

# 14 Financial Conflicts of Interest in Human Subjects Research

It is policy to preserve public trust in the integrity and quality of research at CMU by minimizing actual or perceived conflict of interest in the conduct of research.

**Note:** CMU has separate Financial Conflict of Interest policies for research supported by the Public Health Service (“Managing Conflicts of Interest in Public Health Service Research Projects” [3-34]) and by all other sponsors, including the National Science Foundation (“Conflict of Interest Guidelines” [3-9]).

The policies differ in certain important definitions such as conflict of interest; immediate family members; dollar threshold amounts for reporting a financial interest; and training requirements. The policies should be consulted when making any required disclosures or reports.

## 14.1 Definition of Financial Conflict of Interest

**CMU (Policy 3-9).** A conflict of interest may occur when a University faculty/staff member meets any one of the following criteria:

1. The faculty/staff member is:
  - a. an officer, director, trustee, sole proprietor, partner, employee, sales representative or agent of, *or*
  - b. a consultant, independent contractor or advisory board member to an external organization or corporation either seeking to do or doing business with the University, funding a sponsored project, or providing goods or services under a sponsored project in which the faculty/staff member is participating in any capacity; *or*
2. The faculty/staff member is the actual or beneficial owner of more than five percent (5%) of the voting stock or controlling interest of such organization or corporation, or the market value of her/his stock exceeds \$10,000; *or*
3. The faculty/staff member has dealings with such organization or corporation from which he/she derives income (e.g., royalties, stipends, salary) of more than \$10,000 per year, exclusive of dividends and interest; *or*
4. The assets of the faculty/staff member's Family/Household, alone or in combination with the assets of the faculty/staff member, meet any of the criteria stated in paragraphs 1, 2 and 3 above. Family/Household is defined to include a) immediate family (spouse, parents and children) and b) persons living at the same residence as the faculty/staff member, except their tenants or employees.

**NSF.** Significant financial interests of the investigator (including those of the investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

**PHS.** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

**FDA.** For clinical studies involving the use of new human drugs and biological products or medical devices, certifications and disclosure requirements are defined in FDA regulations, 21 CFR Part 54.

## 14.2 Training in Financial Conflict of Interest

**PHS.** Public Health Service regulations and CMU Policy require that all PHS grantees undergo training in financial conflict of interest at least every 4 years. This obligation can be satisfied by taking the CITI course in Conflicts of Interest in Research Involving Human Subjects.

**All other sponsors.** The Conflict of Interest module included in CMU's mandatory CITI initial and refresher courses for biomedical and social and behavioral research satisfies all other COI training requirements. Refresher training must be taken every 3 years.

## 14.3 Personnel Who Must Disclose (also called Key Personnel or Participating Faculty/Staff)

**PHS:** The Project Director or Principal Investigator and any other person identified as senior/key personnel in Central Michigan University's grant application, progress report, or any other report submitted to the PHS by Central Michigan University.

**CMU Policy 3-34:** Participating faculty/staff members in a sponsored project include:

1. The project director/principal investigator.
2. Co-project director/co-principal investigator, and
3. Any other person at the University who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding through a sponsored project.

## 14.4 Individual Conflicts of Interest

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively disclosed and managed when they cannot be eliminated.

### 14.4.1 Disclosure and Evaluation of Investigator Financial Interests in Research

Investigators conducting externally sponsored research are required to file a Financial Disclosure Statement no later than the time when a grant proposal is submitted, then either annually or as new reportable financial interests are obtained. There are separate forms for PHS-sponsored projects and all other externally sponsored research.

All disclosures of financial interest are reviewed by the Executive Director of the Office of Research and Graduate Studies (XD/ORGS).

