POLICIES AND PROCEDURES

SUBJECT: CONFLICT OF INTEREST ON EXTERNALLY FUNDED PROGRAMS

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SUPERSEDES ISSUE DATE: 3/6/17

Policy Title: Conflict of Interest on Externally Funded Programs

Policy & Procedure Statement:

The teaching, scholarly activity, and service mission of ICOM must be conducted by all applicable individuals in a manner that is free from any inappropriate influence that may arise from an individual’s private interests outside the COM. This policy is intended to serve as a guide for individuals so that their relationships with private industry and any other external agencies are conducted in full consideration of their primary responsibility for teaching, scholarly activity, and service to the college. In addition, this policy ensures compliance with the U.S. Department of Health and Human Services (HHS) financial conflict of interest (FCOI) regulation, which promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research conducted under Public Health Service (PHS), including the National Institutes of Health (NIH), grants or cooperative agreements, will be free from bias resulting from individuals’ financial conflicts of interest. In those situations where a possible conflict of interest exists, this policy will enable applicable individuals to recognize such conflicts and ensure that the facts are reviewed and if necessary, the individual participants comply with these policies and the FCOI regulation and are supervised or monitored to assure that the integrity of the COM’s mission is not compromised. This policy applies to all ICOM faculty and staff and any other person, regardless of title or position with the college, who is responsible for the design, conduct or reporting of research funded by any external sponsor including all grants, contracts and subcontracts funded by the NIH, or proposed for
such funding, including students, collaborators and consultants. The only NIH awards programs that have been excluded from the FCOI regulation are the Small Business Innovative Research (SBIR) and Small Business Technology Transfer Research (STTR) Phase I applications.

It is the policy of ICOM to comply with the FCOI regulation with respect to any research or other activity for which there has been an application for or receipt of research funded by any external sponsor including all grants, contracts and subcontracts funded by the NIH or NIH funding from a grant or cooperative agreement, and that all applicable individuals shall avoid conflicts of commitment and conflicts of interest that may impair their ability to meet their college responsibilities. Each individual proposing for or holding extramurally funded grants and/or contracts must, prior to funding and within thirty (30) days of discovering or acquiring a new financial activity or interest and at least annually thereafter during the period of an award, disclose those outside financial activities or interests that could reasonably appear to or be expected to result in a conflict of interest or to compromise the individual’s ability to conduct teaching, scholarly activity, service or administrative activities at the college.

General Guidelines

a. Individuals must conduct their personal financial affairs in a manner that does not impede or conflict with their responsibilities to the college.

b. As further described below, all individuals applying for, holding extramurally funded grants and/or contracts and all persons responsible for the design, conduct or reporting of research funded by any external sponsor including all grants, contracts and subcontracts funded by the NIH, or proposed for such funding, must provide full and complete disclosures of external financial activities and Significant Financial Interests (as defined below) of such person and his/her spouse and dependent children to ensure no conflicts of commitment or conflicts of interest to college activities arise. These disclosures will allow the college to develop a plan to manage, reduce, or eliminate any conflicts so that the integrity of ICOM’s mission and the continued availability of extramurally funded teaching, scholarly activity, or service are not compromised.

Types of Conflicts

a. Conflicts of Commitment. An individual is engaged in a conflict of commitment if consulting agreements, grants, contracts or activities or other commitments to or
with outside agencies are sufficiently demanding of the individual’s time that such outside commitments interfere or may interfere with the individual’s administrative, teaching, service, research and scholarly commitments to the college. The individual’s commitment to the college must have priority over external interests, and ICOM’s resources may not be used for either personal or private gain or directed for the benefit of others without appropriate approval by the college.

b. **Conflicts of Interest.** A conflict of interest situation exists when the individual uses or would appear to an independent third party to have used his or her position to advance his or her own personal financial interests or the personal or financial interests of his or her immediate family or an associated entity, or when an individual or his or her spouse or dependent children have a Significant Financial Interest (as defined below) that reasonably appears to be related to the individual’s responsibilities.

**Significant Financial Interest**

a. A Significant Financial Interest for purposes of the required disclosures means anything of monetary value, including, but not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights) of an individual and his or her spouse and dependent children, in each case that reasonably appear to be related to any of the individual’s professional responsibilities to or on behalf of the college.

b. The requirement to disclose Significant Financial Interests includes a requirement to disclose the occurrence of any reimbursement or sponsored travel (i.e. that which is paid on behalf of the individual and not reimbursed to the individual so that the exact monetary value may not be readily available.), related to his or her institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a 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. The disclosure must include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. College official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest.
Significant Financial Interest does not include:

a. Salary, royalties or other remuneration from the college if the individual is currently employed or otherwise appointed by the college, including intellectual property rights assigned to the college and agreements to share in royalties related to such rights.

b. Income from investment vehicles, provided that the individual does not directly control the investment decision made in these vehicles.

c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of Higher Education as defined by 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;

d. Income from services on advisory committees or review panels for a federal, state, or local government agency, an Institution of Higher Education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institution that is affiliated with and institution of Higher Education;

e. A current or pending equity interest (including stock, stock options, and other ownership-interests) in a publicly traded entity that when aggregated with any salary, royalties, or other payments for services (e.g. consulting fees, honoraria, or paid authorship) from such entity for the individual and the individual’s spouse and dependent children over the preceding twelve months, does not exceed $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value; or

f. Salary, royalties or other payments for services (e.g. consulting fees, honoraria or paid authorship) from any non-publicly traded entity that when aggregated for the individual and the individual’s spouse and dependent children over the preceding twelve months, does not exceed $5,000, provided that neither the individual nor such individual’s spouse or dependent children hold any equity interest (including stock, stock options or other ownership interest) in such non-publicly traded entity.

