POLICY:
DISCLOSURE OF CONFLICT OF INTEREST FOR PUBLIC HEALTH SERVICE (PHS) SPONSORED STUDIES

Disclosure

Prior to the submission of an application to the PHS Grantee for funding, the Principal Investigator and all other Investigators at Pikeville Medical Center, Inc. must have disclosed to the Chief Legal Officer (CLO) and/or his designee an up-to-date listing of their Significant Financial Interests [SFIs] (and those of their spouse and dependent children), as defined above. Any new Investigator, who, subsequent to the submission of an application to the PHS Grantee for funding from the PHS Grantee, or during the course of the research project, plans to participate in the project, must similarly disclose their SFI to the CLO and/or his designee promptly and prior to participation in the project.

Each Investigator who is participating in research under a subaward where the prime award originates from PHS must submit an updated disclosure of SFI at least annually, during the period of the award. Such disclosure must include any information that was not disclosed initially to Pikeville Medical Center, Inc., pursuant to this Policy, or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a PHS- funded project directly as a PHS Grantee and/or indirectly through a subaward) that was transferred from another Institution), and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in research under a subaward where the prime award originates from PHS must submit an updated disclosure of SFI (including reimbursed travel) within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

Review by Pikeville Medical Center, Inc.’s Designated Official

The CLO and/or his designee will conduct reviews of disclosures. The CLO and/or his designee will review any SFI that has been identified in a disclosure; these interests will be compared to each research subaward funded under a PHS prime award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the award and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research subaward.

Guidelines for Determining “Relatedness” and Financial Conflict of Interest

The CLO and/or his designee will determine whether an Investigator’s SFI is related to the research under a subaward supported by a PHS prime award and, if so, whether the SFI is a financial conflict of interest. An Investigator’s SFI is related to the research under the subaward when the CLO and/or his designee reasonably determines that the SFI: could be affected by the research conducted under the subaward; or is in an entity whose financial interest could be affected by the research. The CLO and/or his designee may involve the Investigator in the determination of whether a SFI is related to the research supported by the subaward.

A financial conflict of interest exists when the CLO and/or his designee reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In determining if an Investigator's SFI is related to the research under a subaward supported by a PHS prime award, and if so, whether the relationship creates a FCOI, the CLO and/or his designee considers the role of the Investigator and the opportunity (if any), to bias the results, the nature of the research being proposed, and the value of the SFI in relation to the size and value of the entity. In addition, the CLO and/or his designee may also consider the following factors:

1. Whether the research is of a basic or fundamental nature directed at understanding basic scientific processes; or
2. Whether the degree of replication and verification of research results is such that immediate commercialization or clinical application is not likely; or
3. Whether the goal of the research is to evaluate an invention linked to the SFI (such as where the SFI is a patent, or an interest in a company that has licensed the invention); or
4. Where the research involves human subjects, whether there are double blind conditions or the involvement of a data and safety monitoring board; or
5. Where the SFI is in a privately held company, whether the researcher's SFI could result in the researcher having influence over company decisions, or whether the research could have a significant impact on the company's business or financial; or
6. The magnitude of the SFIs (e.g., the amount of consulting, or the percentage or value of equity); or
7. Where the SFI is in the sponsor of the research, and the sponsor is a licensee of the Discloser's technology, the amount of commercialization payments received by the Investigator from that technology, both currently or in the future; or
8. The number and nature of relationships an Investigator has with an entity. Multiple entanglements can create a relationship with an outside entity that is stronger than the sum of the parts; or
9. Whether the goal of the research is to validate or invalidate a particular approach or methodology that could affect the value of the SFI; or
10. Whether other scientific groups are independently pursuing similar questions; or
11. Whether sufficient external review of the research conducted, and the reporting of research results exist to mitigate undue bias; or
12. Whether the goal of the project is a comparative evaluation of a technology in which an Investigator has a SFI; or
13. Whether the project involves a subaward to an entity in which the Investigator has a SFI.

Management of Significant Financial Interests that Pose Financial Conflict(s) of Interest

If a conflict of interest exists, the CLO and/or his designee will determine by what means – such as the individual's recusal from decisions affecting the conflicting entity, abstention from the external activity, modification of the activity, and/or monitoring of the activity by a subcommittee – the conflict should be avoided or managed in order to mitigate undue bias. In making those determinations, the CLO and/or his designee will also take into consideration whether the Investigator's ongoing role is necessary to continue advancing the research, based upon the factors such as the uniqueness of his or her expertise and qualifications.

Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

a) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants;
c) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
d) Modification of the research plan;
e) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
f) Reduction or elimination of the financial interest (e.g., sale of an equity interest);
g) Severance of relationships that create financial conflicts;
h) For research projects involving human subjects research, use of a data and safety monitoring board;
i) Double-blind conditions;
j) Provisions to conduct the work simultaneously at multiple sites;
k) Written disclosure of the conflict to all individuals working on the research project;
l) Annual reports on the research progress to the CLO and/or his designee/IRB Chair/Conflicts Committee (if applicable).

