

1 Introduction

The Sunrise Health Office of Research Compliance (SHORC) has developed this manual as a reference book detailing the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the Sunrise Health Institutional Review Board (SHIRB).

Sections of the manual describe and explain the various aspects of the review process and regulatory requirements. Investigators should familiarize themselves with the contents of the manual. In addition, they should carefully review the sections of the manual that address their specific research activities before submitting proposals to the SHIRB.

This manual presents the most current information for reference by potential investigators and their staff. Since the field of human subject protection is constantly evolving, sections of the manual may be subject to change. The SHIRB support staff, which is part of the SHORC, will keep the Sunrise Health research community apprised of all developments. The manual is in a loose leaf binder in order to facilitate the updating of pertinent sections as the need arises.

RESEARCH DEFINED

Virtually all federally funded research with human subjects is governed by federal regulations patterned on those of the DHHS, found at Title 45 Code of Federal Regulations Part 46 (45 CFR 46) (*Please see Appendix 1, "45 CFR 46" for more information*). The list of other agencies' pertinent regulations is included in Appendices 2-5.

Research is defined in 45 CFR 46 as, "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Human subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The Sunrise Health Institutional Review Board (SHIRB) is required by federal regulations to review all Sunrise Health affiliated human subject research, regardless of funding, to ensure the rights, welfare, and protection of all subjects.

Research: A Shared Responsibility

The review of research performed by medical staff, students, or employees of Sunrise Health is conducted by one human subject protection committee. Currently, Sunrise Health has one human subject protection committee, called the Sunrise Health Institutional Review Board (SHIRB), responsible for reviewing both socio-behavioral research applications and applications involving medically invasive procedures. The SHIRB is comprised of representatives from various disciplines at Sunrise Health, clinicians, researchers, non-scientific members, and community subject representatives who are not affiliated with Sunrise Health. The Board operates within the federal guidelines with respect to the review and approval of research protocols involving human subjects.

The dignity and welfare of individuals who participate in research is a central concern of everyone involved with the protection of human subjects. Our primary goal is to develop a fair and explicit

process in which subjects voluntarily decide to take part in a study based on an intelligent and knowledgeable assessment of the risks and benefits of the research.

Sunrise Health investigators, their research staff, and the SHIRB/SHORC share the collective responsibility for the ethical conduct of research. This collaboration must exist in a culture of trust, complete openness, and honesty by upholding the highest ethical principles in the conduct of research. By upholding the highest standards, we build public support for the pursuit of greater knowledge in a safe research environment.

The SHIRB is charged with a two-fold mission: 1) to determine and certify that all projects reviewed by the SHIRB conform to the regulations and policies set forth by the Department of Health and Human Services (DHHS) regarding the health, welfare, safety, rights, and privileges of human subjects; and 2) assist investigators in conducting ethical research which complies with the DHHS regulations in a way that permits accomplishment of the research activity.

The mission is accomplished through an educational process of SHIRB review of protocols and negotiation between investigators and the SHIRB for approval of research, and SHIRB/SHORC outreach to the research community. The process serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects.

Ethics and ethical review are a potentially dynamic and humanizing element in the search for knowledge. In preparing a protocol, the investigator is creating an ethical strategy that should reflect the norms and standards of the scientific community and the society served by the research. The process of creating a written protocol should enable the researcher to become a reviewer of his or her own research before submitting a project to the SHIRB.

The Foundation of 45 CFR 46: The Belmont Report

In 1974, the passage of the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission published the *Belmont Report* which articulates the basic ethical principles that guide the conduct of research with human subjects (*Please see Appendix 7 for more information*) and form the foundation of 45 CFR 46. Three principles were defined in the report as basic to the protection of human subjects: 1) respect, 2) beneficence, and 3) justice. The SHIRB is guided by the ethical principles set forth in the Belmont Report. The Commission also published a report on IRBs and a series of reports on research involving the human fetus, children, prisoners, and mentally impaired individuals (“those institutionalized as mentally infirm”).

Respect

In consideration of respect for persons, investigators are required to seek voluntary, written informed consent from potential subjects. Voluntary informed consent means that subjects are given explicit assurances of the voluntary nature of their taking part in terms that are easy to understand and are not under duress. The consent form also includes adequate information about the study that will assist subjects in intelligently deciding whether to take part in research. In addition, respect means honoring the privacy of individuals and maintaining their confidentiality. Respect for minors and mentally disabled persons require taking extra precautions to protect those individuals who are immature or incapacitated, perhaps even to the extent of excluding them from taking part in certain

research. The extent of protection depends on the risks and benefits of the research to the subjects taking part.

Beneficence

The principle of beneficence requires that researchers maximize the potential benefits to the subjects and minimize the potential risks of harm. Benefits to the subjects, or in the form of generalized knowledge gained from the research, should always outweigh the risks. Finally, if there are any risks resulting from taking part in the research, then there must be benefits, either to the subject, or to humanity or society in general.

Justice

The principle of justice means that subjects are selected fairly and that the risks and benefits of research are distributed equitably. Investigators should take precautions not to systematically select subjects simply because of the subjects' easy availability, their compromised position, or because of social, racial, sexual, economic, or cultural biases institutionalized in society. Investigators should base inclusion criteria on those factors that most effectively and soundly address the research problem.