

SYRACUSE UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM STANDARD OPERATING PROCEDURES			
TITLE: KNOWLEDGE OF LOCAL RESEARCH CONTEXT			DOCUMENT NUMBER: 005
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Title: KNOWLEDGE OF LOCAL RESEARCH CONTEXT

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the process for the collection, submission, and review of sufficient information regarding local research context for research within the jurisdiction of the Syracuse University (SU) Institutional Review Board (IRB).

2.0 Policy:

It is the policy of the SU IRB to obtain sufficient knowledge of the local research context to fulfill its responsibilities under its Assurance, regardless of the geographical location of the research.

The SU IRB must fulfill the responsibilities under its Assurance with the Federal government regardless of its geographic location relative to the Institution and the research. This is particularly critical when the research involves greater than minimal risk to the participants or vulnerable categories of participants.

When the SU IRB is either geographically removed from the site in which the research will be conducted, the SU IRB is serving as another institution's IRB of record, or when the research involves a distinct participant population (e.g. Veterans, Amish, etc.), the IRB must demonstrate that it has obtained the necessary information about the local research context through compliance with required standards. These standards reflect minimal levels of adequacy. More stringent standards may be required, depending on the nature of the proposed research or the relevant research context.

When the SU IRB wishes to avoid duplication of effort, in accordance with DHHS regulations at 45 CFR 46.114, the SU 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 SU IRB has a responsibility to ensure that the particular characteristics of the local research context are considered, either 1) through knowledge of the local research context by the reviewing IRB; or 2) through subsequent review by appropriate designated institutional officials, such as the IRB Chair and/or other members of its local IRB.

3.0 References and Reference Documents:

45 CFR 46.114

OHRP Guidance Document: Knowledge of Local Research Context, July 21, 2000

4.0 Procedure:

4.1 Investigator Responsibilities.

4.1.1 The Investigator will obtain documentation of the necessary information required under the DHHS regulations for verification of local research context when the proposed research will be conducted in an area geographically removed from the SU IRB, the SU IRB is serving as another institution's IRB of Record, or when the research involves a distinct participant population (e.g. Veterans, Amish, etc). This documentation should include:

4.1.1.1 The anticipated scope of the outside institution's involvement in the research activities;

4.1.1.2 The types of participant populations likely to be involved;

- 4.1.1.3 The size and complexity of the institution;
- 4.1.1.4 Any institutional commitments, regulations, and/or applicable laws specific to the outside institutions;
- 4.1.1.5 Standards of professional conduct and practice at the outside institution;
- 4.1.1.6 The methods of equitable selection of participants;
- 4.1.1.7 Methods for protection of privacy of participants;
- 4.1.1.8 Method for maintenance of confidentiality of data;
- 4.1.1.9 Language(s) understood by prospective participants;
- 4.1.1.10 Methods for minimizing the possibility for coercion of undue influence in seeking consent;
- 4.1.1.11 Safeguards to protect the rights and welfare of vulnerable participants; and
- 4.1.1.12 Determination and, specifically, documentation that provisions to protect the privacy of participants and maintain confidentiality of data are adequate.
- 4.1.2 The Investigator is responsible for addressing local research context at each continuing review interval.
- 4.1.3 The Investigator must promptly report to the IRB any changes in the local research context that may influence or alter the risk/benefit ratio.

4.2 IRB Responsibilities.

- 4.2.1 The IRB must have experience and expertise necessary to review and make determinations regarding local research context. This may be achieved through:
 - 4.2.1.1 Submission of sufficient documented information regarding local research context by the Investigator;
 - 4.2.1.2 Personal knowledge of the local research context on the part of one or more IRB members, such as knowledge having been obtained through extended, direct experience with the research institution, its participant populations, and its surrounding community; or
 - 4.2.1.3 The Committee may request a written review by a consultant(s) knowledgeable of the local research context. The consultant may then be invited to participate (either physically or through audiovisual or telephone conference) in the convened meeting of the IRB.
- 4.2.2 The IRB must demonstrate that it has obtained the necessary information about the local research context through compliance with required standards. These standards include the following:
 - 4.2.2.1 **Minimal risk.** When the research involves minimal risk to the participants, the IRB should demonstrate that it has obtained necessary information about the local research context through written materials or discussion with appropriate consultants.
 - 4.2.2.2 **Greater than minimal risk without intervention/interaction with participants.** When the research involves greater than minimal risk to the participants but the local research context involves no intervention or interaction with participants 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:
 - 4.2.2.2.1 Demonstrate that it has obtained necessary information about the local research context through written materials or discussions with appropriate consultants and necessary information under DHHS regulations described above in 4.1.1; and
 - 4.2.2.2.2 Determine and specifically document that provisions to protect the privacy of participants and maintain confidentiality are adequate.
 - 4.2.2.3 **Greater than minimal risk with intervention/interaction with participants.** When the research involves greater than minimal risk and the Investigator and/or key study personnel will have interaction or intervention with the participants or the risk associated with the local research context is broader than 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 one or more of the following mechanisms or through other mechanisms deemed appropriate by OHRP for the proposed research and local research context:

- 4.2.2.3.1** 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, its participant populations, and its surrounding community;
 - 4.2.2.3.2** Participation (either physically or through audiovisual conference) by one or more appropriate consultants in a convened IRB meeting. 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, its participant populations, and its surrounding community. The consultant(s) may participate in the discussion and provide a recommendation but they are not a voting member;
 - 4.2.2.3.3** Prior written review of proposed research by one or more appropriate consultant(s) (see 4.2.2.3.2 above), in conjunction with participation (either physically or through audiovisual conference) by the consultant(s) in convened IRB meetings, when such participation is deemed warranted either by the consultant(s) or by any member of the IRB. The consultant(s) may participate in the discussion and provide a recommendation but they are not a voting member; and/or
 - 4.2.2.3.4** Systematic, reciprocal, and documented interchange between the IRB and elements of the local research context. Such interchange should include:
 - 4.2.2.3.4.1** Periodic visits to the research site, occurring several times per year, by one or more IRB members in order to obtain and maintain knowledge of the local research context, including the research institution, its participant populations, and its surrounding community;
 - 4.2.2.3.4.2** Periodic discussion with appropriate consultants knowledgeable about the local research context;
 - 4.2.2.3.4.3** Regular interaction with one or more designated institutional liaisons; and
 - 4.2.2.3.4.4** Review of relevant written materials.
- 4.2.3** Local research context must be reviewed at the time of continuing review of the proposal.
- 4.2.4** The Committee may monitor the sufficiency of information submitted from the Investigator during its random auditing and monitoring activities.

4.3 ORIP/IRB Administrator Responsibilities.

- 4.3.1** The ORIP/IRB Administrator will pre-review the submitted research proposal to assure that local research context has been addressed, when applicable.
- 4.3.2** The ORIP/IRB Administrator will assist the IRB with identifying a consultant(s) and will assure distribution of the appropriate review materials, when applicable.
- 4.3.3** The ORIP/IRB Administrator will maintain documentation of local research context and will update the database accordingly.

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7-18-07
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