

Policy

General administrative

Disclosure of financial interests and management of conflict of interest, Public Health Service (PHS) contracts policy

POL-GA-203

Revision No. 2.02

Effective date: 11-25-2024



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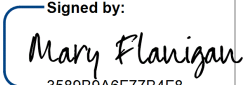
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Document approval

	Printed name, title, and/or department	Signature	Date
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Department Management approval indicates that the document adequately addresses its intended purpose and scope and is consistent with pertinent department requirements.

Quality Department approval indicates that the document is consistent with pertinent company policies and procedures and adequately meets applicable regulatory requirements.



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1. Purpose

- 1.1. The Public Health Service (PHS), which includes funding agencies such as the Centers for Disease Control and the Food and Drug Administration, implemented expanded regulations for financial conflict of interest on grants. The regulations, 42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94 (hereinafter referred to as *'The Regulations'*) cover the disclosure requirements for PHS sponsored Investigators and the review, management, and reporting requirements for Institutions.
- 1.2. The Regulations require Carelon Research to maintain a written policy on financial conflict of interest disclosure as a condition for receiving PHS awards. The Regulations obligate Carelon Research to establish this policy consistent with the regulations to require disclosure, and identification and management of financial conflicts of interest for all Investigators supported by PHS awards. Consistent with the regulations, this policy will be made available via Carelon Research's external internet. Carelon Research Investigators shall be informed where this policy and relevant reporting requirements may be accessed.
- 1.3. NERI (New England Research Institute) is a wholly owned subsidiary of Carelon Research. All references within to Carelon Research and Carelon Research associates shall also refer to NERI.

2. Scope

- 2.1. This policy applies to Carelon Research studies funded by Public Health Services agency funding.

3. Responsibilities

- 3.1. Carelon Research associates serving in the capacity of Designated Official, Investigator or Key Personnel, as those roles are herein defined, for a PHS funded research study conducted by Carelon Research.

4. References

- 4.1. 42 C.F.R. Part 50, Subpart F Promoting Objectivity in Research
- 4.2. 45 C.F.R. Part 94, Responsible Prospective Contractors
- 4.3. POL-GA-202 Conflict of Interest and Disclosure Policy
- 4.4. FM-GA-203-001: Carelon Research PHS Financial Disclosure Form

5. Definitions

- 5.1. Contractor: Means an entity that provides property or services under contract for the direct benefit or use of the Federal Government.
- 5.2. Designated Official: An official designated by Carelon Research management to solicit and review Investigators' completed Financial Interest forms and who may determine whether the Investigator has a Financial Conflict of Interest.



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- 5.3. Financial Conflict of Interest: Means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of Public Health Services (PHS) funded research.
- 5.4. Financial Interest: Means anything of monetary value, whether or not the value is readily ascertainable.
- 5.5. Institutional Responsibilities: Means an Investigator’s professional responsibilities on behalf of Carelon Research which include Research, research consultation which are in the course and scope of the Investigator’s Carelon Research employment.
- 5.6. Investigator: Means the Carelon Research project director or Carelon Research Principal Investigator and any other Carelon Research associate, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS on behalf of Carelon Research, or proposed for such funding, which may include, for example consultants.
- 5.7. Key Personnel: Includes the Carelon Research project director/director/principal investigator and any other Carelon Research personnel considered to be essential to work performance and identified as key personnel in the contract proposal and contract.
- 5.8. 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 includes any such activity for which research is funding is available from a Public Health Service (PHS) Awarding Component through a contract.
- 5.9. Significant Financial Interest: Consistent with federal regulations (42 CFR Part 50.603 and 45 CFR Part 94.3), Significant Financial Interest means a financial interest consisting of one or more of the following interests of the Investigator or the Investigator's spouse or registered domestic partner and dependent children for the following categories, except in the case of travel:
 - 5.9.1. With regard to any publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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. Included are salary (other than salary described in Paragraph 5, below), consulting fees, honoraria, and the equity interest value at the date of disclosure as determined by public prices or other reasonable measure of fair market value.
 - 5.9.2. With regard to any non-publicly-traded entity, a Significant Financial Interest exists if the value of any remuneration (other than remuneration described in Paragraph 5, below) 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, registered domestic partner, or dependent children) holds any equity interest.



