

Institutional Review Board Policy

1. PURPOSE

1.1. The Spectrum Academy Board of Trustees has developed this Institutional Review Board (IRB) policy according to Health and Human Services (HHS) regulations at 45 CFR 46. Policies and procedures are developed and implemented to ensure effective and consistent operation of Spectrum Academy's (SA) IRB and its human research protections program. These policies and procedures are reflections of best practices at SA and peer institutions.

2. POLICY

1. 2.1. The Academic Director, in coordination with SA IRB will maintain written policies and procedures to ensure effective functioning and operations of the IRB and the human research protections program.
2. 2.2. These policies and procedures are applicable to all research investigators conducting human subjects research under the auspices of SA and the IRB members.
3. 2.3. The use of the word *must* or *will* in SA IRB policies and procedures means that something is required under the federal, state, institutional, or other applicable regulations. The use of the word *should* in SA IRB policies and procedures means that something is recommended or suggested, but not required.
4. 2.4. Due to the complex nature and wide breadth of human research, these policies and procedures cannot address all possible scenarios or issues. When scenarios/issues arise that are not covered by the policies and procedures, these will be resolved through discussion with the appropriate personnel. It is further recognized that there will be case-specific departures from these policies and procedures.

3. PROCEDURES

3.1. Development

3.1.1. The Academic Director, with advice from IRB Chair, IRB members and/or investigators determines when new policies and procedures or changes or revisions to existing policies and procedures need to be developed.

3.1.2. The Academic Director and staff are responsible for drafting policies and procedures after review of the federal regulations/guidance and best practices at peer institutions, and if necessary, in consultation with other stakeholders.

3.1.3. Policies and procedures will be written in sufficient detail and describe the actions that are followed to achieve the intended outcome.

3.1.4. The draft policies and procedures are initially reviewed by the IRB Committee.

3.1.5.The final draft is distributed to the IRB members prior to a convened meeting.

3.2. Review and Approval

3.2.1.The IRB will review all new and revised IRB policies and procedures at a convened meeting. Upon approval by the Academic Director, new policies and procedures will be recommended for final approval by the Board of Trustees.

3.3. Implementation and Communication

3.3.1.The Academic Director is responsible for the implementation and communication of IRB policies and procedures.

3.3.3.A revised policy and procedure will supersede all previously approved versions, and will be effective on the date of the most recent approval date.

3.4.2.Policies and procedures will be developed or updated as regulations and needs are recognized and/or changed.

3.4.3.Research stakeholders may recommend needed revisions or additions.