Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 209.2	TITLE: Cooperative Research	Date Effective: 01/01/2022 Last Revision Date: 12/06/2022

I. Purpose

To reduce administrative burden on investigators, circumstances arise in which an investigator at Western Carolina University may rely on an external Institutional Review Board for review and oversight of human subjects research in which WCU is engaged. This procedure establishes the process for relying on an external IRB for review of human subjects research in which WCU is engaged. When conducting cooperative research projects, each institution or unaffiliated investigator is responsible for safeguarding the rights and welfare of human subjects, in accordance with federal regulations. This procedure aligns WCU with NIH Policy and federal regulation regarding cooperative research and the use of a single IRB.

II. Scope

Reliance agreements are entered into at the discretion of the Western Carolina Institutional Review Board and the Office of Research Administration. A Reliance Agreement is appropriate for Expedited and Full Board research protocols where external institutions, organizations, or investigators are engaged in research with a Western Carolina University researcher. Reliance agreements are not applicable to research protocols determined exempt and will not be issued. However, protocols determined to be exempt with limited review do require a Reliance Agreement. Consult with the Office of Research Administration if requesting reliance for international collaborative research.

III. Definitions

Cooperative Research – those projects that involve Western Carolina University and at least one other institution or unaffiliated investigator.

Reliance agreement – document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB. This document can also be referred to as an IRB Authorization Agreement, or IAA.

Relying IRB – the institutional review board that cedes review to another institution.

IRB of Record – (also referred to as the Reviewing IRB) the institutional review board that determines the level of review for the research protocol.

IV. Procedure

<u>This procedure applies when the WCU IRB is the relying IRB</u>

1. Investigators seeking a reliance agreement are to submit a request for *IRB Reliance Agreement* through InfoEd. The submission shall include the following:

    a. Application and all materials (consent form, survey questions, sampling methods, etc.) submitted to the IRB of record;
    b. Determination letter from the IRB of record,
2. The Investigator shall select the appropriate reliance being requested, as determined by the reviewing institution, either expedited or full board.
3. The Office of Research Administration routes the materials to the WCU IRB Chair through InfoEd, for review and approval.
4. If it is determined that the WCU IRB cannot rely on IRB of record, the Investigator may submit the protocol to the WCU IRB for determination.
5. The ORA shall issue the reliance agreement through InfoEd. The following data is required to be included in the agreement, which is to be fully executed:
    a. IRB of Record, including FWA number and IRB Registration Number
    b. Relying Institution, including FWA number and IRB Registration Number
    c. Project Title
    d. Principal Investigator
    e. Signature of Empowered Official for relying institution: Chief Research Officer
    f. Signature of Empowered Official for reviewing institution
6. The WCU Investigator shall comply with the reviewing IRB's policies and procedures for initial and continuing review, record keeping, and reporting requirements. All information requested by reviewing IRB shall be provided in a timely manner
7. Reliance agreements are not applicable to exempt research so no reliance agreement will be issued. However, the Office of Research Administration seeks to reduce administrative burden on its investigators. Therefore, an Investigator may submit a Request for Reliance through InfoEd and select Exempt Reliance. The submission shall include the following:
    a. Application and all materials (consent form, survey questions, sampling methods, etc.) submitted to the IRB of record; please note WCU requires informed consent for all research, including research receiving an exempt determination.
    b. Exempt determination letter from the IRB of record.

    If the IRB agrees with the exempt determination of the IRB of record, an exempt letter will be issued through InfoEd.

V. Responsibilities

Office of Research Administration, IRB Chair, Investigators

VI. References

45 C.F.R. § 46.114(b)(1) (2018)

Final NIH Policy on the Use of a Single IRB Board for Multi-Site Research, 81 Fed. Reg. 40325, 40330 (June 21, 2016)