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**Financial Conflict of Interest (FCOI)**

**Instructional Packet**

Procedures Effective Date: **August 24, 2012**

**Goal**

Brigham Young University shall establish standards that provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from Investigator Financial Conflicts of Interest (FCOI).

**Institutional Responsibility**

BYU must inform each sponsored projects investigator of the regulations, BYU’s policy and procedure concerning FCOI and the investigator’s responsibility regarding disclosure and management of FCOI.

**When Should Investigators Receive FCOI Instruction?** (Required by federal regulation)

* Prior to engaging in research (like sending in a proposal or receiving an award)…

OR…

* At least every 4 years…

OR…

* Immediately when any of the following circumstances apply:
* When BYU revises its policy in a manner that affects the investigator
* When an investigator is new to BYU
* When BYU finds an investigator is not in compliance with the institution’s policy or management plan
* BYU Colleges and Departments may choose to do this instruction/disclosure during the annual stewardship interview.

**Definition: Significant Financial Interest (SFI)**

A Significant Financial Interest (SFI) is an equity interest in, or payments for services exceeding ***$5,000 in a 12 month period*** from a single source such as a business, non-profit entity, or another institution. This includes any equity interest in non-publically traded entities.

**Definition: Financial Conflict of Interest (FCOI)**

An SFI that could directly and significantly affect the design, conduct, or reporting of research.

***Excluded***from disclosure include the following:

* Income from Seminars, lectures or teaching engagements sponsored by and/or service on advisory or review panels for a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher education.
* Income from investment entities, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these entities.

**Disclosure Checklist**

Yes No

 Do you have an equity interest in, or have received payments for services exceeding ***$5,000 in a 12 month period*** from a business, non-profit entity, or another institution directly related to a current research proposal or award?

 Have you received reimbursed travel or sponsored travel relating to your institutional responsibilities from a business, non-profit entity, or another institution? Include purpose of trip, sponsor/organizer, destination, and duration in disclosure.

Note: Individuals are ***NOT*** required to disclose travel that is reimbursed or sponsored by a federal, state, or local government agency, another institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

If either of the questions above are answered ‘Yes’, then a disclosure should be made as a Significant Financial Interest (SFI) *may* exist that *might* create a Financial Conflict of Interest (FCOI).

Disclosure: Investigators must report any SFI that meets the above criteria to their Department Chair/Associate Dean who will review and forward the disclosure to BYU’s RAO Director by the time a research proposal application is to be submitted to an external Sponsor. Additionally, investigators must also submit an updated disclosure statement (on previously disclosed SFI) at least annually, AND/OR within 30 days of “discovering” or “acquiring” any new SFI.

There are two principal situations that could exist:

1) Existing SFI and new research proposal that are related

 PI’s should always disclose SFI’s, independent of existing research agreements or proposals, to their department chair.

2) The research agreement is ongoing and a new or previously unreported SFI is disclosed.

Determination: With the disclosure(s) submitted from the investigator, the Department Chair, Dean/Associate Dean and the Research Administration Office (RAO) Director will determine if any disclosures create an FCOI and/or require further information.

**Once the threshold of a $5,000 SFI is met by an individual in a given year, *ALL* FCOI related to the individual’s institutional responsibility must be disclosed, regardless of dollar value during the remainder of that year.**

**What Must Be Disclosed?**

* Grant/Contract number of the directly related research award (not applicable if project is only in proposal stage)
* Project Director/Principal Investigator (PD/PI) or Contact PD/PI
* Name of Investigator with FCOI
* Whether, and/or how the FCOI has been or will be managed, reduced, or eliminated
* Name of the entity with which the Investigator has a FCOI
* Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria
* Value of the financial interest
* $0-4,999
* $5K-9,999
* $10K-19,999
* Amounts between $20K-$100K by increments of $20K
* Amounts above $100K by increments of $50K
* Or statement that a value cannot be readily determined
* A description how the financial interest relates to your research project and the basis for the Institution’s determination that the financial interest conflicts with such research
* Key elements of the Institution’s management plan (*see the next heading*)

**Management Plan**

Before spending any research funds, the Department Chair, Associate Dean and BYU’s RAO Director must review any applicable investigator SFI disclosures and, with the investigator, develop a formal, written Financial Conflict of Interest Management Plan. Conditions or restrictions that might be established to manage a financial conflict of interest including, but are not limited to:

(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects 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 research against bias resulting from the financial conflict of interest;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest);

(vii) Severance of relationships that create financial conflicts.

Whenever, in the course of an ongoing research project, an Investigator who is new to the research project discloses a SFI, or an existing Investigator discloses a new SFI, the Department Chair will advise the College Dean and forward the disclosure to BYU’s RAO Director who shall, within sixty days:

* Review the disclosure of the SFI
* Determine whether it is related to the proposed or existing funded research
* Determine whether a FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such concerns

Depending on the nature of the significant financial interest, BYU’s RAO Director may determine that additional interim measures are necessary with regard to the Investigator’s participation in the funded research project between the date of disclosure and the completion of the BYU review.

Whenever BYU identifies a significant financial interest that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by the BYU RAO Director during an ongoing research project (e.g., was not timely reviewed or reported by a subrecipient), the BYU RAO Director shall, within sixty days:

* Review the significant financial interest with the investigator, Chair, and Associate Dean
* Determine whether it is related to the funded research
* Determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii) In addition, whenever:

* a FCOI is *not* identified, disclosed or managed in a timely manner, including failure by the Investigator to disclose a SFI that is determined by the BYU’s RAO Director to constitute a financial conflict of interest;
* failure by the Department Chair to review or manage such a financial conflict of interest;
* or failure by the Investigator to comply with a financial conflict of interest management plan,

then BYU shall, within 120 days of the institution’s determination of noncompliance, complete a retrospective review of the Investigator’s activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

(1) Project number

(2) Project title

(3) PD/PI or contact PD/PI if a multiple PD/PI model is used

(4) Name of the Investigator with the FCOI

(5) Name of the entity with which the Investigator has a financial conflict of interest

(6) Reason(s) for the retrospective review

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed

(8) Findings of the review

(9) Conclusions of the review

(iii) Based on the results of the retrospective review, if appropriate, the BYU RAO Director shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found in a federally funded Public Health Service (PHS) project (NIH, Homeland Security, CDC etc.), BYU is required to notify that Awarding Sponsor promptly and submit a mitigation report to the Sponsor. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution’s plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, BYU’s RAO Director will submit FCOI reports annually for the life of the award in question. Depending on the nature of the financial conflict of interest, BYU may determine that additional interim measures are necessary with regard to the Investigator’s participation in the externally funded research project between the date that the financial conflict of interest or the Investigator’s noncompliance is determined and the completion of the Institution’s retrospective review.

Whenever BYU implements a management plan pursuant to this subpart, the Investigator’s Chair shall monitor Investigator compliance with the Management Plan on an ongoing basis until the completion of the research project.