CLEAR FORM

FIU FLORIDA INTERNATIONAL UNIVERSITY
Office of Research and Economic Development

# ORED AGREEMENT REQUEST

11200 SW 8th Street, MARC 430
Miami, FL 33199
Please email request **60 days prior** to start date to oredagremnts@fiu.edu

FIU Principal Investigator: _____ Type of Agreement:

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 Confidentiality Agreements, please provide the **purpose** and the confidential information to be **supplied** (attach additional justification if needed).

**Project Information:**

1. Is this request related to a pending proposal or a forthcoming proposal submission? No ☐ Yes ☐ Is a third party involved? Select
   AWD/Sponsor/RFP : _____
2. Is this request related to an awarded sponsored project? No ☐ Yes ☐ List Project ID: _____
3. Is this request related to any intellectual property (IP)? No ☐ Yes ☐ Briefly describe the IP: _____
4. Will any items or goods be shipped from an international supplier/collaborator to FIU in furtherance of this proposed agreement, including (but not limited to) biological samples, chemicals, raw materials, or scientific instruments, equipment or components? If so, please identify item(s) and provide the estimated monetary value (if any). This information is required to determine whether the University needs to engage its authorized Customs Broker to facilitate the U.S. Customs entry of the item and/or to verify whether an Import Permit (e.g., USDA/APHIS, CDC, NRC, or EPA) is required before FIU can receive the items being shipped.

**1. Approvals relating to project:**

**IRB** Approval: Drop-down menu Protocol Title or Approval Number: _____

**IBC** Approval: Drop-down menu Protocol Title or Approval Number: _____

**IACUC** Approval: Drop-down menu Protocol Title or Approval Number: _____

**2. 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: _____

**3. 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.*

**4. 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.

**5. 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.

**6. 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: _____

_____

**7. 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 HWCOM, FIU CCF, etc.)? No ☐ Yes ☐

*Skip to section 9 of you answered **no** to both questions in section 7.*

**8. 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 8**,** 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.*

**9. 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 9.**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 9**B** or 9C, 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.

**10. 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.

**11. 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: _____

**Signature**

E-mail: _____

PI Name: _____

Title: _____

**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: N/A ___ 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 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 recombinant DNA: ___ Current ___ Pending ___ Expires on:_____

**IRB approval** for project involving humans subjects: ___ Current ___ Pending ___ Expires 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: _____

**Approvals**
Restricted Parties Search (RPS) completed and attached to this form. Date completed: _____

Entity headquarters location: _____. If the entity is located in a designated Foreign Country of Concern, consultation with Ana is required before moving forward.

ORED Award Services Coordinator: _____ Date Completed: _____

Comments: