The following is a summary of the Institutions objectives and plan of action for ensuring proper training, disclosure, review, monitoring, and reporting of Investigators' FCOI's in research funded in whole or in part through the Federal Public Health Service (PHS). These regulations shall apply to all Investigator's who provide any level of effort on a project that is receiving federal monetary support, as defined by the published regulations. Definitions as provided by the PHS are provided in an appendix to this document.

Version 1.1 of the Policy on FCOI reporting for PHS funded research is effective as of the 24th of August 2012 and will be reviewed and updated at least annually, or as otherwise applicable by law.

A1. Training Requirement: Objectives

1. Establish a process to inform each Investigator of the:
    a. Institution's policy.
    b. Investigator's disclosure responsibilities.
    c. Federal regulation.
2. Establish a process to require each PHS-supported Investigator to complete FCOI training:
    a. Prior to engaging in research related to any PHS-funded grant.
    b. At least every four years.
    c. Immediately, if:
        i. Institution revises its FCOI policy that affects requirements of Investigators.
        ii. An Investigator is new to an Institution.
        iii. An Investigator is not in compliance with the policy or the management plan.

A2. Institutional Policy on Training

1. Since June of 2011, all Institutional personnel acting as Principal Investigator on any research being conducted at Jamaica Hospital Medical Center have been required to register with the Jamaica Hospital Medical Center Institutional Review Board (JHMC IRB) through IRBNet.org®. As of August 24th 2012, all Investigators involved in PHS funded research will be required to register with the JHMC IRB through IRBNet.org®.
    a. The Institution's Policy on FCOI reporting for PHS funded research will be available on the Institution's forms and templates page of IRBNet.org®. It will also be available at www.jhmc.org/clinicalresearch.
    b. The Investigator's disclosure responsibilities, as outlined in this document, will be available on the Institution's forms and templates page of IRBNet.org®. It will also be available at www.jhmc.org/clinicalresearch.
    c. The federal regulations will be available in their full, unedited form on the Institution's forms and templates page of IRBNet.org®. It will also be available at www.jhmc.org/clinicalresearch.
    d. At the time when the policy outlined herein goes into effect it will be sent via e-mail to all employees of the Institution with active accounts in IRBNet.org®.

2. Since January of 2012, all Institutional personnel participating in research at the Institution has been required to register at CITIProgram.org®, which provides standardized training in areas relevant to research. As of August 24th 2012, all Investigators involved in PHS funded research will be required to complete the financial conflicts of interest course in CITIProgram.org® and pass a brief quiz with a score of 80% or better in order to ensure comprehension of the most up-to-date PHS regulations regarding FCOI reporting.
    a. All investigators involved in a PHS funded research project must successfully complete the financial conflicts of interest course in CITIProgram.org® and must upload a valid certificate of completion with their initial JHMC IRB application through IRBNet.org® prior to initial board review. For those Investigators who are currently participating as Investigators on PHS-funded research at the time the current FCOI reporting policy goes into effect, the Investigators will have until October 1st 2012 to complete the required training and provide evidence of completion to the JHMC IRB.
    b. All Investigators will be required to take a financial conflicts of interest refresher course in CITIProgram.org® at least every four years and provide proof of compliance by uploading a copy of the certificate to the JHMC IRB through IRBNet.org®.
    c. As appropriate, the initial or the refresher financial conflicts of interest course in CITIProgram.org® must be completed in the following events. Proof of completion must be uploaded to the JHMC IRB through IRBNet.org®.
        i. The institution revises its FCOI policy that affects requirements of Investigators.
        ii. An Investigator is new to an Institution.
        iii. An Investigator is not in compliance with the policy or the management plan.

