

Manual Name: Office of Sponsored Projects

Policy Title: Parkview Health Sponsored Projects Conflict of Interest Policy

Policy Category: Conflict of Interest

Policy Owner: Justin Hull

Policy Statement

- A. Parkview strives to create a climate that promotes objectivity in research and sponsored projects by establishing standards such that the design, conduct, and reporting of research is free from bias resulting from financial conflicts of interest. The purpose of this policy is to manage, reduce, or eliminate any actual or potential financial conflicts of interest (FCOI) that may be presented by sponsored project key personnel or investigators, as defined by this policy, in accordance with federal regulations.
- B. This policy is necessary in addition to the existing IRB conflict of interest policy and annual conflict of interest policy due to the expanded scope of sponsored project agreements, as well as additional PHS/NIH and NSF FCOI requirements.
- C. This policy must be made available through a Parkview public website in order to maintain compliance with NIH Grants Policy section 4.1.10.
- D. This policy is to be updated annually in accordance with 42 CFR § 50.605.

Definition of Terms

A. Designated Official

1. The Director of Sponsored Projects will act as the designated official for purposes of this policy in coordination with the Legal Department and Compliance officer, or their designees.

B. Financial Conflict of Interest (FCOI)

1. A Financial Conflict of Interest (FCOI) is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research or non-research sponsored projects regardless of sponsoring agency.

C. Significant Financial Interest (SFI)

1. Significant Financial Interest (SFI) is a financial interest consisting of one or more of the following interests of any Key Personnel (and those of their spouse and dependent children) that reasonably appears to be related to the Key Personnel's institutional responsibilities:
 - a. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the 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.

For purposes of this definition, remuneration includes 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 twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Key Personnel (or their spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. Key Personnel must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Key Personnel and not reimbursed to the Key Personnel so that the exact monetary value may not be readily available), related to their 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, and institution of higher education, and academic teaching hospital, a medical center or a research institution that is affiliated with an institution of higher education. The details of the disclosure shall include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The institutional officials will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with PHS-funded research or Sponsored Project.
3. The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by Parkview to Key Personnel if Key Personnel is currently employed or otherwise appointed by Parkview, including intellectual property rights assigned to Parkview and agreements to share in royalties related to such rights; income from or holdings in investment vehicles, such as mutual funds and retirement accounts, so long as the Key Personnel 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, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency; an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

D. Key/Senior Personnel

1. Investigators or Project Directors and other individuals who contribute to the programmatic development or execution of a project, program, or research in a substantive, measurable way, regardless of whether they receive salaries or compensation under a sponsored project agreement. (see classification of key personnel)

E. PHS

1. The Public Health Services of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

F. Principal Investigator/Investigator (PI)

1. An individual responsible for directing and managing the activities performed in relation to a sponsored project. Though a project may have both a project director and a principal investigator, these terms are sometimes used interchangeably by sponsoring agencies.

G. Sponsored Project

1. A sponsored project is an activity which is supported wholly or in part by restricted external funding. The presence of any one of the following criteria may necessitate that a project be classified as a sponsored project and administered accordingly:
 - a. A governmental sponsor funds the project. Any sponsor that is receiving funds directly from a government prime contract is also considered a governmental sponsor.
 - b. There is expressed or implied expectation of economic benefit for the sponsoring agency.
 - c. Acceptance of funding commits Parkview entity or affiliate to participate in a specific project or program. This commitment is typically documented by a statement of work or narrative.
 - d. A specific commitment is made regarding the level of personnel effort, deliverables, or milestones.
 - e. Project activities are budgeted, and the award includes conditions for specific formal fiscal reports, and/or invoicing.
 - f. The project requires that unexpended funds be returned to the sponsor at the end of a defined project period.
 - g. The project agreement provides for the disposition of either tangible property (e.g., equipment, records, technical reports) or intangible property (e.g., inventions, copyrights or rights in data) which may result from the project.
 - h. The sponsor identifies a period of performance as a term and condition.

Procedure

A. Classification of Key Personnel

1. It is a best practice to only identify individuals as key personnel when required by the sponsoring agency or the nature of their duties suggests that the classification is appropriate. Classifying individuals as key personnel when unnecessary increases audit risk and administrative burden, as additional approvals and notifications are required for key staff changes and reduction of effort. According to the National Institute of Health (NIH) Grants Policy, senior/key personnel must devote measurable effort to the project whether or not compensation. An individual may be identified as key staff for the following reasons:
 - a. The sponsoring agency has explicitly stated in a solicitation, policy, or other guidance that a position must be classified as key personnel.
 - b. The individual is identified as an investigator or project director
 - c. The individual is otherwise determined to be key personnel as defined by this policy (see Definition of Terms)

