



Davenport PHS Financial Conflict of Interest Policy

For compliance with the regulatory requirements provided in the FCOI(FCOI) regulation at [42 CFR Part 50, Subpart F](#), Promoting Objectivity in Research, applicable to Public Health Service (PHS) (e.g., NIH) grants and cooperative agreements, Davenport University has the following policies and procedures for all Principle PI/co-PIs (PI) and co-Principle PI/co-PIs (co-PI) to adhere before submitting, after accepting, and during implementation of a grant-funded position/project. Davenport's FCOI policy is also posted on our publicly accessible web site as required by the NIH Grants Policy Statement, [Section 4.1.10](#).

TRAINING

To establish a process to inform each PI/co-PI of Davenport's policies, disclosure responsibilities, and federal regulations, each new Davenport employee who is funded by a PHS-funded grant, must attend FCOI training as follows:

- Prior to engaging in PHS-funded research (Grant kick-off training and/or onboard training for a newly hired PI/co-PI: once award is received or PI/co-PI is onboarding);
- Every year of PHS-funded research (Refresher training: Start of each grant-funded year);
- When a PI/co-PI is found to be not in compliance with FCOI policies of management plans (Refresher training with warnings: as needed); and
- When changes have been implemented to FCOI policies (Update training: as needed).

Training will include what constitutes a significant financial interest (SFI), the processes for determining if a FCOI(FCOI) exists, and the process for managing the SFI and FCOI in a PHS-funded grant award.

DISCLOSURE, REVIEW, and MONITORING

Disclosure:

As a PI/co-PI prepares a proposal for submission to a PHS funder, the PI/co-PI will be asked to disclose any Significant Financial Interest (SFI) that they or their spouse or dependent children may have related to the PI's/co-PI's responsibilities on the PHS-funded project that meets or exceeds regulator definitions of SFI (See definitions at the end of this policy).

All significant financial interest disclosures must be forwarded to the Executive Director of Sponsored Programs, as Signing Officer (SO) for grants, to determine if a significant FCOI has occurred and, thus, require a FCOI form to be filled out and reported. This will occur: before submitting any proposal for PHS funding as well as any time during the grant period. The disclosure must be emailed to the SO within 30 days of the conflict and include the following information:

For remuneration or financial affiliations:

- Name of PI/co-PI;
- Name of the company/organization;
- Role/relationship with entity;
- Amount received, or if non-monetary, value of service/product(s) received; and
- Dates/duration of transaction/service.



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For Trips:

- Name of PI/co-PI;
- Purpose of the trip;
- Name of the sponsor/organization;
- Amount received for travel;
- Destination; and
- Dates/duration of the trip.

Review:

Davenport is providing these guidelines to be compliant and consistent with 42 CFR Subpart F so that the designated SO can have the processes in place to determine if a PI/co-PI's significant financial interest (SFI) is related to PHS-funded research and, if it is related, if the significant financial interest is a FCOI. A PI/co-PI's SFI is related to PHS-funded research when Davenport, through its SO, reasonably determines that the SFI: could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research; or, conversely, could affect the PHS-funded research or is in an entity whose financial interest could affect the research. Davenport may involve the PI/co-PI in the SO's determination of whether an SFI is related to the PHS-funded research. A FCOI(FCOI) exists when Davenport, through its SO reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

A review will be conducted (1) prior to Davenport's expenditure of any funds under a PHS-funded research project, (2) when a PI/co-PI is new to participating in the research project, (3) when an existing PI/co-PI discloses a new SFI, or (4) when Davenport identifies an SFI that was not disclosed timely by a PI/co-PI or, for whatever reason, was not previously reviewed by Davenport during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient). The review, in compliance and consistent with §50.604(f), will be conducted within 60 days by the SO and include:

- Review all PI/co-PI disclosures of SFI;
- Determine if any SFIs relate to PHS-funded research;
- Determine if an FCOI exists; and
- Develop and implement a management plan for if an SFI/FCOI exists so as to specify the actions that have been, and will be, taken to manage the FCOTI.

Note: Depending on the nature of the SFI, Davenport may determine that additional interim measures are necessary with regard to the PI/co-PI's participation in the PHS-funded research project between the date of disclosure and the completion of Davenport's review.

Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of FCOI (e.g., when presenting, publishing, reporting the research);
- Disclosure of FCOI directly to participants for research projects involving human subjects research;



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- Appointment of an independent monitor to take measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

When an FCOI is not identified or managed in a timely manner, including failure by the PI/co-PI to disclose an SFI that is determined by Davenport to be an FCOI; failure by Davenport to review or manage the FCOI; or failure by Davenport to comply with a FCOI management plan, Davenport will, within 120 days of the University's determination of noncompliance, complete a retrospective review of the PI/co-PI's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

Davenport is required by 42 CFR 50.605(a)(3)(ii)(a) to document the retrospective review and to include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PI or contact PI if a multiple PI model is used;
- Name of the PI/co-PI with the FCOI;
- Name of the entity with which the PI/co-PI has a FCOI;
- 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);
- Findings of the review; and
- Conclusions of the review.

Monitoring:

Based on the results of the retrospective review, if appropriate, Davenport will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, Davenport is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and Davenport's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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). Thereafter, Davenport will submit FCOI reports annually, as specified in 42 CFR Subpart F. Depending on the nature of the FCOI, Davenport may determine that additional interim measures are necessary with regard to the PI's/co-PI's participation in the PHS-funded research project between the date that the FCOI



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or the PI's/co-PI's noncompliance is determined and the completion of Davenport's retrospective review.

Management:

Davenport will take such actions as necessary to manage FCOIs, including any financial conflicts of a subrecipient PI/co-PI pursuant to 42 CFR 50.604 (c). Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to §50.605(a). Davenport will also provide initial and ongoing FCOI reports to the PHS as required pursuant to §50.605(b).

Davenport will maintain records relating to all PI/co-PI disclosures of financial interests and Davenport's review of, and response to, such disclosures (whether or not a disclosure resulted in Davenport's determination of a FCOI) and all actions under Davenport's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to PHS or, where applicable, from other dates specified in 42 CFR 75.361 for different situations.

Davenport will establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure PI/co-PI compliance as appropriate.

As a PI/co-PI prepares to submit a proposal for PHS funding, Davenport's SO will certify, in each application for funding to which 42 CFR Subpart F applies, that Davenport:

- Has in effect at Davenport an up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from PHS;
- Will promote and enforce PI/co-PI compliance, including those pertaining to disclosure of significant financial interests;
- Will manage FCOIs and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent;
- Agrees to make information available promptly upon request to HHS relating to any PI/co-PI disclosure of financial interests and Davenport's review of, and response to, such disclosure, whether or not the disclosure resulted in Davenport's determination of a FCOI; and
- Will fully comply with the requirements of this 42 CFR Subpart F.

Davenport will implement a management plan pursuant to 42 CFR Subpart F, and will monitor PI/co-PI compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

REPORTING REQUIREMENTS to NIH

Reporting FCOI:

Davenport will send initial, annual, ongoing, and revised FCOI reports, including all reporting elements required by 42 CFR Subpart F to NIH for Davenport and its subrecipients, as applicable, as required by the abovementioned regulations.



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As part of Davenport's management plan pursuant to 42 CFR Subpart F, and will monitor PI/co-PI compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. As follows:

- Prior to the expenditure of funds;
- Within 60 days of identification for a PI/co-PI who is newly participating in the project;
- Within 60 days for new, or newly identified, FCOIs for existing PI/co-PI;
- At least annually (at the same time as when Davenport is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until completion of the project; and
- Following a retrospective review to update a previously submitted report, if appropriate.

Prior to Davenport's expenditure of any funds under a PHS-funded research project, Davenport will provide to the PHS Awarding Component an FCOI report regarding any PI's/co-PI's SFI found by Davenport to be conflicting and ensure that Davenport has implemented a management plan in accordance with 42 CFR Subpart F. In cases in which Davenport identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Davenport will not submit an FCOI report to the PHS Awarding Component.

