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| --- | --- | --- | --- |
|  | *Florida State University* | ORCP Ref # |  |
|  |
| Monitoring Plan for Potential Conflicts of Interest |

|  |  |
| --- | --- |
| Employee Name (hereinafter “Employee”): |  |
| Department: |  |
| College: |  |
| Academic Rank, if applicable: |  |
| Campus Address: |  |
| Campus Phone: |  |
| List all positions currently held at FSU: |  |

**Wherever the term “University” is used in this document, it shall mean “Florida State University” and the “FSU Research Foundation, Inc.”**

**1. Reason for Monitoring Plan**

This Monitoring Plan addresses actual or potential conflicts of interest arising out of the Employee’s relationship with  (hereinafter “Entity)

**A.** I have requested an exemption pursuant to Section 112.313(12)(h), Florida Statutes (copy attached). Yes: [ ]  No: [ ]

**B.** I have a “Significant Financial Interest” as defined in the Public Health Service (PHS) or National Science Foundation (NSF) conflict of interest regulations which requires a monitoring plan. (For PHS or NSF funded projects only. See [FSU Conflict of Interest website](http://www.research.fsu.edu/research-compliance/conflict-of-interest/) for access to regulations, policies, definitions, procedures, etc.). Yes: [ ]  No: [ ]

If yes, identify all OMNI Project IDs or proposal names and sponsors that are impacted (or attach a list of the same):

**C.** I have a financial interest and/or outside activity reported on my Report of Outside Activity/Conflict of Interest (hereinafter “Outside Activity and Financial Interest Report’) that does NOT require an Exemption from Florida Statutes, but which has been determined by the University to be permitted only pursuant to a monitoring plan. Yes: [ ]  No: [ ]

If yes, attach a copy of your applicable Outside Activities and Financial Interests Report(s).

**2. Description of Conflicts**

[ ]  **A.** Check this box if you answered YES to Question 1.A. above, and skip to Question 4., Responsible Persons. (Your *Request for an Exemption of Conflict of Interest Laws* under Section 112.313(12)(h) will provide the answers to this section.)

[ ]  **B.** Check this box, if you answered NO to Question 1.A. above. Describe below, the conflict(s) of interest (both actual and potential) to be addressed by this monitoring plan. It is recommended that you do this by describing (1) your employment responsibilities at the University, (2) your outside activities and/or financial interest(s) that are involved in this, (3) delineation of the differences, and (4) identification of the potential areas in conflict. Areas of conflict should be identified in detail. The delineation of duties should reveal clear distinctions between your obligations to the University and your efforts and duties for the outside or your financial interest(s).

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| Describe (For 2B):  |

**3. Term of Monitoring Plan**

**If YES is checked in Question 1.A., this monitoring plan, if approved, shall be effective for the same period approved for the *Request for Exemption from Conflict of Interest Laws.* If Question 1.A. is checked NO, the effective period of this Monitoring Plan will be:**

**From: Date of Final Signature Through:**

The maximum period shall not exceed five (5) years.

If the personnel monitoring the activities which are the subject of this plan deem that substantive changes to the plan are necessary, this monitoring plan shall be revised as appropriate. The monitoring plan may be terminated with the submission of proper documentation which the monitoring personnel determine appropriately demonstrates the non-existence of a conflict of interest pursuant to applicable policies.

**4. Persons Providing Monitoring**

**A. College Representative**

The individual listed below assumes **primary responsibility** for monitoring Employee’s activities regarding the potential conflict(s) which are the subject of this monitoring plan. This person is referred to in this monitoring plan as the “College Representative.” If under this monitoring plan, the approval of the University is required for any action to be taken, the express written approval of the College Representative must be secured in addition to the specific approvals otherwise required under University rules and policies.

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| --- | --- |
| College: |  |
| College Representative: |  |
| Title: |  |
| Campus Address: |  |
| Campus Phone: |  |
| Campus Fax: |  |
| Campus E-Mail: |  |

**B. Department Representative:**

The Chair of the Employee’s Department or the immediate supervisor of the Employee if the Employee is the Chair of the Department (referred to in this monitoring plan as the “Department Representative”) is also responsible for reviewing the Employee’s outside activities and financial interests as well as reporting any problems or concerns with regard to this monitoring plan to the College Representative. In some instances, it may be necessary to use an alternate or designee assigned by the Chair of the Department or Employee’s supervisor.