B. Financial Conflict of Interest Disclosure Process

1. Disclosure requirements for Key Personnel Proposing to or Awarded funds from PHS and other funding agencies.
 - a. Anyone meeting the definition of Key Personnel must complete a disclosure statement prior to the acceptance of any award, unless required at the time of proposal by the sponsor. Investigators planning to participate in PHS/NIH funded research must disclose SFIs no later than the time of application.
 - b. Key Personnel must disclose SFIs annually during the period of award.
 - c. Key Personnel must disclose all new SFIs within 30 days of discovery or acquisition.
2. Determination of Financial Conflicts of Interest
 - a. At the time of sponsored project being awarded, the assigned designated official will review the disclosures of SFI to determine if further action is required before Parkview expends any awarded funds or issues a purchase order or subcontracts for the acquisition of any goods and services related to any award.
 - b. If any SFI appears related to the award in any way, the designated official will review the SFIs and determine whether a SFI could affect the design, conduct, or reporting of research or sponsored program activities. If so, the designated official will work with the Legal Department and the Compliance Officer, or their designees, and will determine which of the following actions to take:
 - i. Accept the proposed sponsored project

- ii. Accept the proposed sponsored project provided certain conditions or restrictions are imposed so that the FCOI will be managed, reduced, or eliminated.
 - iii. Refuse the proposed sponsored project.
- c. Project IDs will not be made available for grant expenditures until conflict of interest disclosure questionnaires are completed for all individuals covered by this policy and any relevant FCOIs are reviewed by the designated official
- d. Whenever, in the course of an ongoing Sponsored Project, an Investigator who is new to participating in the project discloses an SFI or an existing Investigator discloses a new SFI, or Parkview identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by Parkview, the designated official, along with the Legal Department and Compliance Officer, or their designee, shall, within 60 days:
 - i. Review the SFI;
 - ii. Determine whether the SFI relates to the Sponsored Project; and
 - iii. If so, implement, at least on an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI.

C. Guidelines for whether significant financial interest is a FCOI

1. An Investigator's SFI is related to the research when Parkview, through its designated official, reasonably determines that the SFI:
 - a. Could be affected by the research; or
 - b. Is in an entity whose financial interest could be affected by the research.
2. Parkview may involve the Investigator in the designated official's determination of whether an SFI is related to the research.
3. An FCOI exists when Parkview, through its designated official, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the research.

D. Record Retention

1. Records relating to disclosures of SFI and all actions taken to manage actual or potential FCOIs for all Investigators and Key Personnel, will be maintained for a minimum of:
 - a. 3 years following the submission of final expenditure reports, project period expiration, or termination; or
 - b. Other dates specified by 45 CFR § 75.361, whichever is later.

E. Management of Conflicts of Interest

1. Possible conditions or restrictions that may be imposed as part of a financial conflict of interest management plan, as suggested 42 CFR § 50.605, include but are not limited to:
 - a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - g. Severance of relationships that create financial conflicts.

F. Non-Compliance

1. Whenever an FCOI is not identified or managed in a timely manner, including: failure by the Investigator to disclose an SFI that is determined by Parkview to constitute an FCOI; failure by Parkview to review or manage such FCOI; or failure by the Investigator to comply with an FCOI management plan, Parkview shall, within 120 days of determination of noncompliance, complete a retrospective review of the Investigator's activities and the Sponsored Project to determine whether the Sponsored Project, or any portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
 - a. Parkview shall document the retrospective review, including, at a minimum;
 - i. Project number;
 - ii. Project title
 - iii. Principal Investigator
 - iv. Name of the Investigator with the FCOI
 - v. Name of the entity with which the Investigator has an FCOI
 - vi. Reason(s) for the retrospective review;
 - vii. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
 - viii. Findings of the review; and
 - ix. Conclusions of the review.

2. Based on the results of the retrospective review, if appropriate, Parkview shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Parkview is required to notify the PHS or other sponsor promptly and submit a mitigation report to the PHS or other sponsor. The mitigation report must include, at a minimum:
 - a. The key elements documented in the retrospective review (see above);
 - b. A description of the impact of the bias on the research project; and
 - c. Parkview's plan of action or actions taken to eliminate or mitigate the effect of the bias.

