

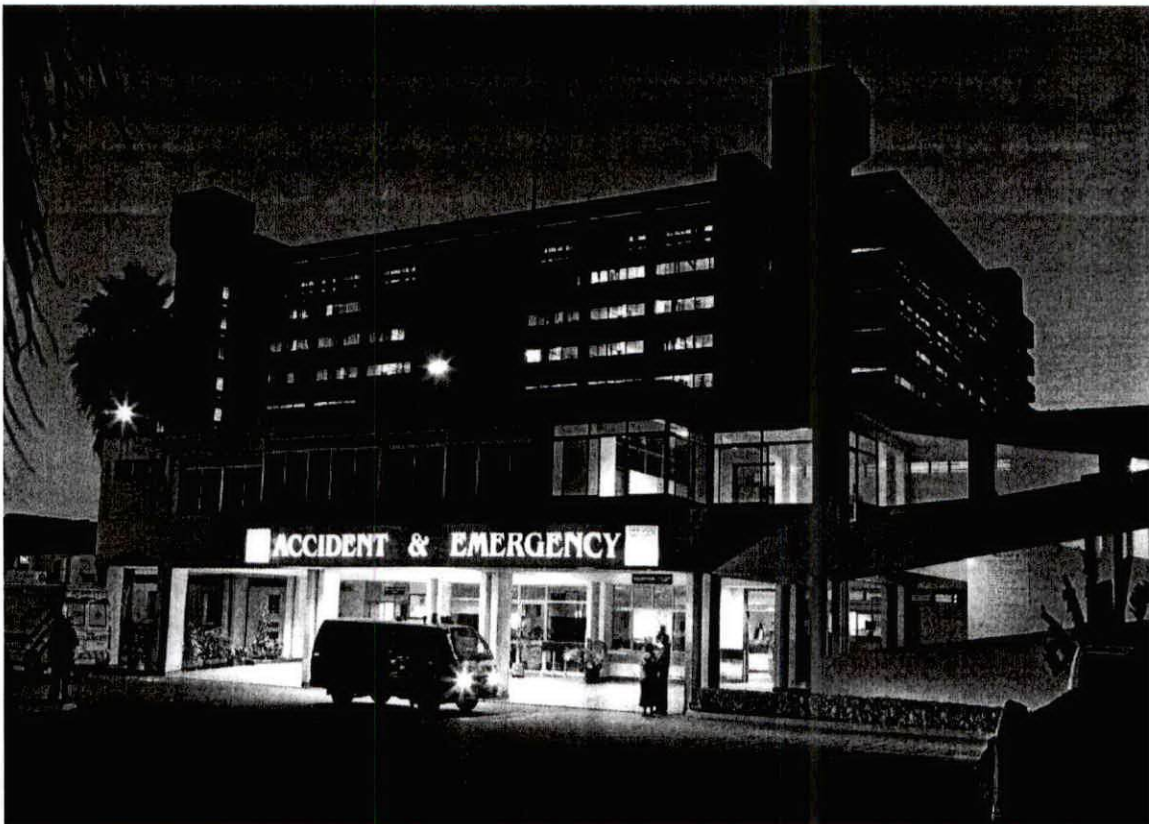


Kenyatta National Hospital

---

## KNH FINANCIAL CONFLICTS OF INTEREST STANDARDS AND PROCEDURES FOR NATIONAL INSTITUTES OF HEALTH AND OTHER APPLICABLE RESEARCH FUNDING

---



DOCUMENT NO.	01
EFFECTIVE DATE	23 <sup>RD</sup> JUNE 2021
SIGNED BY:	
DR. EVANSON KAMURI, EBS CHIEF EXECUTIVE OFFICER	

## **VISION, MISSION AND MANDATE**

### **Vision**

A world class patient- centered specialized care Hospital.

### **Mission**

To optimize patient experience through innovative evidence based specialized healthcare, facilitate training, research and participate in national health policy formulation.

