

ORED AGREEMENT REQUEST

Date of Request: _____ FIU Principal Investigator _____
Name of Entity: _____ Entity Point of Contact: _____
Entity Phone Number: _____ Entity E-Mail Address: _____

Please provide a description of the **Research** related to agreement. For NDAs, please provide the **purpose** and the confidential information to be **supplied** (attach additional justification if required)

1. FIU's Project Information - Does the Agreement:
Relate to proposal pending in ORED? No Yes List sponsor and project name: _____
Relate to an awarded sponsored project? No Yes List Project ID: _____
Relate to any intellectual property (IP)? No Yes Briefly describe the IP: _____

2. Approvals relating to project:
IRB Approval: Protocol Title and Approval Number: _____
IBC Approval: Protocol Title and Approval Number: _____
IACUC Approval: Protocol Title and Approval Number: _____
Other: _____

3. Costs:
Will FIU be required to **issue any payment** related to this agreement? No Yes Amount: \$ _____
If yes, for what purpose: _____
Will FIU be **receiving any payment** related to this agreement? No Yes Amount: \$ _____
If yes, for what purpose: _____

4. Miami-Dade County Public Schools:
As a result of this agreement, will any FIU employees be permitted access to Florida public school grounds when children are present OR have direct contact with Florida K-12 public school students OR have access to Florida public school funds?
No Yes
If answered "yes," such person(s) must undergo Level 2 background screening as required by Fla. law to work on the project.

5. Other EH&S Approval/Insurance
Does the proposed agreement involve: **diving** **boating** **fieldwork** **None**
If **yes**, EH&S prior approval will be required prior to ORED signature on the agreement.

Does the proposed agreement involve FIU receiving equipment? No Yes
If **yes**, does such equipment involve use of: **radioactive materials** **lasers or radiation** **hazardous or biohazardous/biomedical materials** or **chemicals** **select agents**?
If **yes**, EH&S prior approval will be required prior to ORED signature on agreement.

If **equipment** is to be received, the PI should confer with EH&S to determine if additional insurance for the equipment should be purchased, as FIU's insurance may not cover losses to such equipment.

6. Security/Classified Information/Export Control (for all types of Agreements):

Does the proposed agreement seek to involve or potentially involve **classified or sensitive information**?

No Yes

Will any part of this project involve **work outside the U.S.**?

No Yes

Will any **non-U.S. Citizens** or **non-U.S. permanent residents** be involved with this project?

No Yes

Will any **equipment, technology** or **written know-how** be exported or taken to any foreign country(ies)?

No Yes

Will any part of this project involve the purchase and/or use of **drones** whether on or off the FIU campus?

No Yes **If yes, PI must email drones@fiu.edu to request approval prior to the purchase and/use of drones.**

7. For Confidentiality Agreements:

ORED may execute a confidentiality agreement (CA) for the purpose of the FIU employee who countersigns the CA to be able to obtain or exchange documentation to ascertain whether a sponsored project may be performed at FIU. A project **should NOT** be commenced based only on a CA. Rather, if after review of the documentation, it is determined that a sponsored project may be undertaken, the PI must submit a proposal to Pre-Award following the normal ORED procedures and a separate agreement for the project will be executed.

Please explain what potential sponsored project this CA may lead to: _____

8. HIPAA Compliance (For a summary of Privacy Practices and HIPAA, see <http://research.fiu.edu/irb/privacy-practices-and-hipaa>):

Does the proposed agreement require a **Business Associate Agreement**? No Yes

Does the proposed agreement seek to **receive/disclose Protected Health Information (PHI)** (e.g., medical records) from a HIPAA covered entity (i.e., hospital, clinic, FIU HWCOC, FIU CCF, etc.)? No Yes

Skip to section 10 of you answered no to both questions in section 8.

9. HIPAA Data Use Agreement

Data will be transferred to the recipient as a **limited data set** (i.e., will **only** contain one or more of the following HIPAA PHI identifiers and no other PHI identifier: geographic subdivisions other than address [5 digit zip code w/out 4 digit extension, state, county, town] and/or dates [such as dates of birth, death, admission, service, discharge]). See <http://research.fiu.edu/irb/privacy-practices-and-hipaa> for a full listing of the PHI identifiers.

No Yes

If **yes**, and the identifiers are not listed in the proposed data use agreement, list (or attach) the specific identifiers that you will be receiving in the limited data set _____.

If answered "yes" to item 9, and FIU is the recipient of the data, the data security plan will undergo review by the FIU Information Security & HIPAA Security Officer to ensure appropriate data security measures are implemented.

