

OPERATING DEFINITIONS

An **associated entity** means any trust, organization or enterprise other than the University over which the covered individual, alone or together with his/her family, exercises a controlling interest.

Compelling circumstances are those facts that convince the Standing Committee on Conflicts of Interest and Commitment that a financially interested individual should be permitted to engage in the conduct in question. Such circumstances include, but are not limited to, the nature and magnitude of the interest, the degree to which the interest is related to the research or activity, the extent to which the interest may be directly and substantially affected by the research or activity, whether the individual holding an interest is uniquely qualified by virtue of expertise and experience to perform the research or engage in the activity in question, and the extent to which the interest is amenable to effective oversight and management. In the research context, such circumstances also include the nature of the science, the degree of risk to any human subjects involved that is inherent in the research protocol, and whether the research could not be conducted as safely or effectively without the interested individual.

Conducting research means, with respect to a research protocol, designing research, directing research or serving as the principal, co-investigator or key personnel, enrolling research subjects (including obtaining subjects' informed consent) or making decisions related to eligibility to participate in research, analyzing or reporting research data, or submitting manuscripts concerning the research for publication. This term does not apply to covered individuals who primarily provide technical support and/or who are purely advisory, with no direct access to the data (e.g., control over its collection or analysis or, in the case of clinical research, to the trial participants), unless they are in a position to influence the study's results or have privileged information as to the outcome.

Covered individual includes any faculty (full-time, part-time, or non-salaried), key personnel, or administrator who is an investigator; has a management position or above; whose job responsibilities affect purchasing, operating and/or financial decisions of the University or Jefferson University Physicians; and/or who has a significant responsibility with respect to sponsored or non-sponsored research projects. A covered individual further includes any faculty, key personnel, or administrator who, under the aegis of the University or pursuant to the review and approval of the University's IRBs, conducts research.

A covered individual's **family members** include his/her spouse, dependent children, and all other persons living in the same household.

Disclosure means the provision of information about financial interests by a covered individual to responsible institutional officials and to the Standing Committee on Conflicts of Interest and Commitment or the transmission of such information within institutional channels (e.g., from the Standing Committee on Conflicts of Interest and Commitment to the IRB).

Entity means any domestic or foreign, public or private, organization (excluding a Federal agency) from which an Investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.

Equity Interest

Any ownership interest in a company or business, including, but not limited to, stocks, stock options or warrants, membership or partnership interests or rights, or other ownership interests, as determined through reference to public prices or other reasonable measure of fair market value.

Financial Conflicts of Interest

Situations where an Employee's Financial Interest (including an Investigator's Significant Financial Interest, where applicable) compromises, or could appear to compromise, his or her judgment or ability to carry out the Institutional Responsibilities associated with his or her appointment or employment. A Financial Conflict of Interest may take many forms, but in general arises when an Employee in a relationship with an outside person or organization is in a position to influence the University's business, research or decisions in ways that could lead directly or indirectly to financial gain for the Employee or the Employee's Dependents or could give an improper advantage to others to the detriment of the University.

When applied to an Investigator, Financial Conflicts of Interest occur in situations in which such Investigator's Financial Interest (including Significant Financial Interest) compromises, or could appear to compromise, his or her professional judgment regarding the design, conduct or reporting of research or if such Financial Interest (including Significant Financial Interest) could directly and significantly affect the design, conduct or reporting of research. The bias such conflicts may conceivably impart not only affects collection, analysis and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants and the use of statistical methods.

Financial Interest

Any interest that will, may, or is intended to lead to a profit or an increase in the income or net worth of an Employee, Investigator, Dependent, or other covered persons under this policy. Such a profit or increase in income or net worth could be realized through the receipt of anything of monetary or potential monetary value, including, but not limited to, payments of any kind (e.g., salary, consulting fees, honoraria, gifts, dividends, distributions, rent, paid authorship, etc.), Equity Interests, an increase in the value of real estate or Equity Interests, or Intellectual Property Rights.

