



Gramercy Research Group FCOI Policy

Effective 9/1/2021

Policy

Gramercy Research Group Designated Research Official must manage, review, and mitigate all financial conflicts of interest for Gramercy Research Group and non-Gramercy Research Group key research personnel.

Purpose.

To establish standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest (fCOI).

Scope

Applies to all Gramercy Research Group and non-Gramercy Research Group key research personnel.

Definitions:

- Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.
- Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
- HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.
- Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- Investigator means 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.
- Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.



- PHS means the Public Health Service 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).
- PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.
- Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.
- Research means 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. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.
- Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.
- Significant financial interest means:
 - A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - With regard to any publicly traded entity, a significant financial interest 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;
 - With regard to any non-publicly traded entity, a significant financial interest 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 Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
 - Investigators also 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional 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 an FCOI with the PHS-funded research.

- The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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, 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; or income from service on advisory committees or review panels for 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.
- Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

Personnel Responsible

Research Project Manager, President & CEO

Policy Statement

- Disclosure of FCOI
 - Significant financial interests related to institutional responsibilities must be disclosed by all Gramercy Research Group and non-Gramercy Research Group key research personnel involved in clinical research
 - SFI Disclosure Form must be completed annually
 - Investigators must notify the Designated Research Official within 30 days of acquiring or discovering (e.g., through purchase, marriage, or inheritance) any new Significant Financial Interest
- Training
 - Gramercy Research Group and non-Gramercy Research Group key research personnel will receive training on this material at time of implementation and whenever this policy is updated.
 - New key research personnel will receive training as part of their orientation.



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- Training will be conducted immediately if this policy is revised and affects the requirements of Investigators, an Investigator is new to an Institution or if an Investigator is not in compliance with the policy or management plan.
- Significant Financial Interests
 - The following Significant Financial Interests must be disclosed:
 - With regard to any publicly traded entity, 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
 - With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest)
 - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests
 - 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.
 - Purpose of the trip
 - Identity of the sponsor/organizer
 - Destination
 - Dates of travel
 - Estimated or actual monetary value
 - Significant Financial Interests do not include:
 - Financial interests in business enterprises or entities that, when aggregated for the investigator and his/her immediate family, meet both of the following tests:
 - The financial interest does not exceed \$5000 in value as determined through reference to public prices or other reasonable measures of fair market value, and
 - The financial interest does not represent more than a five percent ownership interest in any single entity
 - Salary, royalties, or other remuneration from Gramercy Research Group (or the institution that currently employs any non-Gramercy Research Group key personnel)
 - Salary, royalties, or other payments that, when aggregated for the investigator and his/her immediate family, are not expected to exceed \$5000 during the next 12 month period



- Income from seminars, lectures, or teaching engagements 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
 - Income from service on advisory committees or review panels for 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
 - 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
 - An investigator may choose to disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest.
- Disclosure Review
 - Disclosures will be managed by the Designated Research Official, who will determine whether financial relationships present a source of potential conflict with PHS-sponsored research
 - If the Investigator enrolls patients on NIH Clinical Trials, the Designated Research Official may consider, among other factors, the phase of the study, the number of patients to be enrolled nationally, if drug is provided, the Investigator's specialty (if applicable), and the history of the study (date open for accrual, first patient entered, rate of enrollment, etc.)
 - The Designated Research Official will review the SFI Disclosure Form, determine whether the SFI is related to NIH-funded research, determine whether a FCOI exists, and if so, implement a management plan and submit an FCOI report to NIH within 60 days of disclosure.
 - The Designated Research Official will maintain a FCOI Travel Log to aid in determining FCOI.
 - All FCOI reports shall be submitted to the NIH through the electronic Research Administration (eRA) commons.
- Management Plan
 - Should management of a potential or actual significant financial conflict of interest be required, the Designated Research Official will draft a Management Plan.
 - Such plans will be designed to meet applicable legal requirements, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information.
 - Final management plans are reviewed and approved by the Research Project Manager and the President & CEO.
 - The Management Plan must include the following:
 - The role and principal duties of the conflicted Investigator in the research project
 - Conditions of the management plan
 - How the management plan is designed to safeguard objectivity in the research project
 - Confirmation of the Investigator's agreement to the management plan