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| Department/Unit: |  |
| Dept. Chair/Unit Supervisor: |  |
| Title: |  |
| Campus Address: |  |
| Campus Phone: |  |
| Campus Fax: |  |
| Campus E-Mail: |  |

**C. Institutional Representative:**

Questions regarding this plan may also be directed to the Institutional Representative listed below:

|  |  |
| --- | --- |
| Institutional Representative: | Diana Key |
| Title: | Director, Research Compliance Programs |
| Campus Address: | Office of Research, 2021 Westcott North Annex |
| Phone: | (850) 644-8648 |
| Fax: | (850) 644-5372 |
| E-mail: | dkey@fsu.edu |

**5. Management of Conflicting Interests/Conditions of Approval**

The parameters set forth in this Section 5, are the requirements that Employee must follow in managing the conflict of interest at issue. These requirements define the parameters necessary to effectively manage the conflict, or the potential for conflict, pursuant to Federal, State, and University regulations. Many of the conditions set forth in this section are restatements of rules, regulations, or statutes to which Employee is already subject as a University employee, but which are important to note given the conflicts of interest involved. Additional requirements are included, as deemed appropriate. The Employee, College Representative, and Department Representative should review and discuss all the conditions of this Monitoring Plan.

**A. Integrity of Research and Education Programs.** Employee recognizes that his/her primary professional responsibilities are to the University. Teaching and research, based on the highest standards of scientific objectivity, are paramount to fulfilling that responsibility as well as adherence to the Code of Ethics as established under Part III of Chapter 112, Florida Statutes. To confirm that Employee is meeting applicable standards, the following will apply:

The College Representative may attend all laboratory/program and/or personnel meetings and shall be provided with any information regarding Employee’s activities, upon request.

As part of the annual reporting process described in Section 5.M. below, Employee’s activities will be reviewed. This review may include a discussion of the Employee’s allocation of efforts as well as Employee’s research methodologies and results as applicable. Additional reviews (e.g. quarterly or semi-annual) monitoring of the Employee’s activities by independent reviewers, such as a committee of disinterested scientists, modification of the research plan/protocol, or disqualification from participation in all or part of the research, may also be required depending on the nature and extent of the conflicts of interest. The [*Monitoring Plan Review Checklist*](http://research1.magnet.fsu.edu/media/2314/monitoring_checklist.docx) should be used for all reviews as described herein. Please refer to Section 5.O for special conditions, if any.

**B. University Rights to Intellectual Property.** Employee has agreed not to take any action which would in any way limit the University’s rights to intellectual property developed by Employee or any other University employee or student. The Employee will continue to work diligently with the University to assure that publications of research or work performed are done in such a manner that the intellectual property rights of the University and those associated with the University are maintained. Employee will promptly fulfill all requirements of the applicable University intellectual property policies, including all reporting requirements.

**C. Dissemination of Research Results.** Publication of research results is the cornerstone to the existence of the University’s laboratory/program(s) and to the undergraduate/graduate program(s) that might also be associated with Employee and Employee’s potential conflict of interest. Employee will assure that publications are accomplished in a manner that protects the intellectual property rights of the University and will assure that graduate students are allowed to present, defend or publish theses and dissertations in a timely manner and that post-doctoral personnel are allowed to publish and make presentations in a timely manner.

**D. Use of University Equipment, Facilities, Services, or Personnel in Outside Activity.** University equipment, facilities, services, and personnel are available only for the use and benefit of the University. Therefore, Employee agrees to not use any University equipment, facilities, services, or personnel in the course of any responsibilities he/she has pursuant to his/her activities with Entity. Incidental use of equipment, such as the telephone (local calls), fax machines, and computer resources by the Employee for communication purposes may be permitted.

If in the future Employee wishes to use University equipment, facilities, services, or personnel, he/she must receive approval through the appropriate University departments and representatives. Such use must be only on a non-interference basis, may require compensation to the University, and must be justified by the uniqueness of the equipment or services. Contact the Institutional Representative for guidance.

Authorized use of equipment, facilities, services, or personnel by Entity pursuant to a research agreement between Entity and the University is not subject to this provision.

**E. No Use of University Name.** Employee may not use the name of the University in connection with Employee’s activities with the Entity without the express written permission of the Institutional Representative with regard to each instance of use. Such written approval is required in addition to any approvals required under any agreement between the Entity and the University. Additional conditions may be imposed upon such approval such as the requirement that the Entity include a disclaimer concerning the University in connection with the use of the name.

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| **Modifications to Section 5.E. (if any):**  |

**F. Disclosure to Laboratory/Program or Center Personnel.** Within thirty (30) days of final approval of this Plan, the College Representative will meet with personnel and students working in the Employee’s laboratory/program/area to discuss their duties and responsibilities in the laboratory/program/area, the Employee’s duties and responsibilities in the laboratory/program/area, and the Employee’s relationship with the Entity.

