THE RCOI PROGRAM COMPONENTS—DISCLOSURE, REVIEW AND MANAGEMENT

DISCLOSURE
Under Penn’s RCOI policies, you may be required to disclose certain, relevant financial interests / relationships. See, RCOI Disclosure Process

RCOI REVIEW PROCESS

Screening
When a Disclosure is received by the OVPR, it is reviewed by staff for completeness. You will be contacted via e-mail or telephone if staff need further information or require clarification in order to review your Disclosure. Generally, Disclosures that report Significant Financial Interests are referred to the Conflict of Interest Standing Committee (CISC) for review and management recommendations.

Conflict of Interest Standing Committee (CISC) – Review and Recommendation
The CISC, which consists of members of the standing faculty and ex officio members, all with voting rights, advises the Senior Vice Provost for Research as to whether disclosed Significant Financial Interests constitute conflicts of interest which must be managed, reduced or eliminated. At each bi-monthly meeting, a CISC member presents a summary of information reported in the Disclosure, relevant information about the research, and any supplemental information.

After discussion, the CISC conducts the following analysis:

<table>
<thead>
<tr>
<th>1. Does the research involve a Clinical Trial?</th>
<th>2. Does the research involve a Significant Financial Interest?</th>
</tr>
</thead>
<tbody>
<tr>
<td>If No to both 1 and 2</td>
<td>If Yes to 1 and 2</td>
</tr>
</tbody>
</table>

- The governing policy is [Financial Disclosure and Presumptively Prohibited Conflicts for Investigators Participating in Clinical Trials](#).

  - Individual is presumptively prohibited from participation unless CISC finds Compelling or Ameliorating Circumstances.

  - If the CISC finds Compelling or Ameliorating Circumstances, will recommend a management plan.

- The governing policy is [Financial Disclosure Policy for Research and Sponsored Projects](#).

  - CISC recommends whether the Significant Financial Interest is manageable and if so, a management plan.
STANDARD MANAGEMENT OPTIONS
The CISC has discretion to recommend a variety of management requirements, depending on the type and amount of the financial interests, the nature of the research, the role of the Investigator, and other factors. These options include:
- Limitations on an Investigator’s financial interests
- Required disclosures in all publications and presentations, to study participants in the informed consent for the study, and to all the investigators, research personnel, students, trainees and others working on this research
- Compliance with additional Penn and School policies, including disclosure, review and approval of consulting or other personal service agreements and assurance that any scope of work for such agreements remains in all respects separate from and subordinate to the Investigator’s responsibilities as a Penn faculty member and employee
- Specific restrictions or conditions on the Investigator’s role in the research (e.g., appointment of a co-PI; limitation on involvement in subject selection, recruitment, data analysis); changes in the study design (e.g., blinding)
- Continuing reporting obligations
- Other requirements

FINAL DETERMINATION
The Sr. Vice Provost for Research makes the final determination regarding whether disclosed financial interests constitute conflicts of interest which must be managed, reduced or eliminated, and if management is recommended, determines the required elements of the management plan. The determination will be communicated in writing to the Investigator with copies sent to the Investigator’s chair and other University officials charged with RCOI oversight responsibilities. The Investigator is required to indicate acceptance of the management plan by returning a signed copy of the letter to the OVPR. The Investigator is also required to annually certify that there have been no changes in his/her financial interests relevant to the specific research since last reported to the OVPR and that s/he is in compliance with all aspects of the management plan then in effect.

An executed management plan is required in order for the ORS to spend awarded funds and for the IRB to approve a research protocol.

FEDERAL RCOI REPORTING REQUIREMENTS
If required under federal regulation, the ORS electronically submits RCOI reports via the eRA Commons.

For questions regarding RCOI, please contact:
Irene Soroka
Research Conflict of Interest Program Manager
(215) 898–3603
mailto:coi@exchange.upenn.edu