Form 115: Request for Institutional Authorization Agreement [IRB Reliance]

Office of Research Integrity

researchintegrity@fau.edu

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

An Institutional Authorization Agreement (IAA, or “reliance agreement”) can be established in which one institution delegates its IRB review to another institution. The signed agreement permits a single IRB to review human subject research activities for more than one site.

If the project is NIH funded, a single IRB is [required](https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm). If FAU is the prime awardee of any funding for research that requires IRB review, then FAU’s IRB will serve as lead IRB, or “IRB of Record.” Unfunded projects may also seek an IAA and decisions on which IRB will be IRB of Record will be determined by research activity.

If a collaborating site is only allowing outside investigators to recruit subjects or conduct a study at their site, without collaborating as researchers, these activities may not meet the criteria of “research engagement”, and an IAA may not be required.

If a collaborating site does not have a Federalwide Assurance, and you wish to add personnel to an FAU project, *do not* complete this form. Use Form 115b\_Individual Investigator Agreement.

Contact the FAU Human Research Protection Program at [researchintegrity@fau.edu](mailto:researchintegrity@fau.edu) to request guidance in determining if an IAA is necessary or for questions about IRB Reliance.

**INSTRUCTIONS**:

|  |  |
| --- | --- |
| **Request for FAU to be IRB of Record** | **Request for External IRB to be IRB of Record** |
| * Upload Form 115 and 115a to existing project in Novelution. * May be included with initial review or as an amendment. * Principal Investigator (PI), Department Chair and other college designated signatories must sign for initial review * PI may sign for amendment to existing project. * Submit for review | * “Create new Project” and upload Form 115. * Provide external IRB approval letter, protocol, and applicable supplement documents such as consents, recruitment materials, and data collection tools. * Include CITI completion reports for all FAU affiliated study personnel * PI, Department Chair and other college designated signatories must sign for initial review. * Submit for review |

**SECTION I: Project Overview**

Project Title: Click or tap here to enter text.

FAU PI: Click or tap here to enter text. PI Phone Number:

College/ Department:Click or tap here to enter text. PI Email:Click or tap here to enter text.

Is this a student project?  Yes No

If yes, name of student *(students may not serve as PI at FAU)*:Click or tap here to enter text.

How many sites are engaged in the research study?Click or tap here to enter text.

List all collaborating institutions: Click or tap here to enter text.

\*If FAU will serve as IRB of Record, complete Form 115a for each relying institution.\*

Has FAU IRB (or another IRB) determined the research as Exempt? Yes No

**If yes, DO NOT CONTINUE. Exempt projects are not eligible for an IAA**

**SECTION II: PURPOSE OF REQUEST**

|  |  |  |
| --- | --- | --- |
| Indicate the purpose of this request. Complete the sections as applicable to the request. | | |
| New Project | | |
|  |  | I am requesting FAU to serve as IRB of Record for a NEW project (Continue to Section III) |
|  | I am requesting FAU to rely on another institution for IRB of Record for a NEW Project (Continue to Section III) |
| Amendment to approved FAU project | | |
|  |  | I am requesting to add a new site to my current project and FAU will continue to serve as IRB of Record (Continue to question 3) |
|  | I am requesting FAU to relinquish IRB oversight of my current project to another institution (Continue to question 3) |
|  | Provide a detailed description of changes being made. | Click or tap here to enter text. |
|  | State the reason (justification) for the requested change. | Click or tap here to enter text. |

**SECTION III: Project Funding**

|  |  |  |
| --- | --- | --- |
| Indicate the funding for this project. | | |
|  | Funding Type | No funding (Continue to Section IV)  Internal FAU  External Federal  External Non-Federal |
| If funded, complete the following section as applicable to the project | | |
|  | Is FAU the prime awardee? If *yes*, complete this item. If *no*, continue to #3. | 2a. Funding Source:Click or tap here to enter text.  2b. Funding Proposal Title:Click or tap here to enter text.  2c. Awarded PI:Click or tap here to enter text.  2d. Novelution/ Sponsored Projects Number:Click or tap here to enter text.  2e. Award Dates: MM/DD/YY- MM/DD/YYClick or tap here to enter text.  2f. Will FAU issue a subaward to a collaborating institution? Click or tap here to enter text.  2g. If yes, list all subaward recipients.Click or tap here to enter text. |
|  | Is FAU a sub-awardee? | 3a. Institution issuing sub-award to FAU:Click or tap here to enter text.  3b. Funding Proposal Title:Click or tap here to enter text.  3c. Awarded PI:Click or tap here to enter text.  3d. Novelution/ Sponsored Projects Number:Click or tap here to enter text.  3e. Award Dates: MM/DD/YY- MM/DD/YYClick or tap here to enter text. |

