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Whitworth University IRB Ethical Foundations of the Policy for the Protection of Human Subjects in Research

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Adopted September 16, 2024

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Introduction

The Whitworth University Institutional Review Board for the Protection of Human Subjects in Research (IRB) serves Whitworth's mission of mind and heart by reviewing human subjects research to promote the creation of knowledge and to ensure commitments of respect, care, and equity toward human subjects of research. This document outlines the general ethical commitments of the IRB, which it relies on to form policy and ad hoc judgments. The policies and procedures of the IRB are detailed in other documents.

Whitworth University Policy for the Protection of Human Subjects in Research: Here

Whitworth University IRB Procedures: Here

The Belmont Report

After the ethical problems of the Tuskegee Syphilis Study were revealed, Congress passed the National Research Act, which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission created the Belmont Report outlining guidelines for the ethical treatment of human subjects in research. The National Research Act also provided for the creation of Title 45, Part 46, also known as the Common Rule, and, after its amendment in 2018, as the Revised Common Rule, which serves as the foundation for the Whitworth University Policy for the Protection of Human Subjects in Research.

The Belmont Report identified three central principles for the ethical treatment of human subjects in research, which the Whitworth IRB adopts as the general ethical commitments it relies on to form policy and ad hoc judgments. The three Belmont Principles are:

1. **Respect for Persons.** “Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.” Individuals should decide for themselves whether and to what extent they will participate in research, knowing in advance the risks and benefits of their participation, and in the assurance their decision is theirs. Those less able to understand the risks, benefits, and assurance of their autonomy should be given additional protections.
2. **Beneficence.** “Persons are treated in an ethical manner not only respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. […] (1) do not harm and (2) maximize possible benefits and minimize possible harms.” Research involving human subjects should be clearly grounded in the scholarship so that it is clear that the research involves the least possible risk and is likely to result in new knowledge in the field. If investigators are in a position to benefit subjects, they have an obligation to do so.
3. **Justice.** “An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.” Justice demands that those who are likely to enjoy the benefits of research share proportionately in the burdens (i.e., risks) of that research; conversely, that a single class should not bear the majority of the burdens when other classes are likely to benefit equally. Investigators should consider whether their recruitment strategies will result in a just distribution of risks, especially when using non-representative samples (e.g., convenience samples or snowball samples).

You are encourage to read the full Belmont Report: Read the Belmont Report | HHS.gov

Christian Ethical Foundations

The Whitworth IRB, as a community of Christian teachers and scholars finds that the principles identified by the Belmont Report are congruent with its Christian ethical commitments, though, in some cases its Christian ethical commitments oblige it to extend additional protections beyond those enumerated in the Revised Common Rule. Some such extensions are identified as "extensions" or "interpretations" in the Whitworth University Policy for the Protection of Human Subjects in Research. The foundations for those extensions and similar ad hoc judgments are outlined here.

1. **Respect.** Acknowledging that all people are made in God's image (Genesis 1:27), and that Jesus calls all people to follow him individually (John 12:32), the IRB affirms that the highest degree of respect should be accorded to human subjects, especially that they should choose freely when, how, and to what extent to be involved in research. Acknowledging that Christians are commanded to be a voice for the voiceless (Proverbs 31:8), the IRB affirms that additional protections should be extended to subject populations that are less able to advocate for themselves. To this end the IRB identifies subject populations beyond those prescribed by the Revised Common Rule to which additional protections are extended, and may indicate full board review for any study whose subject population has additional protections.
2. **Care.** Acknowledging that we are instructed to do good to all (Galatians 6:10), the IRB affirms that human subjects research should maximize the benefits and minimize the harms to human subjects. While it is not the primary purpose of the IRB to evaluate the methodology of the studies it reviews, investigators should make clear there is a likelihood of some benefit even if the risks are minimal. Furthermore, acknowledging a duty to prospectively care for everyone (Matthew 7:12), the IRB will look for the inclusion of plans to extend care to subjects where harms or opportunities for benefits are revealed during the research process. For example, if the research reveals that a subject suffers from an undiagnosed condition for which there is a reliable treatment, the investigator should inform the subject of the condition and treatment.
3. **Equity.** Acknowledging God's command to seek justice for the vulnerable (Isaiah 25:4), the IRB affirms that no subject population should disproportionately bear the risks and burdens of research where the benefit extends to other populations and that additional care should be taken to avoid burdening populations that have been at risk of exploitation because of age, gender, race, or the like. Investigators are encouraged to avoid convenience samples and to design a plan for subject recruitment that fits the goals of their research. Conversely, vulnerable populations sometimes lack the benefit of research because of the additional burdens involved in developing appropriate research projects. The IRB affirms that it supports research that benefits vulnerable populations, and, while it may request additional protections, it is committed to keeping such protections minimally burdensome on investigators.