10. Non-HIPAA Data Use Agreements (No PHI involved):

Data will be transferred to the **recipient**:

- a. **In a de-identified (anonymous) format** (i.e., will not contain any identifiers or any unique codes that link to a master key) No Yes
- b. **In a directly identifiable format** (e.g., will contain names or any other identifier that is directly associated with a subject) No Yes
- c. **In a coded format** (i.e., will contain unique codes that link to subjects via a master key) No Yes

If **10.C.** above is marked "**yes**," will the recipient receive the master key to the coded data? No Yes

If answered **no** and FIU will be the recipient of the data, the data use agreement must provide that FIU will not receive access to the master key under any circumstances.

If answered "yes" to items **10B** or **10C**, and **FIU** is the **recipient** of the data **AND** will receive the master key (or when required by the data use agreement), the **data security plan** will undergo review by the FIU Information Security & HIPAA Security Officer to ensure appropriate data security measures are implemented.

List here the **IRB** approval # for the project: _____

The protocol that was approved by the IRB allows for the sharing of data as reflected in the data use agreement being requested:

No Yes

11. Conflict of Interest:

Are there any **potential financial or other conflict of interest** for any FIU personnel who will be involved with this agreement? (For definitions and more information, refer to the Conflict of Interest in Research policy found on http://policies.fiu.edu/record_profile.php?id=572) No Yes

If **yes**, the FIU employee(s) must complete the applicable Outside Activity form disclosing such conflict of interest pursuant to the Conflict of Interest in Research policy. This agreement may not be signed unless and until the Outside Activity form is approved by the appropriate FIU personnel.

12. Nepotism

*Does a "relationship" as defined in the Office of Research & Economic Development Nepotism Policy #2320.060 exist or among any project staff and FIU personnel? No Yes

See the Nepotism in Interest in Research policy, #2320.060, at <https://policies.fiu.edu/policy/258> for more information. Note that disclosures are required from all FIU personnel, whether they are full or part-time employees or volunteers, if Nepotism exists as relates to the research project. This includes, but is not limited to, volunteer faculty, adjuncts, students, and at the contracting entity.

Signatures/Certifications:

By signing below, I certify that:

- I i) agree to the terms and conditions of the agreement will ii) accept responsibility for the scientific and ethical conduct of the project, as applicable ii) will be fully responsible for meeting the requirements of the agreement.
- I am not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from current transactions by any federal department or agency.
- I do not participate in any Malign Foreign Talent Recruitment Program (see definition in Conflict of Interest in Research policy #2370.005, at <https://policies.fiu.edu/files/572.pdf>)
- I will obtain and maintain all compliance approvals required to administer this project.

Date: _____

PI Name: _____

Title: _____

E-mail: _____

DEPARTMENT CHAIR/UNIT DIRECTOR AND DEAN APPROVAL

By signing below, I agree to commit the support of the Department or Unit and College to this project, including financial obligations.

Signature of Chair/Unit Director

To be completed by ORED:

If agreement involves **Export Control Concerns**, route to **Don Fischer** for review and approval:

Technology Control Plan in place: N/A ___ Yes ___

Export Control Signature _____

_____ Date

Comments: _____

If agreement involves EH&S concerns, route to Tamece Knowles for review and approval:

EH&S approval in place: No ___ Yes ___

EH&S Signature _____

_____ Date

Comments: _____

If agreement involves **animals, recombinant DNA or human subjects** route to ORI for the following:

IACUC approval for project involving the animals: ___ Current ___ Pending ___ Expired on: _____

Animal Care Facility (ACF) has the capacity/capability to house the requested type/quantity of animals?

Yes ___ No ___, ACF cannot house animals because: _____

Animals will be **quarantined** at: ___ FIU ___ off-site at (include name of facility and address where animals should be shipped: _____

If **quarantined off-site**, the **cost** of quarantine and transfer is: \$ _____
_____ No cost involved

Cost will be covered by ___ ORED ___ PI

IBC approval for project involving the animals: ___ Current ___ Pending ___ Expired on: _____

IRB approval for project involving the animals: ___ Current ___ Pending ___ Expired on: _____

*IRB Approval: For agreements that require access to **coded data where FIU will have access to the master key, or identifiable human subject data**, verify that IRB approval is in place*

ORI Coordinator Signature _____

_____ Date

ORI Coordinator Comments: _____

ORED Award Services Coordinator: _____ Date Completed: _____

Comments: