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Financial Conflict of Interest- Objectivity in Research

The intent of this policy is to define the Biomedical Research Institute of New Mexico (BRINM) policy regarding objectivity in research and to define the procedures for reviewing potential financial conflicts of interest and addressing such identified instances.

The purpose of this policy is to promote objectivity in research by establishing standards that create a reasonable expectation that the design, conduct, and reporting of research is free from bias resulting from conflicting financial interests of investigators.

A conflict of interest (actual or perceived) occurs when any financial or other arrangement, situation, or action affects or could be perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Conflicts may be related to financial gain, reputation, promotion, or to the role of research investigator vs. health care provider, among others.

The Department of Veterans Affairs (VA) is responsible for developing agency specific guidance regarding the management of financial conflict of interest in research. All research managed by BRINM is VA research and employees engaged in such research hold VA paid or VA Without Compensation (WOC) appointments, therefore, the NMVAHCS policy on Institutional Conflict of Interest in Research is applicable to BRINM activities. In addition dually appointed faculty members are subject to the requirements of the University of New Mexico (UNM) regarding the management of financial conflict of interest. Any project that involves human subjects research is subject to both VA and UNM (if applicable) policy and requirements regarding financial conflict of interest in the conduct of human research.

This policy covers all BRINM administered research projects or programs.

DEFINITIONS

Disclosure of significant financial interests (SFI) means an Investigator's disclosure of significant financial interests to an institution, i.e. BRINM.

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.

Institution for purposes of this policy means BRINM. However, by virtue of their appointments with NMVAHCS and/or UNM institution could include those two institutions.

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of the Institution (but also to include VA and UNM if relevant to a BRINM-administered award); these may include research, teaching/education, clinical activities, committee memberships or other administrative responsibilities. Institutional Responsibilities on behalf of BRINM include research and service on the BRINM Board of Directors.

Investigator means the principal investigator, co-investigators, and other individuals who are responsible for the design, conduct, or reporting of research. It is not intended to apply to individuals who provide primarily technical support or who are purely advisory and without direct access to the data (e.g., control over its collection or analysis), unless they are in a position to influence the study's design, reporting, or results or have privileged information as to the outcome. Senior or key personnel identified on a grant application or progress report, consultants and post-doctoral fellows may or may not be included as Investigators.

Research means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioural and social-sciences research. The term encompasses basic and applied research and product development.

Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's spouse or 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)
- **Intellectual property rights and interests** (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

A significant financial interest does *not* include:

- Salary, royalties, 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;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made by these vehicles.

- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- Income from service from advisory committees or review panels for a federal, state, or local government agency, an Institution of higher education, an academic teaching hospitals, a medical center, or a research institute that is affiliated with an Institution of higher education.

Guidelines

- Entity sponsors research in which the investigator is directly involved;
- Entity has financial interests that could reasonably be considered to have a potential influence on the design, conduct, or reporting of investigator's research;
- Entity has a reasonable possibility of being financially affected by the investigator's research;
- Entity makes gifts to the VA, BRINM or UNM that benefits the investigator's research;
- Entity makes a product that is under study in research in which the investigator is involved;
- Entity licenses VA or UNM intellectual property in which investigator has a financial interest;
- Entity has a Materials Transfer Agreement or Human Tissue Agreement (MTA/HTA) to provide materials used in investigator's research or for materials provided by investigator to the entity;
- Entity sponsors or makes a product that is under study in human subjects in which investigator is directly or indirectly involved.

Disclosure and Review

For all research projects, Investigators must disclose financial interests prior to review and approval by the Research & Development (R&D) Committee.

BRINM Board members must disclose annually for Board review or prior to any vote that may have a potential conflict of interest.

For Investigators under the PHS policy, disclosure is additionally required at the time of application and at least annually thereafter as delineated in the Financial Conflict of Interest Guidelines for PHS Awards. Disclosure should include the relationship of the financial interest to their institutional duties.

Investigators are responsible for disclosing new or changed financial relationships as they occur but no later than within 30 days. These will be reviewed in the same manner as original disclosures.

Retrospective reviews will be required for significant financial interests not disclosed in a timely manner.

BRINM reviews potential conflicts of interest for research through the Conflict of Interest Subcommittee, in which the NMVAHCS is represented. This subcommittee of the NMVAHCS R&D Committee reviews proposed research and makes recommendations regarding management of conflicts of interest. Whenever there is a significant financial interest, disclosures must be submitted by Investigators to BRINM. BRINM will refer significant financial interests related to institutional duties to the Conflict of Interest Subcommittee for review.

