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Assistant VP
Compliance &
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Area Corporate
Compliance

Applicability Erie County
Medical Center

Federally Sponsored Research and Conflict of Interest Policy

Policy Purpose, Statement of Policy, and Policy Goals

This policy applies to all research administered by Erie County Medical Center Corporation ("ECMCC" or the "Corporation") and applies to all Investigators who apply for, receive, plan to participate in or are participating in federally sponsored research. This Policy is intended to supplement, but not replace, any applicable laws governing conflicts of interest applicable to ECMCC.

Background

- A. The Corporation is committed to promoting objectivity in research and to maintaining high ethical standards to ensure that the design, conduct, and reporting of research is not biased by the financial interests or Foreign Affiliations of Investigators. The responsibilities and obligations of Investigators as they relate to ECMCC must be clearly separate from their personal financial interests and obligations and from foreign influences. Investigators must disclose their own and their immediate family members' significant financial interests and non-Corporate significant obligations as well as any Foreign Affiliations.
- B. In all dealings with and on behalf of the Corporation or any affiliated entity, each Investigator shall be held to a strict standard of honest and fair dealing with the Corporation and its affiliated entities, and no such person shall use his or her position, or knowledge gained there from, in such a manner as to create a conflict, or the appearance of a conflict, between the interest of the Corporation or any affiliated entity and the interest of such person.

Definitions

- A. Investigator - The Project Director, Principal Investigator, Co-Principal Investigators and all other key person(s) who are responsible for the design, conduct, or reporting of externally or internally supported activities. Individuals who do not make independent decisions regarding the design, conduct, or reporting of the activity in question, and only work on or are engaged in the activity do not meet the definition of an investigator.
- B. Conflict of Interest - When an Investigator is, or may be, in a position to influence activities or decisions in ways that could lead to personal gain for the Investigator or the Investigator's family, or give an improper advantage to third parties in their dealings with the Corporation. Conflicts may also arise when Investigators have outside obligations of any kind that are in substantial conflict with the Investigator's responsibilities or the public interest.
- C. Significant Financial Interest ("SFI") - A financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's immediate family members) that reasonably appears to be related to the Investigator's responsibilities:
 - 1. with regard to any publicly traded entity, 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 if, when aggregated, exceeds \$5,000;
 - 2. with regard to any non-publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure if, when aggregated, exceeds \$5,000, or when the Investigator or his/her immediate family members hold any equity interest (e.g., stock, stock option, or other ownership interest);
 - 3. intellectual property rights and interests (e.g., patents, copyrights), and royalties from such rights, upon receipt of income related to such rights and interest;
 - 4. income received from foreign entities for seminars, lectures, teaching engagements, or service on advisory committees or review panels; or
 - 5. reimbursed or sponsored travel (e.g. travel paid on behalf of the investigator).
- D. SFI Exclusions - The following types of financial interests are excluded from the definition of significant financial interest:
 - 1. salary, royalties, or other remuneration paid by the Corporation or through SUNY at Buffalo Research Foundation ("RF"), if the Investigator is currently employed by ECMCC or RF;
 - 2. intellectual property rights assigned to the Corporation or RF, and agreements to share in royalties related to such rights;
 - 3. 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; or
 - 4. income received from U.S. based organizations for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with

an institution of higher education.

- E. Financial Conflict of Interest ("FCOI") - Exists when the Corporation reasonably determines through its designated officials that an Investigator's SFI, external obligation, or sponsored travel could directly and significantly affect the design, conduct, or reporting of funded research activity.
- F. Foreign Affiliation – Exists when an Investigator, faculty, staff, or student performs research at ECMCC and has one of the following types of relationships and activities:
 - 1. Foreign components of federally-funded research are defined as “any significant scientific element or segment of a project outside of the United States, either by the recipient or by a researcher employed by a foreign organization, whether or not grant funds are expended”. “Foreign components” may include “collaborations with investigators at a foreign site anticipated to result in co-authorship; use of facilities or instrumentation at a foreign site; or receipt of financial support or resources from a foreign entity;”
 - 2. Other support includes all financial resources, domestic or foreign, available in direct support of a Investigator's research endeavors and includes participation in a foreign talent program;
 - 3. SFI from a foreign entity as defined above; or
 - 4. Foreign consulting and other outside business activities which may include activities such as consulting, teaching courses at outside organization, or entrepreneurial ventures, related to an Investigator's area of research.

Procedure

- A. As part of its commitment to promoting objectivity in research, and consistent with federal regulations, ECMCC has formulated this policy to identify and address potential, actual and apparent conflicts of interest including Foreign Affiliations that may rise to the level of an FCOI.
- B. Disclosures
 - 1. Real and apparent FCOI may arise from any number and type of external commitments and financial interests. Investigators are required to report fully and accurately all external commitments and financial interests they hold, as well as the commitments and interests of their spouse, domestic partner and dependent child(ren).
 - 2. Investigators must complete and submit an Investigator Disclosure Statement:
 - a. at the time of application for funds or prior to the activation of an award, dependent on sponsor requirements;
 - b. annually thereafter during the period of a funded award;
 - c. when required by the sponsor or by the terms and conditions of an award; and
 - d. within 30 days of discovering or acquiring a new SFI, or when an existing SFI materially changes.
 - 3. ECMCC's Research Committee will review the disclosure statement and determine

whether an Investigator's SFI is related to his or her research or sponsored programs activities and, if so, whether the SFI constitutes an FCOI.

4. In the event that the ECMCC Research Committee determines that an FCOI exists, it will develop and implement a management of the FCOI(s).
5. If the FCOI is not disclosed until after completion of research, than a retrospective review of the research will be completed by the ECMCC Research Committee in compliance with applicable regulations (see 42 CFR 50.605(a)(3)(ii)(B)).
6. Investigators at ECMCC, including, but not limited to employees, students, staff, and visiting scientists and scholars, are required to disclose Foreign Affiliations that are related to research to the ECMCC Research Committee to determine if there are any potential conflicts of commitments, duplications of research, and/or diversion or disclosure of intellectual property of confidential information in the performance of research. The Investigator Disclosure Statement includes a question relating to Foreign Affiliations to satisfy the requirement that Investigators disclose Foreign Affiliations.

C. Submitting FCOI reports to National Institutes of Health (NIH) for NIH-sponsored research

1. Corporation will send initial, annual and revised FCOI reports to NIH via the NIA eRA Commons portal
 - a. prior to the expenditure of funds;
 - b. within sixty days of any newly identified Investigator participating in the research project or newly identified FCOI for existing Investigators;
 - c. at least annually at the same time the annual progress report is submitted; and
 - d. after a retrospective review to update a previously submitted report, if new information is discovered following completion of the research project.
2. In the event that bias is discovered within the design, conduct or reporting of the PHS/NIH-funded research activities, then ECMCC will notify NIH promptly and include a Mitigation Report detailing actions to mitigate the effects of such bias, in accordance with applicable regulations.

D. Conflict Resolution and Management

1. If an FCOI cannot be avoided, then it will be managed consistent with this policy and applicable regulations. Any ECMCC employee may request advice about a potential conflict of interest from the ECMCC Research Committee. In the event of an FCOI, the ECMCC Research Committee will develop and implement a Conflict Management Plan designed to remove the bias, or the reasonable perception of bias. Real and apparent FCOI often can be managed, in whole or in part, by:
 - a. public disclosure of the implicated external commitments and financial interests, specifically to journal publishers, granting agencies, conference organizers, audiences at presentations, colleagues, collaborators, and students;
 - b. monitoring by independent reviewers of the related research;

