Financial Conflict of Interest Submission Form

Date: 
Investigator Name: 

In keeping with directives from the Department of Health and Human Services on “Financial Relationships and Interests in Research Involving Human Subjects” published in the Federal Register on May 12, 2004, investigators who are applying to the Seton Hall University Institutional Review Board to conduct human subjects research must disclose the presence of significant financial interests that may be related to the proposed work. This requirement is also intended to be consistent with the Seton Hall University Financial Conflict of Interest Policy for Sponsored Projects. Collaboration(s) with industry, government and other commercial and non-commercial entities may exist to facilitate a research project. However, financial incentives that may accompany this collaboration may also create a financial conflict of interest (FCOI) that has the potential to undermine the validity of the research, create a real or apparent bias in the performance of the study, or jeopardize the safety of human research participants.

A significant financial interest is defined as the receipt by you, your spouse (if applicable), or your dependent children (if applicable), of any of the following during the past 12 months:

- Remuneration that exceeds $5,000 that may be paid in the form of a salary, regular income, consulting fees, honoraria, work-for-hire, or other payment method from a publicly traded or non-publicly traded Entity;
- Any equity interest (e.g., stock, stock option, or other ownership interest) in a privately-held or public company that exceeds $5,000;
- Any remaining remuneration and equity not covered above from an Entity that, when added together, exceeds $5,000 in value;
- An income that exceeds $5,000 from intellectual property right and interests (e.g., patents, copyrights); or,
- All travel that is reimbursed or sponsored by an Entity other than the investigator’s employer, and related to their institutional responsibilities exceeding $5,000 in value from a single Entity.

Payments (including travel) received from Seton Hall University and those received from any of the following entities are also excluded provided that they were received for teaching engagements, lectures, seminars or service on advisory committees or review panels:

- Government agencies;
- US institutions of higher education and research institutes affiliated with them
- Academic teaching hospitals

You do not have to report salary, royalties, travel, or other remuneration from your employer or income from investment vehicles and retirement accounts so long as the investigator does not directly control the investment decisions made in these vehicles.
Financial Conflict of Interest Submission Form

After reviewing this information, do you, your spouse (if applicable), or your dependent children (if applicable), have a significant financial interest related to the proposed research study?

☐ Yes. If so, please use the space below to describe.

☐ No

By signing and submitting this form, you confirm that you understand these rules and acknowledge that any change in circumstance that has the potential to alter your current responses must be disclosed to the Seton Hall University Institutional Review Board within 30 days of your becoming informed.

Investigator Name: __________________________________________

Signature: __________________________________________

Date: __________________________________________

In the space provided, please describe any circumstance that contributed to your selection of Yes. The information provided will be treated as confidential.