



## PI-Exclusion Conflict Management Plan for Human Subject Research

<b>Conflicted Investigator</b>	
<b>Title and Department</b>	
<b>Entity</b>	
<b>Supervisor</b>	
<b>Conflict Management Plan Identifier</b>	

My relationship with the above entity includes significant financial interests under University Policy RI 01. My significant financial interests and participation in the research listed in Attachment A has been reviewed and, in accordance with applicable regulations and University policies, determined to create a conflict of interest that is permissible, subject to the below conflict management plan.

### The following conditions apply to my participation in all research listed in Attachment A:

Condition	Details
1. <b>Supervisor Approval and MyDisclosures</b>	I will obtain approval from my supervisor and update my Annual Disclosure Certification in MyDisclosures when I anticipate changes to my relationship with [Entity]. This includes, but is not limited to, when I intend to initiate new roles or responsibilities for this entity, when the funding sources for the research listed in Attachment A change or when I propose to participate in additional research that is related to this entity. Such changes may require approval from the Conflict of Interest Committee or the Institutional Conflict of Interest Committee.
2. <b>Disclosure to Public</b>	I will disclose my significant financial interests in all abstracts, publications, presentations, and press releases associated with the research listed in Attachment A.
3. <b>Disclosure to Funding and Regulatory Agencies</b>	I will disclose my significant financial interests in applications or proposals to fund research when required by the funding agency or other funding source. I will disclose my significant financial interests to regulatory agencies (e.g., the Food and Drug Administration) when required.
4. <b>Disclosure to Individuals Who are Involved in Research</b>	I will provide the Conflict of Interest Division with a list of names and email addresses of individuals who are employed by or affiliated with the University and who are involved in the research listed in Attachment A. I will send this list to <a href="mailto:coi@pitt.edu">coi@pitt.edu</a> within five business days of the execution of this conflict management plan. When individuals newly employed by or affiliated with the University participate in this research, I will email an updated list to the Conflict of Interest Division.  The Conflict of Interest Division will email these individuals to notify them of my conflict of interest.
5. <b>Student Engagement</b>	Before engaging any students in the research listed in Attachment A, I will seek approval of their non-conflicted department chair or equivalent supervisor.
6. <b>Interpretation of Study Results</b>	Consistent with professional standards, I will not be the sole faculty investigator interpreting study results. I may be part of a team that evaluates study results, provided the team includes at least one non-conflicted faculty investigator.
7. <b>Disclosure to Human Subjects (when applicable)</b>	I will ensure my significant financial interests are disclosed in informed consent forms. The following language will be used:  One or more of the investigators conducting this research has a financial interest in [Entity]. This means it is possible that results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully by the Human Subject Protection Advocate of the University of Pittsburgh at (866) 212-2668 [or by the Principal Investigator, [Name], at [Telephone Number], who has no financial conflict of interest with this research.]
8. <b>Principal Investigator Prohibition</b>	I will not serve as Principal Investigator on the human subject protocol(s). Additionally, I will not serve as the Principal Investigator on an agreement, contract, or award from [Entity] that will provide funding or other support for [this protocol/these protocols].

I may serve as a co-investigator on the above protocol(s). I may serve as a co-investigator on an agreement, contract, or award from [Entity] that will provide funding or other support for the above protocol(s).

9.	<b>Recruitment Prohibition</b> <i>(when applicable)</i>	I will not be involved in the recruitment of human research subjects.
10.	<b>Study Consent Prohibition</b> <i>(when applicable)</i>	I will not be involved in the human subject research consent process, and I will not obtain informed consent from subjects.
11.	<b>Recording of Human Research Subject Data Prohibition</b> <i>(when applicable)</i>	I will not engage in the recording of research data from human subjects.
12.	<b>Clinical Assessments and Intervention Outcomes Prohibition</b> <i>(when applicable)</i>	I will not be involved in clinical assessments of study eligibility criteria or intervention outcomes.
13.	<b>Data and Safety Monitoring Prohibition</b> <i>(when applicable)</i>	<p>I will not directly participate in data and safety monitoring activities for human subject studies, including decisions about adverse event reporting.</p> <p>I may participate in the open portion of data safety and monitoring board or other equivalent meetings, provided I disclose my significant financial interests at the beginning of each meeting and this information is acknowledged in the meeting agendas and minutes.</p>
14.	<b>Disclosure to Other Sites and Steering Committee</b> <i>(when applicable)</i>	I will disclose my significant financial interests to the overall study Principal Investigator and to the study steering committee of the multi-site study associated with [protocol number] within five business days of the execution of this conflict management plan.

## Attachment A: Research

This conflict management plan is applicable to the below research.

Human Research	
PittPRO Protocol Number	Title: Funding Source: Funding Source Award: Protocol Principal Investigator: Funding Source Principal Investigator:

SAMPLE

## Attachment B: Signature Page

### Conflicted Investigator

As a University Member, I will adhere to all applicable University policies, including those that address conflicts of interest and intellectual property, and to the above conflict management plan.

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[Name]

[Date]

### cc:

Supervisor of Conflicted Investigator

Principal Investigator

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