University of Florida

Monitoring Plan for Potential Conflict of Interest

|  |  |
| --- | --- |
| **Name of Employee:** |  |
| **College/Area:** |  |
| **Department/Unit:** |  |
| **Campus Address:** |  |
| **Campus Phone:** |  |
| **Campus E-Mail Address:** |  |
| **List all positions *currently* held at the University of Florida:** |  |
| **Project Number(s):** |  |
| **Project Title(s):** |  |

1. **Reason for Monitoring Plan**

**This Monitoring Plan addresses conflicts of interest arising out of my relationship with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Company”). UFRI# \_\_\_\_\_**

***(Check all that apply)***

1. **I have requested an exemption pursuant to Section 112.313(12) (h), Florida Statutes.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Yes: | **[ ]**  |  | No: | **[ ]**  |

1. **I have a “Significant Financial Interest” as defined by the Public Health Service or National Science Foundation conflict of interest regulations which requires a monitoring plan.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Yes: | **[ ]**  |  | No: | **[ ]**  |

1. **I have a financial interest and/or an outside activity NOT requiring an Exemption from Florida Statutes or a monitoring plan under federal conflict of interest regulations, but which is to be permitted only pursuant to a monitoring plan.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Yes: | **[ ]**  |  | No: | **[ ]**  |

1. **I have an approved exemption to Section 112.313(12), Florida Statutes. Because there is a new license and/ or research agreement a monitoring plan is required.**

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| --- | --- | --- | --- | --- |
| Yes: | **[ ]**  |  | No: | **[ ]**  |

1. **Description of Conflicts**

**Complete A or B**

[ ]  A. Check this box if you answered YES to Question 1A above and skip forward to Question 3. Responsible Persons

[ ]  **B.** **Check this box, if you answered NO to Question 1A** above. ***You will need to describe below*,** the conflict(s) of interest by describing 1) your employment responsibilities at the University, 2) your outside activities and/or financial interest(s), 3) delineation of the differences and 4) identification of the potential areas in conflict.

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| --- |
| **Describe for 2B:**        |

1. **Responsible Persons**

The Dean of the College or Area Administrator, as designee of the President of the University, assumes primary responsibility for monitoring Employee’s activities regarding the potential conflict(s). If under this monitoring plan the approval of the University is required for any action to be taken, the express written approval of the Dean of the College, Area Administrator or designee (hereinafter called the “**College Representative or Area Administrator**”) must be secured in addition to the specific approvals otherwise required under University regulations and policies.

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| --- | --- |
| **C****ollege/Area:** |  |
| College Rep/Area Administrator |  |
| **Title:** |  |
| Campus Address: |  |
| Campus Phone: |  |
| Campus E-Mail: |  |

The Chair of the Department or Unit Supervisor is also responsible for assisting with monitoring and reporting any problems or concerns this plan, to the College Representative or Area Administrator. The Chair of the Department, Unit Supervisor or designee (hereinafter called the “**Chair or Unit Supervisor”**) is listed below:

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

Questions regarding this plan may also be directed to UF Research Integrity, which assists with monitoring and approves this plan as listed below:

|  |  |
| --- | --- |
| **Name:** | Andrew Eisman, JD |
| **Title:** | UF Research Representative  |
| Campus Address: | PO Box 100248 |
| Campus Phone: | (352) 273-7218 |
| Campus Fax: |  |
| Campus E-Mail: | abeisman@ufl.edu |

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

**A. Integrity of Research and Education Programs**. Employee recognizes that his or her primary professional responsibility is to the University. An outside activity should not interfere with one’s UF duties. Teaching and research, based on the highest standards of scientific objectivity, are paramount in fulfilling that responsibility as well as adherence to the Code of Ethics as established under Part III of Chapter 112, Florida Statutes.

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

**B. University Rights to Intellectual Property**. Employee shall not take any action which would limit the University’s rights to intellectual property developed by Employee or any other University employee or student. The Employee will ensure 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 and continually fulfill all requirements of the University’s Intellectual Property Policy, including all disclosure and reporting requirements.

The Company may not use University IP (patents, inventions, software, and other patentable and copyrightable works) either commercially or in any research project without a written agreement negotiated and approved by the Office of Technology Licensing or other authorized University signatory.

**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 ensure that graduate students are allowed to present, defend or publish theses and dissertations in a timely manner.

**D. Use of University Equipment, Facilities, Services, or Personnel in Outside Activity**. University and University of Florida Research Foundation, Inc. (UFRF) equipment, facilities, services and personnel are available only for the use and benefit of the University and UFRF. Therefore, if an Employee desires to use any University facilities, equipment or services in their capacity with the Company, Employee **must obtain prior approval** through the “Request to Use University Equipment, Facilities and Services” form. Such use must be only on a non-interference basis, must be compensated, and must be justified by the uniqueness of the equipment or services.

**E. No Use of University of Florida Name**. Employee shall not use the name of the University or UFRF in connection with Employee’s activities with the Company without the express written permission of the College Representative or Area Administrator with regard to each instance of use.

When communicating or acting on matters related to this conflict, Employee must clearly indicate which organization Employee is representing (e.g., UF or the Company).

**F. Disclosure to UF Personnel**. Employee shall disclose Employee’s outside interest to all members of their research group (including, but not limited to, Co-PI’s and/or Co-investigators), and any personnel and students working in the Employee’s laboratory/program. Lab and research group members should be provided with a copy of this monitoring plan and should also be informed that if they have concerns about Employee’s outside interest or this COI monitoring plan, they may contact their supervisor, UF Research Integrity (UFRI), or the UF Compliance Hotline (https://compliance.ufl.edu/uf-compliance-hotline/). Employee will promptly submit copies of the Employee Disclosing Statement signed by lab and group personnel to UFRI.

