Form 115a: Institutional Authorization Agreement (IAA)

Office of Research Integrity

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<https://www.fau.edu/research-admin/research-integrity/human-subjects-irb/>

This Agreement allows another institution to rely upon Florida Atlantic University’s IRB (FAU) for review and oversight of human research.

**Name of Designated Institution Providing IRB Review; “Reviewing IRB”**: Florida Atlantic University

OHRP Federalwide Assurance (FWA) #: 00000157

FAU IRB Contact: Cortni Romaine cromaine@fau.edu

**Name of Institution Relying on the Reviewing IRB; “Relying Institution”**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

OHRP Federalwide Assurance (FWA) #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Local Contact person regarding study under review: \_\_\_\_\_\_\_\_\_\_\_\_

The Officials signing below agree that the relying Institution may rely on Florida Atlantic University for IRB review and continuing IRB oversight of its human subject research described below.

**This agreement is limited to the following specific protocol:**

Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor or Funding Agency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |
| --- | --- | --- |
|  | **FAU Information** | **RELYING Institution Information** |
| **PI Name** |  |  |
| **Protocol #** |  |  |

By signing this agreement, both institutions have agreed that the Reviewing IRB (FAU) will serve as the IRB of record and are agreeing to uphold their individual responsibilities as listed on page 2 of this document. The Reviewing IRB will follow written procedures for reporting its findings and actions to appropriate officials at the Relying Institution. Relevant minutes of IRB meetings will be made available upon request. The Relying Institution remains responsible for ensuring compliance with the designated IRB’s determinations and with the Terms of its OHRP- approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

**Signature of Signatory Official at FAU:**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Print Full Name: Gregg B. Fields, PhD

Institutional Title: Interim Vice President for Research

**Signature of Signatory Official at RELYING Institution:**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_

Print Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The responsibilities of FAU as the REVIEWING IRB are to:**

1) Maintain an FWA with OHRP and the registration of its IRBs with both OHRP, and if relevant, the FDA;

2) Maintain a Board membership that satisfies the requirements of 45 CFR 46, and if relevant 21 CRF 50 and 56, and provide special expertise as needed from Board members or consultants to adequately assess all aspects of the study;

3) Make available to the Relying Institution upon request, the FAU IRB’s Standard Operating Procedures;

4) Perform initial reviews, continuing reviews, reviews of submitted Adverse Events, reviews of protocol amendments, reviews of DSMB reports, and reviews of any other documents submitted by the Principal Investigator of the research study subject to this agreement;

5) Maintain and make accessible to the Relying Institution, the FAU IRB’s application, protocol reviews, letters to Principal Investigators, approvals and disapprovals, and minutes of the FAU IRB meetings relevant to the protocol;

6) Notify the Relying Institution immediately in the event of a suspension or restriction of the FAU IRB’s authorization to review studies; and

7) Notify the Relying Institution of any FAU IRB policy decisions or regulatory matters that might affect the institution’s reliance on FAU IRB reviews or performance of the research at the Relying institution.

**The responsibilities of the RELYING Institution are to:**

1) Maintain a Federal Wide Assurance (FWA);

2) Maintain a human subjects protection program, as required by the DHHS OHRP;

3) Provide the FAU IRB with a local contact person who has the authority to communicate on matters relating to this agreement;

4) Notify the FAU IRB immediately if there is ever a suspension or restriction by the Relying Institution of FAU IRB’s authorization to review studies;

5) Ensure that the investigators and other staff at the Relying Institution who are conducting the research are appropriately qualified and meet the institution’s standards for eligibility to conduct research; have appropriately disclosed conflicts of interest and completed human subjects research training as required by the Relying Institution;

6) Notify the FAU IRB immediately if there is a suspension or restriction of a listed investigator at the Relying Institution;

7) Ensure the safe and appropriate performance of the research at the Relying Institution. This includes but is not limited to monitoring study compliance or allowing FAU monitors on site to review study compliance and cooperate with those activities; cooperate with any investigation by the FAU IRB, and ensuring a mechanism exists by which complaints about the research can be made by local study participants or others. Any actions taken as a result of problems that are identified in these areas should be shared with the FAU IRB and the Principal Investigator at FAU;

8) Require the Principal Investigator at the Relying Institution to maintain appropriate copies of all approvals, and other correspondence documenting the review and approval of the research as required by the regulations; and

9) Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.