

Policy on Institutional Conflict of Interest in Clinical Trials of Drugs, Devices, or Biologics Supported by University Start-up Companies

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Summary:

This policy establishes principles and procedures designed to ensure that Clinical Trials conducted at the University of Michigan involving a Drug, Device, or Biologic are conducted without untoward influence resulting from University's equity holdings in any Start-up Company supporting the Clinical Trial or from Significant Financial Interests of Senior Management personnel.

Definitions:

“Drug, Device or Biologic” means a drug or device or biologic, as defined by FDA, developed by University employees that is used in a Clinical Trial.

“Clinical Trial” means an evaluation, product testing, or other sponsored activity involving human subjects that is intended to assess the safety, effectiveness, commercial potential or other attribute of the Drug, Device or Biologic and that is supported by a Start-up Company.

“Institutional Conflict of Interest” means a situation in which University Equity Holdings or Significant Senior Management Financial Interests might, or might reasonably appear to, adversely affect the integrity or objectivity of a Clinical Trial, the safety of human subjects involved in the Clinical Trial, or the institutional processes for the design, conduct, reporting, review or oversight of the Clinical Trial.

“University Start-up Company” means a company in which the University has an ownership interest, whose stock is not publicly traded, and that has obtained an option or license to a Drug, Device or Biologic from the University.

“Senior Management” means any University employee who is charged with review and approval on behalf of the University or in a position to oversee or influence a Clinical Trial, or a University unit, of a Clinical Trial supported by a Start-up Company.

“Significant Senior Management Financial Interest” exists if any of the following apply:

- a. The senior manager or his or her spouse, partner or dependent child, owns stock or has other ownership interests of any value in the Start-up Company.
- b. The senior manager, or his or her spouse, partner or dependent child, is expected to receive salary, consulting fees, royalties or other payments from the Start-up Company of any amount during the next 12 months.
- c. The senior manager, or his or her spouse, partner or dependent child, is an inventor of intellectual property rights (patents, copyrights, royalty rights) licensed to the Start-up Company conducting or proposing to conduct a Clinical Trial
- d. The senior manager, or his or her spouse, partner, or dependent child, is an officer, director, or employee of the Start-up Company, whether or not paid.

“University Equity Holding” means any non-publicly held stock owned by the University in a Start Up Company.

I. Overall Statement of Policy

The University of Michigan will exercise care in approving Clinical Trials in which there is or may be an Institutional Conflict of Interest AND the Clinical Trial cannot be satisfactorily managed with appropriate administrative oversight.

II. General principles

In evaluating whether a University Equity Holding or Significant Senior Management Financial Interest might or might reasonably appear to adversely affect a Clinical Trial, the following questions may be considered:

- Is the Clinical Trial inconsistent with the missions of the University and the unit?
- Does the Clinical Trial compete with other activities of the University?
- Does the Clinical Trial impose unusual liability on the University?
- Has the University had experiences with the University Start-Up Company that should be considered in assessing the ICOI?

- Can the Clinical Trial agreement be made at arm's length?

In establishing a conflict management plan, the following questions may be considered:

- What is the University's role in the success of the Clinical Trial?
- Can integrity of Clinical Trial data and analysis be protected?
- Is compliance with the ICOI management plan practicable?
- Can students'/trainees' interests be protected?
- Are human subjects protected from harm and is Clinical Trial compliance being monitored at arm's length?
- Does management of institutional conflicts of interest require additional University resources or impose inappropriate additional burden on other unconflicted employees?
- Are decisions about the conduct of the Clinical Trial and the validity of the results being reviewed by unconflicted people?

III. Establishment and Authority of ICOIC

a. The University has established an Institutional Conflict of Interest Committee (ICOIC)

i. The Committee consists of:

1. at least three University faculty members appointed to renewable 3-year terms.
2. the chair of the MEDCOI, or a MEDCOI member designated by the chair, ex officio.
3. other individuals appointed at the discretion of the President, who may be University administrators, individuals unaffiliated with the University, etc.
4. non-voting representatives from DRDA, OTT, OVPR, OGC, (others) ex officio.

ii. The President of the University shall make committee appointments.

iii. The President shall appoint a chair from the voting

membership of the ICOIC for a renewable 2-year term.

- b. Records of requests brought to the ICOIC and recommendations made by the ICOIC shall be maintained in the President's Office. Final recommendations and determinations will part of the public record.
- c. Final Decision Authority
The ICOIC will recommend disposition of cases brought to its attention to the President. The President shall make the final institutional decision.

IV. Process

- a. Proposed Clinical Trials will be referred to and reviewed by the MEDCOI prior to review by the ICOIC.
- b. The MEDCOI will
 - i. Evaluate Significant Senior Management Financial Interest and significant financial interest of other participants in the proposed Clinical Trial:
 - 1. To determine if there are compelling circumstances to warrant participation of the University in the Clinical Trial.
 - 2. To develop a management plan to address actual and perceived risks related to participation of the University in the Clinical Trial.
 - 3. To address concerns resulting from IRBMED review of the proposed Clinical Trial and related documents such as the protocol and informed consent.
 - ii. Following its review, the MEDCOI will forward a summary of its findings along with a recommendation and proposed management plan to the ICOIC.
- c. Following receipt of the summary, recommendation, and proposed management plan from the MEDCOI, the ICOIC will:
 - i. Evaluate, endorse, or revise MEDCOI's recommendation and management plan
 - ii. Submit a recommendation to the President to
 - a. Allow the Clinical Trial to proceed without a management plan
 - b. Allow the Clinical Trial to proceed with a management plan; or
 - c. Not allow the Clinical Trial to proceed.
- d. The President will make a final determination and will communicate

that decision to the ICOIC and the MEDCOI.

- e. The President's office will send an approved ICOI management plan to any individuals or offices assigned oversight roles in that plan and will ask for reports from those individuals or offices on the implementation of the management plan at agreed-upon intervals.
- f. The ICOI will review reports received by the President's Office on the implementation of management plans and, if warranted, will recommend revisions to the President.

Addendum

Description of proposed internal implementation steps

If OTT negotiates licenses/options with University Start-up Companies that may involve clinical evaluation of a product or process, OTT will notify DRDA and MEDCOI.

MEDCOI will maintain a list of such companies.

OTT will prepare and submit relevant Regental Action Items to OVPR.

OTT will inform DRDA and MEDCOI of UM employees who have equity or management position in such Start-Up Companies.

DRDA will notify MEDCOI of any proposed clinical trial agreement supported by a company on the list.