### **Our Motto**

We listen, We care

### **Mandate**

- i) To receive patients on referral from other Hospitals or institutions within or outside Kenya for specialized health care.
- ii) To provide facilities for medical education for the University of Nairobi Medical School, and for research either directly or through other co-operating health institutions.
- iii) To provide facilities for education and training in nursing and other health and allied professions.
- iv) To participate as a national referral Hospital in national health planning and Policy.

### **Core Values**

- Customer focus
- Transparency & Accountability
- Professionalism & Integrity
- Equity & Equality
- Teamwork & Team Spirit
- Security & Safety

## TABLE OF CONTENTS

<b>VISION, MISSION AND MANDATE</b> .....	<b>1</b>
<b>ABBREVIATIONS AND ACROYNMS</b> .....	<b>3</b>
<b>1. INTRODUCTION</b> .....	<b>6</b>
1.1. Overview.....	6
1.2. Applicability.....	6
1.3. Purpose.....	6
<b>2. FINANCIAL CONFLICT OF INTEREST</b> .....	<b>7</b>
2.1. Conflicts of Interest .....	7
2.2. Significant Financial Interests .....	7
2.3. Collaborative Projects/Sub-agreements .....	8
2.4. Management Plan.....	8
2.5. Managing Conflicts of Interest .....	8
2.6. Violation of Financial Conflicts of Interest Standards .....	8
<b>3. RESPONSIBILITY</b> .....	<b>10</b>
3.1. Chief Executive Officer .....	10
3.2. Senior Director (Clinical Services) .....	10
3.3. Investigator .....	10
3.4. Conflicts of Interest Administrator .....	11
3.5. Conflict of Interest Committee.....	11
3.6. Financial Conflict of Interest Appeal Review Committee.....	12
<b>4. FINANCIAL CONFLICTS OF INTEREST STANDARDS REQUIREMENTS</b> .....	<b>13</b>
4.1. Training of and Reporting by Investigators .....	13
4.2. Who Should Disclose.....	13
4.3. Sub-recipient Requirements.....	14
4.4. Disclosure, Review, Monitoring by COI Administrator .....	15
4.5. Reporting of FCOI to the Funder.....	15
4.6. Maintenance of Records .....	16
4.7. Enforcement Mechanisms and Remedies and Noncompliance.....	16
4.8. Public Accessibility of Information .....	17

**ABBREVIATIONS AND ACROYNMS**

CEO	Chief Executive Office
COI	Conflicts of Interest
FCOI	Financial Conflicts of Interest
KNH	Kenyatta National Hospital
NIH	National Institutes of Health
SDCS	Senior Director (Clinical Services)
SFI	Significant Financial Interests

## DEFINITIONS OF TERMS

Awardee	An institution that receives funding directly from a funding source.
Conflict of Interest	An interest that has the potential to compromise or bias the professional judgment or objectivity of the holder of the interest, or has the appearance of having the potential to compromise or bias the holder of the interest.
Conflict of Interest Administrator	Means the individual(s) within Kenyatta National Hospital who have been assigned the responsibility for reviewing and managing disclosures from Investigators of significant financial interests related to the Investigator's institutional responsibilities. For the purposes of this guideline, the Conflicts Administrator shall be the Head Department of Research and Programs, or his/her designee(s).
Conflict Review Committee	A Committee established to evaluate on a case-by-case basis, complex and unique SFI and FCOI decisions, identified by the designated official. It will be a five-member committee chaired by the COI Administrator.
Disclose	An Investigator's submission of a completed Disclosure and Consent Report, defined herein, to KNH.
Disclosure and Consent Report	A tool for Investigators to disclose the absence or presence of SFIs and to consent to the release of their information according to this guidelines, provincial laws and the NIH Regulation. This reporting tool can be accessed on the KNH website.
Financial Conflict of Interest (FCOI)	A financial conflict of interest exists when an Investigator's significant financial interest could directly and significantly affect the design, conduct, or reporting of the funded research.
FCOI Appeal Review Committee	An <i>Ad-hoc</i> Committee appointed by the CEO constituting of independent assessors to review the decisions made by the COI Committee, when an Investigator challenges the said decision.
Funder	An individual or agency who commits resources towards the implementation of funded research.
Investigator	The principal investigator, co-principal investigators, and any other person at KNH responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding.
Management Plan	A written plan to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias, when a FCOI is determined. The designated official in

Significant Financial Interest (SFI)

consultation with the Investigator creates the management plan. The Investigator is required to comply with the Management plan prescribed by the designated official, and the designated official will monitor compliance with the plan until the completion of the project as well as provide initial and ongoing FCOI reports to the NIH.

A financial interest consisting of one or more of the following interests (monetary value, including but not limited to compensation, equity, gifts, and intellectual property of an investigator or the immediate family member of an investigator, whether or not the value is readily ascertainable) of the Investigator that reasonably appears to be related to the Investigator's institutional responsibilities.

Sub-recipient

An Investigator from the Kenyatta National Hospital, who is the recipient of funding via a sub-grant from an awardee institution.

## **1. INTRODUCTION**

### **1.1. Overview**

Kenyatta National Hospital (KNH) encourages its staff to participate in research activities and in doing so with the highest scientific and ethical standards. While the potential for conflicts of interest is understandable, Investigators must prevent the introduction of bias into their research.

The objective of these standards are to protect the credibility and integrity of the Investigators and to ensure public trust and confidence in the Hospital's research activities by identifying, understanding, and responding to conflicts of interest.

The responsibilities and obligations of Investigators to KNH must be clearly separated from their personal financial interests and obligations. Each Investigator must disclose his or her significant financial interests including those of his or her immediate family members in order to ensure that the design, conduct, and reporting of research or other activity is free of bias.

In addition to compliance with the Kenyatta National Hospital Research Policy and other accompanying policies and procedures, all KNH staff and Research Scientists, acting as Investigators, who are applying for and/or receiving donor funding or who are participating in a funded research project, either as an awardee or sub-recipient, must comply with the Standards.

### **1.2. Applicability**

This standards applies to all Investigators (as defined in this standards) receive, plan to participate in, or are participating in funded research.

### **1.3. Purpose**

- i. To promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under donor grants or cooperative agreements will be free from bias resulting from Investigator FCOI in order to comply with the Funder regulations.
- ii. To clarify reporting requirements regarding training and reporting of SFI by KNH personnel;
- iii. To outline the process by which the COI Administrator confirms whether any disclosed financial interest reasonably appears associated with an Investigator's institutional responsibilities, is therefore an SFI, and if so, determines whether it is related to the funded research and assesses whether it is a FCOI for the funded project; and
- iv. To outline the responsibilities of the COI Administrator and KNH in managing and reporting FCOIs to the funder and/or via an awardee institution.

## **2. FINANCIAL CONFLICT OF INTEREST**

### **2.1. Conflicts of Interest**

A potential conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the Hospital such that an independent observer might reasonably question whether the individual's professional actions or decisions are made by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual. For the purposes of this standards, a conflict of interest exists when the Hospital, through the procedures described in this standards, reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored projects.

### **2.2. Significant Financial Interests**

A financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's immediate family member) that reasonably appears to be related to the Investigator's institutional responsibilities:

- i. With regard to a financial interest consisting of interests of the Investigator when aggregated, exceeds \$5,000 (US Dollars Five Thousand).
- ii. 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 when the annual aggregated amount paid to the specific Investigator, exceeds \$5,000. This disclosure will include, at a minimum the; (i) purpose of the trip, (ii) identity of the sponsor/organizer, (iii) destination, and (iv) duration. The COI Administrator will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI Related to the NIH funded research.
- iii. If an Investigator receives more than \$5,000 dollars per year from one entity in total payments for multiple SFIs (as defined in (1) and (2) above), then the details of each such SFI must be disclosed.

### **SFI Exclusions**

The following types of financial interests are excluded from the definition of significant financial interest:

- i. Salary, royalties, or other remuneration paid by KNH to the Investigator if the Investigator is currently employed or otherwise appointed by the hospital, including intellectual property rights assigned to the hospital and agreements to share in royalties related to such rights;
- ii. Income from investments, such as mutual funds and retirement accounts, as long as an Investigator does not directly control the decisions made in these investment;
- iii. Income received from organizations for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a the Government, an institution of higher education, an academic teaching



hospital, a medical center, or a research institute that is affiliated with an institution of higher education; and

- iv. income from service on advisory committees or review panels for the Government, an institution of higher education, an academic teaching hospital, a medical center, or research institute that is affiliated with an institution of higher education.

### **2.3. Collaborative Projects/Sub-agreements**

Collaborators, sub-recipients, and subcontractors from other organizations must either comply with this standards or provide a certification that their organizations are in compliance with applicable funder policies regarding Investigator SFI disclosure and that their portion of the project is in compliance with their institutional policies.

- i. For purposes of clarification, an individual who receives salary, royalties, or other remuneration from a publishing company to research and publish shall not be considered an investigator for purposes of this standards.
- ii. If the CEO or any member of his or her family is also an Investigator with respect to the research or service activity funded, or proposed for funding, by a sponsor for which disclosures are being reviewed, the Hospital Board Chairperson shall act in place of the CEO for all purposes under this standards.

### **2.4. Management Plan**

The management plan is action plan that shall ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias, when a FCOI is determined. The COI Administrator in consultation with the Investigator creates the management plan. The Investigator is required to comply with the Management plan prescribed by the COI Administrator, and the COI Administrator will monitor compliance with the plan until the completion of the project as well as provide initial and ongoing FCOI reports to the NIH.

### **2.5. Managing Conflicts of Interest**

Actual or potential conflicts of interest shall be satisfactorily managed, reduced, or eliminated in accordance with this standards. Additionally, all required reports regarding the conflict of interest shall be submitted to the sponsor prior to expenditure of any funds under an award in accordance with the applicable federal regulations.

### **2.6. Violation of Financial Conflicts of Interest Standards**

Whenever an Investigator has violated this standards or the terms of any resolution plan required by the COI Administrator (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms), the COI Administrator shall notify the SDCS who may recommend disciplinary actions or sanctions against the violating Investigator to the CEO. If the violation results in a collateral proceeding under the Hospital's policies, then the CEO may defer his or her decision on sanctions until such other proceeding is completed.

In addition, the Hospital shall comply with all applicable funder regulations regarding the notification of the funder in the event an Investigator has failed to comply with this standards. The funder may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

### **3. RESPONSIBILITY**

#### **3.1. Chief Executive Officer**

The Chief Executive Officer (CEO) shall have the responsibility for implementation, monitoring, evaluation, and ensuring compliance to this Policy.

#### **3.2. Senior Director (Clinical Services)**

The Senior Director (Clinical Services) shall have the overall responsibility in ensuring adherence and implementation of the FCOI Standards and Procedures.

#### **3.3. Investigator**

Each Investigator is required to disclose the following Significant Financial Interests: -

- i. Any SFI of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding;
- ii. Any SFI of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding;
- iii. An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: (a) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value; and (b) does not represent more than a 5% ownership interest in any single entity; or
- iv. Salary, royalties or other remuneration that when aggregated for the Investigator and the Investigator's spouse and dependent children, are not expected to exceed \$10,000 during the next twelve months.

Regardless of the above minimum requirements, any staff member or research scientist, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual or potential conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Prior to the submission of a proposal for funding, each Investigator shall complete a SFI Disclosure Form ("disclosure form") and attach all required supporting documentation, if any. An Investigator must submit a disclosure form prior to the time a proposal is submitted even if he or she does not have any SFI.

Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted in a sealed envelope marked confidential and accompany the disclosure form. All financial disclosures must be updated by Investigators during the period of the award, either on an annual basis or as new reportable SFI arise or are acquired.

All disclosure forms and supporting documentation are to be submitted to the COI Administrator. Additional information may be requested by the COI Administrator and shall be furnished upon request. The COI is responsible for the receipt, processing, review, and retention of all disclosure forms.

#### **3.4. Conflicts of Interest Administrator**

The COI Administrator shall review all financial disclosures to determine whether a conflict of interest exists. If the COI Administrator determines that there is potential for a conflict of interest covered by this standards, then he/she shall determine what conditions or restrictions, if any, should be imposed by the KNH to manage actual or potential conflicts of interest arising from the disclosed SFI. Such conditions or restrictions include, but are not limited to, the following:-

- (a) Public disclosure of SFI;
- (b) Monitoring of research by independent reviewers;
- (c) Modification of the research plan;
- (d) Disqualification from participation in all or a portion of the research;
- (e) Divestiture of the SFI; and
- (f) Severance of the relationships that create actual or potential COI.

The COI Administrator may require that a plan for reducing or eliminating conflicts of interest be incorporated into a Memorandum of Understanding between the Hospital and the Investigator.

The COI Administrator shall notify the SDCS of the conditions or restrictions to be imposed. If the SDCS determines that imposing the above referenced conditions or restrictions would be ineffective or inequitable, or that the potential negative impacts that may arise from a SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then he/she may recommend to the CEO, to the extent permitted by the Hospital and funder regulations, the research go forward without imposing such conditions or restrictions. In these cases, the CEO shall make the final decision regarding resolution of any actual or potential conflicts of interest.

The COI Administrator shall review all initial and updated disclosures of Significant Conflicts of Interest in accordance with this standards.

#### **3.5. Conflict of Interest Committee**

The Committee shall comprise of at least five-members appointed by SDCS and chaired by the COI Administrator. The responsibilities of the COI Committee shall include:

- i. Review and accept or modify management plans, as appropriate.
- ii. Determine if funding should be declined if all parties cannot agree to a management plan.
- iii. Evaluate on a case-by-case basis, complex and unique SFI and FCOI decisions, identified by the COI Administrator.

**3.6. Financial Conflict of Interest Appeal Review Committee**

The FCOI Appeal Review Committee shall be an Ad-hoc Committee appointed by the CEO on the recommendation of the SDCS to review the decisions made by the COI Committee, when an Investigator challenges the said decision.

The Committee shall comprise of at least five (5) members drawn from various professional disciplines with the Hospital, on a case-by-case basis.

## **4. FINANCIAL CONFLICTS OF INTEREST STANDARDS REQUIREMENTS**

### **4.1. Training of and Reporting by Investigators**

All investigators must be trained by the Hospital and must demonstrate competency in the training material pertaining to this Standards at the following times: -

- i. At the time of first application for funding or first participation in funded research where KNH is the awardee or sub-recipient;
- ii. At least every four years;
- iii. Immediately when any of the following circumstances apply: -
  - (a) This standards is revised in a manner that affects the requirements of Investigators;
  - (b) An Investigator is new to the Hospital and is receiving project funds, unless the Investigator has demonstrated valid training from a previous institution; and
  - (c) Where the Hospital finds that an Investigator is not in compliance with this procedure or a specific management plan.

