

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 041
SECTION: IRB MEMBERSHIP
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103

SUBJECT: Local Research Context

1. The IRB must fulfill its responsibilities under its Assurance with the federal government regardless of the IRB's geographic location relative to the Institution and the research. This is particularly important when the research involves greater than minimal risk to subjects or vulnerable categories of subjects.
2. When the IRB is geographically removed from the local research context, the IRB must demonstrate that it has obtained necessary information about the local research context through compliance with one of the following standards. These standards reflect minimum levels of adequacy. More stringent standards may be required depending upon the nature of the proposed research or the relevant research context.
 - a) Minimal Risk. Where the research involves minimal risk to subjects, the IRB should demonstrate that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants.
 - b) Greater than Minimal Risk. Where the research involves greater than minimal risk to subjects but the local research context involves no intervention or interaction with subjects and the principal risk associated with the local research context is limited to the potential harm resulting from a breach of confidentiality, the IRB should demonstrate that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants. Examples of information may include anticipated scope of research activities, types of subject populations involved, institutional commitments and regulations, standards of professional conduct, equitable selection of subjects, protection of confidentiality and privacy of subjects, language understood by prospective subjects, and other safeguards to protect the rights and welfare of vulnerable subjects.
 - c) Greater than Minimal Risk. Where the research involves greater than minimal risk to subjects and paragraph (b) does not apply, the IRB should demonstrate that it has obtained necessary information about the local research context through one or more of the following mechanisms, or through other mechanisms deemed appropriate by OHRP or the proposed research and the local research context.

- Personal knowledge of the local research context on the part of one or more IRB members, such knowledge having been obtained through extended direct experience with the research institution.
 - Participation by one or more appropriate consultants in convened meetings of the IRB. Such consultant(s) should have personal knowledge of the local research context, such knowledge having been obtained through extended, direct experience with the research institution.
 - Prior written review of the proposed research by one or more appropriate consultants in conjunction with participation by the consultant(s) in convened meetings of the IRB, when such participation is required by the consultant(s) or the IRB.
 - Systematic, reciprocal, and documented interchange between the IRB and elements of the local research context. Such interchange should include periodic visits to the research site by one or more of the IRB members in order to maintain knowledge of local research context, periodic discussion with appropriate consultant(s) about local research context, regular interaction with one or more designated institutional liaisons, and review of relevant written materials.
3. When the IRB desires to avoid duplication of effort, the IRB may rely on the review of another OHRP Assurance holding institution. The review arrangement must be approved in writing by OHRP and by appropriate officials of the institutions involved. When relying on another IRB's review, the FSU IRB must ensure that the particular characteristics of the local research context are considered, either through knowledge of the local research context by the reviewing IRB (see paragraph 2 above), or through subsequent review by appropriate designated institutional officials.