

KEYSTONE NANO NIH FINANCIAL CONFLICT OF INTEREST POLICY

9-2022

SCOPE: Company Wide. The Compliance Program (CP) covers all projects conducted with government funds in Keystone Nano (KN) and is applicable to all employees, sub recipients, consultants, or any other covered organizations or persons involved in governmental awards.

PURPOSE: Under this policy, Keystone Nano strives to ensure that all work performed under Government Awards meets the highest standard of integrity and is free of any real or perceived conflicts of interest that could harm patients, the reputation of Keystone Nano, the governmental agency providing the funding, and/or external partners. As Keystone Nano must comply with government regulations when making expenditures with Government Awards, this policy governs the disclosure of individual financial interests and the management and reporting of individual financial conflicts of interest in Governmental Awards. It is intended to comply with the requirements of federal regulations, including, but not limited to, the conflict of interest regulations of the U.S. Department of Health and Human Services Public Health Service (“the PHS FCOI Rules”) as found in 42 CFR Part 50 603, 604, 605, and 606 collectively referred to as the “Financial Conflict of Interest Rules”.

DEFINITIONS FOR THIS POLICY:

Conflict Management Plan: the document specifying the actions to be taken to manage a Financial Conflict of Interest.

External Partner: a consultant, subcontractor, university co-investigator, or sub-recipient performing work under a Government Award who is not employed by Keystone Nano

Government Award: government grants and cost reimbursement contracts including research grants or contracts, and other types of government financial assistance (e.g., cooperative agreements, loans, loan guarantees, property, donated supplies, and direct appropriations) that Keystone Nano receives directly from government agencies or indirectly from pass through entities.

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of a research study or other government funded project.

Immediate Family Member: a spouse and dependent children.

Investigator:

(1) For PHS-funded research: the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

(2) For other Government Awards: project staff directly involved in management of the project or who hold key responsibilities on the Government Award. Typically, these would be individuals specifically named to a Government Award or whose participation is key to the success of the project.

Institutional Responsibilities: An Investigator's professional responsibilities on behalf of Keystone Nano, which may include, but is not limited to: research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Public Health Service (PHS): a division of the Department of Health and Human Services, consisting of the following agencies: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

Research: a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research.

Remuneration: salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorships).

Significant Financial Interest:

(1) A financial interest consisting of one or more of the following interests of the Investigator or their spouse or dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(i) the value of any remuneration received from a public entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000; or

(ii) the value of any remuneration received from a non-publicly traded entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or their immediate family) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests in excess of \$5,000.

(2) Investigators must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities in excess of \$5,000. The disclosure will include, at a minimum, the following details: (i) the purpose of the trip; (ii) the identity of the sponsor/organizer; (iii) the destination; and (iv) the trip duration. (This disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency located in the United States (US), a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a US Institution of higher education.)

(3) A significant financial interest does not include the following:

- Salary, royalties, or other remuneration paid by Keystone Nano to the Investigator if the Investigator is currently employed or otherwise appointed by Keystone Nano;
 - Intellectual property rights assigned to Keystone Nano and agreements to share in royalties related to such rights;
 - 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;
 - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency located in the US, a US institution of higher education as defined in an academic teaching hospital, a medical center, or a research institute that is affiliated with a US institution of higher education; and
 - Income from service on advisory committees or review panels for a federal, state, or local government agency located in the US, or a US Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

TRAINING AND EDUCATION REQUIRED

Investigators must complete training regarding this policy and the applicable regulations at the following times: (i) upon becoming an Investigator for Keystone Nano; (ii) before performing work under a Government Award; (iii) when this policy is revised to alter the responsibilities of an Investigator; (iv) and at least every four years. In addition to KN resources NIH resources and tutorials are available to become knowledgeable about FCOI and the appropriate steps required by the company.

At these times each investigator will review: (i) KN's policy, (ii) the responsibilities of the investigator's disclosure responsibilities, and (iii) federal regulations governing FCOI, and (iv) if an investigator is not in compliance with the company's policy or management plan.

DISCLOSURE, REVIEW AND MONITORING

It is the policy of Keystone Nano to comply with the Financial Conflict of Interest Rules ("FCOI Rules") to ensure that the work performed under Government Awards is carried out in a manner that is free from any bias which may result from financial conflicts of interest. All Investigators for Government Awards must disclose any Significant Financial Interests (SFI) to Keystone Nano. Investigators must complete or update the company's disclosure survey at least annually during the period of the award and must disclose any new SFI's within thirty days of discovering or acquiring the SFI. Investigators also must ensure that the disclosure survey is completed or updated no later than the time of application for a Government Award.

