Research and Sponsored Projects Manual (RSP)

RSP 201–01: Human Subjects in Research

Effective: 4/18/1979 **Revised**: 3/1/2025

Purpose

To assure that all research and sponsored projects involving human subjects are conducted in an ethical manner and that ASU complies with government standards for research involving human subjects

Sources

45 *Code of Federal Regulations* § 46

21 *Code of Federal Regulations* § 50, 56, 312, and 812

32 *Code of Federal Regulations* § 219

42 *Code of Federal Regulations* §11

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979

International Conference on Harmonization (ICH) as adopted by the Food and Drug Administration

Federal-wide Assurance, FWA 00009102

Office of Research Integrity and Assurance

Applicability

All research and related activities involving human subjects for which ASU is a responsible participant, regardless of funding source(s), including questionnaires, interviews, and secondary data used in research activities

Policy

Research involving human subjects is an important and necessary activity of the university and must be conducted in an ethical manner. ASU complies with the ethical principles set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its report entitled *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* In addition, ASU has negotiated a federal-wide-assurance with the Office for Human Research Protections and U.S. Department of Health and Human Services, assuring that ASU will comply with federal regulations concerning research involving human subjects regardless of the source of funding for a project.

Before any research project involving human subjects can be started and conducted at ASU, it must be submitted for review to the ASU Human Subjects Institutional Review Board (IRB). When sponsors require IRB approval as part of the applications process, the approval must be received and documented within the Enterprise Research Administration System (ERA) before the proposal is submitted to the sponsor.

For more information on protections of human subjects in research, see the Institutional Review Board Website or contact the Office of Research Integrity and Assurance at 480/965-6788.