

Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #12	Participant and Local Context Reviews and Consultants	Date Effective:
Approved by IRB Chair	<i>R. Andrew Shanely</i>	Date: 1/23/2025
Approved by RP Director	<i>Shante' Mathes</i>	Date: 02/18/2025

I. PURPOSE

This document details Appalachian State University's IRB's standard for research with human participants' review process involving consultants to assist in the review of a study where a local or participant "context" review may be needed to assess risks and benefits to participants. These requirements are designed to address contextual vulnerability of participants and/or regional contexts that must inform research design. The requirements that apply to research that may require an additional "contextual review" are described below.

II. AUTHORITY

In accordance with [45 CFR 46](#), the HHS Policy for the Protection of Human Research participants, compliance with pertinent international, federal, and state laws, or applicable regulations that provide additional protections for participants must be followed.

III. RESPONSIBILITY

1. Research personnel are responsible for complying with all international, federal, state, and local laws pertaining to research with participants for any location where those research activities take place. Research personnel are expected to facilitate additional reviews that may be needed as a result of their research, including a local context review or a participant context review. Research personnel are expected to identify experts, follow directions from the research protections (RP) staff, and use the provided materials from the Appalachian State University IRB to facilitate this review.
2. Research protections (RP) staff are responsible for facilitating the review and approval of all participants research completed by Appalachian State University stakeholders. As a part of this responsibility, the staff must perform a risk/benefits assessment that includes addressing legal issues and participant vulnerability. In some cases, the IRB lacks the specific expertise of international law, customs, and cultures, or they lack expertise with unique populations. When this occurs, the staff must identify what context review is required, provide the research staff with necessary materials to facilitate the review, and then the staff must integrate the findings from the local or participant context review into the risks/benefits assessment before IRB approval is granted.

IV. DEFINITIONS

1. Local Context Review
A local context review is an additional review within the IRB process. This review includes an assessment of the research activities in the context of the laws, regulations, culture, language, customs, norms, accepted activities, and expectations of the target participants in an international setting.
2. Participant Context Review
This review includes an assessment of the research activities in the context of the laws, regulations, culture, language, customs, norms, accepted activities, expectations, community,

and national climate affecting the target population. This review is usually completed for special populations within the United States.

V. PROCEDURES

When research is conducted outside the United States or includes participants within the United States who are a unique population 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/benefits assessment. The IRB office requests the completion of local context or participant context reviews as appropriate, and it is the responsibility of the research personnel to facilitate the completion of the review and provide the IRB with appropriate documentation. These reviews assist the IRB in making appropriate risk/benefits assessments and review determinations.

A. Context Review Procedure

1. A context review will occur when the proposed study requires expedited or full board review and the IRB determines that they do not have sufficient expertise to make risk assessments regarding the population in the context of the proposed research activities. On a case-by-case basis, the IRB may request a context review in order to determine if an exemption determination can be made.
2. A context review is completed by an expert in the country, state, city, town, culture, language, customs, norms, accepted activities, laws, regulations, and expectations that relate to the location where the research takes place or the target participants in the study. The process is as follows:
 - a. The researcher identifies a context reviewer and gives that information to the IRB. The IRB either confirms the appropriateness of the context reviewer or assists the researcher in finding a new context reviewer.
 - b. Once an appropriate context reviewer is identified, the researcher will request a local or participant context review. In some cases, multiple context reviewers may be required due to study design and research questions.
 - c. Once the context reviewer agrees to complete the local or participant context review, the researcher provides the context reviewer with the IRB proposal, all study documents, and an IRB context form to complete. The context reviewer reviews all materials and provides the researcher and IRB office with insight regarding risk to participants. The context form contains a list of questions for the context reviewer to address, including asking for recommendations. This insight may result in required changes to the protocol, informed consent document, or supplemental documents.
 - d. The context reviewer's responses to the provided questions must be completed by the reviewer, digitally or physically signed, saved as an uneditable or digitally locked document, and provided to the researcher or RP staff.
 - e. 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.
 - f. Once the IRB receives the completed context review, the reviewer's assessment is provided to the IRB member(s) responsible for the review for the study.
 - g. The IRB reviewer(s) may require changes to the study design based on the context reviewer's suggestions or requirements.

B. Context Reviewer Requirements

1. The identified reviewer should be someone familiar with the country, state, city, town, culture, language, customs, norms, accepted activities, laws, regulations, and expectations so that they can assess the likely risks and benefits for participants that might otherwise go unrecognized.
2. The identified review can be a local researcher, a colleague at a local university, a senior researcher at Appalachian State University with extensive experience in the setting or with the unique participants, or anyone else with sufficient expertise and experience.
3. Reviewers are not required to have a Ph.D. or other terminal degree, but they must have expertise in the local context or with the unique participants for which the research will be conducted. They can be an active and informed community member, or advocate in the field related to the participants or region where the research is taking place.
4. The IRB office will verify the appropriateness of the identified context reviewer.
5. The context reviewer may be selected by the investigator, or, in some circumstances, by the IRB.
6. Context reviewers may not be a part of the research team or have a stake in the research project.
7. If the study takes place in a territory of the United States, a local context review may be required.