Financially interested company means a commercial entity with financial interests that would reasonably appear to be affected by the conduct or outcome of the activity in question. With regards to research this term includes companies that compete with the sponsor of the research or the manufacturer of an investigational product, if the covered individual actually knows that the financial interests of such a company would reasonably appear to be affected by the research. This term also includes any entity acting as the agent of a financially interested company (e.g., a contract research organization).

Financially interested individual means a covered individual or family member holding a significant financial interest that could reasonably appear to be affected by the individual's activities in the scope of his/her employment.

Institutional Responsibilities

An Employee or Investigator's professional responsibilities discharged on behalf of Thomas Jefferson University (or his/her primary employer), including, but not limited to, research, research consultation, teaching, professional practice, institutional committee memberships and service on panels such as institutional review boards or data and safety monitoring boards.

Institutional Responsibilities include:

- Externally sponsored research or scholarly activities (including proposing, conducting, and analyzing research and disseminating results);
- Departmental/University research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
- Clinical service activities such as performing services for Jefferson University Physicians;
- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or faculty advisory boards.

Institutional responsibilities do not include:

Volunteer community or public service unrelated to one's primary employment responsibilities.

Investigator means the principal investigator, co-investigator, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research.

Public Disclosure means the University's provision of information related to financial conflicts of interest involving senior and key personnel engaged in research on active PHS-sponsored research projects to persons or entities that transmit to the University formal written requests to receive such information.

Public Health Service ("PHS") means the 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 NIH.

Rebuttable presumption against financial interests means the University will presume, in order to assure that all potentially problematic circumstances are reviewed, that a financially interested individual may not conduct or engage in the research or activity in question. This rule

is not intended to be absolute: a financially interested individual may rebut the presumption by demonstrating facts that, in the opinion of the Standing Committee on Conflicts of Interest and Commitment, constitute compelling circumstances. The individual would then be allowed to conduct the research or engage in the activity, subject to final approval by the President and the Institutional Review Boards for research involving human subjects.

Remuneration means salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Research means a systematic investigation designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development.

Senior/Key Personnel means the Principal Investigator (“PI”) and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the NIH by the Institution under current PHS regulations.

Significant Financial Interest

A Financial Interest held by an Investigator and/or an Investigator's Dependent that reasonably appears to be related to the Investigator's Institutional Responsibilities and that consists of one or more of the following:

- Remuneration (including salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from a publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, and/or an Equity Interest held in such publicly traded company, if the aggregate value of such remuneration, plus the value of the Equity Interest as of the date of disclosure, exceeds \$5,000.
- Remuneration (including, but not limited to, salary, consulting fees, honoraria, paid authorship and travel reimbursement) received from a non-publicly traded company during the twelve-month period preceding the date on which an Investigator is making a disclosure, if the remuneration exceeds \$5,000.
- Any Equity Interest in a non-publicly traded company or business, regardless of value.
- Any Intellectual Property Rights, regardless of value, upon receipt of income related to such rights and interests.
- When applied to sponsored project applications (proposals) submitted to and/or awards received from PHS agencies, any reimbursed or sponsored travel (i.e., travel that is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), provided that the travel is not reimbursed or sponsored by a 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.

Significant Financial Interest does not include:

- An Employee's salary, royalties or other remuneration received from the University and/or Jefferson University Physicians. Covered persons who are not University or JUP employees should not include salary or other remuneration from their primary employer in a calculation of reportable income.
- Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or 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 a federal, state or local government agency or institution of higher education as defined at 20 U.S.C. 1001(a), academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education.
- 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.
- For Investigators who are not University Employees, any ownership interest in their primary employer held by the Investigator.

Small Business Innovation Research (SBIR) Program and **Small Business Technology Transfer (STTR) Program** mean the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97219, the Small Business Innovation Development Act, as amended, Pub. L. 102564, respectively.

Sponsored Travel means travel related to a covered person's work on PHS-sponsored research and his or her institutional responsibilities. Travel that is reimbursed or sponsored by a 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 is excluded from this definition.