

Conflict of Interest in Research**PURPOSE**

Outline the organizational process for identifying, assessing and managing potential conflicts to assure that both the integrity of Evergreen and the activities of its staff conducting research at EHMC are protected.

Establish guidelines, in accordance with requirements from federal agencies including the Public Health Service (PHS), for those relationships with outside organizations that will help to assure integrity and delineate the bounds of acceptable conduct for those who conduct any type of research and particularly research involving human subjects.

BACKGROUND INFORMATION

Administrative Policy 126, Conflict of Interest, addresses general conflict of interest across the organization. It asks managers and employees to 'increase their awareness and provides guidelines to assist them in the identification and management of potential conflict of interest situations'. However, the complex financial relationships that exist between EHMC staff and various agencies or businesses funding medical research require a different level of oversight. Adm 125.1, Conflict of Interest in Research, addresses standards set by the PHS 'Objectivity in Research' published in 1995. This policy is also designed to formalize the use of Financial Disclosure Statements to accomplish improved monitoring of Conflict of Interest issues in research projects.

INTRODUCTION

Evergreen encourages and supports outside interactions of its Investigators with federal, state, and local governments, and with business and industry as important parts of their research activities. Outside interactions, however, also carry with them an increased potential for conflicts of interest, either actual or perceived. Therefore, it is important to communicate the following points:

- many conflicts that are properly disclosed can be adequately managed without detriment to the reputation, integrity or position of the institution and the individual;
- in most cases, problems associated with actual or perceived conflicts of interest or commitment do not arise from the conflicts per se, but rather are the result of a failure to openly acknowledge and actively manage them.

This administrative policy statement is designed to facilitate identifying and evaluating potential conflicts of interest for all employees and the institution conducting medical research, and to assist in carrying out the shared responsibility of addressing conflict of interest issues in this arena. The policy applies to all employees who are directly or indirectly involved in conducting, designing, or reviewing research at Evergreen.

POLICY

Investigators who have, or participate in, a privately sponsored clinical study shall not, nor shall their family, concurrently receive any compensation from the sponsor, including honoraria and consulting fees, during the course of the study. In addition, they shall not have any investment in, or serve in a decision making capacity for (such as serving on the Board of Directors or management committee), or be an officer or employee of the company sponsoring the study.

DEFINITIONS

Conflicts of Interest: The term "conflict of interest" refers to situations in which financial or other personal considerations may adversely affect, or have the appearance of adversely affecting, an employee's professional judgment in exercising any Evergreen duty or responsibility in the administration and management of research. Such conflicts may inappropriately affect the goals of research programs. The methods of analysis and interpretation of research data, the hiring of staff, procurement of materials, and other administrative tasks at Evergreen must be free of the undue influence of outside interests. The mere appearance of a conflict may be as serious and potentially damaging as an actual distortion of research, or administrative goals, processes, or outcomes. Reports of conflicts based on appearances can undermine public trust in ways that may not be adequately restored even when the mitigating facts of a situation are brought to light. Apparent conflicts, therefore, should be disclosed and evaluated with the same vigor as actual conflicts.

Family includes the investigator's spouse, minor/dependent children, and other persons living in the same household.

PROCEDURE

Submission: Investigators submitting a research proposal to the Department of Research for review must submit the appropriate Financial Disclosure Form.

Non-Federal: See Attachment A for form

Federal: See Attachment B for procedural requirements and form

Review: The Research Steering Committee (RSC) will review potential financial conflicts of interest and will make recommendations for acceptance, acceptance with conditions, or disapproval of the gift, grant or contract. Such review and recommendation must be completed before Evergreen accepts the funding.

Conflict: If a positive disclosure requires a conflict management plan the RSC will oversee such plan. Possible conditions to manage, reduce, or eliminate conflicts of interest could include:

- public disclosure of significant financial interest;
- monitoring of research by independent reviewers;
- modification of the research plan;
- disqualification from participation in that portion of the research that would be affected by the significant financial interest;
- divestiture of significant financial interests by the investigator; or
- severance of relationships that create actual or potential conflicts of interest.

Evergreen reserves the right to impose any other conditions or restrictions consistent with applicable policies, regulations, and laws.

Appeal: If an investigator whose conflict has been reviewed does not agree with the RSC's decision, then they may request an appeal. The appeal process involves an appearance before the RSC by the investigator to answer questions and to provide additional information to the RSC.

Filing: Conflict of Interest Forms will be filed with the Department of Research and retained for a period of three (3) years after termination of sponsored project or until resolution of any action by the sponsor, whichever is longer

TRAINING

Administrators, investigators, and staff involved in research will be provided training about conflict of interest, including required disclosures and management plans. (This could be a booklet or packet yet to be developed).

SANCTIONS

Violation of this policy may result in disciplinary action, up to and including dismissal or loss of medical staff privileges.

References

Reference Type	Title	Notes
Documents referenced by this document		
Applicable Documents		

Applicable Documents

Documents which reference this document

Referenced Documents

Referenced Documents

Signed by

Anhaita C Jamula

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(03/09/2020 09:29AM PST)

Effective

03/09/2020

Document Owner

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Original Effective Date

08/01/2007

Revised

[08/01/2007 Rev. 0], [03/09/2020 Rev. 1]

Reviewed

[10/07/2009 Rev. 0]

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