

FAQ for Financial Conflict of Interest (FCOI) in PHS-Funded Research

Who does this apply to?

- All investigators, regardless of title or position, who are responsible for the design, conduct, and reporting of PHS-funded research.

Who is classed as an investigator?

- The Project Director/Principal Investigator.
- Anyone identified as Senior/Key personnel in a grant application, progress report, or other report submitted to the PHS.
- Any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research.
- In addition, this requirement also extends to the spouse, registered domestic partner and dependent children of such personnel.

When is disclosure required (either initial or updated)?

- At the time a proposal/application (including any subcontract agreement) is submitted for PHS funding. Note: if you already have a completed disclosure on file for the current calendar year you do NOT need to complete another one unless anything has changed.
- At least annually during the award (in January of each year).
- Within thirty (30) days of acquiring or discovering any new Significant Financial Interest(s).

What must be disclosed?

- All Significant Financial Interests related to an Investigator's Institutional Responsibilities.

What are Institutional Responsibilities?

- They are defined as teaching/education, research, outreach, clinical service, training, and public service on behalf of Legacy Health System/Legacy Research Institute, and directly related to those credentials, expertise and achievements upon which the Investigator's Legacy position is based.

What is classed as a Significant Financial Interest (SFI)?

One or more of the following interests of the Investigator (and those of the Investigator's family, as defined above) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. Income From a Publicly-Traded Entity

- Any income received from an entity in the prior 12 months plus value of any equity interests in entity as of date of disclosure exceeding \$5,000, when combined, for an Investigator and their family from a single Entity (Business, Public or Nonprofit). This includes salary, consultant payments, honoraria, royalty payments, dividend, loan, or any other payments or consideration with value during the prior twelve months. 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;

2. Income From Privately Held or Not-For-Profit Entity

- Any remuneration received from entity in 12 months preceding disclosure, when combined, exceeds \$5,000; or when Investigator or their family holds any equity interest (e.g., stock, stock option, or other ownership interest). Exclude income from seminars, lectures, or teaching engagements 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;

3. Income From Intellectual property rights and interests

- Upon receipt of income exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests. However, Significant Financial Interests do NOT include royalties received from Legacy Health System/Legacy Research Institute.

4. Travel

- Sponsored travel or reimbursements made to or on behalf of, the Investigator and/or their family, exceeding \$5,000 during the twelve months preceding disclosure, from a for-profit or non-profit entity related to the Investigator's Institutional Responsibilities. However, Significant Financial Interests do NOT include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.

FCOI Process Flowchart