Examples of Unacceptable Conflicts (not all-inclusive):
a. Diverting to outside entities grant or contract support that the college might otherwise receive;
b. Using college resources, including assigned time and facilities (in excess of that allowed for consulting), for private gain without proper compensation to or consent from the college;
c. Using college resources for purchases or payments to any entity in which a faculty or staff member (or other applicable individual under this policy) holds a Significant Financial Interest, without approval of the college;
d. Impeding the dissemination of research information;
e. Using a position of influence or authority to involve other faculty, staff or students of the college in non-college activities without the consent and supervision of the college.

Financial Disclosure

Any individual submitting an application for a grant or contract, and any individuals who are participating in or who are planning to participate in research funded by any external sponsor including all grants, contracts and subcontracts funded by the NIH, must file the required conflict of interest policy disclosure form disclosing all Significant Financial Interests:

a. Prior to the submission of the application, disclosing all Significant Financial Interests over the proceeding twelve-month period;
b. Within thirty (30) days of discovering or acquiring (e.g. through purchase, marriage or inheritance) a new Significant Financial Interest; and
c. At least annually thereafter during the period of the award.

All details should be disclosed. At the time of each filing of the conflict of interest policy, if the individual submitting the grant or contract does not have a Significant Financial Interest, he or she must certify on the form that no potential conflict of interest exists. Any potential conflict of interest that appears on the form must be resolved before the college can approve any initial or subsequent expenditures of any funds under the contract, as applicable.

Procedure

i. All individuals applying for extramurally funded grants or contracts and any individuals who are participating in or who are planning to participate in research funded by any external sponsor including all grants, contracts and subcontracts funded by the NIH, must submit the required conflict of interest
disclosure form to their supervisor, who is responsible for providing a preliminary assessment regarding potential conflicts of interest and a recommendation for action.

ii. The supervisor will sign off and forward the forms to the Chair of Research who will certify that no conflict exists, that sufficient controls are in place to manage and identify conflicts or that the activity constitutes an unacceptable conflict. If necessary, the Chair will develop a memorandum of understanding after meeting with the individual involved in the possible conflict of interest. The MOU will address the potential conflicts of interest and specify the details of a management process to assure that any conflicting interests will be managed, reduced or eliminated. Any management process will be promptly implemented.

iii. With respect to a form submitted in the event of a Significant Financial Interest that is acquired or discovered during the awarded project period, the applicable foregoing procedures must be complete within sixty (60) days of receiving the form from the applicable individual.

iv. To manage possible conflicts of interest due to outside interests, the college may impose conditions or restrictions to manage, reduce, or eliminate potential or actual conflicts of interest disclosed by individuals in a Memorandum of Understanding. The Chair of Research may, in his or her discretion, appoint an ad hoc committee of faculty and administration to review the conflict of interest and disclosures and prepare a MOU to manage any conflict. The ad hoc committee may meet with or ask questions of the affected individual to discuss the process of preparing the MOU. The conditions or restrictions imposed by the MOU may include, among others:
   i. Public disclosure of the private interest
   ii. Independent monitoring of all activities under the grant or contract;
   iii. Modification of such activities; Divestiture of the private interest, and/or;
   iv. Severance of the relationship creating the conflict.

If the individual is dissatisfied with the resolution of a conflict of interest provided through a MOU, the individual may appeal to the ICOM Dean. The decision of the Dean shall be final.

If in any case in which the HHS determines that research funded by any external sponsor including all grants, contracts and subcontracts funded by the NIH or NIH-funded project of clinical research whose purpose is to evaluate the safety and effectiveness of a drug, medical devise, or treatment has been designed, conducted, or
reported by an individual with a conflicting interest that was not managed or reported by the college as required by the FCOI regulation, the college must require the individuals 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.

**Reporting and Record Keeping**

a. The college will maintain records of required conflict of interest policy disclosures for three years after the date of the termination of the externally sponsored activity of the submission of the final expenditures report. If an individual fails to comply with ICOM’s conflict of interest policy, the college will notify the appropriate federal agency sponsoring the activity of the corrective action taken or to be taken.

b. The federal agency may inquire into the college’s procedures and actions regarding conflict of interest in federally funded research, including a requirement for submission of, or review on site of all records pertinent to compliance with appropriate federal law.

c. The Chair of Research will act as the college’s certifying officer for reporting to federal agencies. All conflict of interest policy disclosures and memoranda of understanding shall be maintained in confidential files in the office of the Chair of Research.

d. Subject to it duties to report or to share information with appropriate federal or private funding agencies, as well as pertinent faculty, staff, and administrative personnel, the college will maintain the disclosures required to be made under this policy by individuals in confidence.

**Compliance**

Willful failure to comply with this policy on conflict of interest on extramurally funded programs or to truthfully disclose information on the conflict of interest policy disclosure form by any individual employed or otherwise engaged by the college constitutes a serious breach of personal conduct and college policy. Faculty and staff members failing to comply with this policy are subject to progressive discipline, including discharge for cause.
Approved by:

[Signature]

7/11/17

__________________________________________________________
CAO/Dean

__________________________________________________________
Date