



CAP-POL-03

FINANCIAL CONFLICT OF INTEREST POLICY

Document review and approval

Revision history

Version	Author	Date	Revision
1	Devenie Latchmanan	7 August 2014	Revision of SOP ADM-FIN-25
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This document has been reviewed by

	Reviewer	Date Reviewed
1	Carl Montague	15 Aug 2014
2	JCM Swart	30 Aug 2014
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4		

This document has been approved by

	Policy Authority	Date
1	CAPRISA Board of Control	13 Nov 2014
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1. REGULATORY FRAMEWORK

PHS regulation 42 CFR part 50, Subpart F
PHS regulation 45 CFR part 94
Labour Relations Act

2. PURPOSE OF THIS POLICY

CAPRISA is responsible for maintaining objectivity in research by ensuring that the design, conduct, and reporting of research are not biased by conflicting financial, equity or intellectual property interest of investigators responsible for the research, in accordance with the provisions of Public Health Service (PHS) regulations 42 Code of Federal Regulations (CFR) part 50, Subpart F, and 45 CFR part 94.

This policy is intended to identify financial, equity and intellectual property interests of CAPRISA investigators and potential conflicts of interest, or the appearance of such conflicts in activities of CAPRISA. Where an actual, potential, or perceived conflict of interest is identified, a set of actions to resolve/mitigate it must be developed by the individual involved and approved by the CAPRISA Director or designee. It also aims to ensure that any procurement of goods or services by CAPRISA does not constitute a potential Financial Conflict of Interest for any CAPRISA staff or BoC member. When real or potential conflicts in relation to procurement arise, they must be timeously addressed by the individual concerned and approved by the COO.

3. POLICY STATEMENTS FOR FINANCIAL CONFLICT OF INTEREST FOR RESEARCH INVESTIGATORS

- 3.1 All CAPRISA investigators will be trained in the Financial Conflict of Interest (FCOI) Policy.
- 3.2 The FCOI policy will be publicly accessible on the CAPRISA website.
- 3.3 CAPRISA investigators will be required to disclose any significant financial interests (SFI) including equity and intellectual property interest.
- 3.4 The CAPRISA FCOI policy applies to all activities in CAPRISA. Where funder's have additional requirements, these will be implemented and reported to funders.
- 3.5 When grants to CAPRISA have specific additional FCOI requirements, sub-recipients of these grants will also be required to comply with the funder's FCOI stipulations.
- 3.6 Any identified actual, potential or perceived conflict of interest, will require the development of a conflict resolution/mitigation plan by the individual concerned for approval by the CAPRISA Director or designee. Such plans could include steps for a conflict to be managed, reduced, or eliminated.
- 3.7 Information concerning identified FCOIs held by senior/key personnel will be made publicly accessible via the CAPRISA website or as a written response to any requestor within five (5) business days of a request.
- 3.8 FCOI Information on the website will be updated annually or within 60 days of a newly identified FCOI. Written requests will include the updated information.
- 3.9 FCOI Information will remain available for three (3) years from the date the information was most recently updated.
- 3.10 No researcher may engage in any research if they have not been trained on the FCOI policy and have signed an FCOI disclosure.
- 3.11 Payments from CAPRISA or funders to an individual are prohibited, if such payments are conditioned upon a pre-determined research result.

4. POLICY STATEMENTS FOR FCOI FOR SUB-RECIPIENTS

- 4.1 FCOI requirements must be written into all sub-recipient agreements for which CAPRISA is the primary grant holder.

- 4.2 CAPRISA will determine whether the sub-recipient has an FCOI policy that meets all the necessary requirements and will obtain certification from the sub-recipient to confirm this.
- 4.3 Should the sub-recipient not have a FCOI policy that meets all the requirements, the CAPRISA policy must be followed.
- 4.4 Sub-recipients must report identified FCOIs initially, annually and as identified to CAPRISA within 30 days to allow for reporting to the funder.

5. POLICY STATEMENTS FOR FCOI FOR STAFF CONDUCTING CAPRISA BUSINESS

- 5.1 A potential FCOI might arise when a CAPRISA staff member has a Material Financial Interest (MFI) in, or connection with an organization with which CAPRISA transacts or might transact business. This includes accepting expensive gifts and/or travel support from companies with which CAPRISA does business.
- 5.2 Travel support is limited to payment for legitimate professional speaking and consulting engagements to which the CAPRISA staff member has been invited by the supporting company/institution. Travel arrangements must be made in accordance with CAPRISA's Travel and Subsistence Policy.
- 5.3 An MFI could be direct or indirect and can constitute a Financial Conflict of Interest of:
 - 5.3.1 the staff member;
 - 5.3.2 another person such as a family member of the staff member;
 - 5.3.3 the organization in which the staff member or such other person has an interest.
- 5.4 Any staff member who has a FCOI with an organization or service provider from whom CAPRISA contracts or transacts goods or services, may not be involved in the decision making process regarding the goods or services to be provided.
- 5.5 Should a staff member become aware of a FCOI in relation to the procurement of goods or services he or she is involved with, he/she must disclose this to the CAPRISA COO in writing.
- 5.6 The final decision regarding the contracting or transacting of goods or services from a conflicting organization or service provider will be made by the CAPRISA COI Committee on receipt of a clear justification for the purchase of the goods or service from the conflicting organization.
- 5.7 CAPRISA staff, students and trainees may not accept gifts of any value, including cash or commodities, from commercial entities whose businesses are in anyway relevant to their professional duties.
- 5.8 Support from commercial entities, including but not restricted to refreshments served at educational programmes, must be for unrestricted educational use.
- 5.9 Should a FCOI be identified that was known about but not declared by a staff member, this could be cause for disciplinary action against that individual.

