

CONFLICT OF INTEREST GUIDELINES For the Therapeutics Initiative (last revised April 23, 2019)

Purpose of the Guidelines

These Therapeutics Initiative Conflict of Interest Guidelines (Conflict of Interest Guidelines) are intended to ensure the highest ethical standards and maintenance of the integrity of the Therapeutics Initiative (TI). The principles of transparency and disclosure are essential to achieving these objectives. Participants in all aspects of the TI will ensure that conflicts of interest are identified and resolved, thereby preserving the objectivity and credibility of the TI.

Definitions

“Entity” means any company, organization (including government or university) or individual that may have a direct or indirect interest in the matters under consideration in the TI;

“Immediate Family Member” means the spouse or child of the Participant;

“Participant” means a member of staff, Faculty, or any committee or subcommittee that participates (whether through work, consulting, providing advice, recommendations or otherwise) in the TI;

Applicability

These Conflict of Interest Guidelines apply to all Participants.

Scope of Conflict of Interest

A conflict of interest may exist whenever a Participant or an Immediate Family Member of a Participant has a direct or indirect interest or relationship, financial or otherwise, with an Entity that may affect or reasonably appear to affect the objectivity or fairness of the Participant in the TI.

Process for Determining Existence of Conflict of Interest

- 1) Each Participant must provide the disclosure of information as required in these Conflict of Interest Guidelines. The TI Co-Managing Directors will determine if the interest or relationship of a Participant in the TI amounts to a conflict of interest.
- 2) If it is determined that the circumstances or interests of the Participant amount to a conflict of interest, the Participant shall be excused from relevant TI duties.

Disclosures of Conflicts of Interest

- 1) Upon the appointment of a Participant to the TI, the Participant is required to complete and submit a TI Conflict of Interest Disclosure Form to the TI Manager.
- 2) In addition, all Participants must complete and submit an updated TI Conflict of Interest Disclosure Form annually to the TI Manager.

- 3) Notwithstanding paragraphs 1) and 2) above, the obligation to disclose potential conflicts of interest is ongoing, and all Participants must inform the TI Manager of any potential conflict of interest that arises at the earliest opportunity.
- 4) Without limiting the generality of the foregoing, as part of the TI Conflict of Interest Disclosure Form, and as part of the ongoing duty of disclosure, Participants are required to disclose the following information in relation to themselves and their Immediate Family Members:
 - a) amount and source of payments received from any Entity over the previous three years including salary, honoraria, royalties, and payments for services rendered;
 - b) funds received from any Entity for research during the previous three years;
 - c) number of shares and current value of stock (excluding mutual funds) held in any Entity;
 - d) any current ownership interest in an Entity that is not publicly traded;
 - e) employment by or appointment to the Board of Directors of an Entity during the previous three years; and
 - f) any additional interest, affiliation or relationship with an Entity which may create or reasonably be perceived as creating a conflict of interest.
- 5) When Participants receive TI meeting agendas and/or documents, they shall review the details provided in the materials to ensure that neither they nor their Immediate Family Members have potential conflicts of interest with any Entity involved. Any potential conflicts of interest (including any that have been previously disclosed in the initial or annual TI Conflict of Interest Disclosure Form) must be declared in writing, as soon as possible.

Amendment to the Conflict of Interest Guidelines

After appropriate consultation, the Conflict of Interest Guidelines may be amended by the TI Co-Managing Directors.

Appendix 1.1

CONFLICT OF INTEREST DISCLOSURE FORM

To: TI Manager

1. I have read and understood the Therapeutics Initiative (TI) Conflict of Interest Guidelines (“Conflict of Interest Guidelines”) and I agree to be bound by the obligations contained therein. I understand that it is my responsibility to report to the TI Manager any potential conflict of interest as defined in the Conflict of Interest Guidelines, and to disclose the information requested in the Conflict of Interest Guidelines. I understand that if a potential conflict arises, this information may be shared with the TI Co-Managing Directors and Executive Committee. I also understand that the information disclosed will not be made public, unless otherwise agreed to, and will be held on file by the TI Manager.
2. I understand that for the purposes of the Conflict of Interest Guidelines, and for the purpose of this Conflict of Interest Disclosure Form, “Entity” means any company, organization or individual that may have a direct or indirect interest in the matters under consideration by the TI.
3. I have reviewed my activities and interests, and those activities and interests of my immediate family members (spouse or child) as they relate to the matters itemized in the disclosure section of the Conflict of Interest Guidelines. Attached is the full listing of those activities and interests, which I certify discloses all relevant information with respect to my and my immediate family members’ activities and interests in relation to any Entity.
4. I promise to inform the TI Manager of any change in circumstances that may create a conflict of interest, as soon as it is known to me.
5. I agree not to disclose or misuse, in any way, information that I may receive in the course of my duties and activities with the TI.

<i>April 25, 2019</i>	<i>Carla O'Sullivan</i>	<i>CO Sullivan</i>
Date	Print Name	Signature

Appendix 1.2

CONFLICT OF INTEREST CONFIDENTIAL DISCLOSURE FORM

Disclosures are required by the TI Conflict of Interest Guidelines -- All Participants must declare potential conflicts of interest (including any that have been previously included in the TI Conflict of Interest Disclosure Form) as soon as possible.

Participants should provide this information in writing to the TI Manager using this form (add pages as necessary).

Drug/Device Name	Indication	Entity	Potential Conflict
epinephrine auto injector	anaphylaxis		history of anaphylaxis may obscure objectivity in upcoming TI letter

April 25, 2019

Date

Cait O'Sullivan

Print Name

COSullivan

Signature