**Office of Research and Economic Development**

**Agreement Request Form**

***Instructions****:* If a principal investigator (PI) wishes to process an agreement through the Office of Research and Economic Development (ORED) that is NOT included as part of a project proposal packet, the PI must provide this completed form to ORED in MARC 430, together with the draft agreement if the PI has received one.

**1. Type of Agreement:**

**If “Other” - Please describe:**

**2. Contact Information:**

Entity with which FIU is contracting:

Point of Contact at that entity: Name:       Phone:       Email:

**3. 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:

**4. 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:

**5. Costs:**

Any payments from FIU required in regard to the agreement? No [ ]  Yes [ ]  Amount: $

For what purpose?

Project ID or Dept ID to be used the payment:

Will FIU receive payment per the agreement? No [ ]  Yes [ ]  Amount: $

For what purpose?

**6. MDCPS:** 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 [ ]

***NOTE: If answered “yes,” such person(s) must undergo Level 2 background screening as required by Fla. law to work on the project.***

**7. 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? Yes [ ]  No [ ]

**If yes**, does such equipment involve use of: [ ]  radioactive materials, lasers or radiation [ ]  hazardous or biohazardous/biomedical materials or chemicals [ ]  select agents? None [ ]  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.

**8. 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 [ ]

**9. 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:

**10. 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 [ ]

Note: If you answered yes to either of the above questions, , answer all questions in section 11 below. If you answered no to both questions above, skip to section 12.

**11. HIPAA Data Use Agreements:**

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      .

Note: If answered "yes" to item 11, 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.

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

Data will be transferred to the recipient:

1. **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 [ ]  OR
2. **In a directly identifiable format** (e.g., will contain names or any other identifier that is directly associated with a subject) No [ ]  Yes [ ]  OR
3. **In a coded format** (i.e., will contain unique codes that link to subjects via a master key) No [ ]  Yes [ ]

If 12.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.

Note: If answered "yes" to items #12B or 12C, 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. Also, 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 [ ]

**13. 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.

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? ☐Yes ☐No

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 and students.

If you answered YES above, the applicable FIU individual must complete the Nepotism Disclosure Form found on the Nepotism Policy and provide copy of completed form to Office of Research & Economic Development before the subaward may be released.

**PI, are agreement terms acceptable and will you comply with the terms?** Yes [ ]  No [ ]

List agreement terms you would like changed, including any intellectual property terms:

PI Signature Date

Print Name Phone & Email

**Received by ORED:**

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

Technology Control Plan in place: [ ]  Yes [ ]  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Export Control Signature Date

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

EH&S approval in place: [ ]  Yes [ ]  N/A

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

EH&S Signature Date

Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If agreement involves animals, route to ORI (IACUC Coordinator)** 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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IACUC Coordinator Signature Date

IACUC Coordinator Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If agreement involves recombinant DNA, route to ORI (IBC Coordinator)** for the following:

IBC approval for project involving the rDNA: [ ]  Current [ ]  Pending [ ]  Expired on:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IACUC Coordinator Signature Date

IACUC Coordinator Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If agreement involves human subjects, route to ORI (IRB Coordinator)** for the following:

IRB approval for project involving human subjects: [ ]  Current [ ]  Pending [ ]  Expired on:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Coordinator Signature Date

IRB Coordinator Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*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.*

Print name Date

ORED Comments: