OFFICE OF SPONSORED PROGRAMS UNIVERSITY OF NORTHERN COLORADO

Financial Conflict of Interest Pertaining to Sponsored Programs Implementing Procedures for University Regulation 3-3-402(1)

The university policy on Financial Conflict of Interest Pertaining to Sponsored Programs, found at <u>University</u> <u>Regulations</u>, Article 3, Part 4, Section 3-3-402(1), establishes standards that provide a reasonable expectation that the design, conduct, and reporting of activities supported under externally funded awards will be free from bias resulting from Investigator financial conflicts of interest. The university will require the specific processes outlined here to implement that policy.

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A. DEFINITIONS

The following definitions apply throughout these procedures.

- 1. Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or other educational activities funded by an external sponsor
- 2. Financial Interest: anything of monetary value, whether or not the value is readily ascertainable
- 3. Designated Institutional Official (DIO): the individual designated by the university to solicit and review disclosures of significant financial interest from investigators, and who oversees the process of managing and reporting on financial conflicts of interest. The University of Northern Colorado has designated the Assistant Vice President for Research to serve in this capacity.
- 4. Institutional Responsibilities: those professional responsibilities an Investigator has by virtue of being a university employee, including, but not limited to, research, teaching, service, consultation, professional practice, performance, management and administrative duties.
- 5. Investigator: the project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, educational, or other activities funded by an external sponsor, or proposed for such funding. (This may include collaborators or consultants.)
- 6. Manage: taking action to address a financial conflict of interest
- 7. NSF: National Science Foundation

8. PHS: Public Health Service of the U.S. Department of Health and Human Services, including the following components of the PHS:

Agency for Healthcare Research and Quality (AHRQ),

Centers for Disease Control and Prevention (CDC),

Health Resources and Services Administration (HRSA),

Indian Health Service (HIS),

National Institutes of Health - all institutes [NIH],

Substance Abuse and Mental Health Services Administration (SAMHSA),

Agency for Toxic Substances and Disease Registry (ATSDR),

Office of the Assistant Secretary for Health

Office of Global Affairs

Office of the Assistant Secretary for Preparedness and Response

- 9. PHS Awarding Component: the organizational unit of the PHS that funds the project that is subject to these procedures
- 10. Research: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge, including basic and applied research and product development
- 11. Significant Financial Interest (SFI): an Investigator's Financial Interest (see 2, above), and those of the Investigator's spouse and dependent children, which reasonably appear to be related to the Investigator's Institutional Responsibilities (see 4, above), and where:
 - a. With respect to PHS funded projects, a Significant Financial Interest exists if:
 - I. the value of any remuneration received from a publicly traded entity in the twelve months preceding the disclosure, and the value of any equity interest in the entity as of the date of disclosure that, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria, or paid authorships. 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; or
 - II. the value of any remuneration received from any non-publicly traded entity in the twelve months preceding the disclosure that, when aggregated, exceeds \$5,000, or when the Investigator, or his/her spouse or dependent children, holds any equity interest such as stock, stock options, or other ownership interests; or
 - III. intellectual property rights and interests such as patents and copyrights, upon receipt of income related to such rights and interests; however
 - IV. see exclusions in part d, below.

or

- b. With respect to NSF funded projects, a Significant Financial Interest exists if:
 - . the value of any equity interest which, when aggregated for the Investigator and his/her spouse and dependent children, exceeds \$10,000 as determined through reference to public prices or other reasonable measures of fair market value, and represents more than a 5% ownership interest in any single entity; or
 - II. the value of any salary, royalties, or other payments received in the twelve months preceding the disclosure that, when aggregated for the Investigator and his/her spouse and dependent children, are expected to exceed \$10,000; however
 - III. see exclusions in part d, below.

Or

c. With respect to projects funded by other sponsors, a Significant Financial Interest exists if the Investigator (or his/her spouse or dependent children) is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization or corporation that is funding a sponsored project or is providing goods and services under a sponsored project on which the Investigator is participating;

however,

- d. Significant financial interests do not include:
 - salary, royalties, or other remuneration paid by the university to the Investigator if the
 Investigator is currently employed or otherwise appointed by the university, including intellectual
 property rights assigned to the university and agreements to share in royalties related to such
 rights;
 - II. 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;
 - III. 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 center, or a research institute that is affiliated with an institution of higher education; or
 - IV. 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 center, or a research institute that is affiliated with an institution of higher education.

B. UNC'S RESPONSIBILITY TO INFORM INVESTIGATORS

Upon submitting a <u>Notice of Intent to Submit a Grant Proposal</u>, the Principal Investigator will be notified through the NIS automated response message:

- 1. Of the university's policy on financial conflicts of interest;
- 2. Of the Investigator's responsibilities regarding disclosure of significant financial interests;
- 3. Of the regulations found at 42 CFR 50.601-607 if PHS funding is involved;
- 4. That if PHS funding is involved, should an award be received, each Investigator participating on the project must complete the CITI training on financial conflicts of interest prior to engaging in research related to the project;
- 5. That the Principal Investigator is responsible for notifying all other Investigators involved on the project of B. 1-4, above.

C. FCOI TRAINING (Applies only to PHS funded projects)

PHS regulations require that all Investigators complete training on financial conflict of interest prior to engaging in research related to any PHS funded grant, at least every four years for the duration of any grant, and in certain other circumstances. This training requirement also applies to subrecipient Investigators (including consultants and contractors) when the subrecipient is subject to UNC's FCOI policy. While this section is applicable only to PHS funded projects; all Investigators are encouraged to complete the training on financial conflict of interest.

- 1. When a PI/PD sends OSP a Notice of Intent to Submit a Grant Proposal, he/she will be notified through the website response page of the requirement for all Investigators on the project to complete training on financial conflict of interest.
- When an award or notice of award is received, OSP will determine whether all project Investigators have completed FCOI training within the past four years. OSP will inform the PI/PD if there are Investigators who must complete training prior to working on the project.
- 3. Each Investigator will complete the CITI Conflict of Interest: Overview, Investigator Responsibilities, and COI Rules) and Module 2 (Institutional Responsibilities as They Affect Investigators). Additional optional training is available in CITI Module 4 (Conflicts of Commitment, Conscience, and Institutional Conflicts of Interest), and in the NIH FCOI Online Tutorial):
 - a. Prior to engaging in work on a PHS funded project;

- b. At least every four years throughout the duration of the project;
- c. If an Investigator is new to a project (i.e., a replacement for an Investigator who leaves the project or an Investigator who is a new hire and brings an existing project to the university);
- d. Any time the university revises these procedures or the policy on Financial Conflict of Interest Pertaining to Sponsored Projects in a manner that affects the Investigator's obligations; and
- e. When the university finds that the Investigator is not in compliance with the policy, these procedures, or an FCOI management plan.
- 4. The PI/PD is responsible for ensuring that all other Investigators on his/her project, including those subrecipient Investigators who are subject to UNC's FCOI policy, complete training when required.
- 5. Expenses on a new award will not be allowed until the training requirement has been met by all Investigators. If subsequent training for on-going projects is not completed when required, the PI/PD will be notified that the project is at risk, and notices will be sent to the supervisors of Investigators who are delinquent. Continued delay in completing the required training may result in sanctions or termination of the award.

D. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

The university's Disclosure of Significant Financial Interests form and Subrecipient Disclosure of Significant Financial Interests form are available from the Office of Sponsored Programs or by downloading it from the OSP Website.

- 1. Initial Disclosures at Proposal Submission
 - a. Before a full proposal is submitted to any external sponsor, each Investigator on the proposed project must submit a completed Disclosure of Significant Financial Interests form to the Office of Sponsored Programs. The Disclosure must be signed by the Investigator.
 - b. A disclosure is not required for submission of a preliminary proposal.
 - c. The PI/PD is responsible for ensuring that all Investigators submit disclosures to OSP prior to the proposal due date. No proposal will be submitted until OSP has received all required Disclosure forms.
 - d. If a full proposal requesting PHS or NSF funding involves subrecipients who have not implemented written FCOI policies that are compliant with the PHS or NSF requirements, the subrecipient organization must submit a Financial Conflict of Interest Subrecipient Compliance Form, and each subrecipient Investigator must submit a UNC Subrecipient Disclosure of Significant Financial Interests form before OSP submits the proposal to the sponsor.

2. Annual Disclosure Updates – applies to PHS funded projects

Investigators, including subrecipient investigators following UNC's FCOI policy, participating in PHS funded projects must submit annual Disclosures of Significant Financial Interest updates throughout the period of any PHS funded award.

- a. Regardless of when the initial Disclosure was made, annual Disclosures must be submitted to OSP between November 1st and November 31st during each year an award is open. The updates must include information on any significant financial interest that, for whatever reason, was not previously disclosed and updated information regarding any previously disclosed Significant Financial Interest, such as the updated value of a previously disclosed equity interest.
- b. A separate Annual Disclosure Update is required for each PHS funded project.
- c. OSP will notify UNC Investigators of the need for updates by October 1st each year.
- d. PI/PDs are responsible for ensuring that all other Investigators, including subrecipient Investigators who are subject to UNC's FCOI Policy, of the need to submit annual disclosure updates to OSP by the November deadline.

- e. If required annual disclosure updates are not received by November 30, the PI/PD will be notified that the project is at risk and that the university is required to notify the PHS of noncompliance with the FCOI Policy. The Investigator's dean or administrative supervisor will be notified of the noncompliance. Continued delay in submitting required disclosure updates may result in sanctions or termination of the award.
- 3. Any Investigator who is involved in a <u>PHS or NSF funded project</u> is responsible for submitting an updated Disclosure of Significant Financial Interests *within thirty days* of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new interest.

E. DISCLOSURE OF TRAVEL

- 1. Each Investigator must also disclose the occurrence of any travel that is related to his/her institutional responsibilities and that is paid or reimbursed (the exact monetary value may not be readily available) by an external entity. This disclosure requirement does not apply to travel that is paid by:
 - a. a federal, state, or local government agency,
 - b. an institution of higher education,
 - c. an academic teaching hospital,
 - d. a medical center, or
 - e. a research institute that is affiliated with an institution of higher education.
- 2. The travel disclosure will be included on each submission of a Significant Financial Interest Disclosure form.
- 3. Any initial or updated disclosure that includes travel must report the purpose of the travel, the identity of the sponsor/organizer, the destination, and the duration of the trip.

F. DETERMINATION AND MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

- 1. Applies to all Sponsored Projects
 - a. The Office of Sponsored Programs will check all Significant Financial Interest Disclosure forms upon receipt and forward those that report SFI(s) (positive disclosure) to the DIO for review.
 - b. The DIO will review positive Disclosures to make an initial determination as to whether an SFI is related to the Investigator's institutional responsibilities. The DIO will consider whether the SFI could be affected by the investigator's work or is in an entity whose financial interests could be affected by the work. The DIO may call upon the Investigator to provide additional information; confer with others in the same area of expertise; and/or convene the Conflict Review Committee.
- 2. Additional Procedures applies only to work funded by PHS and NSF
 - a. If the DIO determines that an SFI is related to the Investigator's PHS or NSF funded project, he/she will then further determine whether the SFI constitutes a Financial Conflict of Interest (FCOI). He/she may choose to consult with the university's legal counsel and/or convene the Conflict Review Committee to assist in making that determination. Elements considered in making a determination of financial conflict should include, but not necessarily be limited to, the following:
 - I. In what way is the SFI related to the Investigator's sponsored project?
 - II. Is the SFI in an entity whose financial interest could be affected by the project?
 - III. In what way could the SFI be affected by the project?
 - IV. In what way could the SFI have a direct and significant effect on the way the project is designed, conducted, or reported?
 - b. Upon completing the review of a Disclosure, whether or not a Financial Conflict of Interest is found to exist, the DIO will notify the Investigator and the Office of Sponsored Programs. If it was determined that there is an FCOI, the Investigator will be asked to develop and submit to the DIO a management plan that specifies actions that have been, and will be, taken to reduce, eliminate, or otherwise manage the FCOI.

While the requirements of any management plan will depend on the specific details of the SFI and the extent of the conflict, some conditions or restrictions that may be included in a plan include, but are not limited to, the following:

- I. Public disclosure of the significant financial interest(s) when presenting or publishing the results of the project;
- II. For projects involving human subject research, disclosure of financial conflicts of interest directly to participants;
- III. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the project against bias resulting from the financial conflict of interest;
- IV. Modification of the scope of work or research plan;
- V. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the project;
- VI. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- VII. Severance of relationships that create financial conflicts.
- c. The DIO will review the FCOI management plan and work with the Investigator to make any changes deemed necessary. Review and finalization of the plan will be completed in time so as not to delay the start of a project.
 - If a final management plan is agreed upon by the Investigator and the DIO, a copy will be sent to the Investigator and to the Office of Sponsored Programs.
 - If a management plan cannot be agreed upon, the DIO will notify the Office of Sponsored Programs, and no expenditures on the award will be allowed and OSP will inform the sponsor that the university cannot accept the award.
- d. If, in the course of an ongoing sponsored project, an Investigator who is new to participating in the project discloses an SFI or an existing Investigator discloses a new SFI, <u>within 60 days</u> of the disclosure, the DIO will complete a review and take any necessary action as described above.
 - If the DIO determines it necessary, he/she may impose interim measures with regard to the Investigator's participation in the project between the date of disclosure and the completion of its review.
- e. If it is discovered that an SFI was not disclosed in a timely manner by the Investigator or was not previously reviewed by the university for whatever reason, <u>within 60 days</u> the DIO will complete a review and take any necessary action, including developing and implementing a management plan, at least on an interim basis, if an FCOI was found to exist.
- f. It is the Investigator's responsibility to inform the DIO in writing when he/she has met the conditions of an FCOI management plan, providing such detail as to allow the DIO to determine whether the conflict has been adequately addressed.
- g. The DIO will take whatever steps are necessary to ensure that an FCOI management plan is fully implemented and to monitor the Investigator's compliance with the plan on an ongoing basis until the project is completed.

G. DETERMINATION AND MANAGEMENT OF NONCOMPLIANCE – applies only to PHS funded projects

1. Whenever an FCOI is not identified or managed in a timely manner including (a) an Investigator's failure to disclose an SFI that is determined to be an FCOI; (b) the university's failure to review or manage an FCOI; or (c) an Investigator's failure to comply with a management plan, the DIO will, within 120 days of the determination of noncompliance, complete a retrospective review the Investigator's activities and the sponsored project to determine whether any of the work conducted during the time period of the noncompliance was biased in its design, conduct or reporting. The DIO may call upon the Conflict Review Committee to assist with or to conduct the retrospective review.

- 2. The DIO will document the retrospective review and will furnish OSP will all documentation for record keeping purposes. Such documentation will include, at a minimum, all of the following key elements:
 - a. the project number (PHS award number)
 - b. the project title
 - c. the name of the Investigator with the FCOI
 - d. the name of the entity with which the Investigator has a financial conflict of interest
 - e. the reason(s) for the retrospective review
 - f. a description of the detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.)
 - g. the findings of the review
 - h. the conclusions of the review