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- 5.9.3. Intellectual property rights and interests, upon receipt of income, exceeding \$5,000 during the twelve months preceding disclosure from such rights and interests. However, Significant Financial Interests do not include royalties received from Carelon Research.
- 5.9.4. In the case of travel, sponsored travel or reimbursements made to or on behalf of, the Investigator, regardless of amount, by a for-profit or non-profit entity related to the Investigator’s Institutional Responsibilities. However, Significant Financial Interests do not include travel reimbursed or paid by a federal, state, or local government agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education.
- 5.9.5. The term “Significant Financial Interest” does not include the following types of financial interests:
 - 5.9.5.1. Salary, royalties, or other payments made by Carelon Research to a Carelon Research Investigator who is currently employed or otherwise appointed by Carelon Research;
 - 5.9.5.2. Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government, agency, a U.S. institution of higher education, or a research institute, academic medical center or hospital affiliated with an institution of higher education;
 - 5.9.5.3. Income from investment vehicles, such as mutual funds and retirement funds, in which the Investigator does not directly control investment decisions.

6. Applicable groups

- 6.1. Carelon Research associates and contractors

7. Background

- 7.1. The regulations obligate Carelon Research to establish this policy requiring disclosure, and identification and management of financial conflicts of interest for all Investigators supported by PHS awards. This policy will be made available via Carelon Research’s external website.

8. Policy

- 8.1. Disclosure of Significant Financial Interests
 - 8.1.1. Investigators seeking PHS research funding or receiving PHS research support are required to disclose Significant Financial Interests related to their Institutional Responsibilities. These Investigators shall submit a disclosure of Significant Financial Interests in accordance with this policy.



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- 8.1.2. Carelon Research associates working in key roles on PHS funded research must complete and submit the Carelon Research PHS Financial Disclosure Form FM GA 203-001 in accordance with this policy or provide similar disclosure meeting The Regulation requirements to Carelon Research client, study sponsor or funding source.
- 8.1.3. The requirement that an Investigator disclose a Significant Financial Interest under the terms of this Policy does not in and of itself imply the existence of an actual or potential financial conflict of interest. The existence of a financial conflict of interest, based upon the relationship of the Investigators' Significant Financial Interests to the Investigators' Institutional Responsibilities, is determined by a Designated Official with input from the Investigator and Carelon Research Legal. If a financial conflict of interest is identified, the Designated Official shall recommend and implement additional steps to manage or eliminate the conflict.
- 8.1.4. Investigators as defined by this policy, shall disclose to Carelon Research, as applicable, all Significant Financial Interests related to their Institutional Responsibilities annually but no later than at the time of application for PHS funding.
- 8.1.5. This initial disclosure responsibility is separate from and in addition to an Investigator's ongoing duty throughout the period of a PHS research award to disclose to the Carelon Research Designated Official his or her Significant Financial Interests, and those of his or her spouse and dependent children) related to the Investigator's Institutional Responsibilities:
 - 8.1.5.1. Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) any new Significant Financial Interest (with the exception of travel disclosures, noted below); and
 - 8.1.5.2. At least annually throughout the period of the award.
- 8.1.6. Before joining an ongoing PHS-funded research project new Investigators will submit a disclosure of Significant Financial Interests to Carelon Research, as applicable, if no previous annual disclosure has been submitted.
- 8.1.7. Under the terms of this Policy, Principal Investigators must identify all Investigators on the award who (that is, all individuals who will have responsibility for designing, conducting, or reporting the research to be funded by PHS) are required to disclose Significant Financial Interests.
- 8.1.8. Sponsored or reimbursed travel may be disclosed:
 - 8.1.8.1. Prospectively listing all anticipated travel (including information about the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip) for the 12-month period following the filing of the Investigator's annual disclosure form; and/or



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8.1.8.2. Within 30 days of the occurrence of travel that either was not listed on the prospective annual travel report pursuant to paragraph a) or that significantly varied in the threshold reporting details from what was listed in the prospective report.

