3354.1-45-01.01 Conflict of Interest Procedure (NIH)

(A) Conflict of Interest disclosure and training requirements for National Institute of Health ("NIH") Grants.

a. Financial interest disclosure

i. An COI/FSI Disclosure Form must be filed by the following persons who may, in carrying out their institutional responsibilities, meet the definition of "Investigator" under this policy:

1. Faculty who have been identified as a project director, principal investigator or senior/key personnel (including non-College employee consultants), who are responsible for the design, conduct, or reporting of research on a sponsored project during the past twelve (12) months.
2. Faculty, who are investigators, or key personnel on protocols requiring review (or exemption) by the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) during the past twelve (12) months; and
3. Research staff members and students, who are listed as investigators or senior or key personnel on sponsored projects, or protocols requiring IRB, or IACUC review (or exemption) are also required to comply with these reporting requirements and the following procedures.

ii. Financial interest disclosures must be filed annually. Updates must be made to the disclosure within thirty (30) days if the filing party acquires any new financial interests, external professional activities, or business or financial transactions that were previously unreported, or if changes occur in the circumstances of a previously reported transaction or activity.

iii. Faculty financial interest disclosures containing significant personal financial interests (as defined in this policy) must be reviewed by the project's Authorized Official as identified in the grant application. The College's authorized official(s) designates the individuals who will serve on the Financial Conflict of Interest Committee ("FCOIC), composed of individuals not directly involved in the operations of the project and bear no responsibility for the administration of the project. FCOIC shall determine whether the significant financial interest may be related to the investigator's institutional responsibilities.

iv. Electronic disclosures filed by faculty, staff and students will be automatically routed to the appropriate signatory. The College's authorized official(s) will determine whether a significant financial interest may be related to a participant's institutional responsibilities on a case-by-case basis using the following general considerations:

1. Is the financial interest with a company, foundation or other organization that provides products or services in the investigator's academic discipline - or the area of the study/research?
2. Will the entity likely make use of the scholarly work or research - either directly or indirectly?

3. Is the financial interest with a member of an industry, trade, or advocacy group that funds scholarly work or research in the investigator's discipline or area of study?
4. Does the entity have some other relationship not described above that could be related to or could be affected by the faculty, staff member or student's college responsibilities?

b. Travel disclosure
   i. In addition to financial disclosures, faculty, staff and students who have participated as project directors, principal investigators or senior/key personnel on U.S. Public Health Service ("PHS")-funded research projects in the past twelve (12) months or who reasonably expect to receive new PHS funding during the current year must disclose the occurrence of any reimbursed or sponsored travel related to their institutional responsibilities. Public Health Service agencies include the National Institutes of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), Indian Health Service (IHS), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Administration for Children and Families (ACF), or Administration on Aging (AOA).
   ii. This specific travel disclosure requirement does not apply to the following types of travel:
      1. Travel that is reimbursed or sponsored by a federal, state or local government agency (e.g., travel associated with service on an NIH or NSF or other federal agency study section, site visits, and/or grant peer review panel);
      2. Travel that is sponsored by an accredited U.S. college or university (e.g., travel for providing peer review consultation or speaking engagements);
      3. Travel sponsored by a U.S. academic health center (e.g., speaking engagements);
      4. Travel sponsored by a U.S. research institution that is formally affiliated with a U.S. college or university; or
      5. Travel that is paid for as part of an Office of Sponsored Program sponsored research study/program (e.g., investigator meetings).
   iii. The On-line Electronic Conflict of Interest Disclosure application will also be used for travel reporting. At a minimum, investigators who are required to report reimbursed and sponsored travel must indicate the purpose of the trip, the identity of the sponsoring organization/business, the destination of the travel and the duration of the trip.

c. Training requirement
   i. The federal financial conflict of interest regulations also require that the institution provide formal conflict of interest training to investigators. The FCOIC in consultation with the College's authorized official(s) shall recommend a

formal training process, which will reasonably comply with the applicable federal regulations.

ii. The College's authorized official(s) will be responsible for ensuring the faculty, staff and students complete the required formal conflict of interest training before engaging in research related to any PHS-funded grant and at least every four (4) years and immediately when any of the following circumstances apply:
    1. The institution substantially revises its financial conflict of interest policy in a manner that affects the requirements of investigators;
    2. An investigator is new to the institution; or
    3. The institution finds an investigator that is not in compliance with the institution's financial conflict of interest policy or management plan.

