Business Process for Monitoring Plans

I. What is a monitoring plan?

A monitoring plan (sometimes referred to as a “management plan”) is a document that is required by law when a FIU employee (or his/her spouse or dependent children) has a manageable conflict of interest that may affect research to be conducted at FIU and/or when the FIU employee desires FIU to enter into a contract for research or intellectual property (IP) commercialization purposes with an entity in which the FIU employee (or his/her spouse or dependent children) has an interest. The monitoring plan sets forth the conditions to manage conflicts of interest so that the research or contract may proceed.

II. When is a monitoring plan needed?

A. Florida law requirements pertaining to contracts with an employee’s entity

Pursuant to Florida law, FIU is generally prohibited from entering into an agreement with an entity in which a FIU employee or his/her spouse and/or dependent children has an interest. However, Florida law provides a limited exemption which allows for such contracts when they are for the purpose of commercializing FIU IP or for the performance of research and an approved monitoring plan has been instituted to manage conflicts of interest. See, Office of Research and Economic Development (ORED) Procedure # 2370.005(a), Ethics in Purchasing for Research and Intellectual Property Contracts under Florida law, at http://policies.fiu.edu/record_profile.php?id=791

For example, if a FIU employee wishes FIU to enter into a research agreement with the employee’s start-up company so that research may be done at FIU for a Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) project funded to the employee’s start-up company, a monitoring plan must be in place before such research agreement may be executed. Similarly, a monitoring plan is a pre-requisite to FIU entering into a license agreement with the employee’s start-up for the commercialization of FIU IP.

B. Federal law requirements pertaining to conflicts in research

A monitoring plan is also required by Federal regulations if a FIU employee has a manageable conflict of interest that could affect research funded by the PHS or NSF. See ORED Conflict of Interest in Research Policy #2370.005 at http://policies.fiu.edu/record_profile.php?id=572. A monitoring plan is also required in any other research should ORED determine that a conflict of interest exists that must be managed.

III. Process for Implementing a Monitoring Plan

A. The first step is for the FIU employee to:

- Complete the Outside Activity Report (OAR) on the HR electronic portal and explain the employee’s (or his/her spouse’s or dependent children’s) interest in the business entity (e.g., start-up company). All questions, including the research questions in section J of the OAR must be completed. Once
completed, the OAR will proceed to the various approvers for the University, including to ORED for review as relates to research/intellectual property.

- Complete Sections 1 and 2 only of the Monitoring Plan found on the ORED Forms Library at [http://research.fiu.edu/forms/index.html](http://research.fiu.edu/forms/index.html) under the “Conflict of Interest Forms (COI)” section.

- Complete the Exemption/Disclosure under Section 112.313(12)(h) (the “Exemption Request”) found on the ORED Forms Library at [http://research.fiu.edu/forms/index.html](http://research.fiu.edu/forms/index.html) under the “Conflict of Interest Forms (COI)” section only if the employee seeks to have FIU enter into a contract as described in section II.A above.

B. The employee must email the completed Monitoring Plan and the Exemption Request, if applicable, to the Office of Research Integrity at ori@fiu.edu for review to ensure that all required information is provided. If the information is not complete, it shall be returned to the employee for completion.

C. Once the required form(s) is/are complete, ORI shall: (1) forward the Monitoring Plan and the Exemption Request, if applicable, to the following persons; and (2) schedule a meeting for them to discuss the matter:

- The employee’s Chair or supervisor (or other Department representative if deemed appropriate by ORI);

- The representative designated by the employee’s Dean’s Office or, if the employee is from an independent center, a representative designated by the Center Director;

- A representative from ORED.

The foregoing persons shall meet to determine if the conflict may be managed and if so, shall recommend the conditions to be included in the Monitoring Plan to manage the conflict. If any of the above persons has a conflict in relation to the proposed matter or if there is a supervisory conflict between the FIU employee requesting the Monitoring Plan and any of the above personnel, an alternative representative shall be selected by ORED.

D. ORI shall also include the following personnel at the meeting, who shall attend only for the purposes listed below:

- The employee who submitted the Exemption Request who shall attend to answer questions from the meeting participants and shall be excused from the meeting when no further questions remain;
• A representative from the Office of Technology Management and Commercialization (TMC) if the matter involves FIU intellectual property. The TMC representative shall attend the meeting only to provide information requested by the participants regarding the intellectual property at issue; 

• A legal representative (generally, Diana Firvida-Oliva) who shall attend to answer any legal questions.

E. At the meeting, if the employee’s chair, the Dean’s (or Center Director’s for independent centers) representative and the ORED representative determine that the conflict may be managed, they shall prepare the recommended Monitoring Plan terms and shall sign it. ORI shall provide that proposed Monitoring Plan to the employee who shall also sign it, reflecting the employee’s agreement to comply with its terms.

F. ORI will then provide the signed Monitoring Plan and the Exemption Request to the Vice President for Research and Economic Development (VPR) for review and if approved, signature on the Exemption Request. If the Exemption Request is signed by the VPR, the ORED attorney shall forward the Exemption Request together with the Monitoring Plan to the General Counsel’s Office (OGC) for review. If found acceptable, the OGC shall forward the same to the FIU President or his designee for review and if approved, signature.

G. If the Exemption Request is approved by the FIU President or his designee, the OGC shall forward the Exemption Request and the Monitoring Plan to the Chair of the FIU Board of Trustees for review and if approved, signature. The OGC shall return the final Exemption Request, together with the Monitoring Plan to the VPR.

H. ORI shall forward the final Exemption Request and Monitoring Plan to the employee, and to the College, Department and ORED representatives as well as to the Assistant Vice President for Research and the Director of TMC. If the Exemption Request and the Monitoring Plan were fully approved, Pre-Award and TMC may proceed with executing any pending research or IP agreement(s). If the Exemption Request was not fully approved, the agreements may not proceed.

I. If the applicable contract(s) is/are fully executed, the research project and/or IP commercialization, as applicable may proceed. The processing and maintenance of the research agreement or the IP commercialization agreement, as applicable, shall proceed in Pre-Award or TMC per each office’s applicable processes. For example, SBIR/STTR research agreements will be executed and maintained in Pre-Award and license agreements will be executed and maintained in TMC.

J. ORI will ensure that the periodic reviews of approved Monitoring Plans are done as required by the approved Monitoring Plans, and will schedule the meetings for those reviews. If, at any of the monitoring meetings, it is determined that the
conflict cannot continue to be appropriately managed, then appropriate action shall be taken, including terminating any contract(s), as needed.