- c. modification of the research plan;
 - d. disqualification from participation in all or a portion of the research project;
 - e. removal of the investigator as the principal investigator or the appointment of a co-investigator;
 - f. declination of the sponsored award.
2. The ECMCC Research Committee will scrutinize disclosures of Investigators with academic oversight responsibilities for undergraduates, graduate students, or postdoctoral associates who are working on projects that are funded by, or conducted in collaboration with, an external entity in which the research personnel have any financial interests.
 3. The Investigator must provide concurrence and certification for compliance with the Conflict Management Plan prior to participating in the research or sponsored activity. Should an Investigator fail to concur with the recommended Conflict Management Plan, he/she may transmit comments to the Director of Corporate Compliance within ten business days from receipt of the decision. In such a case, the Director of Corporate Compliance will review the case (which may include seeking the advice of appropriate impartial experts and holding discussions with the Investigator and/or Institutional Official) and will render a judgment within twenty business days of the time that the Director of Corporate Compliance's initial determination is made known to the Investigator.
 4. The Institutional Official for Financial Conflict of Interest shall be charged with the monitoring of the Conflict Management Plan.

E. Training

1. FCOI training is recommended for all Investigators engaged in sponsored research activities. FCOI training is required for each Investigator involved in U.S. Public Health Service (PHS) funded research and other funded research when required by the sponsor. ECMCC uses Collaborative Institutional Training Initiative "CITI" program which incorporates federal FCOI training in research conflicts of interest, supplemented with this and related policies of the Corporation. Current training obtained through SUNY Buffalo is acceptable with supporting documentation.
2. Required FCOI training must be completed:
 - a. prior to engaging in the research and at least once every four years thereafter;
 - b. when an Investigator is non-compliant with this Policy or management plan developed for the Investigator
 - c. when ECMCC's FCOI policy is revised, and the revision affects requirements of Investigators
 - d. when the Investigator is new to ECMCC
3. Training includes details of this FCOI policy, Investigator's disclosure responsibilities, and federal regulations that direct the FCOI policy.

F. Requirements for PHS Sub-recipients

1. When funding from the PHS is sub-allocated to another institution, the sub-recipient must comply with all PHS Regulations. Sub-recipients must certify in the written agreement that their policy complies with PHS FCOI Regulations. If the sub-recipient does not have a policy that complies with PHS Regulations, the written agreement must state that the sub-recipient will comply with ECMCC's Policy, as stated in this document.

G. Policy Compliance

1. Persons subject to this policy are required to report fully and accurately their external commitments and financial interests and to comply with any plans developed to manage their real or apparent FCOI. Failure to comply with this policy may result in:
 - a. a hold being placed on the establishment of all new awards;
 - b. a hold being placed on the expenditure of all sponsored and institutional funds;
 - c. institutional approval not being given for the submission of any new proposals to external sponsors; and/or
 - d. no internal financial support being provided for investigator initiated projects.

H. Publication of Policy and FCOIs of Senior/Key Personnel

1. This policy will be posted on the ECMCC website
2. In the event of an FCOI held by senior/key Investigators, the following information will be available to the public prior to the expenditure of funds:
 - a. Relevant elements of the regulations at 42 CFR 50.603-604;
 - b. Identified FCOI, together with the management plan; and,
 - c. Updated information at least annually with within sixty days of a newly identified FCOI.
3. Information is made available within five business days of a written request and will remain available for three years from the date the information was most recently updated.

I. Record Retention

1. All FCOI-related records, including ECMCC Research Committee findings are maintained for at least three (3) years following submission date of final expenditures report, or other dates specified in applicable regulations (including 45 CFR 75.361 where applicable).
2. Records are maintained by Director of Corporate Compliance.

J. Attachment

1. Significant Financial Interest Disclosure Form

ECMCC has developed these policies and procedures in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team in making clinical decisions about patient care. These policies and procedures should not be construed as dictating exclusive courses of treatment and/or procedures. No health care team member should view these documents and their bibliographic references as a final authority on patient care. Variations from these policies and procedures may be warranted in actual practice based upon individual patient characteristics and clinical judgment in unique care circumstances.

Attachments

[Significant Financial Interest Disclosure Form.docx](#)

Approval Signatures

Step Description	Approver	Date
	Sam Cloud: Chief Medical Officer	09/2024
	Joseph Giglia: General Counsel	09/2024
	Lindy Nesbitt: Assistant VP Compliance & Senior Counsel	09/2024
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Applicability

Erie County Medical Center