In addition to BRINM and PHS policy, as noted above, specific conflict of interest rules and ethics standards apply to VA investigators and are considered in the review.

If a Significant Financial Interest that reasonably appears to be related to an Investigator's Institutional Responsibilities is disclosed that information along with supporting documentation shall be forwarded to BRINM's Executive Director. In coordination with VA and UNM (for dually appointed faculty) COI Managers and relevant policies or procedures, a determination as to whether any of the disclosed Significant Financial Interests of the Investigator are related to the project and whether the financial interest could directly and significantly affect the design, conduct, or reporting of the project (a FCOI) will be made. If there is an FCOI it will be eliminated, reduced or managed depending on the specific case. If managed, a management plan will be developed in conjunction with VA and/or UNM and appropriate notifications will be reported to PHS.

Notice of Change in Investigator's Significant Financial Interests OR Addition of Investigator with Significant Financial Interest Submissions and Review

If at any point there is the addition of an Investigator new to the project who might have a Significant Financial Interest or a change in an existing Investigator's financial situation that meets the threshold for SFI disclosure and review of significant financial interest the Principal Investigator must disclose that change within 30 days of addition of the new Investigator or of discovering or acquiring a new SFI. That is accomplished through the use of the Disclosure of Financial Interests form for review and processing as described above. If the Investigator is dually appointed UNM will be informed of such disclosures.

MANAGEMENT OF FCOI

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include but are not limited to:

- public disclosure of significant financial interests
- monitoring of research by independent reviewers
- modification of the research plan
- disqualification from participation in the portion of the NIH funded research that would be affected by significant financial interests
- divestiture of significant financial interests
- severance of relationships that create conflicts.

Enforcement mechanisms and sanctions will be managed in coordination with applicable BRINM, VA and UNM University policies.

AGENCY NOTIFICATIONS (PHS ONLY)

Upon receipt of an award from the Public Health Service and prior to the expenditure of any funds, as well as within 60 days for any new interest that BRINM identifies as conflicting subsequent to the Institution's initial report under the award, BRINM is obligated to notify the sponsoring institute or agency of any FCOI associated with that award. In addition BRINM will provide annual updates on any previously-identified FCOI for the duration of the research project. If an FCOI is identified at the time a proposal is submitted, and that proposal is subsequently awarded, or if an FCOI is identified subsequent to the award of the project, BRINM must prepare a notification to the eRA Commons FCOI Module. That notification is to consist of the following:

- grant number;
- PD/PI or contact PD/PI;
- name of Investigator with the FCOI;
- name of the entity with which the Investigator has an FCOI;
- nature of FCOI, e.g. equity, consulting fees, travel reimbursement, honoraria;
- value of the financial interest (in pre-specified dollar ranges) or a statement that a value cannot be readily determined;
- a description of how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
- key elements of the Institution's management plan including:
 - role and principal duties of the conflicted Investigator in the research project;
 - conditions of the management plan;
 - how the management plan is designed to safeguard objectivity in the research project;
 - confirmation of the Investigator's agreement to the management plan;
 - how the management plan will be monitored to ensure Investigator compliance;
 - other information as needed.

A copy of the notification must be kept with the project records. (Note that this notification requirement currently applies only to the Public Health Service, including the National Institutes of Health (NIH).)

OTHER REQUIREMENTS

Public Accessibility: Prior to the expenditure of funds, BRINM will make certain that information concerning FCOIs held by senior/key personnel is publicly accessible by a written response to any requestor within five business days of a request.

Investigator Training: Each Investigator must have completed the VA CITI on-line training located on the VA intranet, or the VA Talent Management System (VA TMS) at www.tms.va.gov or the UNM web-based training, *HSC Financial Conflicts of Interest Training (HSC 104-002)****, in UNM Research homepage at prior to engaging in research related to any PHS-funded grant. This training must be completed at least every four years after initial training. It must be completed immediately if: a) there is a revision to the BRINM FCOI policy that affects requirements of investigators, b) an Investigator is new to BRINM, or c) an

Investigator is not in compliance with the policy or management plan. The training will be tracked through the Research Administration website.

Subawards: If BRINM carries out PHS-funded research through subawardees, contractors, or collaborators, BRINM must take reasonable steps to ensure that the entity has its own policies in place that meet the requirements of the PHS policy or that investigators working for such entities follow BRINM policies.

Maintenance of Records: All FCOI-related records will be retained for at least 3 years from the date the final expenditure report is submitted to the PHS.