### **4.2. Who Should Disclose**

All Investigators, trained pursuant to the above, must complete and submit a Disclosure and Consent Report for each funded project at the following times: -

- i. Initial disclosure must:
  - (a) Be made at the time of application for funding or participation in funded research; and
  - (b) Include all SFIs in the 12 months preceding the disclosure.
- ii. Subsequent disclosure must occur:
  - (a) Within 30 days of discovering or acquiring (including but not limited to a purchase, marriage/partnership agreement, inheritance, etc.) a new SFI; and
  - (b) On an annual basis during the term of the funded research, disclosing:
    - All SFIs received in the 12 months preceding the disclosure that were not previously reported; and
    - Updated information regarding any previously disclosed SFI.
- iii. All Investigators who are new to KNH and are receiving research funding or who are participating in a funded research project where the KNH is the awardee or sub-recipient, must demonstrate valid training and make the initial disclosure and ongoing disclosures as noted above.

#### **4.2.1. Steps to Disclose to the Hospital**

Trained Investigators must: -

- (a) Complete disclosure and consent reports for themselves, and on behalf of their spouse/adult interdependent partner and their dependent children;
- (b) Complete disclosure and consent reports for each funding application or funded project; and
- (c) Provide information regarding third party entity (ies) or individual(s) named in any disclosed SFI(s), if required by the COI Administrator. Third parties may be informed that their information may be disclosed to the funder, or

in case of FCOI, to the public. Obtaining consent from applicable third party will be done via the Informed Consent from Third Party form, held by the COI Administrator.

#### **4.3. Sub-recipient Requirements**

##### **4.3.1. Sub-recipient (another institution is awardee/prime institution)**

If an Investigator at KNH carries out NIH-funded research as a sub-recipient, the Hospital will take reasonable steps to ensure that any sub-recipient Investigator complies with this Procedure.

- (a) The sub-recipient must complete training, comply with this Procedure and submit disclosures to COI Administrator.
- (b) KNH will certify that its standards complies with the 2011 NIH FCOI Regulations, specifically 42 CFR Part 50 Subpart F or 45 CFR Part 94, upon the sub-recipient Investigator achieving compliance with this Procedure. Depending on the awardee institution, sub-recipients may have to complete other training and/or additional disclosure forms pertinent to the awardee institution's policies.

##### **4.3.2. External subcontractors (KNH is awardee/prime institution)**

If the prime investigator at the KNH carries out the NIH-funded research via an external subcontractor at another institution, KNH will take reasonable steps to ensure that any external subcontracted investigators comply with this Procedure:

- (a) KNH will incorporate, as part of a written agreement with the external subcontracted investigator, terms that establish whether this Procedure or the external subcontracted institution's policy will apply to the external subcontracted investigators.
- (b) KNH shall obtain from the sub-recipient, as part of the written agreement referenced above, certification that the external subcontractor's institutional policy complies with the NIH regulations. The agreement shall also specify FCOI reporting time periods for the external subcontractor. Such time periods shall be sufficient to enable KNH to provide timely FCOI reports to NIH.
- (c) KNH will obtain a written agreement specifying time periods for the external subcontractor to submit all Investigator disclosures of SFIs to the Hospital. Such time periods shall be sufficient to enable the Hospital to comply on time with its review, management and reporting obligations under this Procedure.

#### 4.4. **Disclosure, Review, Monitoring by COI Administrator**

The COI Administrator must review all Disclosure and Consent Reports from Investigators (regardless of the presence or number of SFI) and determine whether: -

- i. **Any disclosed SFI is related to the funded project:** The Investigator's SFI is related to research when the COI Administrator reasonably determines that the SFI could be affected by the funded research; or is an entity whose financial interest could be affected by the research. The COI Administrator may involve the Investigator in the COI Administrator's determination of whether a SFI is related to the funded project.
- ii. **Any SFI is a FCOI:** FCOI exists when KNH, through its COI Administrator, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the funded research.

The review and determination noted above must be conducted by the COI Administrator at the following times:

- (a) Prior to the hospital's release of any funds under a funded research project;
- (b) Within 60 days whenever, in the course of an ongoing funded project, an Investigator who is new to participating in the project discloses a SFI or an existing Investigator discloses a new SFI to Kenyatta National Hospital; and
- (c) Within 60 days whenever KNH identifies a SFI that:
  - was not disclosed in a timely manner by an Investigator; or
  - for whatever reason, was not previously reviewed by KNH during an ongoing funded research project.

