



INVESTIGATOR CHECKLIST

For Exempt and Non-Exempt Research Applications

Instructions: Use this checklist to ensure you have all necessary documents included in the IRB Review Request Application package. *Missing documents will result in delay of review by the IRB.*

All Applications:

Investigator Information Sheet, with Additional Investigator Information Sheets as needed.

Letters of permission to conduct research at proposed location (if applicable).

Letters of permission to access subject population (e.g., email listservs) (if applicable)

Human Subject Recruitment Materials (e.g., email script, flyers, posters, telephone script etc.)

Letter/Script of Informed Consent/Parental Permission Containing:

- a) A concise and focused description of what the research is and why it is being conducted. Include study title.
- b) An idea of how long the study will last. A description of what participants will be required to do.
- c) A statement that the study involves research.
- d) Description of reasonably foreseeable risk or discomforts (including breach of confidentiality), and how you plan to minimize those risks.
- e) Description of any benefits that **may** be reasonably expected (address both direct benefits to the subject, and knowledge generated)
- f) Disclosure of appropriate procedures, treatments, or assignments if applicable (e.g., alternative treatments for psychological interventions, alternative assignments for students used as human research subjects).
- g) Statement describing the extent to which confidentiality or identity of the subject will be maintained.
- h) Include a statement on mandatory reporting if you are a Mandatory Reporter. This applies to SOU Employees (e.g., Faculty, Staff, and Student Employees). Students who are **not** employed by SOU, and who **do not** fit other categories of mandatory reporters, do not need to include this statement.
- i) An explanation describing any compensation or incentives.

j) A statement that participation is voluntary, refusal to participate will not result in penalty or loss of benefits, and subjects may withdraw without penalty.

k) Explanation of whom to contact for questions about the research and research subjects' rights, and in the event of a research related injury or harm, include PI and IRB office information.

Youth Assent Form for minors able to assent (if applicable)

Research/Study Information Sheet introducing research to participant

Data collection/instrument information (e.g., survey questions, interview questions, interview guide, data/information being obtained from records, focus group questions, etc.)

Coding sheet/diagram for identifiable data that will be coded (if applicable)

Deception debriefing script (if study involves deception)

Request for Waiver or Alteration of Informed Consent (if applicable)

Conflict of Interest Form (if applicable)

Translated documents for non-English speaking subjects (if applicable)

In addition to the above listed items, include the items below specific to your research application.

Exempt Research Applications:

Exempt Determination Application - IRB Review Request

Exempt Category Worksheet(s)

Transnational documents of approval for research outside the U.S. (if applicable)

Signed investigator and Faculty Advisor Agreements and Responsibilities

Non-Exempt Research Applications:

Non-Exempt Research Application - IRB Review Request

Research Plan Narrative

I. Introduction and Background

II. Specific Aims/Study Objectives

III. Methods, Materials, and Analysis

IV. Potential Benefits of the Research

Transnational documents of approval for research outside the U.S. (if applicable)

Signed investigator and Faculty Advisor Agreements and Responsibilities