

## 14. Conflict of Interest

### 14.1. Policy

This policy is intended to provide appropriate institutional safeguards to sustain a climate in which human subjects research at the University can be carried out responsibly without undue influence from entrepreneurial and financial aspirations for the University and its researchers. Each financial interest that presents a potential for financial Conflicts of Interest (COI), whether real or perceived, must be fully disclosed, managed, reduced, or eliminated, and the potential conflict of interest and management plan, if any, must be disclosed to the various Institutional Review Boards (IRBs) so that the appropriate IRB can decide whether the interest and its management, if any, allows the human subjects research to be approved.

### 14.2. Definitions

The following definitions apply throughout this document:

**Human subjects research:** for the purposes of this policy, human subjects research is defined in accordance with the definition set down at 45 CFR 46.102(e) and 45 CFR 46.102 (l). Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Non-Exempt Human Subjects Research requires review and approval by an appropriate, officially appointed, Institutional Review Board registered with the Office of Human Research Protections prior to project initiation, and without respect to the source of funding or sponsorship.

***Immediate family member*** means the spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent. This includes “step” relationships.

***Dependent*** means any person who resides with an IRB member or who receives 50% or more support from an IRB member, regardless of age. This includes “step” relationships.

#### **14.3. Specific Policies**

Each institution that utilizes the UMKC IRB must have a policy that identifies whom has the authority to determine when COI exists, institute procedures to eliminate, reduce or manage the COI and to impose and enforce disciplinary action in the event that a COI is not disclosed.

#### **14.4. COI by Institution**

The IRB is informed of potential Institutional COI through the UMKC Office of Research Services (ORS). As a general guide, the following financial and fiduciary interests of the University may warrant formal review of potential Institutional COI with respect to human subjects research, as provided in this policy:

**14.4.1. Royalties:** the University has the potential to receive significant milestone payments and/or royalties from the commercialization of a product based at least in part on technology that is the subject of University research.

**14.4.2. Non-publicly traded equity:** through its technology licensing activities or investments related to such activities, the University has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a *non-publicly traded* company that is (i) the sponsor of human subjects research at the University, or (ii) the manufacturer or distributor of a product to be studied or tested in human subjects research at or under the auspices of the institution or based at least in part on technology developed at the University.

**14.4.3. Publicly traded equity:** through technology licensing activities or investments related to such activities, the University has obtained a significant equity interest or an entitlement to significant equity (including options or warrants), in a *publicly traded* company that is **(i)** the sponsor of human subjects research at the institution, or **(ii)** the manufacturer or distributor of a product to be studied or tested in human subjects research at or under the auspices of the institution, or based at least in part on technology developed at the University.

**14.4.4. Governance/fiduciary roles:** through technology licensing activities or investments related to such activities, the University has obtained the right to appoint one or more members to the governing board of any company that is **(i)** the sponsor of research at the University, or **(ii)** the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed at the University.

**14.4.5. Gifts from companies/sponsors:** The University is offered or has received significant gifts (including, but not limited to, gifts in kind, discounts, fellowships, and unrestricted educational grants) from a person, company or a foundation established by or closely affiliated with a company that is **(i)** sponsoring or offering to sponsor research at the University, **(ii)** the manufacturer or distributor of a product that is either studied or tested in research at or under the auspices of the University, or based at least in part on technology developed at the University; or **(iii)** a company known to be a business competitor of companies described in **(i)** or **(ii)** above.

The following circumstances, among others, should be evaluated in the gifting context:

- Whether a gift is of sufficient magnitude that even when held in the general endowment, it might affect, or reasonably appear to affect, oversight of research at the University;
- Whether a gift is held for the express or limited benefit of a school, department, institute or other unit where some or all of the research is conducted; or
- Whether any institutional official who has the authority to affect or reasonably appear to affect the design, conduct, reporting, review, or oversight of the research has also been actively involved in solicitation of the gift, or in the management of the gift once received by the University.

## **14.5. COI by Investigators and Research Team**

All principal investigators applying for IRB approval of proposed human subjects research shall disclose all financial COI required under the ORS reporting process and, if known, any potential institutional COI with the research as defined by [University of Missouri System Policy on Conflict of Interest](#).

