

UKZN PROCEDURES FOR INVESTIGATORS AND INSTITUTIONAL COMPLIANCE WITH THE NIH FINANCIAL CONFLICT OF INTEREST REGULATION

Document title	UKZN PROCEDURE FOR INVESTIGATORS AND INSTITUTIONAL COMPLIANCE WITH THE NIH FINANCIAL CONFLICT OF INTEREST (FCOI) REGULATIONS	
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1. PURPOSE

The purpose of this procedure is to document the requirements and responsibilities associated with identifying and managing financial conflicts of interest to safeguard the integrity of the University of KwaZulu-Natal (UKZN) with respect to research conducted and to comply with the United State (US) federal regulations.

The University of KwaZulu-Natal is committed to upholding the highest ethical standards in a research community that is committed to the principles of integrity, trust, collegiality and justice.

Research results and the process leading to them must be honest and reliable, and adhere to the highest standards of ethical integrity in the design, review, conduct and reporting of the findings.

All researchers are expected to adhere to the generally accepted principles of scientific inquiry and the highest standards of ethical conduct. These standards are consistent with the requirements of funding agencies that fund research at UKZN. The National Institutes of Health (NIH), has adopted new Financial Conflict of Interest (FCOI) requirements under its Regulation on the Responsibility of Applicants for Promoting Objectivity in Research effective August 24, 2012 (referred to as the “FCOI Regulation”).

“The goal of the FCOI Regulation is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest”.

The procedure document has been developed to address and comply with the specific US Federal Agency Requirements as defined in the Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

This document should be read in conjunction with the University Policy on Research Ethics (Research Policy V).

2. DEFINITIONS

The following definitions are provided as a reference and are considered key definitions in understanding the federal regulations of FCOI. A comprehensive list of official definitions are contained in the Revised Financial Conflict of Interest Regulations Promoting Objectivity in Research (42 CFR 50.603) attached here as annexure A and can be accessed electronically at <http://research.ukzn.ac.za/PoliciesProcedures.aspx>

2.1 Institution – means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for, or receiving NIH research funding.

2.2 Investigator – means the project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is or will be responsible for the design,

conduct, or reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

2.3 Institutional responsibilities – means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

2.4 Financial interest – means anything of monetary value received or held by an Investigator or any member of the Investigator's immediate family (specifically, any dependent children, spouse or common law partner), whether or not the value is readily ascertainable. Financial Interests include salary or other payments for services (e.g. consulting fees, honoraria, or paid authorships for other than scholarly works), equity interests (e.g. stocks, stock options, or other ownership interests), and intellectual property rights and interests (e.g. patents, trademarks, service marks, and copyrights) upon receipt of royalties or other income related to such intellectual property rights and interests.

2.5 Financial conflict of interest (FCOI) – means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

2.6 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.

2.7 Senior/Key Personnel – means the PD/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.

2.8 Significant Financial Interest (SFI) – means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's University responsibilities:

- With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000;

- With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest); or
- Upon receipt of income related to intellectual property rights and interests (e.g. patents, copyrights)

2.9 Sponsored travel – means that the Investigators must also disclose the occurrence of any reimbursed or sponsored travel (that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to the university responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation. For example, if the PI travels to a scientific seminar but does not pay or receive reimbursement by the Company directly (i.e. the travel was paid for by a third party/sponsor), the PI is required to disclose basic information to the Company relating to the trip, such as purpose of the trip, identify of the payer/sponsor, destination and duration. The Company is required to determine if additional information is required (e.g. monetary value) and whether the travel constitutes a FCI with NIH-funded research.

3. PROCEDURES FOR DEALING WITH THE FCOI

3.1 Identification of Persons Required to Disclose a Significant Financial Interest

It shall be the responsibility of the Principal Investigator of a Research project to identify all Investigators who have a SFI requiring disclosure under these procedures and to ensure that a SFI Disclosure Form is prepared and submitted. In addition, the Principal Investigator shall be responsible for ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

3.2 Responsibility of the Investigator to Disclosure

The Principal Investigator is responsible for ensuring that all Investigators involved in the Principal Investigator's NIH funded research project are aware of these procedures and make

any disclosures required by these procedures. Investigators should note that Financial Interests include those of the Investigator's immediate family.

It is the Principal Investigator's responsibility to ensure those with financial interests in research are identified and make the required disclosures in conjunction with submission of a research proposal or application for human subjects' approval.

3.3 What to Disclose

Investigators must disclose their Significant Financial Interests (SFI) and Sponsored Travel as defined in 2.8 and 2.9 above.

3.4 When to Disclose

Disclosure must be made using the UKZN Financial Interest Report ([UKZN-FIR form](#))

3.4.1 no later than at the time of application for funding from NIH (or, in the case of a sub-award, from the prime institution);

3.4.2 at least annually during the period of the NIH funding; and,

3.4.3 within 30 days of acquiring a new SFI.