- How the management plan will be monitored to ensure Investigator compliance
 - Other information as needed
- Non- Compliance
 - If the Department of Health and Human Services determines that an FCOI was not managed or reported as required by the regulation, the Investigator involved must disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.
 - If there are problems in obtaining SFI Disclosure Forms, additional information as requested, or the Investigator refuses to follow the policies and procedures, the Designated Research Official may suspend enrollment privileges to NIH clinical trials.
 - If an Investigator fails to comply with the Financial Conflict of Interest policy or the Management Plan, the Designated Research Official shall within 120 days:
 - complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine any bias in the design, conduct or reporting of research
 - document the retrospective review consistent with the regulation
 - document the Institution's determination as to whether any NIH-funded research, or portion thereof, conducted during the period of time of the Investigator's non-compliance with the Institution's Financial Conflict of Interest policy or a Financial Conflict of Interest management plan, was biased in the design, conduct, or reporting of such research
 - Non-compliance will result initially in re-training, then in disciplinary action if there are further occurrences.
- Retrospective Review and Mitigation Report
 - A retrospective review will be conducted within 120 days when there is:
 - A failure by the Investigator to disclose a Significant Financial Interest that is determined by the Designated Research Official to constitute a Financial Conflict of Interest
 - A failure by the Designated Research Official to review or manage such a Financial Conflict of Interest
 - A failure by the Investigator to comply with a Financial Conflict of Interest management plan
 - The retrospective review must include the following:
 - Project number
 - Project title
 - PD/PI or contact PD/PI if a multiple PD/PI model is used
 - Name of the Investigator with the FCOI
 - Name of the entity with which the Investigator has a financial conflict of interest
 - Reason(s) for the retrospective review
 - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.)
 - Findings of the review
 - Conclusions of the review
 - If bias is found during the review, the Designated Research Official shall notify the NIH promptly and submit a mitigation report, which must include the following:



- the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable)
- Sub-recipients
 - Consortium agreements of the sub-recipients will be modified to accept this policy or to reference an institutional FCOI policy that will be maintained and enforced, and that meets or exceeds the most recent regulatory requirements
 - If the subrecipient chooses to accept this policy, the amendment to the Consortium Agreement will include a requirement to solicit and review subrecipient Investigator disclosures that enable Gramercy Research Group to identify, manage and report identified FCOIs to the NIH
 - If the subrecipient chooses to use its institutional FCOI policy, the subrecipient will provide a certification that its FCOI policy complies with the regulation. In addition, the institutional FCOI policy will be modified to report identified FCOIs for its Investigators in a time frame that allows Gramercy Research Group to report identified FCOIs to the NIH as required by the regulation
- Records
 - The Research Supervisor will maintain records of all disclosures and associated activities securely and confidentially in a secured office
 - All records will be maintained for at least three years from the date of submission of the final expenditures report
- Public Accessibility
 - This policy will be publicly available via the Gramercy Research Group website, www.gramercyresearch.com
 - The information will be updated annually
 - Additional or new SFI that result in an FCOI will be added to the website within 60 days of disclosure
 - The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new Financial Conflict of Interest.
 - If the Institution responds to written requests, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new Financial Conflict of Interest, which should be requested subsequently by the requestor.
 - In addition to this policy, information concerning any SFI disclosed that meets the following criteria will be posted:
 - The Significant Financial Interest was disclosed and is still held by the senior/key personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH
 - The Institution determines that the Significant Financial Interest is related to the NIH-funded research
 - The Institution determines that the Significant Financial Interest is a Financial Conflict of Interest



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- The following information will be posted for each SFI meeting the criteria listed above:
 - Investigator's name
 - Investigator's title and role with respect to the research project
 - Name of the entity in which the Significant Financial Interest is held
 - Nature of the Significant Financial Interest
 - Approximate dollar value of the Significant Financial Interest (dollar ranges are permissible: \$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
 - Name and address of contact person for obtaining written requests
- Upon receipt of a written request for information concerning identified FCOI's held by senior/key personnel, Gramercy Research Group will make that information available within five (5) business days of the request.
 - The information shall include all elements required by 42 CFR Part 50, updated through the date of the response.