Financial Conflict of Interest (FCOI)

for

Kenyon College Faculty Members and Administrative Staff Intending to Seek Federal Funding

To ensure proper and timely management of actual or potential conflicts of interest, the U.S. government requires Kenyon to implement and administer a financial disclosure policy for all investigators seeking federal grants, including provisions for training. The College's FCOI policy meets the standards* set forth by the National Institutes of Health:

NIH requires recipient institutions and investigators (except Phase I SBIR/STTR applicants and recipients) to comply with the requirements of <u>42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting</u> <u>Objectivity in Research for which PHS Funding is Sought"</u> (FCOI Regulation), as implemented in the 2011 Final Rule for grants and cooperative agreements.

*Kenyon has opted to follow NIH's comprehensive policy guidelines because other federal funding agencies have either adopted or are expected to adopt similar standards.

These requirements are intended to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of federally-sponsored research or cooperative agreements will be free from bias resulting from any conflicting financial interest of an investigator.

Further information can be found on the NIH website: <u>FCOI Frequently Asked Questions</u> and/or <u>Financial Conflict of Interest</u> pages.

Key Elements (full FCOI policy below)

Kenyon requires project directors (PDs)/principal investigators (PIs) to disclose all "significant financial interests" on his/her/their part and/or on the part of his/her/their immediate family members that include:

- \$5,000 or more in payments gained in the 12-months prior to disclosure from and/or equity interests in publicly-traded entities, <u>or;</u>
- any equity interest in non-publicly traded entities, or;
- reimbursed or sponsored travel such as a conference trip paid for by corporate or other external organizations.

All relevant financial interests related to a PD's/PI's institutional responsibilities, not just his/her/their federal grant(s), must be disclosed to the College, with two exceptions:

- income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an institution of higher education;
- 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.

FCOI Disclosure Statement Form can be found on the Office for

Sponsored Faculty Projects website: https://www.kenyon.edu/sponsored-faculty-projects/

POLICY: Financial Conflict of Interest (FCOI)

As set by relevant federal regulations, including:

- National Institutes of Health: <u>Financial Conflict of Interest</u> within NIH's Policy & Compliance/ Grants & Funding pages
- National Science Foundation: <u>Conflict of Interest Policies</u> in PAPPG 18-1 Chapter IX-Grantee Standards

Federal Register, Part IV, DHHS, August 25, 2011: <u>42 CFR Part 50, 45 CFR Part 94</u>

Failure to comply with this policy may risk suspension by the funding agency not only of some or all of an individual PD/PI's current and future federal research funding, but also that of <u>any</u> Kenyon grantseeker.

Preamble

Faculty members, academic staff, or other Kenyon project directors applying for grants are often involved with other organizations and the College wants to ensure these individuals are free from conflicts of interest. Although potential conflicts will likely be deemed inconsequential, it's incumbent upon **all grant applicants** to ensure that the College is made aware of any connections that could represent a conflict of interest. To that end, Kenyon **requires** applicants seeking government agency support to: **(1) review** this policy; **(2) disclose** any possible business relationships that might reasonably be or become a conflict of interest for the PD/PI and/or his/her/their spouse/dependent children; and **(3) acknowledge** by signature that he/she/they are in accord with the letter and spirit of this policy.

Disclosure

All Kenyon faculty members, administrators, academic staff, or other College investigators/project directors are required to disclose those significant financial interests (a.k.a. substantive business relationships) that could directly influence or affect the design, conduct or reporting of federally-funded research grants or contracts. This applies to all PDs/PIs seeking support **and** to their spouses, partners, and/or dependent children. Disclosures must be submitted prior to application to the Office for Sponsored Faculty Projects (OSFP) under the auspices of the Provost, who serves as Kenyon's *Institutional Grants Administrator*, known hereby as "Provost/IGA".

Financial conflicts of interest are frequently subjective in nature, and the College expects faculty members, academic staff, et. al., to be mindful of the possible effect of outside activities on the integrity of their decisions and on their ability to fulfill their obligations to the institution and/or to funding agencies. As potential or actual financial conflicts arise, the Provost/IGA, in consultation with the Vice President for Finance and OSFP, will determine which conditions or restrictions might be imposed to manage, reduce, or eliminate them. If unsure of the appropriateness of listing a particular relationship, the grant seeker should first consult with OSFP, which will involve the Provost as necessary.

