

**STANDARD III-1:** In addition to following applicable laws and regulations, researchers and research staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, researchers and research staff have the protection of the rights and welfare of research participants as a primary concern.

**ELEMENT III.1.A.:** Researchers and research staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate.

**ELEMENT III.1.B.:** Researchers and research staff identify and disclose financial interests according to organizational policies and regulatory requirements and, with the organization, manage, minimize, or eliminate financial conflicts of interest.

**ELEMENT III.1.C.:** Researchers employ sound study design in accordance with the standards of the discipline. Researchers design studies in a manner that minimizes risks to participants.

**ELEMENT III.1.D.:** Researchers determine that the resources necessary to protect participants are present before conducting each research study.

**ELEMENT III.1.E.:** Researchers and research staff recruit participants in a fair and equitable manner.

**ELEMENT III.1.F.:** Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

**ELEMENT III.1.G.:** Researchers and research staff have a process to address participants' concerns, complaints, or requests for information.

**STANDARD III-2:** Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.

**ELEMENT III.2.A.:** Researchers and research staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization's policies and procedures regarding the protection of research participants.

**ELEMENT III.2.B.**: Researchers maintain appropriate oversight of each research study, as well as research staff and trainees, and appropriately delegate research responsibilities and functions.

**ELEMENT III.2.C.**: Researchers and research staff follow the requirements of the research protocol or plan and adhere to the policies and procedures of the organization and to the requirements or determinations of the IRB or EC.

**ELEMENT III.2.D.**: Researchers and research staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes, and guidance; the organization's policies and procedures; and the IRB's or EC's requirements.