

Title	Financial Conflicts of Interest
Last Updated	5/9/2019

### Summary

Cytocybernetics is dedicated to maintaining public trust in the integrity of our research-related activities. The U.S. Department of Health and Human Services (HHS) has issued a final rule in the Federal Register that amends the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94). This policy addresses the crucially important responsibilities of the institute, faculty and staff in both safeguarding research objectivity and complying with the requirements of all applicable state and federal regulations.

### Definitions

**Contractor/sub-recipient:** an entity that provides property or services under contract issued by, and for the direct benefit or use of, Cytocybernetics in a research project. In this policy referred to as sub-recipient.

**Disclosure:** an Investigator’s provision of information about their significant financial interest/s to Cytocybernetics.

**Equity Interest:** any interest in the profits of or stock of a commercial or non-profit enterprise, a stock option or any other ownership interest in a commercial or non-profit enterprise.

**Entity:** any domestic or foreign, public or private, for profit or non-profit legal entity or organization other than Cytocybernetics or the federal government.

**Financial Conflict of Interest (FCOI):** a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the Research.

**Financial Interest:** anything of economic or monetary value, whether or not the value is readily ascertainable, possessed by an Investigator and his/her spouse, domestic partner, or dependent child.

**Institution of Higher Education:** an educational institution in any state in the U.S. that meets all the following requirements:

- Admits as regular students only persons having a certificate of graduation from a school providing secondary education;
- Provides an educational program for which the institution awards a bachelor’s degree or provides not less than a two-year program that is acceptable for full credit toward such a degree, or awards a degree that is acceptable for admission to a graduate or professional degree program, subject to review and approval by the U.S. Secretary of Education;
- Is a public or other nonprofit institution; and
- Is accredited by a nationally recognized accrediting agency or association, or if not so accredited, is an institution that has been granted pre-accreditation status by such an agency or association that has

been recognized by the U.S. Secretary of Education for the granting of pre-accreditation status, and the U.S. Secretary of Education has determined that there is satisfactory assurance that the institution will meet the accreditation standards of such an agency or association within a reasonable time.

**Institutional Official:** one or more persons designated by Cytocybernetics as having responsibilities and authority under this policy. For the purposes of this policy, this is the Research Compliance Officer.

**Institutional Responsibilities:** all work performed at or on behalf of Cytocybernetics, including but not limited to: research conducted at, on behalf of, or through Cytocybernetics; research consultation performed on behalf of Cytocybernetics; teaching; professional practice; management duties performed on behalf of Cytocybernetics; and/or service on Cytocybernetics' institutional committees or boards (e.g., steering committees, Institutional Review Boards, Data and Safety Monitoring Boards).

**Intellectual Property:** any direct or indirect rights or interest in a patent, trademark, copyright, trade secret, know-how or other intellectual property right, including but not limited to inventorship, ownership, royalties and license fees. This definition applies regardless of whether such intellectual property right is owned by Cytocybernetics or an outside commercial or nonprofit entity and is effective upon receipt of income related to such rights and interests.

**Investigator:** any person, regardless of title or position, who is responsible for the design, conduct or reporting of the results of a Sponsored Research project. For the purposes of this policy, students, interns, and volunteers are not investigators.

**Management Plan:** a written plan to address a financial conflict of interest to ensure, to the extent possible, that the design, conduct and reporting of Research will be free from bias.

**PHS:** the Public Health Service of the U.S. Department of Health and Human Services and any PHS awarding components to which authority may be delegated, including without limitation the National Institutes of Health.

**PHS Awarding Component:** the organizational unit of the Public Health Service that funds Research that is subject to 42 CFR 50 subpart F.

**PHS-Funded Research:** any Research or sponsored activity for which funding is available from a PHS awarding component through a grant or cooperative agreement, however authorized, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, program project or research resources award. PHS-Funded Research does not include any Phase I SBIR Program application or award.

**Principal Investigator (PI):** any person designated by Cytocybernetics with the title of "Principal Investigator" of a Research or other sponsored project or otherwise having primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a Research project.

**Reimbursed Travel:** travel activity for which the Travel Expenses are paid directly by the Investigator, who is then reimbursed by an Entity for such Travel Expenses.

**Research:** a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug) and includes any activity for which PHS Research funding is available.

**Senior/Key Personnel:** any person identified as such, including the PI, in the grant application, award, or contract or in any progress report or any other report pertaining to the research project submitted to PHS.