The COI Administrator, on behalf of KNH, will maintain records relating to all Investigator disclosures of SFIs and Kenyatta National Hospital review of, and response to, such disclosures (whether or not a disclosure resulted in KNH determination of a FCOI) and all actions under the KNH's standards or retrospective review related to the SFI and/or FCOI, according to the Research Records Stewardship Guidance Procedure as well as the Funder Regulation.

KNH is required to submit to the Funder, or permit funder on site to review, all records pertinent to compliance with this procedure.

#### 4.5. **Reporting of FCOI to the Funder**

If it is determined that there is a FCOI, the COI Administrator must prepare a management plan. This plan will include reporting as follows: prior to the expenditure of funds; within 60 days of identification for an investigator who is newly participating in the project; within 60 days for new, or newly identified, FCOIs for existing investigators; and on annual basis to provide status of FCOI.

The Investigator is required to comply with the management plan prescribed by the COI Administrator.



On behalf of KNH, the COI Administrator will monitor compliance with the management plan until the completion of the project or the FCOI no longer exists.

KNH, through its COI Administrator, must provide initial and ongoing FCOI reports to the funder. FCOI reports must include sufficient information to enable the funder to understand the nature and extent of the financial conflict and to assess the appropriateness of the Hospital's management plan.

#### **4.6. Maintenance of Records**

Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the Conflicts Administrator until three years after the later of the termination or completion of the award to which they relate, or the resolution of any government action involving those records.

#### **4.7. Enforcement Mechanisms and Remedies and Noncompliance**

In the event of non-compliance, KNH may initiate actions under applicable collective, other agreements or other Hospital policies. The COI Administrator retains the ability to advise the Medical Research Department of non-compliance.

When KNH identifies any SFI that was not disclosed in a timely fashion by an Investigator or, for whatever reason, was not previously reviewed by the institution during an ongoing funded project (including but not limited to when the SFI was not reviewed in a timely fashion or reported by an external subcontractor), the COI Administrator will determine within 60 days if any SFI meets the criteria for a FCOI and if so, follow the dictated procedure herein for FCOI management. Within 120 days, the COI Administrator must create a retrospective review of the Investigator's activities with respect to the funded research and submit a mitigation report to the funder.

In any case in which funder determines that a clinical research funded 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 by Hospital as required by the regulations, KNH requires the Investigator involved to disclose the FCOI in each public presentation which involves the results of the funded research, and also to request an addendum to previously published presentations including details of the FCOI.

On the basis of its review of records or other information that may be available, NIH may decide that a particular FCOI will bias the objectivity of the NIH funded project to such an extent that further corrective action is needed or that the KNH has not managed the FCOI in accordance with this Procedure, the COI Administrator may request the Investigator cease spending NIH funds until the matter is resolved.

#### **4.8. Public Accessibility of Information**

KNH shall maintain an up-to-date, written and enforced standards (and associated procedures) on FCOIs, that complies with the NIH regulations and make such policy/standards available for public access at KNH website. Information concerning identified FCOIs shall be made publicly accessible prior to the receipt of funds within 5 calendar days of a written request and will be updated within 60 days of a newly identified FCOI as well as annually.

After an award has been granted, KNH shall record information concerning any SFI that meets all of the following criteria:

- (a) a disclosed SFI, which is held by an Investigator, identified by the KNH as senior/key personnel for the NIH funded research project in the grant application, contract proposal, contract, progress report, or other required report submitted to the NIH;
- (b) any SFI related to the NIH funded research determined by the COI Administrator; and
- (c) any FCOI determined by the COI Administrator.

This recorded information shall be comprised of the relevant project, Investigator and SFI details and shall remain available to written requests for at least 3 years from the date that the information was most recently updated. Information will only be supplied for those Investigators who meet all criteria listed above.