A. Significant Financial Interest

Definition: a Significant Financial Interest (SFI) consists of interests that reasonably appear to be related to the PD's/PI's institutional responsibilities, including all research, teaching and/or service to the College. Specifically, this includes:

a. With regard to any *publicly* traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure *and* the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000.

Remuneration includes any salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

b. With regard to any *non-publicly* traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, *or* when the PD/PI (and/or spouse, partner, or dependent children) owns **any** equity interest, regardless of dollar value.

c. With regard to intellectual property rights and interests (e.g. patents and copyrights), an SFI exists upon receipt of income related to such rights and interests.

d. With regard to any occurrence of reimbursed or sponsored travel (i.e., that which is paid on behalf of and not reimbursed to the PD/PI so that the exact monetary value may not be readily available) related to their institutional responsibilities also must be disclosed, with the exception of any travel reimbursed or sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research center affiliated with an institution of higher education. The PD/PI must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, must be furnished upon request.

Exclusions: the term "Significant Financial Interests" do *not* include:

a. Salary, royalties, or other remuneration from Kenyon College;

 b. Income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; c. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education;

d. Income from service on advisory committees or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with institutions of higher education.

B. <u>Timing of Required Disclosures</u>

Investigators must provide all required financial disclosures **at the time a proposal is submitted**.

In addition, Investigators must **update** those financial disclosures:

a. Within 30 days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new SFI; and,

b. Annually within the period of the award, beginning with the anniversary date of the original disclosure.

C. <u>Review of Financial Disclosures</u>

The following process applies to financial disclosures submitted by PDs/PIs.

Determination of Financial Conflicts of Interest: Initial review of disclosed Significant Financial Interests will be conducted by the Office for Sponsored Faculty Projects (OSFP), under the auspices of the Provost/IGA, to ascertain:

a. Whether SFIs relate to federally-funded research;

- b. If so, whether a financial conflict of interest exists;
- c. And if so, in consultation with the Provost/IGA and the Vice President for Finance, determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflicts.

The Provost/IGA reserves the right to request, depending on the scope of the potential conflict, that additional staff or faculty serve on an *ad hoc* review committee to assist in its timely review.

Management of Financial Conflicts of Interest: If the Provost/IGA determines that an SFI constitutes a Financial Conflict of Interest, the College's extant COI Committee will convene and review the research, the financial interests in question, points of conflict, and initiate a plan for management with a combination of elements it deems most conducive to the continued objective pursuit of research.

The Management Plan may include (but is not limited to):

- a. monitoring of research by independent reviewers;
- b. modification of the research plan;
- c. disqualification from participation in the portion of the federally-funded research that would be affected by SFIs;
- require divestiture of SFIs if the research in question cannot be modified to eliminate conflicts of interest;
- e. severance of relationships that create conflicts;
- f. public disclosure of Financial Conflicts of Interest.

The PD/PI will be consulted regarding implementation of the Management Plan **and** must agree to the parameters of the plan, in writing, before research can proceed. If

the COI Committee and the PD/PI cannot agree upon a management plan, the relevant regulatory bodies and funding agencies will be notified.

Kenyon's Institutional Obligations

Pursuant to the FCIO federal regulations above, the College must:

- Provide public accessibility: FCOI policy on the <u>OSFP website</u>.
- Inform PDs/PIs of regulation, institutional policy, SFI disclosure responsibility, and training requirements. The OSFP will obtain and file signed FCOI Disclosure Forms prior to proposal submission to NIH, NSF, et. al. The OSFP will also email annual reminders for investigators to update their FCOI status and will coordinate, track and verify investigator training.
- Provide access to FCOI training.
- Incorporate language as part of *subrecipient agreement* contracts that establish FCOI policy.
- Designate an *Institutional Grants Administrator* (Provost, acting through OSFP) to (a) solicit and review disclosure statements from each investigator planning to participate in federally-funded research at time of application and annually, (b) oversee guidelines to identify conflicting interests, (c) develop and maintain FCOI management plans.
- Provide *disclosure* of FCOI to NIH prior to expenditure of funds, annually during the period of the award (at time of annual progress report or extension request, via eRA Commons FCOI Module), and within 60 days of a PD/PI discovering or acquiring a new SFI.
- Maintain *records* of all PD/PI disclosures of financial interests and of the College's review of and response to such disclosures, for at least three years from submission of final expenditures report; provide initial and ongoing reports per NIH specifications through the eRA commons FCOI Module; make information available upon federal agency request. The OSFP will collect these records, which

will be added to investigators' personnel files in Kenyon's Office of Human Resources.