### 14.4.2 Management of COI

If the XD/ORGS determines that a significant financial interest in a research project presents a conflict of interest, then she will develop a COI Management Plan to protect the rights and welfare of human research participants and the integrity of the institution. The elements of a management plan might include:

1. Disclosure to subjects through the consent process.
2. Modification of the research protocol or safety monitoring plan.
3. Monitoring of research by independent reviewers.
4. Disqualification of the conflicted party from participation in all or a portion of the research.
5. Appointment of a non-conflicted PI.
6. Divestiture of significant financial interests.
7. Severance of relationships that create actual or potential conflicts.
8. Prohibition of the conduct of the research at CMU.

The XD/ORGS will communicate the COI Management Plan to the IRB, which will consider it when it reviews the protocol. The CMU IRB has final authority to decide whether the financial conflict of interest and its management, if any, allows the research to be approved.

If the conflict cannot be adequately resolved, the matter will be referred to the Conflict Review Committee (previously known as the Conflict of Interest Committee), which will consider the matter, develop a management plan, and refer it to the IRB for review and approval.

## 14.5 Institutional Conflict Of Interest

These procedures apply to all human subjects research conducted under the auspices of CMU. This policy applies to investigators, IRB members and staff, and institutional officials.

The policy of CMU is to ensure that the welfare of human subjects and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations. Although CMU policy has separated technology transfer functions from research administration, circumstances may exist in which separation of function is not sufficient to avoid the appearance of institutional conflict of interest.

### 14.5.1 Responsibilities

The Conflict Review Committee (CRC) will be responsible for evaluating potential institutional conflict of interest and will take actions as required to avoid, or to appropriately manage, apparent institutional COI. These actions may involve referral to appropriate advisors outside the facility or obtaining advisement from CMU General Counsel. If used, outside advisors will be individuals who have sufficient seniority, expertise, and independence to evaluate the competing interests at stake and to make credible and effective recommendations. All outside advisors will be independent of the management of oversight for the HRPP within the institution. The use of outside advisors will increase the transparency of the deliberations and enhance the credibility of determinations.

After reviewing a significant financial interest in research, the CRC will communicate its conclusions, along with any management arrangements to be imposed, to the IRB. All relevant

conflicts will be disclosed to research participants in a form to be determined by the IRB. The CRC also will communicate conclusions and COI management strategies to the IO and the PI.

#### 14.5.2 Management of Conflict of Interest

As part of its review of institutional COI, the CRC will ask if any related research involves human subjects. If yes, any conflict management plan which is developed will be forwarded to the IRB.

##### *Presumption of Conflict of Interest*

If Central Michigan University retains a significant financial interest, or if an IO with direct responsibility for the HRPP holds a significant financial interest in the invention, then the CRC must assess the potential conflict of interest and weigh the magnitude of any risk to human participants. When reviewing potential institutional conflict of interest, the CRC will assume an inclination against the conduct of human participants research at, or under the auspices, of the institution where a COI appear to exist. However, the assumption may be overturned by the Committee when the circumstances are compelling and the Committee has approved an effective conflict management plan.

##### *Decision-Making*

A key aspect in decision-making is to analyze when it would be appropriate and in the public interest to accept and manage a COI, rather than require that the COI be eliminated. In some cases, the benefits of conducting a proposed research activity at the institution will be potentially high, and the risks will be low. In other cases, the scientific advantages of conducting the research may be speculative and the risks may be great. In these latter instances, the conflict should be avoided by disapproving the research application.

##### *Evaluation of Risk*

Each case should be evaluated based upon the following:

1. The nature of the science.
2. The nature of the interest.
3. How closely the interest is related to the research.
4. The degree of risk that the research poses to human participants.
5. The degree to which the interest may be affected by the research.

The COIC will consider whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved.

##### *Potential Actions*

Potential actions to be considered to better protect subjects are any or a combination of the following:

1. Public disclosure of the financial interest.
2. Not conducting proposed research at that institution or halting it if it has commenced.
3. Reducing or otherwise modifying the financial (equity or royalty) stake involved.

4. Increasing the segregation between the decision-making regarding the financial and the research activities.
5. Requiring an independent DSMC or similar monitoring body.
6. Modifying of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change in investigator.
7. Establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work and of CMU.