Florida State University IRB Standard Operational Procedures

7-IRB-12

Title of Standard Operational Procedure: Cooperative Project/Multi-site projects – IRB Review

Responsible Executive:	Gary K. Ostrander
Approving Official:	Gary K. Ostrander
Effective Date:	Readopted –June 13, 2018
Revision History:	**New:** August 13, 2003 **Revised:** June 1, 2018

1 INTRODUCTION

Both the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) permit an Institutional Review Board (IRB) the option to rely on the review of another IRB. When this is the intention, the two institutions enter into an agreement referred to variously as either a Cooperative Agreement, an IRB Authorization Agreement or an IRB Reliance Agreement. These agreements are executed between a Reviewing IRB and one or more Relying Institutions and delineate the roles and responsibilities of the involved parties. The agreements can be for a single research study or for multiple studies.

FSU investigators involved in multi-site research are encouraged to discuss with collaborators the possibility of shared IRB review, i.e., having one IRB review on behalf of all sites. If the research is part of a multicenter grant awarded from NIH, single IRB (sIRB) review is required under most circumstances (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html). Investigators should contact the FSU Human Subjects Office early in the multi-site grant/contract process to discuss possible sIRB options.

Reliance agreements must be in place for all shared IRB review arrangements. The Human Subjects Office ensures that these agreements are negotiated to reflect study-specific, respective responsibilities of the reviewing IRB and the relying Institutions.

1.1 The Reliance Agreement and written procedures supporting the Agreement:

- Documents the respective authorities, roles, responsibilities, and communication between an organization providing the review and a participating organization relying on a reviewing IRB

- Describes the responsibilities of all parties and how communication between parties will occur (such as notifications of the outcome reviews and management of federally-mandated reports such as reports of unanticipated problems, serious or continuing noncompliance, and suspensions or terminations of IRB approval)

- When IRB certification requirements apply (e.g., for Genomic Data Sharing), the agreement or written procedures will indicate who is responsible for meeting the certification requirements

- Specifies contact information and personnel for both the sIRB and relying institution(s)

- Address whether the relying organization applies its Federalwide Assurance (FWA) to some or all research, and ensure that the IRB review is consistent with requirements in the relying organization's FWA

- Address which organization is responsible for obtaining any additional approvals from DHHS when the research involves Subpart B, C, or D determinations

The institution that is awarded the funding for the research is responsible for maintaining all agreements and for ensuring that adequate and appropriate communication channels between the sIRB and participating sites are in place. Participating sites are responsible for maintaining copies of the site agreement in accordance with the terms of their FWA.

2 PROCEDURES

When engaged in multi-site research, research involving external collaborators, or research that is otherwise under the jurisdiction of more than one IRB, the University acknowledges that each organization is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. The University may choose to review the research in its entirety, only those components of the research the University is engaged in, rely on the review of another qualified IRB, or make other arrangements for avoiding duplication of effort. When the University is the prime awardee on a HHS grant, it will ensure that at least one IRB reviews the research in its entirety.

When relying upon another IRB or when serving as the reviewing IRB for an outside organization or external investigator, a formal relationship must be established between the University and the outside organization or investigator through a written agreement as noted in Section **1** of this document. The written agreement must be executed before the University will accept any human research proposals from the outside organization or investigator or rely on the review of an external IRB.

IRB reliance agreements establish the authorities, roles, and responsibilities of the reviewing IRB and the relying organization. The procedures for reliance, including for communication, information-sharing, and reports, may be outlined in the reliance agreement or other materials. The Human Subjects Office utilizes checklists and other related documents to ensure that reliance agreements and any accompanying materials address all requirements and are consistent with the University's standards.

The University has signed the SMART IRB joinder agreement. When the organizations participating in the research are signatories to the joinder agreement, IRB reliance may be requested and documented utilizing the SMART IRB online reliance platform or via the SMART Acknowledgement paper form available via the SMART IRB Reliance website. The University will determine on a study-by-study basis whether the SMART IRB SOPs or alternative procedures will be utilized to implement the reliance via a reliance arrangement agreed upon between the relying and reviewing sites.

Regardless of which IRB is reviewing the activity, if the FSU PI is the lead investigator, or the University is the coordinating center for multi-site or collaborative research, regardless of location of the research, the PI must document and submit to the IRB how the research plan and issues relevant to the protection of human subjects (initial and continuing approvals, reports of unanticipated problems, study changes, reports, etc.) will be communicated among participating sites and investigators.