**Significant Financial Interest (SFI):** a financial interest that reasonably appears to be related to an Investigator’s Institutional Responsibilities and meets one or more of the following criteria, after accounting for any specified exclusions:

Criteria	Exclusions
<p>Reimbursed Travel or Sponsored Travel received in the preceding 12 months Disclosure will include the following information:</p> <ul style="list-style-type: none"> <li>• Purpose of the trip</li> <li>• Identity of the sponsor/organizer</li> <li>• Destination</li> <li>• Duration (start and end dates)</li> </ul>	<p>Travel for which expenses are paid for or reimbursed by:</p> <ul style="list-style-type: none"> <li>• Cytocybernetics</li> <li>• a Federal, state or local government agency</li> <li>• an Institution of higher education (as defined above)</li> <li>• an academic teaching hospital</li> <li>• a medical center</li> <li>• a research institute affiliated with an institution of higher education</li> </ul> <p>For example, travel which relates institutional responsibilities paid for by NIH is excluded. However, travel related to institutional responsibilities paid for by a pharmaceutical company or a professional association is not excluded.</p>
<p>Compensation totaling more than \$5,000 received in the preceding 12- month period (e.g., salary, consulting fees, honoraria or other payments)</p> <p>SFI = (\$ in past 12 months) &gt; 5K</p>	<p>Compensation received from Cytocybernetics, or SUNY, University at Buffalo.</p> <p>Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for:</p> <ul style="list-style-type: none"> <li>• Cytocybernetics</li> <li>• a Federal, state or local government agency</li> <li>• an Institution of higher education (as defined above)</li> <li>• an academic teaching hospital</li> <li>• a medical center</li> </ul>

	<ul style="list-style-type: none"> <li>• a research institute affiliated with an institution of higher education</li> </ul>
<p>Any equity in a non-publicly traded entity as of the date of disclosure which has a potential bias impact on research activities.</p> <p>SFI = Equity at disclosure</p>	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g., mutual funds, retirement accounts)</p>
<p>Equity in a publicly traded entity valued in excess of \$5,000 which has a potential bias impact on research activities.</p> <p>SFI = Equity at disclosure &gt; 5K</p>	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g., mutual funds, retirement accounts)</p>
<p>Equity in a publicly traded entity and Compensation received from the same entity in the preceding 12 months equals a combined total value exceeding \$5,000</p> <p>SFI = (\$ in past 12 months + Equity at time of disclosure) &gt; 5K</p>	<p>Equity in investment vehicles where the Investigator does not directly control investment decisions (e.g., mutual funds, retirement accounts) Compensation received from SCH, CUMG and/or UW Income from seminars, lectures or teaching engagements sponsored by and/or service on advisory committees or review panels for:</p> <ul style="list-style-type: none"> <li>• Cytocybernetics</li> <li>• a Federal, state or local government agency</li> <li>• an Institution of higher education (as defined above)</li> <li>• an academic teaching hospital</li> <li>• a medical center</li> <li>• a research institute affiliated with an institution of higher</li> </ul>
<p>Intellectual property rights and income received from such rights</p>	<p>Intellectual property rights from which an Investigator has not received income.</p> <p>Intellectual property assigned to Cytocybernetics or The Research Foundation of SUNY Buffalo. Royalty payments paid by Cytocybernetics to the Investigator.</p> <p>Agreements entered into by Cytocybernetics which, either via Cytocybernetics' policy or specific provisions of the agreement, provides for the investigator to share in royalties.</p>

**Sponsored Research:** Any research project for which an application/proposal is submitted to an external funding source.

**Sponsored Travel:** travel expenses paid directly by an Entity on behalf of an Investigator and not reimbursed directly to the Investigator so that the exact monetary value may not be readily available.

This does not include travel expenses paid directly by a Cytocybernetics' research study budget (also known as an activity).

**Travel Expenses:** expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging and related amenities.

## **POLICY**

A: No research or technology transfer activities occurring at, on behalf of, or through Cytocybernetics shall be adversely affected by the financial interests of persons involved in those activities. Any investigator possessing a significant financial interest related to their Institutional Responsibilities must disclose the interest to the Research Compliance Officer (RCO) at least annually and/or prior to participating in a research or technology transfer activity. The Research Compliance Officer is responsible for reviewing disclosures and instituting an adequate plan for the elimination, reduction or management of any identified financial conflicts of interest. The goal of this policy is to protect the integrity and credibility of activities related to research and to maintain public trust and confidence in Cytocybernetics and its employees.