- Respond, within 120 days of determination, to *non-compliance* by completing and documenting a retrospective review of the investigator's activities and NIH-funded research project to determine if there was bias in design, conduct, or reporting.
- Address these particulars if/when a management plan for FCOI Reporting is needed: 1) role and principal duties of the conflicted PD/PI in the research project; 2) conditions of the plan; 3) how the management plan design will safeguard objectivity in the research project; 4) confirmation of PD/PI agreement to the plan; 5) how the plan will be monitored to ensure investigator compliance (following guidelines of Federal Register Vol. 76, No. 165, section 50.605 "Management and reporting of financial conflicts of interest").

Training: Kenyon is responsible for providing access to appropriate FCOI training.

Investigators on NIH/PHS-funded projects (*including senior/key*

personnel): Must complete or have completed training on Kenyon's FCOI policy (and make the disclosures described above) prior to submission of any proposals. FCOI training will include an approved online tutorial (NIH, CITI, etc), with certificate verifying completion submitted to the OSFP. This also applies to all investigators found non-compliant and to those who are new to Kenyon.

Investigators on non-NIH/PHS projects: Training is optional but strongly recommended for investigators seeking funding from NSF and/or other federal agencies, as well as any research sponsored by a private, for-profit entity.

Repeat training: Group training of active NIH/PHS-funded investigators, consisting of a mandatory workshop, will be repeated (i) every four years and (ii) on any occasion when Kenyon revises its FCOI policy and/or procedures in any manner that affects the requirements of Investigators.

College Reporting: The OSFP, under the direction of the Provost/IGA, will compile regular reports for review by the Audit Committee of the Kenyon College Board of Trustees.

Indemnity: Participation by Kenyon faculty or staff members on a (F)COI review committee, at the request of the Provost/IGA, is to be considered part of their institutional responsibilities and are thereby indemnified by the College. Participants must abide by strict confidentiality in these matters.

Enforcement: The College will establish appropriate mechanisms for enforcement of this policy, including sanctions as appropriate. Disciplinary proceedings initiated in connection with this policy will be conducted in accordance with the Kenyon College *Faculty Handbook* or the Kenyon College *Staff Handbook*. All relevant regulatory bodies and funding agencies will be promptly informed of any disciplinary sanctions.

Disclosure Statement: Copies are available online <u>here</u>. This must be completed by all senior personnel who are submitting proposals to a federal funder. The certification page of a proposal cannot be signed until forms for **all** investigators are submitted to the OSFP. By signing this form, the applicant(s) certifies that he/she/they have read Kenyon's FCOI, have completed documented training, and that he/she/they have, to the best of the applicant's knowledge, made all required financial disclosures. In the event that investigators become aware of situations contradictory to those disclosures, the applicant will immediately notify the OSFP and make full disclosure of any conflict, real or potential.

Subrecipients: Kenyon is responsible for ensuring that all subrecipients are compliant with the applicable federal regulations regarding Financial Conflicts of Interest. To that end, the College will enter a written agreement with each subrecipient that specifies whether this policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient investigators. This agreement will also specify the timeline for reporting financial conflicts by subrecipients to Kenyon.

Sanctions: In the event an investigator refuses to comply with the College's FCOI policy, sanctions may include, but are not limited to, one or more of the following:

- Letter of admonition;
- Temporary suspension of access to active research funding, either for a fixed term or pending completion of a remediation plan;
- Temporary suspension of rights to apply for internal and external research funding as a PD/PI, either for a fixed term or pending completion of retraining and remediation;
- Investigation and mitigation of possible research bias resulting from improperly disclosed SFIs, and reporting of corrective action to the relevant funding agency(ies);
- Inquiry into possible research misconduct in accordance with the Kenyon's policies and procedures;
- Non-renewal of appointment, as per the terms and procedures outlined in the *Faculty Handbook*;
- Involuntary termination of employment, as per the terms and procedures outlined in the *Faculty Handbook*.

These sanctions must not be construed to contradict or supersede any disciplinary policies and procedures detailed elsewhere in the *Faculty Handbook*.

Questions: William Billiter (billiter1), Executive Director of OSFP and Strategic Initiatives, or Deedra Sukrungruang (sukrungruang2), Assistant Director of OSFP.