(B) The College's authorized official(s) will review financial disclosures containing significant financial interests for possible conflicts of interest within 15 days of receipt. If the College's authorized official(s) determine(s) that a disclosed financial interest or activity presents a potential conflict of interest related to a particular research project, the College's authorized officials will forward to the *FCOIC* for review. Disclosures and documentation of plans to minimize or manage possible conflicts of interest will be maintained in the project's files by the College's authorized official(s).

a. The *FCOIC* will review significant personal financial interests related to an investigator's activities, which are reported to the College's authorized official(s). The *FCOIC* will determine whether a financial interest with an external entity (or travel sponsored by an external entity if travel disclosure is required) is related to a particular research project or protocol on a case-by-case basis using the following general considerations:
    i. Is the financial interest with a sponsor, subcontractor, supplier or lessor of goods, materials, proprietary information, services, or facilities of the investigator's current or proposed research?
    ii. Will the entity likely make use of the research or scholarly work - either directly or indirectly?
    iii. Is the financial interest with a member of an industry, trade, or advocacy group that funds the involved research or scholarly work?
    iv. Is the entity manufacturing, commercializing or developing a product that is being used, evaluated, or further developed by the research or scholarly work at issue?
    v. Will the entity receive materials, data, or other information from the investigator?
    vi. Is the entity a competitor of the investigator's sponsor?
    vii. Does the entity have some other relationship not described above that could be related to or could be affected by the investigator's college responsibilities?

b. If the *FCOIC* determines that a financial interest (or travel sponsored by an external entity when travel disclosure is required) is reasonably related to an investigator's institutional responsibilities, the *FCOIC* will then review the potential impact of the financial interest on the following:
    i. The integrity of the research;
    ii. Risks to the rights and safety of human research subjects;

iii. Risks to the rights and obligations of participant's in research;
iv. The availability of research results to the scientific community for use in the public interest;
v. The appearance of a conflict of interest; and
vi. The perception to the College community (In agreements and contracts related to the arrangements under review by *FCOIC*, the College will require terms that ensure the freedom of timely academic publication, uphold the rights and responsibilities of students and trainees, and ensure appropriate reporting of inventions and assignment of intellectual property rights.)

(C) Conflict of interest management standards

a. Upon completing its review, *FCOIC* will recommend that the personal financial interests of the individual in a financially interested company or entity are either eliminated or managed, subject to the development of a formal conflict management plan developed by the College's authorized official(s). The *FCOIC* will render a final decision and will communicate that decision, along with the recommended management plan to the involved investigator in writing.
b. Conflict of interest management plans
    i. Conflict of interest management plans may include one or more of the following requirements:
        1. Disclosure: public disclosure of potential financial conflicts of interest is required in all management plans and includes the following:
            a. public disclosure of the financial interests of the investigator and of the College, if applicable, in all relevant publications, presentations (whether or not academic), including presentations at the level of the individual's primary department or higher
            b. disclosure to the appropriate co-investigators, members of the laboratory or research group, and/or participants
            c. disclosure of an investigator's financial interest on human subjects consent forms
        2. Restriction on equity: investigator owned/controlled options, warrants, and similar instruments not be exercised without prior disclosure to the authorized official(s) and must be in accordance with any agreed upon conditions outlined in the conflict of interest management plan (Researchers should be aware that separate Securities and Exchange Commission and other state and federal regulations may apply to their ownership of such equity. Obtaining the necessary information and complying with such regulations is the responsibility of the individual researcher.)
        3. Limiting the role of the investigator with a financial interest: requiring that the role of the investigator with a significant financial interest be limited in some way; in research involving the use of human or animal subjects, investigators are generally not permitted to:
            a. serve as principal investigator

b. analyze data
c. determine whether potential subjects are eligible for enrollment
d. solicit consent or determine whether an adverse event report is required

4. Oversight: appointment of a disinterested individual or group to monitor the relevant research activity; an oversight committee might be charged with:
    a. reviewing abstracts and manuscripts before they are submitted for publication to ensure that the research is conducted and reported according to scientific and ethical standards and that conflict of interest management measures are observed
    b. meeting at specific intervals to review protocols, subject accrual, subject safety and complications, review the resulting project data before publication, and other issues as appropriate
    c. Oversight committees are required in management plans involving human subjects research where the principal investigator has a significant financial interest in the research and the research involves greater than minimal risk to human subjects
5. Divestiture: allow arrangements to go forward contingent upon sale or disposal of specified financial interests to eliminate or reduce the financial conflict of interest by a certain date
6. Severance of relationships that heighten or create actual or potential conflicts: relinquishing a seat on a board of directors or terminating a consulting arrangement with an outside entity in order to reduce the financial or fiduciary conflict of interest.

ii. The College's authorized official(s) and FCOIC may recommend other conditions or restrictions on the proposed arrangements if, in its view, such conditions will contribute to the elimination, reduction, or management of the conflict of interest. For conflict of interest management plans involving human subject research, the FCOIC will make a recommendation to the IRB.

iii. A written update will be required annually for all active personal financial conflict of interest conflict management plans. Significant financial interests disclosed or discovered after a funded research project has begun must be reviewed and approved and any necessary conflict of interest management plans must be in place within sixty (60) days.

