

**GRANTS MANAGEMENT OFFICE (GMO)
FACULTY OF MEDICINE AND HEALTH SCIENCES (FMHS)
STELLENBOSCH UNIVERSITY (SU)**

PROCEDURE AND REGULATIONS FOR COMPLIANCE TO THE UNITED STATES (US) NATIONAL INSTITUTES OF HEALTH (NIH) AND OTHER US PUBLIC HEALTH SERVICES (PHS) DEPARTMENTS FINANCIAL CONFLICT OF INTEREST (FCOI)

SCOPE: This document applies to all Stellenbosch University (SU) Faculty of Medicine and Health Sciences (FMHS) Principal Investigators (PIs) and all Key Personnel (KP) of research grants funded by the United States (US) National Institutes of Health (NIH) or any other US Public Health Services (PHS) departments.

BACKGROUND AND REASON FOR THE PROCEDURE AND REGULATION: If any SU FMHS PI carries out research funded by National Institute of Health (NIH) or any other United States (US) Public Health Services (PHS) department, whether through a direct award or sub-award (collaborator or contractor), SU FMHS must, according to Title 42 of the Code of Federal Regulations (42 CFR), take reasonable steps to ensure that PIs and their sub-awardees comply with Part 50 Subpart F of 42CFR, i.e. to comply to Financial Conflict of Interest (FCOI).

RESPONSIBILITIES

1. **Disclosure:** SU FMHS designate the Grants Management Office (GMO) to solicit and review disclosure statements from each PI, and KPs who is planning to participate in research funded by the NIH or PHS. The GMO must maintain records of disclosures and actions taken.
2. **Compliance:** The PIs are responsible for assuring compliance with the [SU Policy on Conflict of Interest](#) and providing assurances to SU FMHS that will enable SU FMHS to comply with 42CFR Part 50 Subpart F ([42CFR PART 50 Subpart F - Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought](#))
3. **Training:** All PI's and KP must undergo the NIH FCOI training and submit the certificate to GMO before any submission to NIH can be made

PROCEDURE

1. The PIs inform(s) the GMO of the intent to apply for NIH or other PHS funds as per the "*Procedure and Regulations of the Timelines for Successful Submission of Proposals for Sponsored Projects*".
2. The GMO informs the **PIs** of the SU Policy on Conflict of Interest and "42CFR Part 50 Subpart F" and request them and **KP** to complete, sign and date the Financial Conflict of Interest (FCOI) disclosure forms (**Annexure 1**) before the proposal is submitted to NIH or PHS.
3. The PI ensures that all **sub-recipients** (KP, collaborators, contractors, consultants) of the award comply with 42CFR Part 50 Subpart F by completing the FCOI disclosure form for sub-awardees (**Annexure 2**).
4. The GMO informs the PI's and KP of the NIH FCOI training. PI's and KP complete the training and submit the certificate to GMO before any grant submission is made.
5. Link to training: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html
6. The PI(s) and KP complete, sign and date a new FCOI disclosure form when the Notice of Award (NOA) is received and thereafter annually **or** as soon as any new reportable significant FCOIs are obtained.
7. Any reportable significant FCOI's are reported to the SU Council as per the SU Policy and procedure on Financial Conflict of Interest and the SU Council decides on an action to ensure the research is protected from bias.
8. The GMO report to the NIH or PHS the existence of conflicting interest prior to SU FMHS expenditure of any funds under the award.
9. The GMO maintain the records of all the financial disclosures and actions taken to protect the research from bias, with respect to each conflicting interest for at least three (3) years from the date of the final submission report.
10. The GMO will make information available to NIH or PHS upon request.

ACRONYMS AND DEFINITIONS

CFR	Code of Federal Regulations
FCOI	Financial Conflict of Interest
NIH	National Institutes of Health
PHS	Public Health Services
PIs	Principal Investigator –the primary individuals responsible for the preparation, conduct, and administration of a research grant, in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.
NOA	Notice of Award
GMO	Grants Management Office
KP	Key Personnel