US Public Health Service Financial Conflicts of Interest Disclosure Procedure

Section 1 - Purpose

(1) This Procedure sets out the requirements for disclosing Financial Conflicts of Interest (FCOI) for research projects applied to and funded by the US Public Health Service (PHS), including those provided by the National Institutes of Health (NIH). The full NIH Financial Conflict of Interest (FCOI) policy and associated detailed guidance (including FAQs) are available on the NIH website: NIH FCOI Policy.

(2) This Procedure should be read in conjunction with Macquarie University's research policies and Macquarie University's Conflict of Interest Policy.

Scope

(3) This Procedure applies to all staff and affiliates who are planning to participate in or are participating in funded research from the PHS (through the NIH).

(4) These requirements differ from, and are in addition to, the University's general requirements relating to Conflicts of Interest, and as such must be addressed by investigators on any PHS/NIH proposal/project.

Section 2 - Policy

(5) Nil.

Section 3 - Procedures

Disclosure Requirements

(6) The NIH requires institutions and investigators to comply with the requirements of 42 CFR Part 50, subpart F Promoting Objectivity in Research (hereafter the Regulation), including the disclosure of FCOI (as defined in section 5).

(7) Any Macquarie University researcher who meets the definition of a Public Health Service funded Investigator (hereafter referred to as Investigator) must disclose their significant financial interests (SFIs) (as defined in Section 5) and those of the Investigator's spouse and dependent children to the Grant Development Team, Research Services. This must be done by:

a. Investigators who have not previously disclosed their SFIs must do so no later than at the time of application for PHS/NIH-funded research using the Macquarie University FCOI Disclosure Statement Form and
    i. within thirty (30) days of discovering or acquiring a new SFI
    ii. at least annually during the period of the award.
b. New investigators joining an existing PHS/NIH funded project must disclose any SFIs within 30 days of joining the project.

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(8) The Macquarie University disclosure statement at a minimum must include:

a. name of the entity with which the investigator has an FCOI;
b. nature of FCOI (for example, equity, consulting fees, travel reimbursement, honoraria);
c. for SFI disclosures related to sponsored or reimbursed travel, the purpose of the trip and the name of the entity;
d. value (or approximate) of the SFI if the interest is one whose value cannot be readily determined; and
e. if needed, the Grant Development Team, Research Services, may request supporting documentation (for example, a copy of any applicable agreement) to determine whether an FCOI exists.

FCOI Monitoring requirements

(9) Disclosures will be managed by the Grant Development Team, Research Services who:

a. review all Investigator SFI disclosures;
b. determine whether the SFI relates to PHS-funded research;
c. determine whether an FCOI exists, (e.g., the SFI that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research);
d. may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research; and
e. develop and implement a management plan to manage the FCOI.

FCOI Management Plans

(10) If an FCOI is found to exist, Research Services must:

a. submit an FCOI report (through eRA Commons FCOI module) prior to the expenditure of funds upon the issuance of a new award or if the FCOI is identified during the period of an award (e.g. 6 months into the project). The report is due to the to the NIH or PHS-agency within 60 days of identifying the FCOI;
b. conduct a retrospective review of SFIs for the PHS-funded investigator within 120 days of identifying non-compliance when there is an untimely or unmanaged FCOI; and
c. develop an FCOI management plan and maintain an FCOI management log.

(11) An FCOI management plan will be used to manage a potential or actual FCOI. At a minimum, the management plan will include:

a. the role and principal duties of the investigator;
b. conditions and/or restrictions of the plan (refer statement 4.8);
c. how the plan will safeguard objectivity in the research project;
d. confirmation of the investigator’s agreement to the plan;
e. how the plan will be monitored to ensure investigator compliance;
f. any ongoing changes to the plan; and
g. any other information as needed.

(12) Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

a. public disclosure of FCOI (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution’s Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc);
b. for research projects involving human subjects research, disclosure of FCOI directly to participants;
c. appointment of an independent monitor capable of taking measures to protect the design, conduct, and

reporting of the research against bias resulting from the FCOI;

d. modification of the research plan;
e. change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
f. reduction or elimination of the financial interest (e.g. sale of an equity interest); or
g. severance of relationships that create financial conflicts.