8.1.9. Collaborators from other institutions or subcontractors who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a sub-grant or subcontract from Carelon Research are expected to comply with the policies and procedures for disclosure and review of a Significant Financial Interests at the institution at which they are employed or, if their institution does not have a conflict of interest policy that complies with The Regulations, collaborators/subcontractors will comply with Carelon Research's policy for disclosure and review of a Significant Financial Interests related to PHS sponsored awards. Subawards issued by Carelon Research will ask the subrecipient institution and subcontractors to certify that its policy is in compliance with the conflict of interest regulations, and unless the subrecipient does not have a compliant policy, will indicate that the recipient organization is responsible for reviewing the disclosures submitted by its Investigators and, if a Financial Conflict of Interest is identified, for sending Carelon Research notification of the conflict and of the subrecipient institution's plan to manage, reduce or eliminate the identified conflicts, in accordance with PHS reporting requirements.

8.2. Review of Disclosures; Management Plan

8.2.1. With each PHS proposal, progress report, incremental funding or extension, Investigators' Significant Financial Interests disclosures will be reviewed by the Designated Official(s) to determine whether there are any Significant Financial Interests that reasonably appear to be related to the PHS-funded research activity in which the Investigator is engaged. Investigators shall have an opportunity to indicate whether or not they believe the Significant Financial Interest(s) they reported are related to their PHS-funded research activities.

8.2.2. In the event that the Carelon Research Designated Official conclude that an Investigator's Significant Financial Interest reasonably appears to directly and significantly affect the design, conduct or reporting of the PHS-funded research; or is in an entity whose financial interest could be affected by the research, the Designated Official, working with Carelon Research Counsel shall make a final recommendation and implement the conditions or restrictions that should be placed on the project to eliminate or manage the Financial Conflict of Interest before the support can be accepted.

8.2.3. The management plan is to be implemented prior to the Carelon Research's expenditure of PHS funds awarded for the research project, and shall specify the actions that are required to manage the Financial Conflict of Interest, and shall include:

8.2.3.1. The role and principal duties of the conflicted Investigator;

8.2.3.2. Conditions of the management plan;



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8.2.3.3. How the plan will safeguard objectivity in the research activity;

8.2.3.4. Confirmation of the investigator’s agreement to the plan; and

8.2.3.5. How the plan will be monitored.

8.2.4. The same review process takes place when an Investigator reports a new Significant Financial Interest.

8.3. Reporting to the PHS Funding Agency

8.3.1. Prior to Carelon Research’s expenditure of any funds provided under a PHS award, Carelon Research will provide to the PHS funding agency or the prime awardee as applicable, an initial report regarding Investigator Financial Conflict of Interest. If Financial Conflicts of Interest are eliminated before research funds are expended, Carelon Research is not required to submit a report to the PHS funding agency or prime awardee.

8.3.2. During the period of the award, Carelon Research shall, within 60 days of receipt of disclosure of a new or newly-discovered Significant Financial Interest, review the disclosure, determine whether it is related to PHS-funded research, determine whether it constitutes a Financial Conflict of Interest, and if so, implement a management plan and report the Financial Conflict of Interest to the PHS funding agency or prime awardee, as applicable.

8.3.3. For Financial Conflict of Interests reportable to a PHS awarding agency, Carelon Research shall provide an annual Financial Conflict of Interest report that addresses the status of the conflict and any changes to the management plan, for the duration of the project. The annual report shall specify whether the financial conflict is still being managed or explain why it no longer exists. Carelon Research will provide annual reports to the PHS awarding agency or prime awardee for the duration of the project period (including extensions with or without funds).

8.3.4. Within 60 days of determining that a Financial Conflict of Interest exists for a new Investigator who joins an ongoing PHS-funded research activity, Carelon Research will implement a management plan and submit a report to the PHS funding agency or prime awardee.

8.3.5. In any case in which the Department of Health and Human Services (DHHS) determines that a PHS-sponsored 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 a Financial Conflict of Interest that was not managed or reported by Carelon Research as required by this policy and Federal regulation, Carelon Research shall require the Investigator 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.

