FINANCIAL CONFLICTS OF INTEREST – PHS FUNDED RESEARCH

I. Introduction.

The National Institutes of Health (and other PHS agency) funding represents a large source of funding of research activities of the Memorial Healthcare System. The PHS financial conflict of interest regulations have unique financial conflict of interest reporting and conflict management requirements. This policy is for the purpose of ensuring compliance with these important regulations (hereinafter, the FCOI Policy). All Investigators (as defined in III below) applying for funds from the NIH or other PHS agencies are obliged to comply with the requirements of this FCOI Policy.

Specifically, all United States Public Health Service ("PHS") agencies (includes National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ)) require awardee institutions to ensure objectivity in research through compliance with its comprehensive regulations, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought and Responsible Prospective Contractors" issued at 42 CFR Part 50, Subpart F (the "FCOI Regulations"). See: http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/xml/CFR-2011-title42-vol1- part50-subpartF.xml

For purposes of this FCOI Policy, all references to "PHS" shall be a reference to the respective PHS funding agency. This FCOI Policy shall be made available by Chief Compliance Officer on a publicly available Web site.

The purpose of the FCOI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest of an Investigator. The NIH Office of Extramural Research Conflict of Interest Website contains helpful information and resources about the FCOI Regulations. See http://grants.nih.gov/grants/policy/coi/coi_faqs.htm

The FCOI Regulations covering PHS funded activities provide for a more comprehensive level of disclosure, together with compulsory reporting to the applicable PHS agency. Disclosure to the Institution is required of ALL "Significant Financial Interests" that reasonably appear related to the Investigator(s) "Institutional Responsibilities." As more precisely defined below, "Significant Financial Interests" include all travel reimbursements of any amount, any equity interest in a privately-held entity and all other financial interests having a value in excess of $5,000.

All financial interests of a lesser amount that do not require handling under this FCOI Policy (and which are not covered under the Human Subjects Guidelines) instead remain subject to disclosure and management under the Business Ethics and Conflicts of Interest.

II. Mandatory Training

The Director of Office for Human Research (OHR) shall be responsible for ensuring that each Investigator is informed about (i) this FCOI Policy, (ii) the Investigator's responsibilities regarding disclosure of Significant Financial Interests relating to the Investigator's Institutional Responsibilities, and (iii) the FCOI Regulations. The Director of OHR,through the designated

institutional official(s), shall require each Investigator to complete training regarding items (i)–(iii) prior to engaging in research related to any PHS-funded grant, cooperative agreement or contract and at least every four (4) years thereafter, and immediately when any of the following applies: (1) this FCOI Policy, the PHS Disclosure Form or OHR procedures are revised in any manner that affects the requirements of the Investigators; (2) an Investigator is newly appointed at the Institution; or (3) the Institution finds that an Investigator is not in compliance with this FCOI Policy or management plan. "Immediately" shall mean the training is provided or made accessible and the Investigators participate in the training expeditiously following the event that triggers the training requirement.

III. Disclosure Procedures

a. IRB office shall develop and administer an efficient and effective method for soliciting and reviewing timely disclosures from Investigators planning to participate in PHS-funded research, which may be through means of a written disclosure statement and/or electronic questionnaire ("PHS Disclosure Form").

b. The PHS Disclosure Form shall provide that the Investigator will submit the PHS Disclosure Form no later than at the time the respective application is submitted to the PHS. "Investigator" means the principal investigator stated in the application and any other personnel who would be responsible for the design, conduct, or reporting of research funded by the PHS or proposed for such funding, which may include, for example, consultants and unpaid collaborators. The lead principal investigator on a proposed PHS application for funding is responsible for obtaining a PHS Disclosure Form for all participating Investigators.

c. The PHS Disclosure Form shall ask the Investigator to list all of the Investigator's Significant Financial Interests (and those of the Investigator's spouse or domestic partner and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities (as defined below).

"Significant Financial Interest" means (subject to the exclusions listed below):

(i) Publicly Traded-Entities - 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.

(ii) Privately Held Entities - With regard to any n

on-publicly traded entity, a s*ignificant 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 domestic partner and dependent children) holds any equity interest (*e.g.,* stock, stock option, or other ownership interest).

(iii) Intellectual Property - Intellectual property rights and interests (*e.g.,* patents, copyrights), upon receipt of income related to such rights and interests.

(iv) Travel Reimbursements - Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.,* that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their Institutional Responsibilities in the twelve months preceding the disclosure; provided,

however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, and Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

The term "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 in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. With respect to human subjects research, the term "Significant Financial Interest" shall include cases involving any amount of remuneration and any equity ownership.

"Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the Institution, including activities such as research, teaching, clinical or other professional practice, academic activities, scholarly events, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

d. The PHS Disclosure Form must conform to the requirements of the FCOI Regulations and shall include a link to the FCOI Regulations and the NIH Conflict of Interest Website. For items III.c(i)-(iii) above, the disclosure must include, at a minimum, the name of the entity, the nature of the financial interest (e.g., equity, consulting fee), the monetary value of the financial interest or its approximate value if the interest is one whose value cannot readily be determined, and any supporting documentation determined by the Conflict of Interest (COI) Committee or the designated official(s) as needed to make a determination of whether a FCOI exists (such as a copy of the applicable consulting agreement or stock purchase agreement). For Item III.c(iv) above, the disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and the approximate monetary value. In addition, the Investigator must cooperate with all requests from the applicable PHS Awarding Component for additional information as needed. All such internal disclosures shall be treated as confidential personnel information with all necessary precautions to protect any sensitive proprietary company or sponsor information.

e. The Investigator shall update the disclosure of Significant Financial Interest during the period of the award, at least annually, in accordance with the specific time period prescribed by Corporate Compliance. One annual disclosure will suffice to cover all on-going PHS awards. With respect to Investigator transfers, an annual disclosure shall be made to the Institution promptly to support acceptance of the appointment or employment to the Institution. The reporting and management plan requirements described in Article V shall then be required to be completed prior to expending any funds under a PHS funded grant, cooperative agreement or contract. In addition, an Investigator participating in PHS-funded research shall submit an updated PHS Disclosure Form within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or

inheritance) a new Significant Financial Interest. An Investigator who is new to participating in PHS-funded activities shall submit a PHS Disclosure Form at the time the Investigator is identified as a possible participant in a PHS-funded research project, such that training can be completed and timely reporting of a FCOI (if any) can be made to the respective funding agency. The PHS Disclosure Form shall notify the Investigator of this requirement to provide updated disclosures.

f. All disclosures are required to be reviewed by the Chief Compliance Officer and Deputy General Counsel in a prompt manner such that within sixty (60) days of receipt of the disclosure an assessment of the significant financial interest can be made, a management plan can be developed and all the necessary reviews and approvals can be secured, such that any required report to the applicable PHS funding agency is submitted within sixty (60) days of the determination that a FCOI (as defined in IV below) exists. The Investigator's timely cooperation with the efforts of the designated institutional official(s) is needed to ensure timely reporting. Upon a failure to make timely reporting to the PHS funding agency of a FCOI, the Institution is required under the FCOI Regulations to conduct a retrospective review of the Investigator's activities and the research project.

IV. Management of Financial Conflicts of Interests

a. The IRB Office shall solicit PHS Disclosure Forms from each Investigator planning to participate in, or participating in, PHS-funded research.

b. The Chief Compliance Officer and Deputy General Counsel must review all PHS Disclosure Forms and determine whether an Investigator's Significant Financial Interest is related to PHS-funded research and, if so related, whether the Significant Financial Interest is a financial conflict of interest (FCOI). (The Chief Compliance Officer shall Chair the Conflict of Interest Committee. The COI Committee will be appointed by the Chief Medical Officer to assist with these determinations.) An Investigator's Significant Financial Interest is related to PHS-funded research when the Chief Compliance Officer and Deputy General Counsel and/or COI Committee reasonably determines that the Significant Financial Interest could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest (FCOI) exists when the Chief Compliance Officer and Deputy General Counsel and/or COI Committee reasonably determines that the Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. In making the determination, the Chief Compliance Officer and Deputy General Counsel and/or COI can take into account financial interests in that same entity related to PHS or other Federal funded research disclosed in an earlier disclosure by the Investigator.

c. The following are examples of when an Investigator would be deemed to have a financial conflict of interest (FCOI): (i) if the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that could be affected by the research results from a proposed PHS-funded contract based on an analysis of the scope and subject matter of the proposed project described in the application; or (ii) the Investigator (together with Investigator's spouse or domestic partner and dependent children) has a Significant Financial Interest in an entity that licenses technology from the Institution which has resulted in license income and that technology is the subject of a proposed PHS-funded award. In making this determination, the Chief Compliance Officer and Deputy General Counsel and/or COI Committee may consult with all appropriate institutional and governmental officials.

d. Following initial review by the Chief Compliance Officer and Deputy General Counsel of whether or not the Significant Financial Interest is a FCOI, all cases involving the disclosure of Significant Financial Interest having a value greater than $10,000 in value (measured by

aggregating the various categories of interests reported) shall be submitted to the next monthly meeting of the COI Committee for its consideration for expedited review or full review (depending the level of financial interest involved). The COI Committee will decide upon one of the following dispositions of the case: approval, approval with conditions or restrictions, or prohibition. All conflicts which are approved shall include a management plan which shall be implemented by the Conflicts of Interest Committee.. Following initial review by Chief Compliance Officer and Deputy General Counsel and/or COI Committee of whether or not the Significant Financial Interest is a FCOI, for all cases involving the disclosure of Significant Financial Interest having a value less than $10,000 in value, these institutional official(s) shall be responsible for determining whether the potential FCOI can be managed and, if approved by the designated institutional official(s), what are the necessary components of the management plan.

e. The management plan shall be implemented with oversight by the Institution's COI Committee. The standards for review differ between from the Business Ethics and Conflicts of Interest Policy and this FCOI Policy (and the FCOI Regulations). The standard for review under this FCOI Policy (and the FCOI Regulations) is whether a FCOI exists. This FCOI Policy shall govern the disclosure, management and reporting of PHS funded research FCOIs for the Institution.

f. For all management plans, examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of significant financial interests; (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts. Additional conditions and restrictions (including a lower threshold for review) shall apply to cases involving human subjects as provided for under the Human Subjects Guidelines.

g. For all management plans, the Institution is required to monitor Investigator compliance with the management plan on an on-going basis until the completion of the PHS-funded research project.