If the CLO and/or his designee determines that a conflict exists, it will communicate its determination and the means it has identified for eliminating or managing the conflict, in writing, to the individual, to the relevant Principal Investigator/Project Director, and the appropriate direct supervisor. The CLO and/or his designee will keep a record of the disclosure and other relevant information for at least three years. If the CLO and/or his designee prescribes monitoring of the activity, it will describe what monitoring shall be performed and what records are to be kept.

No expenditures on a subaward supported by a PHS prime award will be permitted until the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any plans determined by the CLO and/or his designee necessary to manage the Conflict of Interest. The CLO and/or his designee will communicate, in writing, with the PHS Grantee to notify it of the existence and the nature of a Financial Conflict of Interest and whether the conflict has been managed, reduced, or eliminated. No expenditures can be incurred until the PHS Grantee has reported the FCOI to PHS. The PHS Grantee will notify Pikeville

Medical Center Inc. when it may incur expenditures.

The CLO and/or his designee will keep a record of Investigator disclosures of financial interests and the CLO and/or his designee's review of, and response to, such disclosure and all actions under this policy. Such records will be maintained and kept for at least three years from the date the final expenditures report is submitted and in accordance with the terms and conditions of the subaward and relevant PHS Regulations.

Public Accessibility to Information Related to Financial Conflicts of Interest

Prior to the expenditure of any funds under a subaward funded by a PHS prime award, Pikeville Medical Center, Inc. will ensure public accessibility, via a publicly accessible Web site or by written response to any requestor within five business days of a request of information concerning any SFI disclosed that meets the following three criteria:

(i) The Significant Financial Interest was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by Pikeville Medical Center, Inc. in the subaward application to the PHS Grantee, progress report or any other report submitted to the PHS Grantee;

(ii) Pikeville Medical Center, Inc. has determined that the Significant Financial Interest is related to the research funded through a subaward; and

(iii) Pikeville Medical Center, Inc. has determined that the Significant Financial Interest is a financial conflict of interest.

The information that Pikeville Medical Center, Inc. will make available via a publicly accessible Web site or in a written response to any requestor within five days of request will include, at a minimum, the following:

(i) The Investigator's name;
(ii) The Investigator's title and role with respect to the research project;
(iii) The name of the entity in which the Significant Financial Interest is held;
(iv) The nature of the Significant Financial Interest; and
(v) The approximate dollar value of the Significant Financial Interest in the following ranges: $0-$4,999; $5,000-9,999; $10,000 - $19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If Pikeville Medical Center, Inc. uses a publicly accessible Web site to comply with the public disclosure requirements of the PHS regulations, the information posted will be updated at least annually, and within sixty days of receipt or identification of information concerning any additional

Significant Financial Interest of the senior/key personnel for the PHS-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the PHS-funded research project, if it is determined by the COIC/designated official that the Significant Financial Interest is related to the research and is a financial conflict of interest.

If Pikeville Medical Center, Inc. responds to written requests for the purposes of public accessibility, it will ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the Pikeville Medical Center Inc.'s identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

Information concerning the Significant Financial Interests of an individual, as limited by this Policy, will remain available, for responses to written requests or for posting via Pikeville Medical Center, Inc.'s publicly accessible Web site for at least three years from the date that the information was most recently updated.

Reporting of Financial Conflicts of Interest

Prior to the expenditure of any funds under a subaward funded by a PHS prime award, Pikeville Medical Center, Inc. will provide to the PHS Grantee a FCOI report compliant with PHS regulations regarding any Investigator's Significant Financial Interest found to be conflicting and will ensure that the Investigator has agreed to and implemented the corresponding management plan. Pikeville Medical Center, Inc. cannot incur expenditures until it has received notification to do so from the PHS Grantee.

While the subaward is ongoing (including any extensions with or without funds), Pikeville Medical Center, Inc. will provide to the PHS Grantee an annual FCOI report that addresses the status of the FCOI and any changes in the management plan.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), Pikeville Medical Center, Inc. will provide to the PHS Grantee, within forty five days, an FCOI report regarding the financial conflict of interest and ensure that Pikeville Medical Center, Inc. has implemented a management plan and the Investigator has agreed to the relevant management plan.

Training Requirements

Each Investigator must complete training on *Conflict of Interest* policies prior to engaging in research related to any PHS-funded subaward and at least every four years, and immediately (as defined below) when any of the following circumstances apply:

1) Pikeville Medical Center, Inc revises this Policy, or procedures related to this Policy, in any manner that affects the requirements of Investigators (training is to be completed within the timeframe specified in communications announcing such changes);
2) An Investigator is new to Pikeville Medical Center, Inc. research under a subaward issued under a PHS prime award (training is to be completed prior to his/her participation in the research); or
3) Pikeville Medical Center, Inc. finds that an Investigator is not in compliance with this Policy, or a management plan issued under this Policy (training is to be completed within 30 days in the manner specified by the CLO and/or his designee or Conflict of Interest Committee, if applicable).

