



Financial Conflict of Interest (FCOI) Policy

Federal regulations regarding Financial Conflict of Interest (FCOI) are outlined in Title 42 CFR Part 50, subpart F: Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought:

http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

What is the purpose of this regulation? This regulation promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH grants, cooperative agreements or contracts will be biased by any conflicting financial interest of an Investigator.

This regulation requires that each dfusion Investigator maintain a written, enforced policy on conflict of interest that conforms to the following requirements:

- Complies with the regulation
- Informs each Investigator of dfusion's policy as well as the regulation
- Informs each Investigator of his or her reporting responsibilities
- Provides adequate guidelines for enforcement mechanisms and sanctions where appropriate

Who is covered by this regulation? This regulation is applicable to each Institution that applies for NIH grants or cooperative agreements for research or submits a proposal for a research contract whether in response to a solicitation or otherwise and, through implementation of the regulation by each Institution, to any Investigator participating in that research. An Institution is defined as any domestic or foreign, public or private, entity or organization (excluding a Federal agency).

dfusion Inc. is required to take reasonable steps to ensure that Investigators working for subrecipients/subcontractors comply with the FCOI regulation, either by requiring the Investigators to comply with dfusion's FCOI policy or by requiring the entities to provide appropriate assurances to dfusion. Subrecipients/subcontractors must report identified FCOIs to dfusion; dfusion must report to NIH the existence of any conflicting interests arising from subrecipients/subcontractors and assure that the interest has been managed, reduced, or eliminated in accordance with the regulation.

Who is considered an "Investigator" for this purpose? An "Investigator" is defined as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by NIH, or proposed for such funding, including subgrantees, contractors, or collaborators. The definition of Investigator includes the Investigator's spouse and dependent children.

What financial interests are covered by the regulation? A "Significant Financial Interest" is defined by the regulation as anything of monetary value, **including** but not limited to:

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

The term does **not** include:

- Salary, royalties, or other remuneration from dfusion
- Any ownership interests in dfusion, if dfusion is an applicant under the SBIR and STTR programs
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees or review panels for public or nonprofit entities

- An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity
- Salary, royalties, or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not reasonably expected to exceed \$10,000

Who at dfusion will implement this regulation? As required by the regulation, dfusion has designated the current Director of Operations, Erica Marsh, as the Institutional official whose responsibility it is to solicit and review financial disclosure statements from each Investigator who is planning to participate in the research. Mrs. Marsh will determine whether a financial conflict of interest exists; and, if so, determine what actions should be taken to manage, reduce, or eliminate such conflict of interest.

What information must be obtained from Investigators and when should it be collected? By the time an application/proposal is submitted to NIH, each Investigator planning to participate in the research must have submitted to Erica Marsh, Institutional designated official, a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): 1) that would reasonably appear to be affected by the research for which funding is sought from NIH, and 2) in entities whose financial interests would reasonably appear to be affected by the research.

What about interests incurred during the award period subsequent to the initial expenditure of funds? All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

What about enforcement mechanisms and/or sanctions? dfusion is required to establish adequate enforcement mechanisms and provide for sanctions where appropriate. Types of sanctions that may be applied include, but are not limited to:

- Public disclosure of Significant Financial Interests
- Monitoring of research by independent reviewers
- Modification of the research plan
- Disqualification from participation in all or a portion of the research funded by NIH
- Divestiture of Significant Financial Interests
- Severance of relationships that create actual or potential conflicts

Required FCOI online tutorial. NIH has developed an online tutorial which reviews the requirements of, and the Institutional and Investigator responsibilities for compliance with, the FCOI regulation. The tutorial is designed for use by Institutional officials responsible for managing NIH funded projects and for individuals who are responsible for the design, conduct or reporting of NIH-supported research. dfusion requires that **all** dfusion Investigators complete this tutorial.

The NIH online FCOI tutorial can be found at: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

Upon completion of the tutorial, an Investigator prints out the completion certificate and forwards a copy to the Director of Operations who maintains the FCOI files.

Where can I find additional information? More information specific to grants is available on the Financial Conflict of Interest page of the Grants Policy & Guidance section of the NIH Office of Extramural Research site: <http://grants.nih.gov/grants/policy/coi/index.htm>.