Both execution of an agreement and IRB review/approval of the research at individual sites must occur prior to any human subjects research commencing at any site for which FSU IRB is the IRB of record. Additionally, if FSU IRB is not the IRB of record, there must be administrative review and acknowledgment of the research occurring at the FSU site by the FSU Office of Human Subjects.

2.1 FSU Serving as the Reviewing IRB

2.1.1 Factors considered by the Human Subjects Office to have FSU provide IRB Services

The Human Subjects Office evaluates the following factors, and others as appropriate, when considering a request for FSU IRB to serve as the IRB of record:

- The terms of the external site(s) FWA
- Prior experience with the site(s) and investigators
- The compliance history of the site(s) and investigators (e.g., outcomes of prior audits or inspections, corrective actions)
- The research activities to be conducted at the external site(s)
- The willingness of the external site(s) to accept FSU's reliance terms and procedures; and/or
- The ability of the site(s) to collaboratively provide meaningful oversight of the proposed research, taking into account factors such as:
    a. The risks and procedures of the research
    b. The resources available at each site and ability to accommodate or collaborate with each other in observing the consent process, performing compliance reviews, investigations of potential noncompliance, and similar matters
    c. The expertise and experience of the FSU IRB with the proposed research, subject population, and applicable regulations
    d. The ability of the FSU IRB to comply with the relevant local context considerations of the external site(s), as provided by that site(s); and/or

e. The willingness or ability of the external site(s) to provide information and respond to questions regarding investigator qualifications, conflicts of interest (COI), organizational requirements, local context, and other matters that may inform the IRB review.

After reviewing the above factors, The Human Subjects Office will forward the Reliance Agreement for consideration by the Institutional Official (IO), who will make the final decision regarding whether or not the FSU IRB will serve as the reviewing IRB. The PI will be notified of the decision.

2.1.2 Responsibilities when FSU is the Reviewing IRB

2.1.2.1 Responsibilities of the FSU IRB

A. The following FSU IRB responsibilities apply to all sites:

1. FSU IRB has the final authority to decide whether FSU or external researcher or research staffs COI and the associated management, if any, allows the research to be approved
2. FSU IRB has the authority to request an audit of research being reviewed
3. FSU IRB makes relevant IRB policies readily available to relying external sites, including their HRPP staff, researchers, and research staff, and ensure that changes to those policies are communicated as well
4. FSU IRB will ensure that a Human Subjects Office contact person along with contact information is specified for researchers and research staff to obtain answers to questions, and express concerns regarding the FSU IRB
5. Adding sites to an already approved IRB study will be considered a change, and will be conducted by the expedited or full board process. In order for the review to be conducted via the expedited process criteria, such a change is usually considered a “minor change to previously approved research’. Factors that will indicate that a full review is required may include, e.g., involvement of investigators with financial COI, FDA issues, or any other site-specific issues noted. Additional site changes (regardless of type of review) do not change the expiration date of the IRB approval for the ‘main’ protocol.

2.1.2.2 Responsibilities of the FSU Principal Investigator

1. Coordinate with the Human Subject Office for the PIs at collaborating sites to have access to current status and current protocols, consent documents, etc. regarding the study. The IRB will review the Communications Plan Form (available on the HSO website or by request) provided by the FSU PI or their delegate to ensure open communication with the collaborating site(s).
2. Submission to the IRB information pertaining to the particular characteristics of each site’s local research context to be considered either:

a. through knowledge of its local research context by the IRB
b. through consultants, or
c. through review by appropriate designated institutional officials at external site(s)

3. Additionally, the submission will also include details for the IRB's evaluation regarding the management plan for information that is relevant to the protection of participants (e.g., unanticipated problems involving risks to participants or others, interim results, protocol changes).

2.1.3 FSU Ceding IRB Review to an External IRB

2.1.3.1 Standing Reliance Agreements

1. OneFlorida collaborative agreement
2. FSU is a participating institution in the SMART IRB initiative, having signed an overarching agreement indicating willingness to cede to other institutions' IRBs, pending satisfactory evaluation of factors identified below

Research that falls within the above parameters must be registered with the University, via the Human Subjects Office, prior to submission to the external IRB, as per Section **2.1.3.3.1.2**.

