Appendix I COI Implementation

Definitions

“Financial Conflict of Interest” (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

“Financial Interest” means anything of monetary value or potential monetary value that reasonably appears to be related to the individual’s duties and responsibilities, including, but not limited to:

- Payment for service (e.g., a consulting fee, lecture payment, or honorarium), except as otherwise excluded by this policy;
- A gift (e.g., money, hospitality, or a physical item);
- An equity interest (e.g., stock, stock option, security, or other ownership interest);
- An intellectual property right (e.g., a patent, copyright, or royalty from such right);
- Other interests as determined by Duke. For example, a financial interest may only have potential to be of value, like an option in a non-publicly traded company. Because this potential value may be an economic incentive, such a situation is considered a financial interest.

The term does not include:

- Ownership of shares in a mutual fund;
- Salary or other remuneration from Duke or another accredited institution of higher education;
- Salary or other remuneration from the U.S. Department of Veterans Affairs or another federal, state, or local government entity; and
- A distribution from Private Diagnostic Clinic, PLLC.

“Individual” means the principal investigator/project director, co-investigators, and any other person regardless of title (and/or their immediate family) who is responsible for the design, conduct, or reporting of research. The principal investigator is responsible for identifying other persons who are responsible for the design, conduct, and reporting of the research for which extramural funding is sought or received.

“Immediate family” means spouse or spousal equivalent and dependent children.

“Institutional responsibilities” means an Individual’s professional responsibilities on behalf of the School, as defined by the School in its policy on financial conflicts of interest, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

“Investigator” means the principal investigator and any other person regardless of title or position who has responsibilities for the design, conduct, or reporting of research and includes the investigators’ immediate family.

“Manage” means taking action to address a financial conflict of interest, which can include reducing
or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

“PHS Awarding Component” means the organizational unit of the PHS (Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH)) that funds the research subject to 42 CFR 50, subpart F and 45 CFR, part 94.

“Research” means a systematic investigation, study, experiment or project intended to develop or contribute to generalizable knowledge.

“Small Business Innovation Research” (SBIR) means the extramural research program for small business that is established by the awarding components of the PHS and certain other federal agencies under Public Law 97-219, the Small Business Innovation Development Act as amended and includes the Small Business Technology Transfer (STTR) program, established by Public Law 102-564.

“Significant Financial Interest” (SFI) means receiving anything of monetary value whether or not the value is readily ascertainable, that reasonably appears to be related to the Individual’s institutional responsibilities, including, but not limited to:

- Payments for services (e.g., consulting fees, lecture payments, paid authorship or honoraria);
- Equity interests (e.g., stocks, stock options, or other ownership interests); and
- Intellectual property rights and interests (e.g., patents, copyrights, and royalties from such rights).

The term does not include:

- Ownership of mutual funds;
- Salary or other remuneration from the School;
- Private Diagnostic Clinic distributions;
- Income from seminars, lectures, or teaching engagements sponsored by Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education;
- Income from service on advisory committees or review panels for Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education (e.g., NIH). Reporting is necessary when a foundation is supported by industry.
- Payments made to the School by outside organizations.
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.