

## Conflict of Interest Policy

The disclosure of financial conflicts of interest is intended to promote objectivity in research. The requirements for disclosure may vary from sponsor to sponsor with the most stringent requirements (CFR 42 Part 50, Subpart F) for Public Health Service (PHS) entities including NIH, AHRQ, FDA, and others. The Federal Demonstration Partnership website maintains a list of PHS entities and applicants.

Dordt University investigators should verify the inclusion of PHS regulation in their award terms.

### Definition

For the purposes of this policy, significant financial interest is defined as a financial interest that reasonably appears to be related to the investigator's institutional responsibilities and includes:

- Any payments or equity interests in the 12 months preceding the disclosure that, when aggregated, exceeds \$5,000 for any publicly traded entity
- Any payments exceeding \$5,000 in remuneration or any equity interest in a non-publicly traded entity, including intellectual property when related income is received.
- 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 within the U.S.; a U.S. institution of higher education as defined at 20 U.S.C. 1001(a); or an academic teaching hospital, medical center or research institute that is affiliated with an institution of higher education in the U.S.

A financial interest is not necessarily a conflict of interest. A person who has a financial interest may have a conflict of interest only if the appropriate governing board or committee decides that a conflict of interest exists. Note: The determination of a financial conflict of interest must include consideration of whether the significant financial interest could be affected by the funded research or is an entity whose financial interest could be affected by the research and a determination that this interest could affect the design, conduct, and reporting of the funded research.

Anyone involved in conducting sponsored research under a covered entity must complete a conflict of interest disclosure in the following instances:

- 1) Initial application for the award,
- 2) annually thereafter, or
- 3) when there is acquisition of a new significant financial interest.

Disclosures should be submitted to the Kielstra Center Director. The Director and VPAA will determine the appropriate committee for review. If the committee determines that a conflict of interest exists, a management plan will be developed and implemented following requirements in §50.605 and an FCOI report will be made to the awarding agency.

### Training

All investigators must complete FCOI training either using CITI or the NIH training module ([https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html)) prior to receipt of any PHS/NIH funded grant and every four years thereafter or immediately in the following situations: 1)the policy changes in a way that would impact investigators, 2)a new investigator joins that Dordt faculty with PHS/NIH funding, or 3)an investigator is determined not to be in compliance with this policy.

## **Implementation**

*Disclosure, Review and Monitoring:* The Director of the Kielstra Center will ensure that an Investigator's significant financial interest disclosures are reviewed no later than at the time of application for PHS-funded research, at least annually during the period of the award, and within 30 days of discovering or acquiring a new SFI.

*Reporting:* The Director of the Kielstra Center will submit initial, annual, and ongoing FCOI reports via eRA Commons following guidelines for reporting in 42 CFR 50.605. Reporting is required prior to new funding expenditures, within sixty (60) days of the addition of a new investigator, receipt of new disclosures, or identification of previously undisclosed or not reviewed significant financial interests.

All FCOI records will be maintained for three years from the date of the final expenditures report or other timeframes, if required (45 CFR 75.361).

The Kielstra Center will incorporate language related to FCOI in subrecipient agreements that establish FCOI policy (establish whether the Dordt University FCOI policy or that of the subrecipient will apply to the subrecipient investigators and establish reporting timelines, as needed).

The VPAA and Director of Human Resources and Organizational Development will be notified whenever an FCOI management plan is implemented and will implement any necessary sanctions or administrative actions to ensure compliance with the management plan.

This FCOI policy is posted to the Dordt University grant website and requests for additional information about FCOIs held by senior/key personnel will be made available to requestors within five (5) business days.