

Inimmune Conflict of Interest Policy

1. Objective

The objective of Inimmune's Conflict of Interest (COI) policy is to assist employees in the identification of situations that have potential conflicts of interest and to manage potential conflicts such that research conducted at Inimmune is designed, conducted and reported objectively and without consideration of personal financial gain. It is our goal to foster collaborations and maintain scientific integrity without significant concerns about undue influence and bias.

2. Scope

This policy identifies and addresses the real or apparent financial conflicts of interest (FCOI) that may occur when an employee's or company representative's private interests (such as outside professional or financial relationships) may compete with his or her obligations to Inimmune, and defines the requirements of all workers to ensure that those activities are conducted objectively and without consideration of personal financial gain. This Guidance contains Inimmune policies and procedures for identifying, managing and reporting FCOI in compliance with Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94).; it does not include all the possible state or federal laws that may be applicable in any given situation.

3. Responsibilities

It is the responsibility of each Inimmune employee to identify, report and manage potential conflicts of interest (including those of their spouse and/or dependent children). Transparency and understanding of potential conflicts will aid Inimmune in managing potential conflicts of interest in the advancement of our projects, consulting, contract service work and collaborations. All employees will report their FCOIs to the FCOI Officer who will maintain a database of all employee FCOIs and provide a detailed summary to the FCOI Management Team. FCOI Officer will report any personal FCOI directly to the FCOI Management Team. The FCOI Management Team will review the annual disclosure and any supplementary documents to determine whether there is a potential or actual conflict, as indicated by the affirmative response on the COI Disclosure Form. All potential or actual FCOIs will be addressed with a Conflict Management Plan (CMP) developed by the FCOI Officer and approved by the FCOI Management Team.

4. Terms and Definitions

FCIO Officer: The Inimmune FCIO Officer shall be the Vice President of Discovery Research, Chief Scientific Officer or designee appointed by the CEO.

FCIO Management Team: The Inimmune FCIO Management Team shall be at least 3 people, including the FCIO Officer, appointed by the Inimmune COO.

Responsible Person: any person, regardless of title, position, or employment status who is responsible for the design, conduct, or reporting of research, instruction, or service at, on behalf of, or in collaboration with Inimmune.

Financial interests: Financial Interest means anything of monetary value received or held by an Responsible Person or a member of the Responsible Person's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); equity interests (e.g., stocks, stock

options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of income related to such rights and interests. ONLY financial interests that arise to the level of significant (SFI, defined below) represent potential FCOI. Financial Interest does NOT include:

- Salary, royalties, or other remuneration received from or through Inimmune
- Intellectual property rights assigned to Inimmune and agreements to share in royalties related to such rights
- Income from the authorship of academic or scholarly works
- Income or reimbursements from travel, seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or U.S. research institutes that are affiliated with institutions of higher education, academic teaching hospitals, and medical centers
- Financial interests arising solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the employee does not exercise direct control

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (SFI) and that Inimmune reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

Significant Financial Interest (SFI): Significant Financial Interest (SFI) means a Financial Interest consisting of one or more of the following interests of the Responsible Person (and those of the Responsible Person's Family) that reasonably appears to be related to the Responsible Person's Institutional Responsibilities, and:

- If with a publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure, and the value of any equity interest during the twelve-month period preceding or as of the date of disclosure, exceeds \$5,000. For the purposes of this definition, services include, but are not limited to, consulting fees, honoraria, or paid authorship; equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- If with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure exceeds \$5,000; or is an equity interest of any value during the twelve-month period preceding or as of the date of disclosure. For the purposes of this definition, services include, but are not limited to, consulting fees, honoraria, or paid authorship; equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- Income related to intellectual property rights and interests (e.g., patents, copyrights, but NOT including income from the authorship of academic or scholarly works) not paid through the Institution.
- Reimbursed or sponsored travel (applies to Responsible Person involved in Public Health Service funded research only). Disclosures shall include the purpose of the travel, the identity of the sponsor/organizer, the destination and the duration of the travel, and any other information as requested by the disclosure form or FCOI Officer.

Conflict of interest (COI): A Contract or Transaction between Inimmune and an entity in which a Responsible Person or Family Member has a Material Financial Interest or of which such person is a

director, officer, agent, partner, associate, trustee, personal representative, receiver, guardian, custodian, conservator, or other legal representative.

A Responsible Person competing with Inimmune in the rendering of services or in any other Contract or Transaction with a third party.

A Responsible Person's having a Material Financial Interest in; or serving as a director, officer, employee, agent, partner, associate, trustee, personal representative, receiver, guardian, custodian, conservator, or other legal representative of, or consultant to; an entity or individual that competes with Inimmune in the provision of services or in any other Contract or Transaction with a third party.

Gifts, Gratuities and Entertainment. A Responsible Person accepting gifts, entertainment, or other favors from any individual or entity that: does or is seeking business with, or is a competitor of Inimmune; or has received, is receiving or is seeking to receive a loan or grant, or to secure other financial commitments from Inimmune; is a charitable organization; under circumstances where it might be inferred that such action was intended to influence or possibly would influence the Responsible Person in the performance of his or her duties. This does not preclude the acceptance of items of nominal or insignificant value or entertainment of nominal or insignificant value (< \$50) that are not related to any particular transaction or activity of Inimmune.