G. Additional Requirements for PHS/NIH and NSF Investigators

1. FCOI Reporting to PHS/NIH
 - a. The PHS and other sponsors regulations require Parkview to provide initial and ongoing reports on Investigator's Financial Conflicts of Interest to the funding agency. For Financial Conflicts of Interest with other sponsors adopting the PHI (or similar) regulations, Parkview will provide the sponsor with Financial Conflict of Interest information as reflected by individual sponsor policy.
 - b. The information that Parkview must provide to PHS includes:
 - i. Grant number;
 - ii. Principal Investigator;
 - iii. Name of Investigator with Financial Conflict of Interest;
 - iv. Nature of the Financial Conflict of Interest (e.g., equity, consulting fees, travel reimbursement, honoraria);
 - v. Value of the Significant Financial Interest (\$0-4,999; \$5k-9,999; \$10k-19,999; amounts between \$20k-\$100K by increments of \$20K; amounts above \$100K by increments of \$50k) or 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. A description of how the Financial Interest relates to the PHS-funded research and the basis for Parkview's determination that the Financial Interest conflicts with such research; and
 - vii. Key elements of Parkview's management plan.
 - c. In addition to reporting Financial Conflicts of Interest to the PHS funding agency, PHS regulations require that Parkview make available to the public, within 5 calendar days, upon written request, the following information regarding Financial Conflicts of Interest for Key Personnel:
 - i. Investigator's name;
 - ii. Investigator's title and role with respect to the research project;
 - iii. Name of the entity in which the Significant Financial Interest is held;
 - iv. Nature of the Significant Financial Interest; and

- v. Value of the Significant Financial Interest (\$0-4,999; \$5k-9,999; \$10k-19,999; amounts between \$20k-\$100K by increments of \$20K; amounts above \$100K by increments of \$50k) or 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.
 - d. Ongoing management and reporting of FCOI to the PHS, other sponsors, and the public, in accordance with the established sponsor requirements, will be the responsibility of the designated official.
- 2. FCOI Training for Investigators
 - a. Parkview will inform each Investigator of this policy, the Investigator's responsibilities regarding disclosure of SFI's, and the applicable regulations, and require each Investigator to complete training regarding the same prior to engaging in research or sponsored programs related to any funded grant to which this policy applies and at least every four (4) years and immediately when any of the following circumstances exist:
 - ii. Parkview revises its Financial Conflict of Interest Policies in any manner that affects the requirements of Investigators;
 - iii. An Investigator is new to Parkview; or
 - iv. Parkview finds that an Investigator is not in compliance with Parkview's Financial Conflict of Interest policy or management plan.
- 3. Sponsored Travel Disclosure
 - a. According to 42 CFR § 50.603, Investigators for PSH/NIH funded projects must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their 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.
 - b. PHS/NIH Investigators must disclose reimbursed or sponsored travel, as defined by this policy, if the travel exceeds \$5,000 when aggregated (see NIH policy clarification NOT-OD-13-004):
 - i. At the time of application to any PHS/NIH funding opportunity over the previous 12-month period;
 - ii. Upon discovering that the travel will take place;
 - iii. At the latest, within 30 days of the travel taking place
 - c. Sponsored travel will be disclosed by submitting a PHS/NIH Investigator Travel Disclosure Form to OSP@parkview.com. This form must include:
 - i. The purpose of the travel;

- ii. Sponsor/organizer;
 - iii. Destination; and
 - iv. Duration of the travel
- d. The designated official will review PHS/NIH Investigator Travel Disclosure Forms and determine if additional information is required to determine whether the travel constitutes an FCOI with the PHS/NIH-funded research.

H. Availability of FCOI Information

1. Parkview entities covered under this policy will make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and will fully comply with 42 CFR § 50.604.
2. Information regarding an SFI related to any PHS funded research that meets the criteria described by 42 CFR § 50.605 shall be made to any requestor within 5 business days. SFI information will be made available for requestors for 3 years following the most recent update of an individual's SFI information.

I. Third-Party and Subrecipient Investigators

1. Any third-party PHS investigator(s) must be either included in the processes described in this policy or provide reasonable assurance that they are participating in a PHS compliant FCOI process through another entity. The designated official will develop an FCOI management plan for any third-party investigators who have a FCOI.
2. For subrecipient investigators, the subrecipient authorized official may attest that the entity has a PHS compliant FCOI policy through the use of a subrecipient commitment form or be included in the Parkview FCOI policy and related processes.
3. Parkview will manage, disclose, and report any subrecipient investigator FCOIs related to PHS/NIH research in the manner described in this policy, and monitor Investigator compliance with management plans until completion of the project.
4. When applicable, Parkview will establish, via written agreement, whether the subrecipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the subrecipient. If the subrecipient will follow its own FCOI policy, Parkview will obtain a certification from the subrecipient that its FCOI policy complies with the PHS regulations. If applicable, Parkview will include in the written subrecipient agreement a requirement for the subrecipient to report identified FCOIs for its Investigators in a time frame that allows Parkview to report FCOIs to the PHS or the NIH as required.

References

42 CFR § 50.603-§ 50.606

45 CFR § 75.361

NIH Grants Policy section 4.1.10.

NIH policy clarification NOT-OD-13-004

Sponsored Projects Application Policy

History and Updates