All principal investigators must notify the IRB of a COI;

- During initial IRB application process;
- During continuing review application process;
- By submitting an amendment or notifying the IRB of a previously undisclosed conflict within 10 days of becoming aware of it.

#### **14.5.1. IRB Responsibilities**

The IRB:

- Accepts or rejects the recommendations of the Conflict of Interest Committee (COIC). If the IRB does not accept all the recommendations or requires additional safeguards for patient protection due to a COI, it will provide reason(s) for its actions in writing to the principal investigator and the COIC.
- The IRB of record has the final authority to decide whether the interest and its management, if any, allows the research to be approved.

#### **14.5.2. Research Compliance Office (RCO) Responsibilities**

Refer notifications and disclosures, if any, of COI on initial, continuing review or amendment applications to the ORS.

The following information will be provided to the ORS at the time of referral:

- Principal investigator's name
- Title of protocol
- Sponsor
- IRB protocol number

Communicate with the PI the required COI management plan, as put forth by the COIC and agreed to by the IRB, as it pertains to human subjects research.

#### **14.5.3. Institutional Responsibilities**

The COIC:

- Reviews COI of investigator(s) including study staff performing human subjects research to determine significance of any conflicts and develops conflict management plans to reduce mitigate, or eliminate any conflicts.
- Provides written determinations on management of COI or notification that no COI exist related to the protocol under consideration by the IRB. Information must be in sufficient

detail for the IRB to assess the importance of the COI and its proposed management to protect the subjects rights and welfare;

- Reports findings or determinations of known or potential COI to the IRB.

#### **14.6. COI by IRB Committee Members**

An IRB member will not review, participate in the deliberations on, or vote upon any research in which the member has a conflicting interest whether personal, professional, or financial, except to provide information about the research at the request of the IRB whether the research is reviewed by a convened board meeting or expedited procedures.

- *A personal conflicting interest* means the IRB member or an immediate family member serves as a contributor to the research project as an investigator, collaborator, and consultant or research staff.
- *A professional conflicting interest* means the IRB member (or immediate family member) serves as a Trustee, Director, Officer, Manager, or Scientific Advisor of any entity sponsoring the research.
- *A financial conflicting interest* means the IRB member or the spouse or dependent of a member or the spouse has or receives anything of monetary value (beyond the NIH de minimus value of \$5,000), including but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests), intellectual property rights (e.g., patents, copyrights, and royalties from such rights) with respect to the research (including the product or service being evaluated) or research sponsors.

Financial conflicting interest excludes an interest arising from investment in a business by publicly traded mutual, pension, or institutional investment funds over which the IRB member, spouse, or dependent does not exercise control of investment decisions. The above policy applies to both convened board and expedited review procedures and to IRB consultants as if they were IRB members.

IRB members must disclose a conflicting interest to the IRB and shall excuse themselves from a convened board meeting during deliberation and voting. The IRB will develop procedures to identify and disclose conflicting interests of members and consultants for full and fair review of research. The IRB will not retain consultants with conflicting interests unless it is impracticable to get needed information otherwise.

Notwithstanding the above, IRB members may, exercising their own judgment, absent themselves from discussion, deliberation, or vote on any agenda item to avoid the appearance, in their own judgment, of a conflicting interest, bias, or effects of undue influence.

#### **14.6.1. Procedure for Identifying and Managing IRB Member and Consultant Conflicting Interest**

This procedure lists responsibilities of the IRB and the Office of Research Compliance in managing COI of IRB members and IRB consultants.

#### **14.6.1.1. IRB Responsibilities**

An Individual IRB member:

- At the time of appointment, reads and signs a written acknowledgement to abide by the conflicting interest policy for IRB members, regarding required disclosure of conflicting interest when reviewing human subjects research.
- Reports to the IRB Chair or RCO staff if (s)he believes another member has not disclosed a conflicting interest.
- Notifies the IRB Chair at a convened meeting before being involved in the review of a protocol, an Unanticipated Problem involving risks to participants and others, or a report of Non-Compliance with the human research protection program or the requirements of the IRB (preferably at the time the meeting starts) in which the member has a conflicting interest.
- Notifies the RCO staff if assigned as a reviewer using the expedited procedure for a protocol in which the member has a conflicting interest.
- Does not participate in any portion of the review of research activities in which (s)he has a conflicting interest except to provide information requested by the IRB and leaves the meeting during deliberation and voting.
- Absents him/herself from a meeting at any time to avoid, based on personal judgment, the appearance of a conflicting interest, or the effects of personal bias or undue influence.