If Keystone Nano determines that a SFI constitutes a Financial Conflict of Interest ("FCOI"), Keystone Nano will establish and monitor a Conflict Management Plan ("CMP") to manage or eliminate the conflict of interest. The CEO or upon delegation the COO of the company will be the conflict of interest official responsible for managing the conflict-of-interest process for Government Awards. No Government Award funds may be expended unless the Conflicts

Manager has determined that no FCOI exists or that any FCOI is manageable in accordance with the terms of a CMP that has been adopted and implemented in accordance with the procedures set forth in this policy.

Duty to Cooperate

If the conflict of interest official requests additional information from an Investigator to assess whether a SFI constitutes a Financial Conflict of Interest, (including but not limited to documents relating to the SFI), the Investigator must cooperate with the request. If a CMP is implemented in connection with a SFI, the Investigator must comply with the CMP. Compliance with the requirements of this policy is a condition of employment with Keystone Nano for employed Investigators and a condition of participating in Government Award projects as an External Partner. Failure to comply may result in appropriate sanctions.

ELEMENTS OF PROCEDURE

This procedure is for use by Keystone Nano employees and External Partners that do not have their own FCOI policy.

TRAINING REQUIREMENTS

- 1) KN requires each participating investigator or researcher to review:
 - (a) Institution's policy
 - (b) Investigator's disclosure responsibilities
 - (c) Federal regulation

- 2) Each PHS-supported investigator shall complete FCOI training:
 - (a) Prior to engaging in research related to any PHS-funded grant
 - (b) At least every 4 years
 - (c) Immediately, if:
 1. Institution revises its FCOI policy that affects requirements of Investigators

2. An Investigator is new to an Institution
 3. An Investigator is not in compliance with the policy or management plan
 4. Before the expenditure of funds under a Government Award, Investigators must complete the training on Keystone Nano's FCOI Policy.
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- 3) All external investigators must complete FCOI training required under the policy. Training can either be completed using the NIH FCOI tutorial found at: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> or CITI COI training found at: <https://about.citiprogram.org/en/homepage/> .
 - 4) Training must be documented by submitting the Government Award FCOI Training Certification form to Keystone Nano Administration. The required training is valid for four years; however, Investigators are required to certify annually that they understand and have complied with their responsibilities under Keystone Nano's Government Awards FCOI Policy.
 - 5) After the training is completed, the Investigator will complete the Government Award FCOI Questionnaire. This survey must be completed no later than the time of application for a Government Award and before any funds are expended. It also must be updated as required by the policy.
 - 6) The principal investigator/project director will complete the Government Award Approval form, which requires verification that those meeting the definition of Investigator and External Partners have been informed of the requirement to comply with this policy.
 - 7) The Investigator must report and update their Government Award FCOI Questionnaire when he/she is a recipient of sponsored travel. The Investigator will disclose: the purpose of the trip; the name of the entity that

paid for the travel; the travel destination; the duration of the trip; the dates of the travel; and if known, the approximate value of the Sponsored Travel.

- 8) If the CEO Manager determines a FCOI exists, he/she will create a draft CMP. The draft CMP will be presented to the KN Compliance Oversight Committee (KN COC) for consideration and approval. The KN COC will act as the Conflict-of-Interest Committee for purposes of Government Awards.
- 9) The actions taken by the KN COC will be documented in the KN COC meeting minutes. The CEO Manager will ensure that CMP's are properly implemented and will monitor compliance with CMP's on an ongoing basis. The KN COC will review the status of established CMP's at intervals determined by the KN COC and indicated in the CMP, and will have oversight responsibility for the enforcement of CMPs and compliance with this policy.
- 10) Each Investigator under a CMP must comply fully and promptly with the CMP, and each person identified in the CMP as having responsibility for monitoring compliance with the CMP must carefully and fully monitor that compliance.
- 11) For PHS-funded projects, CEO will disclose the FCOI and CMP to the PHS awarding component before the expenditure of any federal funds.
- 12) For PHS-funded projects, Keystone Nano will be provide FCOI information available to those who submit a request by sending an email to jdavidson@KeystoneNano.com or by writing CEO at the address below. Responses will be sent within five business days.
- 13) KN COC will regularly evaluate compliance with this policy and will review the effectiveness of CEO's conflict of interest management program,

including a review of the implementation and effectiveness of these procedures.

REPORTING REQUIREMENTS TO NIH

- 14) KN's Compliance Officer will send initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the Institution and its subrecipients, if applicable, as required by the regulations.
 - a. Prior to the expenditure of funds
 - b. Within 60 days of identification for an Investigator who is newly participating in the project
 - c. At least annually (at the same time when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at the time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project
 - d. Following a retrospective review to update a previously submitted report if appropriate.
- 15) KN's Compliance Officer will promptly notify the NIH if bias is found in the design, conduct, or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation.
- 16) KN's Compliance Officer will insure the policy and or procedures includes all reporting elements as required by the regulation.
- 17) KN's Compliance Officer will notify the NIH promptly if an investigator fails to comply with the company's FCOI policy or a FCOI

management plan appears to have biased the design, conduct, or reporting of the NIH funded research.