B1. Disclosure, Review and Monitoring Requirement: Objectives

1. Establish a process to require each Investigator to disclose significant financial interests (SFI's) (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities that meets or exceeds the regulatory definition of SFI:
    a. No later than at the time of application for PHS-funded research.
    b. At least annually during the period of the award.
    c. Within 30 days of discovering or acquiring a new SFI.
2. Designate an Institutional official(s) to:
    a. Solicit and review disclosures of SFI's of the Investigator (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities.
3. Provide adequate guidelines consistent with the regulation for the designated official(s) to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI.
4. Establish a process to require the designated official(s), prior to Institution's expenditure of funds, to:
    a. Review all Investigator SFI disclosures.
    b. Determine if any SFI's relate to PHS-funded research.
    c. Determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research).

   d. Develop and implement management plans, as needed, to manage FCOI's.
5. Establish a process to review disclosures of SFI's, make determination of FCOI's, and implement a management plan when required for an Investigator who is new to participating in the research project or for an existing Investigator who discloses a new SFI.
6. Establish a process to review disclosures of SFI's, make determination of FCOI's, and implement a management plan when required within sixty days whenever an Institution identifies an SFI that was not disclosed timely by an Investigator or not previously reviewed by the Institution.
7. Establish a process to take such actions as necessary to manage FCOI's, including any financial conflicts of a sub-recipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.

B2. Institutional Policy on Disclosure, Review and Monitoring

1. As of August 24th 2012, all Investigators involved in PHS funded research will be required to register with the JHMC IRB through IRBNet.org®.
   a. All Investigators will be required to complete a COI disclosure form for submission to the JHMC IRB through IRBNet.org® for each project funded by the PHS at the time the project is submitted for review, or, if the project is already ongoing at the time of this policy, by October 1st 2012.
   b. All investigators will be required to update the COI disclosure form at least annually for each project funded by the PHS.
   c. All investigators will be required to update the COI disclosure form for all relevant projects within 30 days of discovering or acquiring a new SFI.
2. Three institutional officials, including the Chief Operating Officer, the Chairman of the IRB, and the Director of the Department of Research, will be responsible for the solicitation and review of all SFI's.
   a. The designated Institutional officials will solicit and review disclosures of SFI's of the Investigator (and those of the Investigator's spouse and dependent children) related to the Investigator's institutional responsibilities through the use of IRBNet.org®.
3. The designated Institutional officials will utilize the guidelines as published by the PHS to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is an FCOI.
4. The designated Institutional officials will be required to address any newly submitted COI forms from Investigators within 30 days of receipt through IRBNet.org®, including the following:
   a. Review all Investigator SFI disclosures.
   b. Determine if any SFI's relate to PHS-funded research.
   c. Determine if an FCOI exists (SFI that could directly and significantly affect the design, conduct, or reporting of the PHS-funded research).
   d. Develop and implement management plans, as needed, to manage FCOI's.
5. The designated Institutional officials will utilize the JHMC IRB and IRBNet.org® as a vehicle for identifying new Investigators or new research projects requiring disclosures of SFI's or new SFI's being disclosed by existing Investigator's on existing projects.

6. The designated Institutional officials will require access to Institutional COI's completed for other purposes (i.e. other research projects, corporate compliance) to help determine whether additional SFI's may exist that were not previously disclosed by the Investigator. A review of such disclosures, determination of SFI's, determination of potential FCOI's, and implementation of a management plan when required will occur within sixty days.
7. Monitoring of FCOI's will be conducted through the Department of Clinical Research and the JHMC IRB on an ongoing basis.

C1. Reporting Requirement to NIH: Objectives

1. Establish a process to send initial, annual (i.e. ongoing) and revised FCOI reports, including all reporting elements required by the regulation, to the PHS for the Institution as required by the regulation:
   a. Prior to the expenditure of funds.
   b. Within 60 days of identification for an Investigator who is newly participating in the project.
   c. Within 60 days for new, or newly identified, FCOI's for existing Investigators.
   d. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.
   e. Following a retrospective review to update a previously submitted report, in appropriate.
2. Establish a policy and procedure to notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research and to include the requirement to submit a mitigation report in accordance with the regulation.
   a. The policy and/or procedure include all reporting elements as required by the regulation.
3. Establish a policy and procedure to notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy, or an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.
   a. The policy addresses the Institution's requirements to notify NIH promptly and take corrective action for noncompliance with the Institution's policy or the management plan.