The Chair (or designee):

- Calls upon members to declare any conflicting interest with items on the agenda at the beginning of the IRB meeting;

A Consultant:

- Signs a written certification that (s)he has received the conflicting interest policy and has no conflicting interest related to the human subjects research assigned for review.

#### **14.6.1.2. RCO Responsibilities:**

- Reassigns protocols to another reviewer, if possible, when notified in time by a member of a conflicting interest.
- Assists in obtaining identification and disclosure of any conflicting interest and informs the Chair.
- Determines if consultants have a COI and informs them of the COI policy.

- Ensures RCO staff record in the minutes when a member is absent from the deliberations and voting for reasons of a conflicting interest.

#### **14.7. COI by RCO Staff and Others**

1. Institutional staff whose job status or compensation is affected by research that is reviewed by the IRB must excuse themselves from any deliberations at which such a protocol is reviewed. This includes discussion of protocols involving sponsors with whom they have a potential COI.
2. Consultants must complete a financial disclosure report regarding all potential sponsors as soon as they agree to assist with the review of a research protocol. This disclosure should include any relevant COI and must be updated annually and more frequently when significant changes have occurred.

#### **14.8. IRB Review of COI**

In cases of COI, the IRB shall have the final authority to determine as part of the review of the proposed human subjects research whether any suggested plans to manage, reduce or eliminate the COI are sufficient to allow the research to be approved and what information must be disclosed to prospective research subjects.

In considering whether to approve or strengthen the management plan, the IRB should consider the following issues:

- Whether there is sufficient public disclosure of financial interests;
- Whether there is sufficient disclosure to subjects through the consenting process;
- Reduction of equity holdings;
- Divestiture of financial interest (complete or partial);
- Severance of relationships that create actual or potential COIs;
- Clear separation of research from paid activities;
- Disqualification of the investigator with the conflict in obtaining consent and/or from participation in all or a portion of the research; and
- More frequent continuing reviews by the IRB.

In considering whether a protocol specific COI exists, the IRB should consider the following additional issues with regard to the impact of the economic interests on:

- Study design;
- Protocol;
- Consent document (particularly representations of risks and benefits);
- Data collection and reporting;
- Eligibility determinations and application of inclusion and exclusion criteria;
- Continuing consent clinical determinations (e.g., dose modifications, removing patients from study, related care);

- Determination and reporting of Unanticipated Problems and their relationship with study mechanism for data and safety monitoring;
- Data made available on continuing review (i.e., integrity and sufficiency); and
- Consequences affecting the clinician researcher's clinical duties to patient as a participant.

With respect to protocol specific COIs, the IRB has the final authority to determine whether the interest and its management, if any, are sufficient for IRB approval. The IRB may disapprove research that involves a COI or it may require changes at the investigator's or sponsor's expense to eliminate or manage the conflict. Possible IRB determinations include, but are not limited to:

- Requiring divestiture or termination of relevant economic interest;
- Requiring investigator recusal from study;
- Altering participation by the investigator in all, or a portion, of the research funded;
- Monitoring of research (i.e., independent review of data and other retrospective reviews for bias, objectivity, comprehensiveness of reporting);
- Requiring Independent clinical review of appropriateness of clinical care given to research participants;
- Monitoring the consent process; and/or
- Requiring disclosure to institutional committees, research participants, journals and data safety monitoring boards.

**Regulations and Guidelines:** 21 CFR 46.103, 107; 21 CFR 56.107; 21 CFR 54; 42 CFR 50 Subpart F; 45 CFR 94; OHRP May 2004 Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection; Um System Collected Rules and Regulations 330.015 Policy on Conflict of Interest; UM System Policy 410.020; UM System Policy 420.030

Approved by: Lawrence Dreyfus, PhD  
Name of University Institutional Official

  
Signature of University Institutional Official

3/27/19  
Date