B: All Research and technology transfer activity undertaken at Cytocybernetics shall be conducted in compliance with the following regulations and policies, as applicable:

1. PHS regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 CFR Part 50, Subpart F August 25, 2011)
2. PHS regulations on Responsible Prospective Contractors (45 CFR Part 94 August 25, 2011)
3. The United States National Science Foundation's Investigator Financial Disclosure Policy (60 FR 35820 – 35823 July 11, 1995)

C. Persons failing to comply with this policy shall be subject to sanctions as provided herein.

D. Investigator Responsibilities - All Investigators are required to:

1. Disclose significant financial interests
  - a. Annually to the Research Compliance Officer (RCO);
  - b. Within 30 days of discovering or acquiring a new significant financial interest. In the case of Sponsored or Reimbursed Travel, the disclosure must be made within 30 days of the trip end;
  - c. As part of the on boarding process after joining Cytocybernetics;
  - d. Upon direction from RCO.
2. Ensure their SFI disclosure is current prior to the submission of a proposal/application.
3. Comply with any Management Plan established by RCO
4. Complete FCOI training:
  - a. At least every 4 years;
  - b. As part of the on boarding process after joining Cytocybernetics;
  - c. As mandated by RCO, upon determination of non-compliance with this policy or an existing Management Plan;
  - d. When Cytocybernetics revises this policy in any manner that affects the requirements of investigators;
  - e. As otherwise dictated by Cytocybernetics.

5. Regarding the disclosure of Sponsored or Reimbursed Travel, if an Investigator can reasonably anticipate the occurrence of Sponsored or Reimbursed Travel, the Investigator may elect to disclose such travel up to twelve (12) months in advance of the anticipated travel. If an advance disclosure of travel becomes materially inaccurate, the Investigator must provide an updated disclosure within 30 days of the change.

E. Principal Investigator Responsibilities - in addition to the responsibilities outlined for all Investigators above, Principal Investigators are required to:

1. Ensure all Investigators involved in a research project, including newly hired Investigators, have submitted required SFI disclosures prior to their participation in the project;
2. Ensure all Investigators involved in a research project promptly disclose any new or updated SFIs (see section D.1. above);
3. Ensure all Investigators involved in a research project have completed the FCOI training required under this policy;
4. Identify the Key Personnel on a research project upon request;
5. Indicate, upon submission of a proposal/application, if they or any project Investigators have SFI that may be related to the proposed project.

F. Review of Disclosures

1. RCO shall review all Investigator SFI disclosures and determine whether SFI disclosures are related to a specific research project.
2. Depending on the nature of the disclosed SFI, RCO may implement additional interim measures regarding the Investigator's participation in the research project between the date of disclosure and the completion of the SFI review.
3. Reviews generally will not be conducted until after a Research proposal has been funded.

G. Management of FCOI

1. If RCO determines that a SFI Disclosure constitutes an FCOI relating to a Research project, it shall develop and implement a Management Plan specifying actions that have been or will be taken that in the reasonable judgement of the RCO will reduce or manage such FCOI.
2. No Investigator having an FCOI may participate in the related Research project without prior written approval from RCO. A completed or updated Management Plan will generally serve as such written approval.
3. In developing a Management Plan, RCO may conduct factual inquiries and consult with and receive recommendations from such persons or committees as RCO deems necessary and appropriate.
4. For PHS-Funded Research, the actions detailed above (sections F and G) will be completed prior to the expenditure of any research project funds, or within 60 days of a disclosure of a SFI during the course of a research project by an existing Investigator or an Investigator new to the project.
5. Whenever a Management Plan is implemented, RCO shall take such actions as it deems reasonable to audit and/or monitor compliance with the Management Plan until the completion of the research project or until the Management Plan is no longer required.

H. Management of Other Interests

1. When a disclosed SFI is determined not to constitute an FCOI, CytoCybernetics may nonetheless determine that some type of management or oversight of the interest is appropriate before



certain research activities may proceed. Cytocybernetics may develop additional procedures or guidance regarding these types of interests and any associated limitations or requirements.

#### I. FCOI Reporting to PHS Awarding Components for PHS-Funded Research

1. RCO will submit FCOI reports to a PHS Awarding Component
  - a. Prior to expenditure of any funds under a PHS-Funded Research project, if an FCOI has not been eliminated;
  - b. Within 60 days of identifying an FCOI during an ongoing research project;
  - c. Annually for any FCOI previously reported regarding an ongoing PHS-Funded Research project. The report shall specify the status of the FCOI (if the FCOI is still being managed or explain why it no longer exists) and if appropriate, any changes to the Management Plan. The report shall be submitted annually for the duration of the research project at the same time as the submission to NIH of the annual progress report, multi-year progress report, if applicable, or at the time of extension.
2. Any FCOI report submitted to a PHS Awarding Component shall include the minimum elements as required by 42 CFR Part 50 Subpart F and contain sufficient information to understand the nature and extent of the financial conflict and assess the appropriateness of the Management Plan.