An *Employee Disclosure Statement* will be provided to them at the meetings. A template is provided in Attachment A. Employee will inform the College Representative whenever any personnel changes (both additions and deletions) are made in Employee’s laboratory/program/area that in any way impact this Monitoring Plan. Furthermore, Employee will keep the College Representative informed of any changes in student supervision that impact this Monitoring Plan.

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| **Modifications to Section 5.F. (if any):**  |

**G. Disclosure in Proposals and Publications.** Appropriate disclosures of Employee’s interests in, or relationship to, the Entity, will be made in all reporting of work or research, which is funded by the Entity, and in all reporting of work or research, which may favorably or unfavorably affect any financial interests (e.g. increased royalty payments and equity growth) Employee derives from the Entity.

A sample disclosure statement is provided below:

*[Insert Name of Employee] [owns stock or stock options in, and/or receives royalties from, and/or describe any other relationship to] [Insert name of Entity] and may benefit financially as a result of the outcomes of [Insert Name of Employee’s] research or work reported in this publication.*

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| **Modifications to Section 5.G. (if any):**  |

**H. Human Subject Research.** If Employee is conducting research involving human subjects and the outcome of that research may favorably or unfavorably affect any financial interests Employee derives from the Entity, Employee shall fully disclose Employee’s interest in, or relationship to, the Entity to the Institutional Review Board (IRB) and follow any requirements or limitations placed on Employee or the research imposed by the IRB. In addition, Employee will disclose Employee’s interest in, or relationship to, the Entity in the IRB-approved informed consent to be provided to each human subject involved in the research.

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| **Modifications to Section 5.H. (if any):**  |

**I. Entity’s Use of University Personnel and Students.** Employee agrees to notify University whenever he/she becomes aware that Entity is employing any students or other University employees, even on a part-time or voluntary basis, without the express written approval of the University.

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| **Modifications to Section 5.I. (if any):**  |

**J. Confidentiality of Information.** Employee will not disclose or provide any University information or work products, including research results, not available to the general public to Entity except under the terms of an appropriate written agreement between the University and the Entity.

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| **Modifications to Section 5.J. (if any):**  |

**K. No Competition with University.** Employee will not process any research contracts or grants through Entity if those grants may otherwise have been processed through the University. Employee may apply for such grants/contracts through Entity only after College Representative has determined there is no University interest in pursuing them.

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| **Modifications to Section 5.K. (if any):**  |

**L. Avoidance of Contractual Conflicts.** In order to avoid conflict situations, Employee has agreed not to participate in any negotiations concerning agreements between the University and the Entity except to provide information concerning Employee’s activities at the University in connection with proposed agreements or research agreements.

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| **Modifications to Section 5.L. (if any):**  |

**M. Annual Report.** By June 1 of each year this plan is in effect, Employee must make a report not less than annually to the College Representative using the [*Monitoring Plan Review Checklist*](http://research1.magnet.fsu.edu/media/2314/monitoring_checklist.docx).

The College Representative and Employee shall discuss the report; copies of which must be maintained by the College Representative and forwarded to the Institutional Representative with all other required disclosures. The discussion and report will include, at a minimum, the following:

* A description of Employee’s University efforts, including publications, teaching, and research;
* A description of the outside activities allowed under this plan;
* A description of the use of University resources in the outside activity and by the Entity;
* A description of how all the conditions of this plan have been met; and
* Any changes and/or alterations to the established monitoring plan

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| **Modifications to Section 5.M. (if any):**  |

**N. Changes to Disclosure**. Employee will promptly report to the College Representative any changes to the information disclosed by Employee in connection with this Monitoring Plan, including changes in the Employee’s relationship to the Entity, significant changes in Employee’s responsibilities at the University, and new sources of funding for research in areas in which the Entity also has an interest. The College Representative must also be informed of any new additional outside activities or financial interests required to be reported under applicable University policies. This disclosure will allow the College Representative to evaluate whether any changes to this Monitoring Plan or the Employee’s request for exemption, if applicable, are necessary. The College Representative shall confer with the Institutional Representative, as needed, in making a determination of whether any changes are required. This reporting required from the Employee is in addition to any other disclosures or reporting that is required to other University personnel pursuant to applicable University policies.

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| **Modifications to Section 5.N. (if any):**  |

**O. Other Conditions.** Other parameters necessary to effectively manage the conflict, or the potential for conflict, are set forth below *(Check all that apply and delineate action to be taken)*:

[ ]  Monitoring of activity or research by independent reviewers;

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| [ ]  Advisory committee of disinterested scientists,[ ]  Other committee or individuals as described below: |
| Describe: |

[ ]  Modification of the research plan/protocol;

|  |
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| Describe: |

[ ]  Disqualification from participation in all or a portion of the research/protocol;

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| --- |
| Describe |

[ ]  Other

|  |
| --- |
| Describe: |

**P. Compliance with University policies.** Employee must comply in all respects with University policy, which includes filing all required Outside Activities and Financial Interests Reports, following all federal reporting requirements, as applicable, and filing new requests for exemption as needed.