Executive Position: Any position that includes responsibilities for a material segment of the operation or management of a business. This would include a position on a Board of Directors.

Family: A spouse, registered domestic partner, and/or dependent child/children. **Responsible Person:** The principal investigator, co-investigator and other Inimmune employees or volunteers, or any Inimmune research collaborator, including visiting scientists, responsible for the design, conduct or reporting of research or responsible for preparing a proposal for research funding.

Outside Business: Any business that is not affiliated with or controlled by Inimmune.

Participate: To be part of the described activity in any capacity or position that may influence an outcome.

Project Period: The project period should match the performance dates on the grant or contract or similar document. This may be an anticipated start and completion date.

Revision to Previous Disclosure: A revised COI form is required prior to the annual update, within 30 days of discovering or acquiring a new SFI if any response to an item in Section I has changed from "NO" to "YES". A revised COI form does not have to be submitted to update Section II unless the new project involves a financially interested business with which you have a significant financial interest.

Student: Any person enrolled in an undergraduate or graduate program, postdoctoral fellows, interns, or other

5. Policy

Inimmune requires that each employee disclose to the Inimmune FCOI officer all significant financial interests of the employee (including those of the Responsible Person's spouse and dependent children) on an annual basis. Any new FCOIs during the year or FCOIs for new employees must be reported to the FCOI officer within 30 days: (i) that would reasonably appear to be affected by research or activities or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

5.1 Confidentiality. Each Responsible Person shall exercise care not to disclose confidential information acquired in connection with such status or information the disclosure of which might be adverse to the interests of Inimmune. Furthermore, a Responsible Person shall not disclose or use information relating to the business of Inimmune for the personal profit or advantage of the Responsible Person or a Family Member.

5.2 Training and Review of Policy.

- a) Each new Responsible Person shall be required to train on this Policy and to acknowledge electronically (Qualio System) or in writing that he or she has done so and will comply with all provisions of this policy.

- b) The FCOI Officer and all members of the FCOI Management Team must complete the NIH or Citi on-line COI training programs every 4 years and provide documentation of training to the FCOI Officer.

Each Responsible Person shall annually complete COI Questionnaire (see Section 8: Attachments) identifying any relationships, positions, or circumstances in which the Responsible Person is involved that he or she believes could contribute to a Conflict of Interest arising. Such relationships, positions, or circumstance might include service as a director, advisory board member or consultant to a not-for-profit organization or ownership of a business that might provide goods or services to Inimmune. Any such information regarding business interests of a Responsible Person or a Family Member shall be treated as confidential and shall generally be made available to the FCOI Officer and FCOI Management Team appointed to address Conflicts of Interests, except to the extent additional disclosure is necessary in connection with the implementation of this Policy.

- c) This policy shall be reviewed annually by the Inimmune Management Team in consultation with the FCOI Officer. Any changes to the policy shall be communicated immediately to all Responsible Persons.

5.3 Conflict management plan (CMP)

The FCOI Officer will review the annual disclosures and any supplementary documents to determine whether the interest may reasonably be thought to directly and significantly affect the design, conduct, or reporting of the project activities. If a conflict is found, the FCOI Officer shall determine how to manage, reduce, or eliminate the conflict. The individual Conflict Management Plan must be approved by the FCOI Management Team and the FCOI Officer shall inform the employee of the decision.

Considerations in developing the conflict management plan (CMP) include the nature of the work/project, the magnitude of the interest and the degree to which the conflict is related to the work/project, the extent to which the interest could be directly and substantially affected by the work or project. The CMP will include the following elements at a minimum:

- The role and principal duties of the conflicted employee in the work/project;
- Conditions of the management plan (see examples below);
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the employee agreement to the management plan; and
- How the management plan will be monitored to ensure employee compliance.

Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; journal editors, to Institution's Institutional Review Board(s))
- Monitoring the project by independent reviewers
- Modification of the research plan to manage, reduce or eliminate the COI
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest);
- Severance of relationships that create financial conflicts.

5.4. Records Retention. All disclosure forms, conflict management plans, and related documents shall be maintained in accordance with Montana state law; or where no policy is specified, for a period of five years after the FCOI has been completely resolved and no longer requires a CMP.

5.5 Failure to comply

Disclosure of SFI is essential for Inimmune to implement its FCOI policy. Non-compliance with this policy or with the restrictions imposed under this policy may result in disciplinary action and/or sanctions including suspension or termination of employment.

6. Institutional Reporting Requirements

Prior to the expenditure of funds under an NIH award (with the exception of SBIR/STTR Phase I awards), the FCOI Officer will report all FCOIs to the PHS Awarding Agency in accordance with regulations (43 CFR 50.605) and assure that the interest has been managed, reduced, or eliminated. Financial disclosures will be made on an annual basis or when there has been a change in FCOI. For any financial COI identified as conflicting subsequent to the initial report, the report will be updated within 60 days of notification with a written description indicating that the new COI has been managed, reduced, or eliminated.

7. References

National Science Foundation Award Administration Guide (NSF 09-29) (April 2009).

Department of Health and Human Services (HHS), Public Health Service (PHS), 42 Code of Federal Regulations (CFR), Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" for grants and cooperative agreements; and 45 CFR Part 94, "Responsible Prospective Contractors" for contracts.

8. Attachments

COI Questionnaire

FCOI-NIH tutorial (2018): https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html