6. TRAINING

- 6.1 Each new staff member, as part of the induction programme, will be informed of the FCOI policy, the reasons for the policy and the responsibilities of the researchers/staff in complying with this policy.
- 6.2 All staff will be trained in the FCOI policy and its requirements initially when employed and at least every four years subsequently.
- 6.3 Should the policy be revised, all staff will be trained in the revisions to the FCOI.

7. DISCLOSURE, REVIEW AND MONITORING

- 7.1 All staff will be required to disclose FCOI's (and those of spouses/partners and dependent children) as follows:
 - 7.1.1 No later than at the time of application for research funding;
 - 7.1.2 At least annually during the period of the award;
 - 7.1.3 Within 30 days of discovering or acquiring a new FCOI.

- 7.2 If the study is NIH funded, reports must be submitted to the NIH initially, prior to the start of the project, annually and ad hoc as follows:
 - 7.2.1 prior to the expenditure of funds;
 - 7.2.2 within 60 days of identification of an investigator who is newly participating in a project;
 - 7.2.3 Within 60 days for new, or newly identified FCOIs for existing investigators;
 - 7.2.4 At least annually (with annual progress reports) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
 - 7.2.5 If an investigator fails to comply with the CAPRISA FCOI policy or management plan and appears to have biased the design, conduct or reporting of the research;
 - 7.2.6 Following a retrospective review to update a previously submitted report, if appropriate.

- 7.3 A retrospective review will be required when a FCOI has not been identified or managed in a timely manner and includes non-disclosure by an investigator. Retrospective reviews must be completed and documented within 120 days of determining non-compliance with this policy.
- 7.4 All FCOI records will be maintained for at least 3 years from the date that the final financial report has been submitted to the funder.
- 7.5 A Conflict of Interest (COI) Committee will be maintained and consist of three members of the CAPRISA Executive Committee. The COI Committee will be responsible for reviewing the list of staff that disclose SFI.

8. INTELLECTUAL PROPERTY AND PUBLICATION RIGHTS

Patents, royalty and license agreements must be disclosed as applicable on CAPRISA's FCOI statements. Each CAPRISA investigator is accountable for the integrity of any publication that bears his/her name. CAPRISA investigators are not permitted to enter research agreements that permit a sponsor or other financially interested organisation to require more than a reasonable period of pre-publication review, or that interferes with an investigator's access to the data or ability to analyse and interpret the data independently.

9. STUDENTS AND TRAINEES

Agreements with sponsors or financially interested organisations that place restrictions on the activities of students or trainees or that bind students or trainees to non-disclosure provisions are prohibited.

10. SCOPE

This policy applies to all staff employed by CAPRISA or through agencies and their spouses/partners and dependent children as well as all CAPRISA sub-recipients, Members of the CAPRISA Board of Control and all fellows and research placements at CAPRISA.

11. DEFINITIONS APPLICABLE TO THE POLICY

- 11.1 CFR – Code of Federal Regulations.
- 11.2 COI Committee – Conflict of Interest Committee.
- 11.3 COO – Chief Operations Officer.
- 11.4 Equity Interest – is defined as any ownership interest in a relevant entity. Staff are required to disclose all equity interests in any and all relevant entities that, when aggregated with family members' holdings, amount to more than a five percent ownership interest (excluding ownership of diversified mutual fund shares), or exceed \$5,000 (ZAR equivalent at date of signing) annually, determined by fair market value.
- 11.5 FCOI – Financial Conflict Of Interest.
- 11.6 Family member: For FCOI in research the family member is defined as a Spouse/partner or dependent child of an investigator. For FCOI during conduct of CAPRISA business a family member is defined as any and all family members.
- 11.7 Intellectual Property Interest – these are intellectual property rights with a relevant entity (patents, pending patents, copyrights, licensures, and royalties) or potential earnings from any patent held by any other party.
- 11.8 Investigator: CAPRISA principal investigator and any other person regardless of title or position who is responsible for the design, conduct or reporting of research or educational activities funded or proposed to be funded by CAPRISA or an external sponsor.
- 11.9 MFI - Material Financial Interest: a financial interest of any kind, which, in view of all the circumstances, is substantial enough that it could, or reasonably could, affect a Staff Member's or Family Member's judgement with respect to financial transactions to which CAPRISA is a party.
- 11.10 PHS – Public Health Service.
- 11.11 Relevant entity: A company with business interests in pharmaceutical, diagnostic, biologic products or other fields relevant to CAPRISA.
- 11.12 SFI – Significant Financial Interest: 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), and intellectual property rights (e.g. patents, copyrights, and royalties from such rights), at present as well as in the future, that exceeds \$5,000 (ZAR equivalent at date of signing) or represents any shares or ownership interest in any single entity. This also includes reimbursed or sponsored travel i.e. travel which is paid on behalf of the Investigator and not reimbursed to the Investigator.

12. RELATED POLICIES

- Travel and Subsistence Policy
- Procurement Policy
- Research Integrity Policy

13. POLICY AUTHORITY

Effective Date: 13 Nov 2014

Policy Owner: Chief Operations Officer

Policy Manager: Compliance Officer

Confirmation of Approval



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Prof SS Abdool Karim
Director