V. Reporting Financial Conflicts of Interests to PHS

a. Prior to expending any funds under an PHS funded grant, cooperative agreement or contract, the Institution, through the Office of Human Research (OHR) must report to the applicable PHS funding agency the existence of any FCOI (as defined in IV above) and assure that the Institution has implemented a management plan in accordance with the FCOI Regulations as discussed in IV above. If the Institution identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the Institution is not required to submit a FCOI report to the respective agency. The requirements of the FCOI Regulations do not apply to PHS funded Phase I SBIR or STTR funding, instead those financial interests are subject to disclosure and management under the Conflicts Policy and any other applicable campus procedures.

b. For any FCOI reported to the respective agency relating to an on-going PHS-funded research project, an annual report that conforms to the requirements of the FCOI Regulations shall be made to the applicable funding agency by Office for Human Research for the duration of the research project in the time and manner specified by the applicable funding agency.

c. For any Significant Financial Interest that the Institution identifies as being a FCOI subsequent to the Institution's initial FCOI report under the award, the report will be made to the applicable funding agency and a management plan shall be implemented, at least on an interim basis, within sixty (60) days of that identification. Such a disclosure could include a new Significant Financial Interest received by the Investigator during the on-going research project, or a Significant Financial Interest held by an Investigator who is new to the research project. However, if that

FCOI is one that was not timely made to the applicable funding agency, for whatever reason, the OHR is required under the FCOI Regulations to conduct a retrospective review of the Investigator's activities and the research project within 120 days of the Institution's determination of non-compliance. If bias is found during the course of this review, a mitigation report will also be required to be submitted. These reviews and reports must be documented in accordance with the requirements of the FCOI Regulations.

d. The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations. The FCOI Regulations provide that, to the extent permitted by law, the Government will maintain the confidentiality of all records of financial interests.

e. Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the Institution, through the Chief Compliance Officer and/or Deputy General Counsel, shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning a Significant Financial Interest which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be a FCOI. The information shall consist of the information required to be provided under the FCOI Regulations.

VI. Subrecipient Compliance and Reporting

a. All proposed subrecipients under a PHS-funded research of the Institution shall conform to the requirements of the FCOI Regulations and this policy. With respect to these subgrantees, subcontractors, and collaborators, the OHR with the Office of General Counsel must require these entities to enter into a written agreement and make a certification to the Institution at the time of award that its financial conflicts of interest policy complies with the FCOI Regulations. The written agreement shall include all of the terms required under the FCOI Regulations.

b. The Institution, through Director of OHR, will report to the PHS funding agency any FCOI which are identified by any subgrantee, subcontractor, or collaborator to the Institution in the manner required under the FCOI Regulations, prior to the expenditure of funds and within sixty (60) days of any subsequently identified FCOI.

VII. Remedies

a. If an Investigator fails to comply with this FCOI Policy or a management plan and the non-compliance appears to have biased the design, conduct or reporting of the PHS-funded research, the Institution, through the Conflicts of Interest Committee, as required under the FCOI Regulations, shall promptly notify the agency of the corrective action taken or to be taken. In every respect, the Conflicts of Interest Committee shall ensure compliance with the requirements for retrospective review and prepare a mitigation report, if needed, for submission to the applicable funding agency as required under the FCOI Regulations. The agency may take its own action as it deems appropriate, which may include suspension of funding, or require the Institution to take further action to maintain the objectivity of the research.

b. For clinical research projects supported by the PHS, if the Department of Health and Human Services determines that a PHS-funded project of clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with a FCOI that was not properly disclosed or managed as required under the FCOI Regulations, the Institution, through Chief Compliance Officer, must require the Investigator(s) to disclose the FCOI in each public presentation (such as articles, manuscripts and oral presentations, including classroom materials) of the results of the research and to request an addendum to previously published presentations.

VIII. Enforcement and Sanctions

a. All persons subject to this FCOI Policy are expected to comply with it fully and promptly. Whenever an Investigator has violated this FCOI Policy, for example by a failure to disclose a Significant Financial Interest, the Chief Compliance Officer may refer the matter to the appropriate Institution official or committee for disciplinary action or other appropriate action.

b. Violations of this FCOI Policy and the FCOI Regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the respective Institution policy and procedures governing allegations of research misconduct.

IX. Records

The Institution, through the Chief Compliance Officer, is required pursuant to the FCOI Regulations to maintain all PHS Disclosure Forms and all related records of actions taken by the Institution with respect to disclosures of financial interests (whether or not a disclosure resulted in the Institution's determination of FCOI) for a period of three years from the date of submission of the final expenditures report to the PHS or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42(b) for different situations.