**6.** **Employee Acknowledgement**

Employee understands and agrees that violation of the conditions of this Monitoring Plan or University rules and policies governing outside activities and conflict of interest or the unauthorized use of University equipment and personnel and intellectual property, is grounds for withdrawing approval of Employee’s Exemption of outside activity or interest, this Monitoring Plan and the termination of any agreements between the University and the Entity.

 Acknowledge & Agreed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

 Employee Signature

 Type Name:

**7. Institutional Approvals**

The signatures below reflect the approvals of the following personnel to implement the Monitoring Plan set forth in this document.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Role** | **Signature** | **Name** | **Title** | **Date** |
| College Representative |  |  |  |  |
| Department Representative |  |  |  |  |
| Institutional Representative |  | **Diana Key** | **Director, Research Compliance Programs** |  |

Check Attachments:

[ ]  Exhibit A - Employee Disclosure Statement (The “To” name may be left blank if the individual to receive the disclosure is unknown, or if there are multiple individuals to receive the disclosure.)

[ ]  Request for Exemption/Disclosure Under Section 112.313(12)h, Florida Statutes per Section 1.A above

 [ ]  List of proposed and awarded projects per Section 1.B above

 [ ]  Outside Activities and Financial Interests Report(s), per Section 1.C above

 [ ]  Other; describe:

**Exhibit A**

**Employee Disclosure Statement**

TO:  [Name of individual to receive disclosure]

FROM: (“Employee”)

The University has determined that a conflict of interest or potential conflict of interest exists by the Employee’s relationships and financial interests noted below. The University has determined that the noted conflict can be managed through an appropriate monitoring plan agreed to by the Employee. As part of that monitoring plan, all applicable FSU personnel and students are being advised of these relationships and financial interests by means of this disclosure statement.

[ ]  The Entity referenced in this disclosure is:  (the “Entity”)

[ ]  Employee has filed a Request for Exemption/Disclosure under Section 112.313(12)(h), Florida Statutes. The exemption was requested in order to:

[ ]  Allow Entity to enter into a licensing agreement with the University.

[ ]  Permit research which will be conducted under a research contract between the University and the Entity.

[ ]  Other:

Financial Interests:

[ ]  Employee has invention(s) that are licensed by the University to the Entity.

[ ]  Employee has an ownership interest in the Entity.

[ ]  Employee may receive royalties under the University’s intellectual property policy.

[ ]  Employee has entered into a consulting agreement with the Entity.

[ ]  Employee has a “Significant Financial Interest” as defined by the Public Health Service and/or National Science Foundation regulations (For PHS or NSF funded projects only. See University Policy 7A-21, [Conflict of Interest](http://www.research.fsu.edu/media/2284/policy-7a-21.docx) for more information).

[ ]  Other:

Briefly describe the outside activity or financial interest. Describe work of the Employee at the University and distinguish it from any work done for the Entity.

**College Representative**

The following College Representative has the primary responsibility on behalf of the University to monitor the Employee’s activities as described herein:

|  |  |
| --- | --- |
| College/Center (for independent centers): |  |
| College Representative: |  |
| Title: |  |
| Campus Address: |  |
| Campus Phone: |  |
| Campus Fax: |  |
| Campus E-Mail: |  |

In addition to the Employee, the College Representative is available for consultation with you should you have any questions regarding these relationships or regarding any potential conflicts of interest, including questions concerning research design and conduct, use of University resources, employee or student assignments and ownership of intellectual property.

You may also contact the following Department Representative or Institutional Representative concerning these matters:

**Department Representative:**

|  |  |
| --- | --- |
| Department/Unit |  |
| Dept. Chair/Unit Supervisor |  |
| Title: |  |
| Campus Address: |  |
| Campus Phone: |  |
| Campus Fax: |  |
| Campus E-Mail: |  |

 **Institutional Representative:**

|  |  |
| --- | --- |
| Representative: | Diana Key |
| Title: | Director, Research Compliance Programs |
| Campus Address: | 2021 Westcott North Annex |
| Campus Phone: | (850) 644-8648 |
| Campus Fax: | (850) 644-5372 |
| Campus E-mail: | dkey@fsu.edu |

 **Acknowledgement of Individual Receiving this Notification:**

 Received: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature

 Name:

 Title:

 Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_