C2. Institutional Reporting Requirement to NIH

1. Initial, annual (i.e. ongoing) and revised FCOI reports, including all reporting elements required by the regulation, will be generated through the use of IRBNet® based on information provided by the Investigator and the management plan developed by the designated Institutional officials. These reports will be submitted to the PHS for the Institution by the Department of Clinical Research as required by the regulation:
   a. Prior to the expenditure of funds.
   b. Within 60 days of identification for an Investigator who is newly participating in the project.
   c. Within 60 days for new, or newly identified, FCOI's for existing Investigators.
   d. At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide

the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

e. Following a retrospective review to update a previously submitted report, if appropriate.

2. The JHMC IRB requires annual renewal/progress reports for all ongoing research. At the time of annual renewal, and anytime during the research period, the project may be subject to an internal audit in order to assess for bias with respect to design, conduct, or reporting of NIH-funded research. If bias is identified, the PHS will be notified within 30 days of initial identification of such bias.
   a. A mitigation report including all reporting elements as required by the federal regulations will be submitted as appropriate.
3. The Institution will notify NIH promptly if an Investigator fails to comply with the Institution's FCOI policy, or an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.
   a. The policy will be submitted within 30 days and will address the corrective action for noncompliance with the Institution's policy or the management plan.

D1. Maintenance of Records: Objectives

1. Establish a policy and procedure to maintain all FCOI-related records that meets or exceeds the regulatory requirements:
   a. For at least 3 years from the date the final expenditures report is submitted to the PHS (NIH).
   b. From other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable.

D2. Institutional Policy for Maintenance of Records

a-b. The Institution will maintain all FCOI-related records electronically through the use of IRBNet.org® as required by applicable laws and as outlined in the IRBNet.org® SOP's.

E1. Enforcement Mechanisms, Remedies, and Noncompliance: Objectives

1. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance.
2. Establish a policy requirement to complete and document retrospective reviews within 120 days of the Institutions determination of noncompliance for SFI's not disclosed timely or previously or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulations.
3. Establish a policy and procedures to ensure that in any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research 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 an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to:
   a. Disclose the FCOI in each public presentation of the results of the research.
   b. Request an addendum to previously published presentations.

E2. Enforcement Mechanisms, Remedies, and Noncompliance: Objectives

1. Through the collaboration with the IRB, adequate enforcement mechanisms to ensure Investigator compliance have been implemented. Any Investigator not in compliance with the Institutions FCOI rule will be prohibited from participating in research at the Institution until compliance has been gained.
2. Retrospective reviews will be completed within 120 days of the Institutions determination of noncompliance for SFI's not disclosed timely or previously or previously reviewed, or whenever an FCOI is not identified or managed in a timely manner. This process will be documented through the use of standardized reporting forms available through the JHMC IRBNet®.
3. In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research 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 an FCOI was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to:
    a. Disclose the FCOI in each public presentation of the results of the research.
    b. Request an addendum to previously published presentations.

F1. Sub-recipient Requirement Objectives

1. Establish a policy and procedures to address sub-recipient requirements.
2. Where applicable, establish, via a written agreement, whether the recipient will follow the FCOI policy of the awardees Institution or the FCOI policy of the sub-recipient Institution.
    a. If applicable, obtain a certification from the sub-recipient that it's FCOI policy complies with the regulation.
    b. If applicable, include in the written sub-recipient agreement a requirement for the sub-recipient to report identified FCOI's for its Investigators in a time frame that allows the awardees' Institution to report identified FCOI's to the NIH as required by the regulation.
    c. Alternatively, if applicable, include in the written agreement a requirement to solicit and review sub-recipient Investigator disclosures that enable the awardees' Institution to identify, manage and report identified FCOI's to the NIH.

F2. Sub-recipient Requirement Objectives

1. At this time, this requirement does not apply to our Institution. The regulation will be revised as appropriate in a timely manner.

This final rule has been reviewed and approved by:

William Lynch	Kelly L. Cervellione
Chief Operating Officer	Director, Department of Clinical Research
Jamaica Hospital Medical Center	Jamaica Hospital Medical Center