In fulfillment of the training requirement, Pikeville Medical Center, Inc. requires its investigators to complete the National Institutes of Health's Financial Conflict of Interest tutorial located at: http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm in accordance with the requirements and expectations of this Policy. All investigators must print a certification of completion at the end of training and retain it for audit purposes.

Failure to Comply with Pikeville Medical Center, Inc.'s Conflict of Interest Policy Applicable to Public Health Service Funded Subaward

When a FCOI is not identified or managed in a timely manner, including, for example, because the underlying Significant Financial Interest is not disclosed timely by an Investigator or, because a FCOI was not timely reviewed or reported by a second tier subrecipient or by Pikeville Medical Center, Inc.; or because an investigator failed to comply with a management plan; then Pikeville Medical Center, Inc. will within 90 days:

a) Complete a retrospective review of the Investigator's activities and the research project to determine any bias in the design, conduct or reporting of research;
b) Document the retrospective review consistent with the regulation;
c) Document Pikeville Medical Center, Inc.'s determination as to whether any research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with this Policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research; and
d) Notify the PHS Grantee in writing.

If bias is found, Pikeville Medical Center, Inc. shall notify the PHS Grantee promptly and submit a mitigation report to the PHS Grantee that shall address the following:

- Impact of the bias on the research project and
- Pikeville Medical Center, Inc.'s plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, Pikeville Medical Center, Inc. shall submit FCOI reports annually to the PHS Grantee, in accordance with the regulation and terms and conditions of the subaward agreement. Depending on the nature of the Financial Conflict of Interest, Pikeville Medical Center, Inc. may determine that additional interim measures are necessary with regard to the Investigator's participation in the research project between the date that the Financial Conflict of Interest is identified and the completion of Pikeville Medical Center, Inc.'s independent retrospective review.

Clinical Research

If the PHS Grantee determines that one of its funded clinical research projects 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 Financial Conflict of Interest that was not managed or reported by Pikeville Medical Center, Inc., Pikeville Medical Center, Inc. shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Failure to Comply with This Policy
No expenditures of funds on a subaward supported by a PHS prime award will be permitted unless the Investigator has complied with the Disclosure requirements of this Policy and has agreed, in writing, to comply with any FCOI management plan determined necessary by the CLO and/or his designee.

Any failure by an individual to adhere to this Policy may be cause for disciplinary action, including, in severe cases, termination, and termination of the subaward by the PHS Grantee.

DEFINITIONS

Acronyms

***CLO* =** Chief Legal Officer
COI = Conflict of Interest
FCOI = Financial Conflict of Interest
PHS = Public Health Service
SFCOI = Significant Financial Conflict of Interest
SFI = Significant Financial Interest

Terms

Institutional Responsibilities means an Investigator's professional activities on behalf of Pikeville Medical Center, Inc. (i.e., teaching, administration, research, or clinical care). Specifically, these include:

1. Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, an analyzing research and disseminating results);
2. Research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
3. Instruction or Academic activities in conjunction with PMC's affiliation with University of Pikeville, Big Sandy Community and Technical College, or other academic institution.

4. Clinical Services provided at Pikeville Medical Center, Inc.;
5. Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities, etc.; or
6. Special Service activities on behalf of Pikeville Medical Center, Inc. including institutional community service.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by a subaward, or proposed for such funding, which may include, for example, collaborators or consultants. Pikeville Medical Center, Inc.'s Principal Investigator/Project Director, upon consideration of the individual's role and degree of independence in carrying out the work, will determine who is responsible for the design, conduct, or reporting of the research.

Significant Financial Interest means:
(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities on behalf of Pikeville Medical Center, Inc.

(i) **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 for the investigator, investigator's spouse, and dependent children, 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) **With regard to any non-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, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) **With regard to** intellectual property rights and interests *(e.g., patents, copyrights),* a *significant financial interest* exists upon receipt of income of greater than $5,000 related to such rights and interests.

(iv) **Third party reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator and/or the Investigator's spouse/dependent children so that the exact money value may not be readily available) that is related to the Investigator's institutional responsibilities (i.e., administrative, teaching, research, or clinical activities) must be disclosed to Pikeville Medical Center, Inc. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement excludes travel paid for by Pikeville Medical Center, Inc. and does not apply to travel that is reimbursed or sponsored by an U.S. federal, state, or local government agency, an U.S. 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.

(2) The term *significant financial interest* does not include the following types of financial interests:

(i) Salary, royalties, or other remuneration paid by Pikeville Medical Center, Inc. to the Investigator if the Investigator is currently employed or otherwise appointed by Pikeville Medical Center, Inc., including intellectual property rights assigned to the Pikeville Medical Center, Inc. and agreements to share in royalties related to such rights;

(ii) 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;

(iii) Income from seminars, lectures, or teaching engagements sponsored by an U.S. 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

(iv) Income from service on advisory committees or review panels for an U.S. 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.

REFERENCES

42 CFR Part 50 Subpart F

45 CFR Part 94