## DIVISION OF RESEARCH

SUBJECT: Institutional Authorization	Policy Number: 10.3.18	Effective Date:	
Agreements (IAA) and Reliance Agreements	•	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 subjerm-2 u590 Td[s)-2 anane

If a cooperative project is funded by a federal agency that complies with the C sites are required to utilize sIRB. Each institution is responsible for safeguardi and welfare of human subjects and for complying with this policy. Any institution the U.S. that is engaged in cooperative research must rely upon approval by a portion of the project that is conducted in the U.S. The sIRB may be identified department or agency supporting or conducting the research or proposed by the sites of the cooperative project is funded by a federal agency that complies with the C sites are required to utilize sIRB. Each institution is responsible for safeguardi and welfare of human subjects and for complying with this policy. Any institution is responsible for safeguardi and welfare of human subjects and for complying with this policy. Any institution is responsible for safeguardi and welfare of human subjects and for complying with this policy. Any institution is responsible for safeguardi and welfare of human subjects and for complying with this policy. Any institution is responsible for safeguardi and welfare of human subjects and for complying with this policy. Any institution is responsible for safeguardi.

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

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.

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 <a href="SmartIRB">SmartIRB</a> 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:

- Industry-sponsored clinical trials involving drugs, biologics, devices (FDA-regulated)
- 2. Investigator-initiated clinical trials<sup>\*</sup> involving drugs, biologics, devices (FDA-regulated)
  - \* Current FAU practice does not allow for Phase 0 or Phase I clinical trials
- 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,

POLICY APPROVAL Initiating Authority

Signature: 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)