Investigators should refer to the form for further instructions regarding its completion and submission or consult the Research office.

3.5 How to Disclose

All Investigators must complete and forward a signed Financial Interests Report using a prescribed UKZN-FIR form to the Director: Research Financial Services (referred to as the Institutional Delegate). Should an Investigator disclose an SFI or Sponsored Travel, the Director: Research Financial Services will forward the UKZN-FIR form to the Deputy Vice Chancellor: Research for final review and determination of FCOI.

The Director: Research Finances is responsible for evaluating and instituting a plan for managing any disclosed financial interests, for producing institutional reports and other required reports to external funding agencies, and for the general administration and enforcement of these procedures.

Annual updates are required of all Investigators and key personnel participating in research. Any Investigator who has acquired a new or increased financial interest during the course of a research project shall report it immediately to the Director: Research Financial Services. Annual updates and newly acquired interests are reported using the UKZN-FIR form and are loaded to the NIH Era commons by the Director: Research Financial Services.

4 INSTITUTIONAL REVIEW, MANAGEMENT AND REPORTING

4.1 Role of the Institutional Delegate

The Financial Interests Report is reviewed by an Institutional Delegate to determine whether any disclosed SFIs or Sponsored Travel relate to NIH funded research and, if so, whether an FCOI exists.

4.2 Review and Management

The Institutional Delegate may request further information from the Investigator and consult confidentially with the Investigator and others as necessary. In consultation with the University Dean of Research, DVC: Research and a respective College Dean of Research (or delegate), the Institutional Delegate will determine whether an SFI or Sponsored Travel that relates to NIH funded research constitutes an FCOI and, if so, whether the FCOI could be managed through the development and implementation of a Management Plan.

The Principal Investigator and a respective College Dean (or delegate) are responsible for developing the Management Plan, together with any other Investigators determined to have an FCOI. The Management Plan must specify the actions that have been and will be taken to manage the FCOI, including a mechanism for monitoring compliance with the Management Plan until the completion of the subject research project, and will be subject to the approval of the DVC: Research.

Notwithstanding these procedures or any Management Plan, Investigators also remain subject to all of the University's applicable policies and procedures, including without limitation, those with respect to conflict of interest, financial regulations and research involving human participants.

4.3 Reporting to NIH

The Institutional Delegate will submit online reports on any FCOI determined to exist, together with any applicable Management Plan, to NIH as required by the FCOI Regulation. In particular, reports will be made:

4.3.1 before any NIH funds are spent;

4.3.2 within 60 days of the identification of new FCOIs; and,

4.3.4 annually to update the status of the FCOI and any changes to an applicable Management Plan (normally at the same time as the annual progress report is due).

5. PUBLIC ACCESSIBILITY

The FCOI Regulation requires public accessibility of certain information concerning FCOIs. Upon written request to the Institutional Delegate, the following information concerning FCOIs after authorisation by the DVC: Research will be made available:

5.1 the Investigator's name, title and role with respect to the research project;

5.2 the name of the entity in which the SFI determined to constitute an FCOI is held; and,

5.3 the nature and approximate dollar value of that SFI.

6. NON-COMPLIANCE

In the event of any noncompliance with these procedures or any Management Plan, the FCOI Regulation requires the University to conduct a review of the Investigator's activities and the NIH funded research project to determine whether any NIH funded research conducted during the time period of noncompliance was biased in the design, conduct or reporting of such research. The review will be documented and reported to NIH as required by the FCOI Regulation.

Contravention of these procedures, including the failure to reveal material conflicts of interest in connection with research or the failure to abide by any Management Plan, will constitute research misconduct under the University's Policy on Research Ethics (Research Policy V)

pertaining to the Ethical Conduct of Research and its companion Framework to Address Allegations of Research Misconduct.

In the event of noncompliance, access to NIH funds will be suspended and remedial actions and/or sanctions applied in accordance with Conditions of Service applying to staff of the university or under student Disciplinary Code as appropriate.

7. TRAINING

The NIH Financial Conflict of Interest tutorial was designed by the National Institutes of Health (NIH) to provide education training on what constitutes financial conflict of interest. This course is required for anyone involved with an NIH funded project, which includes all Investigators, students, consultants and employees of the university engaged in NIH-funded research or its compliance.

The course is accessible at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> Upon completion of the training, a certificate of completion must be turned into the DVC: Research. You should retain a copy for your records. This training is required prior to engaging in research relating to any NIH-funded grant or as deemed necessary by the university due to changes in the FCOI procedures, non-compliance of the Investigator/Key Personnel or new to the institution. At a minimum, the FCOI training shall be taken every three (3) years.