

Title: Local Context and Participant Context Reviews

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Standard Operating Practice: 16

16.1. Executive Summary

When reviewing research in international settings or research involving people considered contextually vulnerable, the IRB may need additional expertise and insight to properly evaluate potential risks and benefits to participants as a result of the research. This document details information regarding the additional review procedures, how they occur, and what they contribute to the IRB review process.

16.2. Standard Operating Practice

The NC State IRB may require local context or participant context reviews for international research or research including populations that may be contextually vulnerable before final IRB approval is granted.

16.3. Operational Procedures

When research is conducted outside the United States or includes participants within the United States who are likely vulnerable due to the research, investigators and the IRB must evaluate the appropriateness of the research in the local setting. The IRB does not always have the expertise to make this determination and must consult an outside expert for their risk assessment. The IRB office requests the completion of local context or participant context reviews, and it is the principal investigator's responsibility to facilitate the completion of the review and provide the IRB with appropriate documentation. These reviews assist the IRB in making appropriate risk assessments and review determinations.

16.3.a. Local Context and Participant Context Reviews

16.3.a.i. Local Context

1. A local context review is an additional review within the IRB process. The researcher provides the IRB protocol and all supplemental materials to an identified expert. The expert reviews all materials and provides the researcher and IRB office with insight regarding risk to participants. This insight may result in required changes to the protocol or supplemental documents. This review includes an assessment of the research activities in the context of the participant's culture, language, customs, norms, accepted activities, and laws and expectations.
2. A local context review will occur when the proposed study requires expedited or full board review. On a case-by-case basis, the IRB office staff may request a local context review in order to determine if an exemption determination can be made.
3. A local context review is completed by an expert in the culture, language, customs, norms, accepted activities, and laws and expectations that relate to the participants in the study (see section 16.3.b below).

16.3.a.ii. Participant Context

1. A participant context review is an additional review within the IRB process. The researcher provides the IRB protocol and all supplemental materials to an identified expert. The expert reviews all materials and provides the researcher and IRB office with insight regarding risk to participants within the United States. This insight may result in required changes to the protocol or supplemental documents. This review includes an assessment of the research activities in the context of the participant's culture, language, customs, norms, experiences, accepted activities, laws, expectations, and community and national climate affecting the target population.
2. A participant context review will occur when the IRB office or a full board member determines that they do not have sufficient expertise to make risk assessments regarding the population in the context of the proposed research activities.
3. A participant context review is completed by an expert in the culture, language, customs, norms, experiences, accepted activities, laws, expectations, and community and national climate affecting the target population (see section 16.3.b below).

16.3.b. Selection of Reviewers

16.3.b.i. Local Context

1. If it is noted in the IRB application that the research will take place in an international setting, the investigator will be prompted to include the contact information for a consultant with cultural expertise who is willing to provide the review.
2. The identified reviewer should be someone familiar with the local culture who can identify any context or culture-specific risks to human subjects that might otherwise go unrecognized. A local researcher, a colleague at a local university, a senior researcher at NC State with extensive experience in the local setting, or a community member in the local setting who also understands research and advocacy. The IRB office may verify the appropriateness of the identified reviewer.
3. Reviewers may not be a part of the research team or have a stake in the research project.
4. Reviewers are not required to have a Ph.D. or other terminal degree, but they must have expertise in the local context in which the research will be conducted. An example of expertise would be an individual who, for a lengthy period of time, is a current or former participating member of the community targeted for research.
5. If the study takes place in a territory of the United States, though it is not considered international research, a local context review may be required.

16.3.b.ii. Participant Context

1. In addition to vulnerable subject populations that are covered in the subparts of the federal regulations for human subjects research such as children, those who are incarcerated, and pregnant people, other individuals may be contextually vulnerable or otherwise require additional considerations in terms of their research participation. If the IRB reviews research that involves participants it deems contextually vulnerable to additional risk, coercion, undue influence, or exploitation, a participant context review process will be required.
2. The participant context reviewer will be selected by the investigator, or, in some circumstances, by the IRB.
3. When full board members do not have sufficient expertise to conduct a participant context review to evaluate if risks are minimized and the safeguards in the study are appropriate, the IRB will request the investigator to facilitate a participant context review.
4. The participant context review must be able to identify any context- or participant-specific risks to human subjects.
5. The participant context review must be done by someone with expertise regarding the participant population.
6. This reviewer may be a researcher, practitioner, or advocate in the field related to the participants. Reviewers are not required to have a Ph.D. or other terminal degree
7. Reviewers may not be a part of the research team or have a stake in the research project.

16.3.c. The Review Process

1. Once the reviewer is identified, the researcher will request a local or participant context review. In some cases, multiple reviewers may be required due to study design and research questions.
2. Once the reviewer agrees to the review, the researcher provides the reviewer with the IRB proposal, all study documents, and an IRB form to complete that contains a list of questions for the reviewer to address.
3. The reviewer's responses to these questions must be completed by the reviewer, digitally or physically signed, saved as an uneditable or digitally locked document, and uploaded to the IRB application by the researcher.
4. Any changes suggested or required as a part of this context review must be made by the researcher. The completed context review is used to aid the IRB in its evaluation of the risks and benefits to participants, thus enabling the criteria for approval to be addressed in relation to the local culture or the inclusion of a vulnerable population.

16.3.d. Use of the Local or Participant Context Review

1. Once the IRB receives the completed local/participant context review, the review is reviewed and provided to the final reviewer for the study.
2. The final study reviewer may require changes to the study design based on the local/participant context review suggestions or requirements.