H. PUBLIC ACCESSIBILITY – applies only to PHS funded projects

- 1. Before the expenditure of any funds on a PHS funded project, and whenever an SFI was determined to be an FCOI related to that project, and the SFI is still held by the Investigator, the following information will be made available to the public on the Office of Research Website:
 - a. the Investigator's name;
 - b. the Investigator's title and his/her role with respect to the project;
 - c. the name of the entity in which the significant financial interest is held;
 - d. the nature of the significant financial interest; and
 - e. the approximate dollar value of the SFI or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value. (Values may be posted in the following dollar ranges: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; and amounts above \$100,000 by increments of \$50,000)
- 2. Whenever it is discovered that an SFI was not previously disclosed, or when an Investigator new to a PHS project discloses an SFI, and it is determined that the SFI constitutes an FCOI, within sixty days of that discovery or disclosure, the Office of Research will update the website to include the required information about the FCOI.
- 3. Information on the website will be updated by the Office for Research at least annually, and the website will note that the information provided is current as of the date listed and is subject to updates on an annual basis and *within 60 days* of the university's identification of a new FCOI.

I. SUBRECIPIENT COMPLIANCE – applies to PHS and NSF funded projects

- 1. Prior to a proposal being submitted to the sponsor, if subrecipients are involved, OSP will ensure that letters of commitment required of subrecipients include a statement regarding financial conflict of interest, with an option to indicate whether:
 - a. the subrecipient has a financial conflict of interest policy that is compliant with the PHS regulations found at 42 CFR Part 50 and 45 CFR Part 94 or Chapter IV of the NSF Proposal and Award Policies and Procedures Guide, as appropriate; and the subrecipient's Investigators will comply with that policy should the proposal result in an award; or
 - the subrecipient does not have such a policy, and the subrecipient's Investigators are subject to UNC's financial conflicts of interest policy according to the requirements of the PHS regulations or NSF Standards.
- 2. Any subaward made under a PHS or NSF funded award will incorporate terms establishing whether the University of Northern Colorado financial conflict of interest policy or that of the subrecipient will apply to the subrecipient's Investigators.
 - a. If the subrecipient's Investigators are to comply with the subrecipient's policy:

- the subaward will include a certification that its policy complies with the 42 CRF Part 50 and 45 CFR Part 94 or Chapter IV of the NSF Proposal and Award Policies and Procedures Guide, as appropriate;
- II. the subaward will specify times period(s) for the subrecipient to report all identified FCOIs to the University of Northern Colorado; such time period(s) to allow for UNC to provide timely FCOI reports, as necessary; and
- III. the subaward will specify the information to be included in FCOI reports, and the manner in which they are to be submitted to UNC.
- b. If the subrecipient cannot certify that it has a compliant financial conflict of interest policy to which its Investigators will be subject, and the subrecipient's Investigators must comply with UNC's financial conflict of interest policy:
 - the subaward will state that the subrecipient Investigators are subject to UNC's financial conflict
 of interest policy for disclosing Significant Financial Interests that are directly related to the
 subrecipient's work for UNC;
 - II. the subaward will specify time period(s) for the subrecipient to submit all Investigator disclosures of Significant Financial Interests to UNC; such time period(s) to allow adequate time for UNC to comply with its review, management, and reporting obligations.
 - III. the subaward will specify the information to be included in SFI disclosures, and the manner in which they are to be submitted to UNC.
 - IV. a copy of UNC's policy and a copy of these procedures will be attached to the subaward.