iv. As required by (PHS) rules, the College must report potential financial conflicts of interest involving federally-sponsored research to the sponsor prior to the expenditure of federal research funding, or within sixty (60) days of the College identifying potential financial conflicts of interests after a project has begun. The conflict of interest administrator and the Offices of Research Compliance and Sponsored Programs will be responsible for reporting potential financial conflicts of interest to the PHS, National Science Foundation or other sponsors,

along with additional information concerning the FCOIC-approved management plan that may be requested by the sponsor. PHS regulations require that the College also submit an annual conflict of interest update to the agency at the time the investigator's annual project report/update is due.

v. PHS regulations also require that the College provide the following information within five (5) business days to a public records request for information disclosed by faculty and staff investigators under this Policy: the investigator's name; the investigator's title and role with respect to a specific research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the value of the significant financial interest within the following dollar ranges ($0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

vi. If an investigator fails to disclose a significant financial interest that the FCOIC determines to be a financial conflict of interest related to a particular research project, if the College fails to review or manage a financial conflict of interest, or if an investigator fails to comply with the terms of a conflict of interest management plan, the College will within one hundred and twenty (120) days complete a retrospective review of the investigator's research to determine whether there was any bias in the design, conduct or reporting of the research. The College's authorized official(s) will keep a record of the retrospective review in the project files and make any necessary reports to funding agencies in accordance with federal regulations.

vii. In cases where the FCOIC or a federal sponsor determines that a financial conflict of interest was not managed or reported by the College as required by federal law, the investigator involved will be required 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.

(D) Review and management of potential conflicts of interest in human subjects research

a. Financial interests in human subject research require special scrutiny. Such interests may present real or perceived risks to the welfare and rights of human subjects, in addition to presenting risks to research integrity.

b. The College presumes that faculty may not participate as principal investigators in greater than minimal risk research projects involving human subjects (as determined by the IRB) while they have a significant financial interest in the research project or in a financially interested company. Limited exceptions may be made in specific cases when, in the judgment of the FCOIC, individuals holding significant conflicting financial interests provide the FCOIC with a compelling justification (the investigator is the only researcher at the College who possesses the expertise, know-how, or the necessary technical or procedural skills) in writing for being permitted to simultaneously hold the financial interest and participate in the human subjects research project. Principal investigators who seek exceptions to the above presumption are required to obtain a

letter of support from the College's authorized official(s) , noting that the College supports the compelling justification and will provide the resources necessary to manage the potential financial conflict of interest. Such resources may include, for example, the cost of external review boards, data integrity consultants or committees, or subject safety monitoring committees that may be needed to ensure the integrity of the research and the protection of human subjects involved in the research.

c. Investigators who hold financial interests in companies commercializing technology owned by the College may not serve as principal investigators in sponsored research projects funded by technology commercialization companies in which they have a personal financial interest if the projects involve the use of human subjects or veterinary clinical trials involving the use of animals.
d. The FCOIC will review reports of all significant financial interests in proposed human subjects research projects. Information concerning a faculty, staff, or student's relationship to the outside sponsor will be communicated in writing to the appropriately convened IRB, including the proposed management plan. To ensure the primacy of the welfare and rights of the human subjects, the convened IRB will have the full and final authority for implementing the decision concerning the role of the concerned individual in the human subjects research protocol. Accordingly, the convened IRB will communicate its decision concerning participation in the human subjects research protocol to the investigator and will provide a copy of that communication to the FCOIC.
e. Conflict of interest issues associated with research projects involving human subjects that are determined by the IRB to be exempt are subject to the FCOIC review.
f. The FCOIC's recommendation may involve either prohibition or management.
    i. Prohibition: If, upon reviewing specific information provided by the investigator with the relevant financial interest, FCOIC believes that a conflict of interest is incompatible with human subjects research, it will recommend to the appropriate IRB that the involved investigator be required to eliminate the relevant financial interest before beginning the project or be barred from participating in the research.
    ii. Management: In a limited number of cases involving significant financial interests, if the FCOIC concludes that the justification provided by the investigator is sufficiently compelling and that the conflict of interest can be managed, it will recommend specific project-related management measures to the appropriate IRB.
g. In all cases involving human subjects research in which informed consent is required and an involved investigator has a relevant financial interest of any magnitude, a financial disclosure statement including the name of the financially interested individual and description of the source and nature of the relevant financial interests must be included in the consent process/form.
h. Additional project-related management measures may include prohibiting the investigator from one or more of the following:
    i. Serving as principal investigator
    ii. Analyzing data
    iii. Determining whether potential subjects are eligible for enrollment

iv. Soliciting consent
v. Determining whether an adverse event report is required.

i. The FCOIC's recommendation, accompanied by a description of the nature and magnitude of the potential conflict of interest, will be communicated in writing to the appropriate IRB. The IRB, which is responsible for ensuring the ethical acceptability of the research, will evaluate the recommendations of the FCOIC and decide whether to:
    i. Accept the recommendations
    ii. Accept the recommendations with additional management measures prescribed by the IRB
    iii. Conclude that the human subjects research cannot proceed. The FCOIC will communicate its determination to the investigator in writing. Upon concluding its evaluation, the IRB will inform the FCOIC of its determination, and the IRB's decision is final.

