FLORIDA ATLANTIC UNIVERSITY

DIVISION OF RESEARCH

SUBJECT: Institutional Authorization Agreements (IAA) and Reliance Agreements	**Policy Number:** 10.3.18	**Effective Date:** December 8, 2022
	Supersedes: NA	**Pages: 5**
	Responsible Authorities: Vice President for Research Assistant Vice President, Research Integrity Human Research Protection Program Staff	

I. Background

FAU researchers may be involved in research that involves multiple organizations, also referred to as cooperative projects. Reliance agreements authorize one institution's IRB to review the project and serve as the sole IRB of Record ("sIRB") for a human subject research. Typically for research occurring at multiple sites or that involve personnel from multiple institutions, these agreements document respective authorities, roles, responsibilities, and communication between organizations.

II. Purpose

The purpose of this policy is to set forth requirements of a sIRB for non-exempt human subjects research.

III. General Statement

If the FAU researcher's activities are determined to be non-exempt human subject research, the FAU's project personnel are prohibited from initiating and/or engaging in the project's performance until or unless the FAU IRB has documented its approval of the research, or an Institutional Authorization Agreement is entered into between the participating institutions through which one entity will rely on the other's IRB.

If a cooperative project is funded by a federal agency that complies with the Common Rule, sites are required to utilize sIRB. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. Any institution located in the U.S. that is engaged in cooperative research must rely upon approval by a sIRB for the portion of the project that is conducted in the U.S. The sIRB may be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. In certain cases, it may be inappropriate to utilize sIRB. The following research is not subject to sIRB requirements:

1. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
2. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

IV. Definitions

Federalwide Assurance (FWA): An assurance between an institution and the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP). This is the only type of assurance currently accepted and approved by OHRP. Through the FWA, an

institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

Individual Investigator Agreement (IIA): An agreement between FAU and an individual collaborator not affiliated with an institution covered by a Federalwide Assurance (FWA).

Institutional Authorization Agreement (IAA): An agreement between two institutions that hold a FWA. This agreement is used to establish the IRB of Record and outlines the responsibilities of each organization or institution. The IAA is signed by the Institutional Officials at each institution.

IRB of Record: An IRB to which authority for review and oversight has been ceded by another institution (relying institution) for one or more research studies.

V. Policy

Unless other requirements must be satisfied, FAU IRB will aim to use a single IRB for multi-institutional collaborative non-exempt research. When FAU is the prime awardee of a federally or non-federally funded research award, FAU will serve as the IRB of Record, unless project specific aims would make this unreasonable (eg: activities interacting or intervening with human subjects occurs elsewhere). Under certain circumstances, FAU may use a commercial IRB to serve as the sIRB for a project. Any single IRB effort requires a written agreement, under which the respective responsibilities of the two institutions are documented and agreed to..

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Ensuring all FAU project personnel have satisfied the human subjects protection training requirement when requesting a reliance agreement.
- Providing all requested documentation such as protocols, consents, Data Use Agreements, auxiliary compliance approvals or other documents necessary for reliance agreement finalization.

HRPP Staff will:

- Review and determine appropriateness of reliance requests. This includes reviewing project for risk level, funding mechanism, FAU engagement in research activities, and standing of other engaged institutions.
- Obtain all documentation from PI necessary to finalize reliance request.
- Correspond with FAU and external institutional representatives to finalize reliance request.
- Conduct local review to ensure compliance with FAU institutional policy and procedure.
- Maintain reliance agreements and monitor for changes to agreements as needed.

Institutional Official (IO) will:

- Provide final approval of reliance agreements.
- Authorize designated HRPP staff to execute reliance agreements under Master agreements previously signed by the IO.

VII. Procedures

FAU IRB of Record:

Institutional Authorization Agreement

- Complete and upload Form 15, “IRB Reliance Request” and Form 15a, “IAA for FAU Lead”. These documents may be submitted at initial review or at any time when a reliance is needed.
- All required signatures must accompany submission.
- Submit for review.
- HRPP staff will conduct review to assess the appropriateness and feasibility of the request (e.g. resources and expertise needed; proposed study staff dedicated to the effort, and the plan describing how communications between sites participating and the IRB of record will be handled). Additional information may be required.
- HRPP staff will initiate routing of signatures for agreement finalization.