2.1.3.2 Factors Considered by the Human Subjects Office in the decision to allow FSU to Cede to an External IRB

FSU may choose to enter into an agreement to rely upon other external IRBs. The Human Subjects Office evaluates the following factors, and others as appropriate, when considering a request to rely upon an external IRB:

- Prior experience with the IRB
- The compliance history of the IRB (e.g., outcomes of prior audits or inspections, corrective actions)
- The federal IRB registration and organizational FWA
- The expertise and experience of the proposed IRB (e.g., with reviewing the type of research, research procedures, and subject population(s))
- The research activities to be conducted at the University
- The risks and complexities of the proposed research
- The proposed reliance terms and procedures, including acceptance of FSU local context issues, as well as the procedures for collaborative management of matters such as COI disclosures, investigator training, noncompliance, unanticipated problems, and federal reports
- The plan for review and allowance of the incorporation of site-specific consent language and plan for incorporation of other relevant local requirements or context information in the review process

2.1.3.3 FSU, External IRB, and FSU Investigator Responsibilities When FSU Cedes Review

- The External IRB has the same authority as the FSU IRB and all determinations and requirements of the external IRBs are equally binding
- FSU remains responsible for the conduct of the research in which it engages. Research reviewed by external IRBs remains subject to review, approval, oversight, and monitoring by FSU (in cooperation with the reviewing IRB when appropriate) and must adhere to all applicable policies, procedures, and requirements of the University. As with FSU IRB-reviewed research, officials of FSU may not approve research that is subject to a reliance agreement if it has not been approved by the reviewing IRB.

2.1.3.3.1 Responsibilities of the FSU Investigator When Using an External IRB

2.1.3.3.1.1 General Compliance Requirement

The FSU Investigator must be familiar with, and comply with the external IRB's policies and procedures for initial and continuing review, record keeping, prompt reporting, and any additional requirements or procedures outlined in the IRB reliance agreement or companion materials (e.g., reliance SOPs). All information requested by the reviewing IRB must be provided in a timely manner. FSU will support investigator compliance with the terms of reliance agreements by providing investigators with necessary documentation and information as needed.

Expectations of PI compliance, as detailed in these SOPs, remain in place regardless of the reviewing IRB.

Even though the External IRB may be reviewing the study, it must not commence at FSU until all human subjects training, COI disclosure, and required ancillary reviews and certifications have been completed.

2.1.3.3.1.2 Institutional Registration Requirement

- Studies that will be reviewed by external IRBs must be registered with FSU and receive administrative acknowledgement
- The Human Subjects Office will review the information and verify that CITI training, COI review, and any other applicable approvals or requirements have been completed, and determine the need for relaying local context information to the external IRB in accordance with the reliance agreement. Where waivers or alterations of HIPAA authorization are requested, and the external IRB will not be responsible for review, the Human Subjects Office will forward such requests to an FSU IRB Chair or a designated expedited reviewer for review. The Human Subjects will notify the investigators by e-mail or via the electronic management system once the proposed research has been cleared for submission to the external IRB. Once approved by the external IRB, investigators must submit a copy of the approval letter and any approved consent document(s). If the protocol was modified during the external IRB review process, the approved version of the protocol should be provided as well.

2.1.3.3.1.3 Post-IRB Approval Requirements

- Investigators approved through external IRB review must report local unanticipated problems, complaints, and any noncompliance to the Human Subjects Office for review by the IRB in addition to reporting to the external IRB. Copies of the report submitted to the external IRB are generally acceptable, but additional information may be requested on an as needed basis.
- Investigators must also submit copies of continuing review reports, updated protocols, updated consent forms, study closures and corresponding IRB approval or acknowledgment
- Changes in PI and the addition of other research team members must be submitted to the Human Subjects office prior to the new PI or research team member assuming any study responsibilities. CITI trainings, COI review, and any other applicable requirements will be verified.
- Notices about, and reports from, Data Safety Monitoring Boards, external monitors, sponsors, auditors, or inspectors must be provided to the Human Subjects Office

3 SPECIAL CONSIDERATIONS

Any projects that do not fit into the above criteria will be reviewed on a case-by-case basis to ensure appropriate oversight so that all research is conducted as per regulations.

JUSTIFICATION FOR THIS SOP

45 CFR 46.114
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html