(E) V. Legal Obligations

a. Investigators should be aware that financial interests in companies or external entities may result in personal or institutional obligations under federal and state laws, formal contractual requirements of commercial research sponsors, as well as with conflict of interest requirements of accreditation entities. The College is also required to comply with federal conflict of interest regulations, including maintaining a written and enforced financial conflict of interest policy, managing, reducing or eliminating identified conflicts, and reporting identified conflicts to federal agencies within prescribed timeframes.
b. When the institution carries out federally-funded research through a subrecipient (e.g., subcontractors or consortium members), the institution must also meet applicable agency requirements to ensure that subrecipient investigators also comply with the federal conflict of interest regulations.
c. The IRB, in consultation with the Offices of Legal Services, will be responsible for complying with sponsor and regulatory agency reporting requirements, as well as the maintenance of conflict of interest records, pursuant to applicable federal and state requirements and the College's record retention policies.
d. Public Health Service (PHS)/National Science Foundation (NSF)
    i. Individuals who receive research funding from either the Public Health Service (PHS) (including the National Institutes of Health) or National Science Foundation (NSF) must comply with agency regulations, which ensure that personal financial interests do not affect the design, conduct, or reporting of federally-funded research. The PHS regulations on "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (42 C.F.R. Part 50, Subpart F) and "Responsible Prospective Contractors" (45 C.F.R. Part 94) can be found at http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf. The NSF conflict of interest policy can be found in Chapter V, Grantee Standards, Section 510, Conflict of Interest Policies, in the NSF Grant Policy Manual at http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510
e. Food and Drug Administration

i. The FDA requires applicants, under its regulations at 21 CFR Part 54, to submit to the FDA a list of clinical investigators who conduct covered clinical studies and to certify the absence of and/or disclose the existence of certain financial arrangements. The FDA's most recent guidance is available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM256525.pdf (May 2011).

ii. In cases where an individual investigator holds an Investigational New Drug application (IND) for a study drug, or an Investigational Device Exemption (IDE) for an experimental study device, the investigator him/herself may be required to personally comply with the above FDA conflict of interest reporting requirements and should consult the FDA or legal counsel at the Office of Legal Services concerning applicable rules and regulations.

iii. The IRB, in consultation with the Offices of Legal Services, will be responsible for complying with sponsor and regulatory agency reporting requirements, as well as the maintenance of conflict of interest records, pursuant to applicable federal and state requirements and the College's record retention policies.

f. Securities and Exchange Commission (SEC)

i. The SEC enforces regulations concerning equity ownership, including insider trading, which may affect investigators who hold equity in research sponsors. For additional information, investigators should seek advice from their personal legal counsel or the Office of Legal Services. It is the obligation of the financially interested individual to ensure that s/he complies with applicable SEC regulations.

g. Other Sponsors

i. Outside sponsors may also have specific requirements regarding investigators who have personal interests with the sponsor. For more information, contact the College's authorized official(s) or the IRB.

h. Accreditation Entities

i. Outside academic accreditation entities and programs may have additional requirements and standards related to potential conflicts of interests and significant financial interests. The College's authorized official(s) and investigators affiliated with the project must identify and adhere to accreditation standards throughout the award period.

(F) Appeals

a. If an investigator believes that a determination made by the FCOIC is not appropriate or is based on erroneous information, the investigator may request reconsideration by FCOIC by submitting a written request to the chair of the FCOIC. If, after a second review by FCOIC, the investigator still wishes to appeal the FCOIC's decision, the investigator may appeal to the College's Office of Legal Services. The College General Counsel or the General Counsel's designee's decision is final.

b. Investigators who believe that the conflict of interest management measures adopted by an IRB are not appropriate or are based on erroneous information must follow applicable IRB procedures for requesting additional review. Decisions made by the IRB are final.

(G) Sanctions for Failure to Comply

a. Failure by faculty to comply with the conflict of interest policy or procedures, or with FCOIC management plans, will be subject to review by the faculty member's supervising dean. If the supervising dean determines that a violation of College rules may have occurred, the dean may refer the faculty member for disciplinary review pursuant to College policies and procedures. Failure by College staff or students to comply with the conflict of interest policy or procedures, the respective collective bargaining agreement, or with FCOIC management plans, will be subject to review by Human Resources (for staff) or the Office of Learning & Success (for student) policies.

Effective Date: January 27, 2022