. At a convened meeting, the IRB shall review substantial, major proposed changes to approved human subjects research. This excludes those projects that either meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) or one or more of the expedited categories as provided in 45 CFR 46.110.
5. Notification of approvals by Chair and Minutes. The agenda will include a section on Notification of Approvals by the Chair such as expedited approvals, exempt approvals, and the previous month Committee minutes.
6. Noncompliance. The IRB Office shall report promptly to the IRB Committee members any serious or continuing noncompliance with the regulations or requirements of the IRB by including an item on the next official IRB Committee meeting agenda.
7. Serious and unexpected adverse events. The IRB shall review serious, unexpected adverse events. Factors that help determine the need for review at the convened meeting are the seriousness of the event, whether the event is described in the study

protocol and informed consent document, whether the event occurred at a location for which the IRB is the IRB of records, and the Investigator's recommendation as to whether the adverse event was a direct result of a subject's participation in the research study.

8. Audits and monitoring. The results of any audit or monitoring by the IRB should be reported to the Committee on the agenda of the next regularly scheduled meeting. However, if information gathered during the audit or monitoring process indicates that a subject of a research project is or has been exposed to unexpected serious harm, the IRB may suspend or terminate the research project prior to the next regularly scheduled meeting.
9. Monthly education for IRB members. At each convened meeting, a member of the IRB or the IRB Office shall educate and update the IRB members in regard to current federal regulations, local policies and procedures, changes to federal regulations, human subject research news or topics, or any other relevant items as requested by the IRB.