FCOIs and Clinical Research

(13) If the NIH determines that an NIH-administered clinical research project to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an investigator with a FCOI that was not managed or reported, the investigator must disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

Reporting requirements to NIH

(14) Send initial, annual (i.e., ongoing) and revised FCOI reports, including all required information defined in the regulation and/or NIH's FAQ H.5, to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients, if applicable, as required by the regulation and as stated below:

a. prior to the expenditure of funds;
b. after a retrospective review to update a previously submitted report, if new information is discovered following completion of the review;
c. at least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension). The annual report will provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project;
d. within sixty (60) days for new, or newly identified, FCOIs for existing Investigators; or
e. within sixty (60) days of identification for an Investigator who is newly participating in the project.

(15) If an investigator fails to comply, or the FCOI was not managed or reported as required, and there appears to be a conflict with the PHS-funded research, Research Services must immediately notify the PHS-agency of the corrective action taken or to be taken.

(16) Research Services must prepare a mitigation report, as applicable, for submission to the PHS-agency and comply with any requirements for a retrospective review. At a minimum, the mitigation report will include:

a. key elements documented in the retrospective review;
b. description of the impact of the conflict with the research project;
c. plan of action(s) to eliminate or mitigate the FCOI; and
d. submission of FCOI reports annually.

(17) The PHS agency may take its own action as it deems appropriate, which may include suspension of funding, or require Macquarie University to take further action to maintain the objectivity of the research.

(18) Non-compliance will result initially in re-training, then in disciplinary action if there are further occurrences, in accordance with the Macquarie University Code for the Responsible Conduct of Research.

Subrecipient Requirements

(19) When working with subrecipients for a portion of PHS-funded research, a written agreement must be put in place to clarify:

a. which organisation's (Macquarie University or subrecipient) FCOI policy or procedures will be followed. If the subrecipient chooses to use its institutional FCOI policy, the subrecipient must provide certification that its FCOI policy complies with the regulation; and
b. in either case, the timeline for disclosure and reporting.

(20) In the case that Macquarie University is the prime recipient of PHS-funded research, Macquarie University is responsible for monitoring subrecipient's compliance with these procedures and the regulation, and for reporting all identified FCOI.

Public Accessibility Requirements

(21) This Procedure will be publicly accessible on the University's website.

(22) The University will, within five (5) business days of a request, disclose requisite details of any FCOIs whenever such information is requested from the PHS/NIH.

(23) Information will be updated at lease annually or within sixty (60) days of a newly identified FCOI.

(24) Information will remain available for three (3) years.

FCOI Training Requirements

(25) Investigators must complete the NIH Financial Conflict of Interest Training available from the National Institutes of Health FCOI website.

(26) Training is required for an Investigator:

a. prior to engaging in research related to any PHS/NIH-funded grant;
b. at least every four (4) years;
c. immediately, if:
    i. Macquarie University revises its FCOI policy or procedure that affects requirements of Investigators;
    ii. an Investigator is new to Macquarie University and participating on a PHS/NIH-funded grant; or
    iii. an Investigator (or other relevant staff member) is not in compliance with the policy, procedure, or management plan.

(27) On completion of the training, investigators must submit the FCOI certification to the Grant Development Team, Research Services.

(28) Relevant Macquarie University research support staff will receive training on this Procedure.

Section 4 - Guidelines

(29) Nil.

Section 5 - Definitions

(30) The following definitions apply for the purpose of this Procedure (refer to section 50.603 Definitions, Electronic Code of Federal Regulations):

a. Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
b. Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
c. Investigator is the Macquarie University project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by PHS (e.g., NIH), or proposed for such funding. Depending on their roles, collaborators or consultants may be considered investigators.
d. PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).
e. Research For PHS-funded projects, the term includes any such activity for which research funding is available from a PHS awarding component through a grant or cooperative agreement, whether authorised under the United States or other statutory authority, such as a research grant, career development award, centre grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.
f. Significant financial interest (SFI) means:
    i. 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 institutional responsibilities:
        - With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
        - With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve 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
        - Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
    ii. Royalties from, and/or agreements to share in royalties related to, intellectual property rights paid to an Investigator (or his/her spouse or dependent children) are covered by the regulation and are subject to the $5,000 threshold. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., 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) when aggregated exceeds $5000 in the 12 months preceding disclosures, related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an Institution of higher education.
        - The disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organiser, the destination, and the duration.
    iii. The term significant financial interest does not include the following types of financial interests: salary, royalties (unless as above f.i.4), or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;

any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organisation; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical centre, or a research institute that is affiliated with an Institution of higher education.

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