- 18) KN's Compliance Officer is required to notify the NIH promptly and take corrective action for noncompliance with the Institution's policy or the management plan.

MAINTENANCE OF RECORDS

- 19) Keystone Nano will keep records related to FCOI and the related CMP for the longer of at least three years from the submission of the final expenditures report, or where applicable from other dates specified in 45 CFR 75.361 for different situations.
 - a. the date of creation;
 - b. the date of termination or completion of the Government Award and submission of the final expenditure report for the Government Award identified in the disclosure statement;
 - c. the date of final resolution of any investigation, audit, or similar action involving the records; or
 - d. the date required to be in compliance with Keystone Nano's Record Retention policies.

ENFORCEMENT MECHANISMS AND REMEDIES AND NONCOMPLIANCE

- 20) KN's employee agreements and contracts establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance. 42 CFR 50.604(j)
- 21) KN establishes a policy requirement to complete and document retrospective reviews within 120 days of the Institution's determination of

noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation. 42 CFR 50.605(a)(3)

- 22) KN establishes a policy and procedure to ensure that in any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to:
- a) Disclose the FCOI in each public presentation of the results of the research, and
 - b) To request an addendum to previously published presentations

SUBRECIPIENT REQUIREMENTS

- 23) Each subrecipient will be required to have their own FCOI policy and requirements, or to agree to comply with KNs policy.
- 24) Where applicable KN will establish, via a written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient.
- a) If applicable, obtain a certification from the subrecipient that its FCOI policy complies with the regulation.
 - b) If applicable, include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows the awardee Institution to report identified FCOIs to the NIH as required by the regulation.

- c) Alternatively, if applicable, include in the written agreement a requirement to solicit and review subrecipient Investigator disclosures that enable the awardee Institution to identify, manage and report identified FCOIs to the NIH.

PUBLIC ACCESABILITY REQUIREMENTS

- 25) This policy will be posted on a publicly accessible Internet site for Keystone Nano.
- 26) KN establishes a process to make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible prior to the expenditure of funds. The information will:
 - a) Include the minimum elements as provided in the regulation
 - b) Be posted on a Public Website or made available by email or mailing within 5 calendar days of a written request
 - c) Be updated, at least annually (Web site only but any response to a written request should include the updated information)
 - d) Be updated, within 60 days of a newly identified FCOI (Web site only but any response to a written request should include the updated information)
 - e) Remain available for three years from the date the information was most recently updated.

Reporting of Financial Conflicts of Interest for PHS-Funded Projects

Before the expenditure of any funds under a PHS-funded project and within sixty days of subsequently identifying a Financial Conflict of Interest, the CEO Manager will report all Financial Conflicts of Interest that have not been eliminated to the PHS awarding component and will ensure that an appropriate Conflict

Management Plan has been implemented. The report will include the elements required under the PHS FCOI Rules. For subsequently identified FCOI's, the CEO Manager will conduct a retrospective review to determine whether the PHS-funded project was affected by the financial conflict of interest, and if bias is found, will submit a mitigation report to the PHS awarding component. The CEO Manager also will provide an annual FCOI report that addresses the status of any previously reported FCOI's and CMP's related to an ongoing PHS-funded project.

External Partners

Any individual or organization acting as a consultant, subcontractor, or subrecipient ("External Partner") to Keystone Nano on a PHS-funded award must either: (1) have a FCOI policy that meets the requirements of the PHS FCOI Rules or (2) follow this policy.

- Organizations with their own policy will certify that the policy meets the requirements of the PHS FCOI Rules by submitting an External Partner Financial Conflict of Interest Disclosure form or registering with the FDP Clearinghouse [insert link] before submission of the Government Award. The CEO Manager will verify registration with the FDP Clearinghouse before submission. The contract with Keystone Nano will contain language requiring compliance with the organization's FCOI Policy.
- Individuals and organizations without their own FCOI policy are required to follow this policy. The contract with Keystone Nano will contain language requiring compliance with Keystone Nano's Government Awards FCOI Policy.

Procedure for External Partners with their own PHS Rule policy

1. The principal investigator/project director will complete the Government Award Approval form, which requires them to inform any External Partner if they need to comply with FCOI Rules.

2. Prior to any application submitted by Keystone Nano for a Government Award, CEO must receive confirmation the External Partner has a FCOI policy that meets the PHS FCOI Rules.
3. The External Partner will have two options to verify they have a FCOI:
 1. Register with the FDP Clearinghouse, <https://fdpclearinghouse.org/> .
At this time, this website is acting as a central registration location for many colleges. Keystone Nano will accept this method of verification. Registration is free and you may contact CEO if you have questions.
 2. Submit the External Partner Financial Conflict of Interest Disclosure.

Contact information:

Jeff Davidson, CEO
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