**SECTION IV: Research Activities**

|  |  |  |
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| Provide detailed information including specific research activities (i.e. recruiting, consenting, data collection, identifiable data analysis, etc.), location of activities, and data storage. | | |
|  | Which activities will FAU researchers be conducting? | Click or tap here to enter text. |
|  | Which activities will collaborating researchers be conducting? List each and their respective activities. | Click or tap here to enter text. |
| 2a. | If any of the above listed activities are new to an FAU approved protocol, list them here and ensure an amendment is submitted for FAU IRB review. | Click or tap here to enter text. |
|  | Where will research activities involving human subjects occur? | Click or tap here to enter text. |
|  | How will research data research data be managed? | 4a. Describe how research data will be stored:Click or tap here to enter text.  4b. Which identifiers will be stored with research data?Click or tap here to enter text.  4c. How will data be shared?Click or tap here to enter text.  4d. Has a Data Use Agreement and/ or Material Transfer Agreement been completed?Click or tap here to enter text.  4e. When will research data be destroyed?Click or tap here to enter text.  4f. How will collaborative data decisions be made, such as data ownership?Click or tap here to enter text. |
|  | Will [[Protected Health Information (PHI](https://www.fau.edu/research-admin/docs/policies/research-integrity/10-3-7-disclosure-and-use-of-phi-in-research-v3-24march2022.pdf))](https://www.fau.edu/research-admin/research-integrity/human-subjects-irb/irb-policies-and-procedures/) be collected? | Yes  No  If yes, which institution will be responsible for HIPAA compliance?Click or tap here to enter text. |
|  | Is the research being conducted in a country outside of the United States? | Yes  No  If yes, which countries?Click or tap here to enter text.  *\*Researchers are responsible for understanding and complying with required international research* [*regulations and requirements*](https://www.hhs.gov/ohrp/sites/default/files/2020-international-compilation-of-human-research-standards.pdf). |
|  | Is the project FDA regulated? | Yes  No |

**SECTION V: Collaborating Institution**

|  |  |  |
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| Information below should be specific to collaborating institutions. Add additional information for each institution, if needed. | | |
|  | Name of institution | Click or tap here to enter text. |
|  | Local protocol or reference number | Click or tap here to enter text. |
|  | Local PI Name | Click or tap here to enter text. |
|  | Will the collaborating institution serve as IRB of Record? | Yes  No  If yes, answer the following:  4a. Has the collaborating institution approved this project?  Yes  No  If yes, provide approval memo. |
|  | If you answered yes to #4 above, is this institution a member of “SmartIRB”? | Yes  No |
| If yes to question #5, PI from IRB of Record institution should initiate the IAA request within the [SmartIRB Portal](https://smartirb.org/reliance/) and continue to Section VI. | | |
|  | IRB Contact | Name:Click or tap here to enter text.  Phone:Click or tap here to enter text.  Email:Click or tap here to enter text. |
|  | Federalwide Assurance Number | FWA:Click or tap here to enter text. |
|  | Institutional Official | Name:Click or tap here to enter text.  Title:Click or tap here to enter text. |
|  | IRB Registration Number | Click or tap here to enter text. |

**SECTION VI: Investigator Responsibilities**

As Principal Investigator:

1. I accept responsibility for the ethical conduct of this research and protections of participants as set forth in the Belmont Report, Common Rule, and IRB of Record’s institutional policies and procedures.
2. I accept responsibility for ensuring the research is conducted in accordance with:
   1. Sound research design and methodology;
   2. The parameters of the research plan and activities as outlined in this request and as approved by the IRB of Record;
   3. The applicable terms of funding agents and research grants, contracts, or other agreements;
   4. Applicable laws and regulations, including those protecting the rights, safety, and welfare of human subjects.
3. I certify that I am sufficiently qualified by education, training, and experience to assume responsibility for the proper conduct of this research.
4. I accept responsibility for ensuring that all members of the research team have or will complete requisite human subjects protection training prior to beginning any work on the project that involved human subjects, identifiable data, or identifiable biospecimens,
5. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/ or supervise this research.
6. I will comply with the IRB of Record’s institutional regulatory and reporting requirements, relevant to this research.
7. I accept responsibility to ensure that research personnel, including myself, that are responsible for the design, conduct, or reporting of the research have reported any conflicts of interest to the appropriate oversight bodies as required by collaborating institutions. It is my responsibility to ensure research team members promptly report any changes in conflicts of interest to the appropriate oversight bodies as required by collaborating institutions.
8. I will notify the IRB of Record when all research activities involving human subjects or identifiable participant data or identifiable biospecimens have been completed.
9. I will cooperate with any post-approval monitoring or auditing of study activities and/ or study records as requested or required.