Employee will promptly inform the College Representative or Area Administrator and UFRI whenever **any personnel changes** are made in Employee’s laboratory/program, and must promptly disclose the outside interest to all new personnel.

Employee is strongly encouraged, though not required, to disclose the Employee’s outside interest to University colleagues and collaborators, as appropriate.

**G. Disclosure in Proposals and Publications**. Employee must disclose their relationship with the Company in all reporting of work or research which (a) is funded by the Company, or (b) may favorably or unfavorably affect any financial interests (e.g. increased royalty payments and equity growth) Employee derives from the Company.

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 Company] and as such may benefit financially as a result of the outcomes of [Insert Name of Employee’s] research or work reported in this publication.

**H. Company’s Use of University Personnel and Students**. Company will not employ any students or University employees, even on a part-time or voluntary basis, without the express written approval of UFRI. In the event University consents to such employment, Employee shall **not** have any supervisory authority over such students or employees at **both** University and the Company.

**I. Confidentiality of Information**. Written agreements, negotiated and approved through standard UF processes, and signed by an appropriate UF official are required in order to share data or confidential/proprietary information between the company and UF, both outgoing and incoming. Employee will not disclose any University or UFRF information, including research results not available to the general public, to Company except under the terms of such a written agreement.

**J. No Competition with University**. Company shall not accept any research contracts and/or grants that may otherwise have been accepted by the University. Employee shall **disclose** **all** potential applications for research contracts and/or grants to the College Representative or Area Administrator. Company may apply for such grants and contracts only after the College Representative or Area Administrator has determined there is no University interest in pursuing them.

**K. Avoidance of Contractual Conflicts**. In order to avoid conflict situations, Employee **shall** **not participate** in any negotiations (on behalf of any party) concerning agreements between the University, UFRF, and/or the Company. Such agreements (including awards, subcontracts, purchase orders, vendor agreements and amendments) between UF and the Company must be negotiated and approved through standard University processes. Employee may not take part in these agreement negotiations or approvals, or otherwise represent either party in the transactions. Additionally, financial exchanges between the Employee’s department, division, college or lab group and the Company must be monitored and approved by the College Representative or Area Administrator. In the event of a conflict between the responsibilities of Employee to UF and any contract between the Employee and any outside entity impacting Employee’s responsibilities to UF, the terms of this Monitoring Plan and the policies and regulations pertaining to UF employees shall control.

**L. Restrictions on Research Participation.** Employee may participate in the conduct of this research project at UF, but not at the outside company, and under no circumstances at both.

Employee may not act as PI on any clinical research project involving human subjects sponsored by the Company. If the Employee plans to initiate research involving human subjects, Employee will immediately notify UFRI and the College Representative prior to undertaking such research. If approved, UFRI will amend the monitoring plan with conditions specific to human subject research.

**M. Human Subject Research.** Not applicable.

**N. Research Data.** All research data will be stored on UF drives and accessible only by UF personnel, unless a written agreement is in place as specified in (I).

Employee, in consultation with College Representative and UFRI, will appoint an independent, non-conflicted data analyst (statistician), who will be responsible for reviewing all data collected and analyzed in support of any research sponsored by the Company. The analyst must conduct an independent data review no less frequently than yearly. The results of the review, including any identified data or methodology anomalies, will be shared with the Employee, College Representative and UFRI at the time of the Annual review, as specified in (O).

**O. Monitoring Plan Review**. Employee must meet with the Department Chair, College Representative, UFRI Representative, and others requested by them, to review this Monitoring Plan at least every six (6) months, and more often if requested by UFRI or the College Representative. Prior to such meeting, Employee shall complete a Monitoring Checklist and shall provide such checklist to the other attendees, who shall review the Checklist with the Employee to ensure Employee’s compliance with the Monitoring Plan. Employee shall immediately provide Chair, College Representative, or UFRI any additional documentation requested to confirm such compliance. After the Meeting, the Checklist and all additional documentation shall be forwarded to UFRI for review. Should the annual review identify non-compliance with the plan or areas of concern, UFRI may, at its sole discretion, institute additional monitoring requirements as an amendment to this monitoring plan or take any other necessary action to protect the interests of UF.

**P. Changes to Disclosure**. **Employee will promptly report** to the College Representative or Area Administrator **any changes** to the information disclosed by Employee in connection with this Monitoring Plan. If the employee anticipates a change in title, time commitment, or decision-making authority at the Company, the employee must report the change to, and receive **prior approval** from, UFRI and the College Representative before such a change may occur. Additionally, any changes should be reflected by an amended outside activity or financial interest disclosure.

**Q. Access to the Conflict Management Plan.** The following parties, as required under University policies and/or practices, will be provided with a copy of this plan:

* Conflicted Party’s Department Chair and Department Administrator
* Conflicted Party’s Division Chief and Division Administrator
* Employee’s lab team and research group
* Institutional Animal Care & Use Committee (IACUC)
* Office of Technology Licensing
* UF Sponsored Programs
* UF Office of Compliance & Ethics
* UF Conflict of Interest Office
* Investigators and study coordinators named on this study

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

**Acknowledged & Agreed To:**

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| **Employee: Date:**  |
| *Typed Name:* |

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| Chair or Unit Supervisor (or designee) Date:  |
| *Typed Name:*  |

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| --- |
| College Representative or Area Administrator Date: (or designee) |
| *Typed Name:*  |

Approved:

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| --- |
| UF Research Integrity Representative Date:  |
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