8.4. Retrospective Reviews and Mitigation Reports



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- 8.4.1. When during the course on ongoing PHS-funded research project, Carelon Research identifies a Significant Financial Interest that was not disclosed in a timely manner by an Investigator or which was not previously reviewed, the Designated Official will, within 60 days, review the Significant Financial Interest to determine whether it is related to PHS-funded research activity, determine whether a Financial Conflict of Interest exists, and if so, implement a management plan on at least on an interim basis.
- 8.4.2. For Carelon Research is responsible for conflict of interest reporting, if a Financial Conflict of Interest is not identified or managed in a timely manner, regardless of whether the Investigator did not disclose a Significant Financial Interest that was later determined to be a Financial Conflict of Interest, or Carelon Research did not review or manage the Financial Conflict of Interest, or the Investigator failed to comply with a previously implemented management plan, Carelon Research will within 120 days of the determination of non-compliance, complete a retrospective review of the Investigator’s activities and the PHS-funded research. The purpose of this retrospective review is to determine if the ongoing PHS-funded research was biased in its design, conduct or reporting. Carelon Research will document, as required, the retrospective review; such documentation will include the project number; project title; name of Investigator with the Financial Conflict of Interest; name of the entity with which the Investigator has a Financial Conflict of Interest; the reasons for the retrospective review; detailed methodology used for the retrospective review; findings; and conclusions.
- 8.4.3. Based on the results of the retrospective review, if appropriate, the previously submitted Financial Conflict of Interest report should be updated to specify the actions that Carelon Research will take to manage the identified Financial Conflict of Interest going forward.
- 8.4.4. If bias was found during the retrospective review, Carelon Research will promptly notify the PHS funding agency or prime awardee and will draft a mitigation report that at a minimum documents the key elements of the retrospective review, describes the impact of the bias on the research, and outlines Carelon Research’s plans to eliminate or mitigate the effect of the bias.

8.5. Record Retention

- 8.5.1. Records of financial disclosures and the Carelon Research’s review of, or response to such disclosures, whether or not a disclosure resulted in the Carelon Research’s determination of a Financial Conflict of Interest, and all actions under this policy or retrospective review shall be maintained for at least 3 years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. for the subject award or as otherwise required under 45 CFR 74.53(b) and 92.42(b)(Records relating to unfunded awards need not be retained.

8.6. Training



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8.6.1. Each Investigator, including consultants or subcontractors, as applicable must complete training about the PHS financial conflicts of interest policy prior to engaging in research related to any PHS-funded project and at least every 4 years thereafter, while receiving PHS research funding, and at other times as may be required by Carelon Research or the contracting entity in accordance with DHHS regulations.

8.7. Public Access to Information

8.7.1. The Carelon Research Designated Official shall create one Carelon Research e-mail address and one office address as the recipient addresses for public requests for information concerning PHS funded studies and this policy and shall take action necessary to provide reasonable notice of those addresses to the public, including prominently posting this information on Carelon Research’s web site.

8.7.2. Carelon Research will respond within 5 business days to request for information about Significant Financial Interests held by Key Personnel when Carelon Research has determined that the disclosed Significant Financial Interests are related to the PHS-funded research and constitute Financial Conflicts of Interest.

8.7.3. Disclosure forms, Disclosure Update forms, and Management Plans including determinations of Financial Conflicts of Interest under this policy are public records open to public inspection, under federal and state law.

8.8. Sanctions

8.8.1. Failure of an individual to file a complete and truthful financial disclosure for pending proposals, or when a new interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed award monitoring bodies, will be grounds for discipline.

9. Attachments

9.1. None

10. Document revision history

Revision	Date	Author	Description
1.0	09-01-2016	T. Hughes	Initial Financial Conflict of Interest Policy for federal work
2.0	12-31-2020	T. Hughes/D. Cuff	Updated to include NERI



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2.1	04-11-2023	D. Cuff	Updated to clarify Carelon Research responsibilities/prime awardee responsibilities; update name change from HealthCore to Carelon Research; scope clarified; within the revision history table: corrected revision # for this version to align with SOP-QA-101 and formatting of all revision dates for consistency.
2.02	09-03-2024	D. Cuff	Annual/Biennial Review: Updated to new policy template; will make this policy available on public facing website; removal of appendix for COI PHS Form and added to reference section.