#### J. PHS-Funded Research through Sub-recipients

1. If the PHS-Funded Research or portions of it is carried out through a sub-recipient, Cytocybernetics will take reasonable steps to ensure that any sub-recipient Investigator complies with 42 CFR Part 50 by incorporating the following as part of the written agreement with the sub-recipient:
  - a. terms that establish whether this policy or the sub-recipient's FCOI policy will apply to the sub-recipient Investigators;
  - b. time period(s) for the sub-recipient to report all identified FCOI or for submission of all sub-recipient Investigator SFI disclosures to Cytocybernetics.

#### K. Publicly Accessible Information

1. This policy shall be available via Cytocybernetics' publicly accessible website.
2. For PHS-Funded Research, RCO shall make information concerning significant financial interests that meet the criteria below available to the public, upon written request for such information:
  - a. SFI was disclosed and is still held by Senior/Key Personnel (as defined in this policy);
  - b. RCO determined the SFI is related to a PHS-Funded Research project;
  - c. RCO determined the SFI constitutes a FCOI.
3. The above information made available shall consist of the minimum elements as required by 42 CFR Part 50 Subpart F, and shall be provided by written response to the requestor.
4. The above information shall remain available for public request for at least three years from the date that the information was most recently updated.

#### L. Retrospective Review of PHS-Funded Research

1. Whenever RCO identifies a SFI that was not disclosed in a timely manner or was not previously reviewed by RCO during an ongoing PHS-Funded Research project, RCO shall within 60 days:
  - a. Review the SFI;

- b. Determine whether it is related to a PHS-Funded Research project;
- c. Determine whether a FCOI exists;
- d. If RCO determines a FCOI exists, RCO shall implement (at least on an interim basis) a Management Plan that specifies the actions that have been taken and will be taken to manage such FCOI.

2. Whenever a FCOI related to a PHS-Funded Research project is not identified or managed in a timely manner due to noncompliance by Cytocybernetics or an Investigator, including if an Investigator fails to comply with a Management Plan, RCO shall:

- a. Notify the Chief Executive Officer (CEO) and the President of Cytocybernetics (see section M of this policy).
- b. Within 120 days of non-compliance identification, complete and document a retrospective review of the Investigator's activities and the Research project. Documentation of the review will include all elements as specified by 42 CFR Part 50 Subpart F.
- c. Based on the results of the retrospective review, if appropriate, update the previously-submitted FCOI report and specify the actions that will be taken to manage the FCOI moving forward.
- d. If bias is found, notify the PHS Awarding Component promptly and develop and submit a mitigation report. The mitigation report shall consist of the minimum elements as required by 42 CFR Part 50 Subpart F.
- e. Submit FCOI reports to the PHS Awarding Component annually thereafter for the duration of the Research project.

#### M. Sanctions and Remedies for Violation of Policy

1. If RCO determines an Investigator has violated this policy, including failure to submit required disclosures or failure to comply with the requirements of a management plan, RCO shall report the violation to the Chief Executive Officer (CEO) and the President of Cytocybernetics. The CEO and President shall take reasonable steps to respond appropriately to violations, including, but not limited to:

- a. Suspending research activity expenditures;
- b. Administratively suspending any research study related to the FCOI;
- c. Instituting disciplinary measures up to and including suspension or termination.

2. If required to do so, Cytocybernetics will submit to HHS, or permit on site review of, all records pertinent to compliance with this policy and federal regulations.

3. In the case in which it is determined that a PHS-Funded Research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported, Cytocybernetics shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and shall request an addendum to previously published presentations.

#### N. Record Keeping

- 1. RCO shall maintain records relating to:
  - a. all Investigator disclosures of financial interests;



- b. RCO's review and response to such disclosures;
- c. actions taken under this policy or retrospective reviews.

2. For PHS-Funded Research, these records shall be maintained for at least three years from the date the final expenditures report is submitted to the PHS Awarding Component or as required by 45 CFR 74.53(b) and 92.42(b). For all other research, these records shall be maintained for at least three years from the date of the final expenditures report.

**APPROVED BY**

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