

Florida State University Human Research Protections Program and Related Regulatory Compliance

Florida State University (FSU) has a Human Research Protection Program (HRPP) and related staffing, policies, standard operating procedures and electronic protocol management and IRB record system, within which program are included an internal Institutional Review Board (IRB) and the Office for Human Subjects Protection (OHSP). Pursuant to FSU policy ([7-IRB-0](#)) the HRPP and its key elements, IRB and OHSP operate under the auspices of the FSU Office for Research. Collectively the IRB and OHSP provide human research regulatory oversight for more than 3,600 active studies. These studies comprise wide range of social, behavioral and educational research as well as biomedical, health and other human sciences, including clinical trials, which reflect the extensive breadth and depth of FSU research and creative arts.

The FSU maintains an active Federalwide Assurance (FWA) agreement (FWA00000168) with the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services (DHHS). The FWA is recognized under federal law by other U.S. regulatory and sponsoring agencies for the purpose of indicating and documenting FSU's adherence to applicable tribal, local, federal and international laws and ethical principals for the protection of human subjects from research risks. These laws include the Federal Policy for the Protection of Human Subjects ("[Common Rule](#)"), as well as related laws that provide vulnerable human subjects with additional protection against research risks. Ethical principles to which FSU adheres are embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research ("[Belmont Report](#)").

In compliance with the Common Rule, other laws and the Belmont Report, the IRB and OHSP provide the required review and on-going oversight of human research, and the IRB is registered with OHRP and the U.S. Food and Drug Administration to demonstrate that the IRB satisfies the qualifications for safeguarding the rights and welfare of human subjects (IORG0000263). Aside from human research internal to FSU, the IRB also serves as the IRB of record for other many other institutions engaged with FSU in cooperative research; the FSU IRB is prepared to serve as the Single IRB for cooperative research as may be required by federal law and study sponsors. In the discharge of its responsibilities, the IRB is composed of scientists, non-scientists and laypersons, including faculty and staff who are drawn from across FSU academic and other units as well as community members not affiliated with FSU but who represent the perspectives of the community from which human subjects may be drawn. Composition of the IRB is diverse with regard to race, gender, ethnicity and cultural background, and their academic backgrounds and affiliations reflect the nature and scope of FSU human research to ensure that the necessary experienced and expertise is brought to bear on the IRB's review and on-going oversight of human research.

In accordance with applicable law, the IRB is also supported by OHSP staff, who provide a range of HRPP subject matter expertise, guidance, and pre- and well as post-review and compliance monitoring of IRB approved human research. OHSP maintains the regulatory documentation required for human research, and provides the research community with professional, administrative and technical support in the submission and review of their human research studies. The OHSP staff hold various professional IRB, human subjects, clinical research and health compliance certifications and completion of related HRPP training to demonstrate their advanced human research compliance knowledge,

skills and abilities and participate in professional development in order to maintain and advance their credential. The OHSP staff also arrange for initial and continuing human research protections education and training for the FSU research community, including education and training provided by regulatory agencies and leading organizations in the field.

Selection as the Single Institutional Review Board

Should the FSU IRB be selected to serve as the Single IRB (sIRB) for non-exempt human research, the appropriate IRB reliance arrangement to document this selection and responsibility will be executed before human research may be conducted at a cooperative research site. Under a cooperative research arrangement, participating domestic sites will agree to rely on the FSU IRB; any domestic sites added after an award for which sIRB is required will be required to agree to this reliance arrangement unless they meet the federal regulatory criteria for exception to the policy. Provided below is an outline of FSU's statement of sIRB compliance and qualifications, reliance agreement documentation plans, and the communication plan between the local sites, local IRB, lead site, and sIRB. Where FSU will rely upon an external sIRB, the converse will apply.

Reliance Agreements

Before initiating the study, each participating site will execute an IRB reliance agreement with the sIRB; the reliance agreement will designate the sIRB as well as clarify the roles and responsibilities of the sIRB and the site. FSU has significant experience processing, executing and exercising oversight for many different types of reliance agreements, and is a signatory to the SMART IRB Agreement and other cooperatives to reduce IRB regulatory burden. The OHSP will maintain a copy of all reliance documentation for which the FSU IRB has sIRB responsibility or for which FSU is a participating study site. This documentation will also be made available to the lead PI and all cooperative research sites relying on the sIRB.

Communication Plan

The FSU IRB uses an electronic protocol management system that is accessible online by FSU employees and agents (RAMP IRB) and by site PIs. All human research application materials must be submitted for human research regulatory review by the FSU PI or other FSU study team members designated by the PI, using the RAMP IRB system. Participating sites will provide necessary information or assurances to the FSU study team for submission to the FSU IRB for its review. The FSU OHSP office will communicate directly with the FSU study team as the proxy for all participating sites. Participating sites are required to follow their local procedures for dissemination of information and documentation (e.g., if the local IRB office or ancillary services require copies of the IRB approval). When appropriate, the FSU OHSP will communicate directly with participating site Human Research Protection Program offices.

The FSU study team, under the supervision of the lead PI, will provide coordination services in order to:

Coordinate communications with partnering sites:

- Request and receive information and documentation from partnering sites
- Develop template materials for review by the FSU IRB and for limited modification by participating sites

- Submit materials from all sites to the FSU IRB and coordinate responses to any IRB queries
- Provide documentation to participating sites

Participating sites will follow their own local institutional procedures to coordinate, collect and verify information such as:

- Local context
- Site variations in areas such as recruiting, informed consent, HIPAA, populations
- Conflict of Interest disclosure and management
- Completion of ancillary reviews
- Training and qualifications of study team
- Continuing Review or Closure information
- Reportable Events

The lead PI will maintain a copy of this communication plan and any other communication plans that are developed. Copies will be made available to the participating sites as appropriate. Where FSU is the participating site, the above documentation and communication procedures will be followed by FSU, including the FSU study team.