Key Definitions

There are key definitions that you must know in order to understand the regulations on Financial Conflict of Interest.

**Institution** refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives NIH research funding. In this tutorial, “institution” refers to the University of New Mexico Health Sciences Center.

**Investigator** refers to the Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research which may include, for example, subgrantees/contractors/subcontractors/collaborators. The term Investigator includes the Investigator’s spouse, domestic partner and dependent children. An investigator is not the same as senior/key personnel. UNM HSC is applying the investigator definition to include all personnel included in any project (research and non-research) conducted at or through the UNM.

**Senior/Key Personnel** includes the Project Director/Principal Investigator (PO/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 the regulation.

Conflicts of Interest disclosures are required by all investigators of a research project not just senior/key personnel.

**Institutional responsibilities** means an Investigator’s professional responsibilities on behalf of the Institution which includes, but is not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on such panels Institutional Review Boards or Data and Safety Monitoring Boards.

**Financial Interest** refers to anything of monetary value, whether or not the value is readily ascertainable.

**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.

A **significant financial interest (SFI)** is defined as:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the investigator’s spouse/domestic partner and dependent children) that reasonably appears to related to the investigator’s institutional responsibilities:

a) When the value of any remuneration received from a publicly traded entity in the 12 months preceding the disclosure AND the value of any equity interest in the entity at the date of disclosure, when aggregated, exceeds $5,000. A “publicly traded entity” refers to any domestic or foreign, public organization (excluding a Federal agency) that offers its
securities (stocks/shares, bonds/loans, etc) for sale to the general public, typically through a stock exchange or through market makers operating in over-the-counter markets. “Remuneration” includes any salary and any payment for services (e.g. consulting fees, honoraria, paid authorship). “Equity interest” includes any stock, stock option, or other ownership interest.

b) When the value of any remuneration received from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated exceeds $5,000 OR when the Investigator holds ANY equity interest in non-publicly traded entity.

c) Intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests (except if through the Institution, see the next slide).

(2) Reimbursed or sponsored travel (i.e. paid on behalf of the Investigator and not reimbursed) related to institutional responsibilities must be disclosed unless the travel is reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Information disclosed includes the purpose of the trip, the identity of the sponsor/organizer, the destination and duration.

Significant Financial Interest does NOT include:

- Salary, royalties, or other remuneration paid by the Institution to the investigator if the investigator is employed or appointed by the Institution. This includes intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.
- Any ownership interests in the Institution, if the Institution a commercial or for-profit organization.
- 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.
- Income from seminars, lectures, or teaching engagements sponsored by federal, state, or local government agency, an Institution of higher education, 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, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.