J. REPORTING OF FINANCIAL CONFLICTS OF INTEREST – applies only to PHS funded projects

- 1. Upon notification by the DIO that an Investigator has an FCOI, expenditures under the PHS funded project will not be allowed until the DIO has provided a report to the PHS Awarding Component regarding the Financial Conflict of Interest and ensuring that the university has implemented a management plan. However, if the FCOI is eliminated prior to expenditure of any PHS funds, a report is not required.
- 2. Within 60 days of the discovery of any FCOI that is identified subsequent to the DOI's initial FCOI Report (e.g., that of an Investigator who is new to the project), the DIO will provide to the PHS Awarding Component an FCOI Report regarding the FCOI and ensure that the university has implemented a management plan.
 - a. When such FCOI report involves an SFI that was not disclosed in a timely manner by an Investigator or was not previously reviewed or managed by the university (e.g., was not properly reviewed or reported by a subrecipient), the DIO will complete a Retrospective Review to determine whether any portion of a PHS project conducted before the identification and management of the FCOI was biased in its design, conduct, or reporting.
 - b. If a Retrospective Review finds bias, the DIO will promptly notify and submit a mitigation report to the PHS Awarding Component.
- 3. The DIO will provide the PHS Awarding Component with an Annual FCOI Report for any previously reported FCOI throughout the duration of the award (including no-cost extensions).
 - a. Annual FCOI Reports will address the status of the FCOI and any changes to the management plan. It will specify whether the financial conflict is still being managed or explain why it no longer exists.
 - b. Annual FCOI Reports will be submitted in the time and manner specified by the PHS Awarding Component.
- 4. All FCOI reports submitted to the PHS by the DIO will include sufficient information to enable the PHS to understand the nature and extent of the FCOI and to assess the appropriateness of the university's management plan. Reports will include, but are not limited to:
 - a. Project number (PHS Award Number);
 - b. PI/PD or Contact PI/PD if a multiple PI/PD model is used;

- c. Name of the Investigator with the FCOI;
- d. Name of the entity with which the Investigator has an FCOI;
- e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- f. Value of the financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- g. A description of how the financial interest relates to the PHS-funded project and the basis for the university's determination that the financial interest conflicts with the project; and
- h. A description of the key elements of the university's management plan, including:
 - I. Role and principal duties of the Investigator with the FCOI;
 - II. Conditions of the management plan;
 - III. How the management plan is designed to safeguard objectivity in the project;
 - IV. Confirmation of the Investigator's agreement to the management plan;
 - V. How the management plan will be monitored to ensure Investigator compliance; and
 - VI. Other information as needed
- 5. For any FCOI that has been reported to the PHS, and for the duration of the project (including no-cost extensions), the DIO will submit annual FCOI Reports in the time and manner specified by the PHS Awarding Component. Annual reports will address:
 - a. the status of the FCOI;
 - b. any changes to the management plan;
 - c. whether the FCOI is still being managed; or
 - d. why the FCOI no longer exists.
- 6. If an Investigator's failure to comply with the university's FCOI policy, procedures, or FCOI management plan appears to have biased the design, conduct, or reporting of the project, the DIO will promptly notify the PHS Awarding Component of corrective action taken or to be taken.
 - The PHS Awarding Component will take appropriate action as necessary, or refer the matter to the university for further action.
- 7. If the Department of Health and Human Services requests information relating to any Investigator disclosure of SFIs and the university's review of and response to such disclosure, the DIO will promptly make that information available.

K. MAINTENANCE OF RECORDS AND CONFIDENTIALITY – applies to all sponsored projects

- 1. All records relating to Investigator disclosures, the university's review or and response to, reports related to, and all actions taken in regard to such disclosures (records) will be maintained by the Office of Sponsored Programs.
- 2. The DIO will provide copies of all relevant documents and correspondence related to the review, determination, management, and reporting of FCOIs to OSP in a timely manner. Documents requiring a signature will be provided to OSP in the original.
- 3. Records will be maintained for a period of three years from the date the final expenditure report was submitted to the sponsor or until the resolution of any sponsor action involving the records, whichever is longer.
- 4. All information provided and records related to disclosures will be held in confidence to the extent permitted by law and in accordance with the UNC policy on <u>Financial Conflict of Interest Pertaining to Sponsored Programs</u> (go to Article 3, Part 4, Section 3-3-402) and these procedures.
- 5. If any external entity requests FCOI records, OSP will inform the Investigator of the request and whether the information was provided to the requestor.

RELATED RESOURCES

<u>Public Health Service Regulations – Promoting Objectivity in Research</u>

NIH Financial Conflict of Interest Website

NSF Award and Administration Guide – Conflict of Interest Policies