

Florida International University
Office of Research & Economic Development
Subaward/Amendment Request Form

NOTE: Please return the completed and signed form, with attachments, to oredagemnts@fiu.edu for processing. Failure to provide all of the requested supporting documentation will result in a delay in processing your Subaward request. Appendices must be in Word format.

Once the Subaward/amendment is complete, it will be returned for your review before being forwarded to the Subawardee for execution.

Project ID: _____ **Principal Investigator:** _____

Sponsor: _____

Subawardee Name: _____

Period of Performance: _____

Action Type: New Subaward Amendment to existing Subaward

If this is an amendment request, what type of modification is being requested:

- No Cost Extension
- Continuation (extension of time and increase in funding) Please attach and updated Scope of work and budget.
- Increase/Decrease of funds
- Change in Scope of Work. Please attached revised scope of work.
- Other (please describe):

Contact Information for **Subawardee PI:**

Name: _____ Title: _____

Address: _____

Telephone: _____ Fax: _____

Email: _____

Contact Information for **Subawardee Administrator:**

Name: _____ Title: _____

Address: _____

Telephone: _____ Fax: _____

Email: _____

Contact Information for **Subawardee Financial Contact:**

Name: _____ Title: _____

Address: _____

Telephone: _____ Fax: _____

Email: _____

Subawardee Reporting Requirements: Please indicate the FIU PI's preferred technical reporting schedule (more than one may be selected). A final technical report is required automatically. Annual technical reports are required for on all federal.

Annual Quarterly Monthly Other: _____

Please provide the following **Attachments** in word format:

Attachment 1 Detailed Statement of Work with Deliverables (, detailed deliverables with set due dates)

Attachment 2 Detailed Budget (cost reimbursable agreements) or Deliverable Schedule (fixed price agreements)

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Conflict of Interest: Is there an existing or potential conflict of interest related to this Subaward and the research project?
Yes No

See the **Conflicts of Interest in Research policy, #2370.005**, at <http://policies.fiu.edu/files/572.pdf> for more information. Note that disclosures are required from all FIU personnel, whether they are full or part-time employees or volunteers, if such persons have a conflict of interest as relates to the research project. This includes, but is not limited to, volunteer faculty, adjuncts and students.

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.

IRB, IBC, IRE, or IACUC Approvals: Will there be any studies carried out by the Subawardee which involve human subjects (including surveys or data analysis), animal, dual use research of concern (one or more of the agents/toxins listed at <http://research.fiu.edu/ire/>) ("DURC") or recombinant DNA molecules?

- No, none apply
- Yes, human subjects
- Yes, animal use
- Yes, DURC
- Yes, recombinant DNA.

If any have been checked YES, please attach a copy of the approval protocol. Please note that IRB/IBC/IRE/IACUC approval from **both** FIU and the Subawardee may be required. The subaward and/or amendment will not be executed by FIU until satisfactory documentation is received to meet this requirement.

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

Does the proposed agreement seek to disclose Protected Health Information (PHI)? No Yes
Does the proposed agreement require a Business Associate Agreement? No Yes
If either of the above is answered yes, answer all following questions

Data Collection Information

1. Data will contain sensitive information (e.g., illegal behaviors, alcohol/drug use, sexual attitudes, health information).
No Yes
2. Data will be transferred to the recipient in a de-identified (anonymous) format (i.e., will not contain any of the 18 HIPAA identifiers listed at <http://research.fiu.edu/irb/privacy-practices-and-hipaa>).
No Yes
3. Data will be transferred to the recipient in a directly identifiable format (e.g., will contain any of the 18 HIPAA identifiers such as name, address, etc.).
No Yes

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- 4.A. Data will be transferred to the recipient in a coded format. No Yes
B. The recipient will receive the master key to link the coded data. No Yes
5. PHI will be transferred to the recipient as a limited data set (see <http://research.fiu.edu/irb/privacy-practices-and-hipaa> for discussion of limited data set). No Yes

Note: If answered "yes" to any of the following items: **1, 3 4A AND 4B or 5** (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

Clinical Trail Approval

Will Subawardee be engaging in clinical trial work? No Yes If so, list the IRB of record and the IRB approval #: _____

Prior Approval Requirements: Does the sponsor award require prior sponsor approval of the Subawardee or the Subaward Agreement? No Yes

If you answered Yes above, list the section of the Sponsor Award that addresses that: _____
Attach a copy of the written approval from the sponsor for this Subaward agreement.

Export Control Limitation: Does the sponsor award contain any conditions pertaining to export control s (e.g., foreign national prior approval, publication limitations) or other confidentiality requirements? No Yes

If you answered YES above, list the sponsor award sections that address those requirements:

If yes, further review, including review of the Technology Control Plan, is needed to determine if the Subaward may proceed from an export control perspective. ORED will confer with the Compliance Office to ensure Subaward may proceed.

Previously Executed Agreements: Is this subaward related to a previously executed confidentiality or other agreement with the Subawardee?

If YES, please identify which prior agreement: _____

Please sign below and send completed request form and attachments to oredagreements@fiu.edu

PI Signature: _____ Date: _____

Name: _____

Phone: _____ Email: _____

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FOR ORED USE ONLY

Export Controls:

- Restricted Parties Search (RPS) completed on: _____/_____/_____
- RPS results attached to this form.
- N/A.

Risk Assessment Score (Please attach): _____

- High Risk Medium Risk Low Risk

IRB/IACUC/IBC/IRE Approvals:

If subaward SOW involves human subjects, animal use, dual use research of concern, or Recombinant DNA, verify that IRB/IACUC/IRE/IBC approval from BOTH the Subawardee and FIU are in place.

- Subawardee IRB approval No: _____ received
- FIU IRB approval No: _____ in place

- Subawardee IACUC approval No: _____ received
- FIU IACUC approval No: _____ in place

- Subawardee IBC approval No: _____ received
- FIU IBC approval No: _____ in place

- Subawardee IRE approval No: _____ received
- FIU IRE approval No: _____ in place

Was "yes" checked in Export Control Limitation above? No Yes If yes, review was done with Compliance Office, as needed, and the subaward may proceed. Yes, see

If subaward scope of work requires IRB, IRE, IACUC and/or IBC approval and such approval(s) from the Subawardee and/or FIU cannot be verified, route to ORI for review of IRB, IRE, IACUC and/or IBC requirements.

ORED Representative Signature: _____ Date: _____

ORI, please check as applicable:

Appropriate IRB/IACUC/IBC/IRE approval is in place for Subawardee's work. Subaward may proceed to execution.

- Subaward may not be executed. IRB/IACUC/IBC/IRE has not approved Subawardee's involvement in the study.

Signature

Print name

Date

ORI Comments: