

Statement on the Scope of IRB Review

Title 45, Code of Federal Regulations, Part 46 (45 CFR 46) codifies the authority and responsibility of an Institutional Review Board (IRB). To **protect the rights, safety, and welfare of human subjects involved in research**, the UWF IRB reviews all research involving human subjects and has the **authority** to **approve, require modifications** to secure approval, or **disapprove** research activities involving human subjects conducted with or by members of the UWF community.

The UWF IRB is responsible for determining that **risks to human subjects** are minimized, consistent with sound research design, reasonable relative to any anticipated benefits to human subject participants, and carefully monitored for adverse events. The IRB is also responsible for determining that the **selection of human subjects** is equitable, participation is voluntary, privacy is carefully protected, and legally effective **informed consent** is documented (or waived), with careful consideration of human subjects who may be vulnerable to **coercion or undue influence**, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. When some or all of the subjects are likely to be vulnerable, the IRB is responsible for ensuring that additional **safeguards** have been included in the study to protect the rights, safety, and welfare of these subjects.

In summary, it is the responsibility of the IRB to carefully review all research protocols involving human subjects to ensure the rights, safety, and welfare of those human subjects. Researchers are responsible for submitting sufficient information for the IRB review to evaluate the research protocol for adherence to all of the criteria outlined above. To protect human subjects, the IRB may request additional information to evaluate these aspects of a research protocol and/or may require modifications to materials or procedures to ensure the rights, safety, and welfare of human subjects.