Individual Investigator Agreement

- Complete and upload Form 15b, “Individual Investigator Agreement”. This may be included at initial review or when adding external personnel to a project.
- All required signatures must accompany submission.
- Submit for review.
- HRPP staff will review for current and appropriate human research protection training.
- HRPP staff will initiate routing of signature for agreement finalization.

Using SmartIRB

- Complete and upload Form 15, “IRB Reliance Request.” This document may be submitted at initial review or at any time when a reliance is needed.
- All required signatures must accompany submission.
- Submit for review.
- HRPP staff will conduct review to assess the appropriateness and feasibility of the request (e.g. resources and expertise needed; proposed study staff dedicated to the effort, and the plan describing how communications between sites participating and the IRB of record will be handled). Additional information may be required.
- Upon HRPP staff acknowledgement of reliance request, PI will initiate a reliance agreement via SmartIRB platform.
- HRPP staff will finalize agreement with relying institution and provide PI with copy of final agreement, which may also be accessed via SmartIRB platform.

FAU Relying on External IRB:

Institutional Authorization Agreement

- Complete and upload Form 15, “IRB Reliance Request, copy of lead IRB reliance form, protocol, external IRB approval, and applicable supplemental documents such as consents, recruitment materials, and data collection tools. Include CITI completion reports for all FAU affiliated study personnel. These documents may be submitted at initial review or at any time when a reliance is needed.
- All required signatures must accompany submission.
- Submit for review.
- HRPP staff will conduct review to assess the appropriateness and feasibility of the request (e.g. resources and expertise needed; proposed study staff dedicated to the effort, and the plan describing how communications between sites participating and the IRB of record will be handled). Additional

information may be required.

- HRPP staff will initiate routing of signatures for agreement finalization.

Using SmartIRB

- Complete and upload Form 15, "IRB Reliance Request", external IRB approval, and applicable supplemental documents such as consents, recruitment materials, and data collection tools. Include CITI completion reports for all FAU affiliated study personnel. These documents may be submitted at initial review or at any time when a reliance is needed.
- All required signatures must accompany submission.
- Submit for review.
- HRPP staff will conduct review to assess the appropriateness and feasibility of the request (e.g. resources and expertise needed; proposed study staff dedicated to the effort, and the plan describing how communications between sites participating and the IRB of record will be handled). Additional information may be required.
- Upon HRPP staff acknowledgement of reliance request, PI at lead institution should initiate a reliance agreement via SmartIRB platform.
- HRPP staff will finalize agreement with relying institution and provide PI with copy of final agreement, which may also be accessed via SmartIRB platform.

Using a commercial IRB (WIRB or Advarra):

FAU's Division of Research uses the services of external, commercial IRBs as an additional resource for overseeing specific types of human subjects' research. FAU faculty, staff or students can conduct clinical trials including:

1. Industry-sponsored clinical trials involving drugs, biologics, devices (FDA-regulated)
2. Investigator-initiated clinical trials* involving drugs, biologics, devices (FDA-regulated)

   ** Current FAU practice does not allow for Phase 0 or Phase I clinical trials*
3. Certain multi-site studies.

- Complete and upload the "Commercial IRB Submission Checklist," protocol, and applicable supplemental documents such as consents, recruitment materials, and data collection tools. Include CITI completion reports for all FAU affiliated study personnel.
- All required signatures must accompany submission.
- Submit for review.
- HRPP staff will conduct review to assess the appropriateness and feasibility of the request (e.g. resources and expertise needed; proposed study staff dedicated to the effort). Additional information may be required.
- Upon acknowledgement from HRPP staff, submit materials to relevant commercial IRB as indicated by study sponsor.

VIII. Policy Renewal: As needed

IX. References

Office for Human Research Protections, *Initial Considerations for Single IRB: Points to Consider*
Office for Human Research Protections, Single IRB Exception Determinations
National Institutes of Health, *Final NIH Policy on Use of a Single Institutional Review Board for Multi-site Research*, Effective January 25, 2018

POLICY APPROVAL
Initiating Authority

Signature: Daniel C. Flynn Digitally signed by Daniel C. Flynn Date: 2023.01.06 17:44:36 -05'00' Date: 1/6/2023

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)