

QUICK REFERENCE GUIDE
FINANCIAL
CONFLICT OF INTEREST
IN RESEARCH
FEBRUARY 2022

<p>Who must disclose?</p>	<ul style="list-style-type: none"> All investigators submitting proposals to or receiving an award.
<p>Who is an investigator?</p>	<ul style="list-style-type: none"> The Project Director or Principal Investigator and any other person, regardless of title or position, who is independently responsible for the design, conduct, or reporting of funded research or research proposed for funding. A rule of thumb to determine if an individual should be considered an “investigator” is if they will likely be included as an author for any publications resulting in the research. Examples of investigators include: <ul style="list-style-type: none"> Key personnel identified in the grant application, progress report or other report submitted to the funding agency by URI. Personnel likely to be included as an author of reports and/or scientific journal submissions. Collaborator/consultants/contractor/subcontractor/sub-recipient that are responsible for design, conduct or reporting of the research. External advisory committee members for specific grants if they are responsible for design, conduct or reporting of the research. Graduate students that are responsible for design, conduct or reporting of the research.
<p>What must be disclosed?</p>	<ul style="list-style-type: none"> A SFI consisting of one or more of the following interests of the Investigator (and those of the Investigator's family and business associates) that reasonably appears to be related to the <u>Investigator's institutional responsibilities</u>: <ul style="list-style-type: none"> With regard to any publicly traded entity, any income received from entity in 12 months preceding disclosure and value of any equity interests in entity as of date of disclosure exceeding \$5,000 when aggregated for an Investigator, Investigator's family or business associates from a single Entity (Business, Public or Nonprofit) including 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; With regard to any non-publicly traded entity, any remuneration received from entity in 12 months preceding disclosure, when aggregated, exceeds \$5,000; or when Investigator holds <u>any</u> equity interest (e.g., stock, stock option, or other ownership interest). This does not include 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; Intellectual property interest held by the Investigator, or Investigator's spouse or dependent children on a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the URI upon receipt of income related to such rights and interests that exceed \$5,000 in 12 months preceding disclosure. Any reimbursed or sponsored travel (i.e., that which is paid on behalf of Investigator and not reimbursed to Investigator so that the exact monetary value may not be readily available), related to institutional responsibilities. Excludes travel reimbursed or sponsored by Federal, state, or local government agency, an Institution of higher education as defined by 20 U.S.C. 1001(A), an academic teaching hospital, a medical center, or a research institute affiliated with Institution of higher education. Significant financial interests <u>do not</u> include (1) payments made by URI (salary, royalties, honoraria, expense reimbursement or any other remuneration) or (2) 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 or (3) an investment by a mutual fund, pension fund or other investment fund over which the investigator or his/her immediate family member does not

	<p>exercise management of fund investment.</p> <ul style="list-style-type: none"> • See the URI Conflict of Interest in Research Policy and/or InfoEd COI Disclosure Form for more information.
What are institutional responsibilities?	<ul style="list-style-type: none"> • Institutional Responsibilities are defined as teaching/education, research, outreach, clinical service, training and University and public service, on behalf of URI and directly related to those credentials, expertise and achievements upon which the Investigator's URI position is based.
When do I disclose?	<ul style="list-style-type: none"> • Annually • Reviewed and updated (if necessary) prior to spending on an award. • Within 30 days of identifying new SFI's (including reimbursed travel).
How do I disclose?	<ul style="list-style-type: none"> • Complete the InfoEd COI Disclosure Form.
Who will see my information?	<ul style="list-style-type: none"> • Limited staff in the Office of Research Integrity will review all disclosures. • Disclosures indicating there may be a financial conflict of interest may be shared with the Vice President of Research and Economic Development, the Conflict of Interest Management Committee (CIMC), legal counsel, the Investigator's department head, or other relevant individuals, administrative offices or units. • If it is determined that a financial conflict of interest (FCOI) exists on a PHS funded award, URI is required to provide certain information to the PHS funding agency. • If it is determined that a FCOI exists on a PHS funded award, URI is required to make certain information available to the public, upon request.
How is it determined if an SFI is a FCOI?	<ul style="list-style-type: none"> • An investigator's SFI is related to the proposed research when it is reasonably determined that the SFI could be affected by the proposed research; or is in an entity whose financial interest could be affected by the proposed research. • An FCOI exists if CIMC reasonably determines that the SFI related to the proposed research could directly and significantly affect the design, conduct or reporting of the proposed research.
What if I have a FCOI?	<ul style="list-style-type: none"> • FCOI's must be managed, reduced or eliminated. Management plans are often used to manage risk of bias in research and allow the research to be conducted. • Following identification of a SFI, CIMC will review and approve of a management plan or determine the FCOI is not manageable. • In certain cases, following CIMC approval, the Public Private Partnership Act (R.I.G.L. §16-59-26) requires review by the URI Board of Trustees and the RI Ethics Commission.