For any SFI that Davenport identifies as conflicting subsequent to Davenport's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of a PI/co-PI who is new to the research project), Davenport will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the FCOI and ensure that Davenport has implemented a management plan in accordance with 42 CFR Subpart F. Pursuant to paragraph 42 CFR 50.605(a)(3)(ii), where such FCOI report involves an SFI that was not disclosed timely by an PI/co-PI or, for whatever reason, was not previously reviewed or managed by Davenport (e.g., was not timely reviewed or reported by a subrecipient), Davenport also will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph 42 CFR 50.605(a)(3)(iii), if bias is found, Davenport will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report required under paragraphs 42 CFR 50.605(b)(1) or (b)(2) will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of Davenport's management plan. Elements of the FCOI report will include, but are not necessarily limited to the following:

- Project number;
- PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of PI/co-PI with the FCOI;
- Name of the entity with which the PI/co-PI has a FCOI;



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- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible, 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);
- A description of how the financial interest relates to the PHS-funded research and the basis for Davenport's determination that the financial interest conflicts with such research; and
- A description of the key elements of Davenport's management plan, including:
 - Role and principal duties of the conflicted PI/co-PI in the research project;
 - Conditions of the management plan;
 - How management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the PI's/co-PI's agreement to the management plan;
 - How the management plan will be monitored to ensure PI/co-PI compliance; and
 - Other information as needed.

For any FCOI previously reported by Davenport with regard to an ongoing PHS-funded research project, Davenport will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for duration of the PHS-funded research project. The annual FCOI report will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Davenport will provide annual FCOI reports to the PHS Awarding Component for duration of the project period (including extensions with or without funds) in time and manner specified by the PHS Awarding Component.

Prior to Davenport's expenditure of any funds under a PHS-funded research project, the University will ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to Davenport that meets the following three criteria:

- SFI was disclosed and is still held by the PI/co-PI as defined by 42 CFR Subpart F;
- Davenport determines that the SFI is related to the PHS-funded research; and
- Davenport determines that the SFI is an FCOI.

The information that Davenport makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, will include, at a minimum, the following:

- PI's/co-PI's name;
- PI's/co-PI'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 SFI; and
- Approximate dollar value of the SFI 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.



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Davenport will update this information at least annually. In addition, Davenport will update within 60 days of the University's receipt or identification of information concerning any additional SFI of the PI/co-PI for the PHS-funded research project that was not previously disclosed, or upon the disclosure of an SFI of PI/co-PI new to the PHS-funded research project, if Davenport determines that the SFI is related to the PHS-funded research and is an FCOI. Responses to written requests for the purposes of this subsection will note 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 Davenport's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFI of an individual subject to paragraph 42 CFR 50.65(a)(5) will remain available, for responses to written requests by Davenport for at least three years from the date that the information was most recently updated.

Reporting Bias:

Davenport will, during the course of the review, notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research and submit a mitigation report in accordance with 42 CFR 50.605 (a)(3)(iii). The mitigation report must include, at a minimum, the following:

- Project number;
- Project title;
- PI or contact PI if a multiple PI model is used;
- Name of the PI/co-PI with the FCOI;
- Name of the entity with which the PI/co-PI has a FCOI;
- 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);
- Findings of the review;
- Conclusions of the review;
- Description of the impact of the bias on the research project; and
- Davenport's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., 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).

Thereafter, Davenport will submit FCOI reports annually. Depending on the nature of the FCOI, Davenport may determine that additional interim measures are necessary with regard to the PI's/co-PI's participation in the PHS-funded research project between the date the FCOI or PI's/co-PI's noncompliance is determined and completion of Davenport's retrospective review.

Davenport will notify NIH promptly if a PI/co-PI fails to comply with the University's FCOI policy or if an FCOI management plan appears to have bias toward the design, conduct, or reporting of the NIH-funded research.



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Reporting Failure of PI/co-PI Compliance:

If Davenport finds that a PI/co-PI fails to comply with the University's FCOI or an FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, Davenport will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to Davenport for further action, which may include directions to the University on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Davenport, as the employer of the PI/co-PI, to enforce any applicable corrective actions prior to any PHS award or when the transfer of a PHS grant(s) involves that same PI/co-PI.

The PHS Awarding Component and/or HHS may inquire at any time before, during, or after award into any PI/co-PI FCOI and Davenport's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in Davenport's determination of an FCOI. Davenport is required to submit, or permit on site review of, all records pertinent to compliance. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that Davenport has not managed the FCOI in accordance with 42 CFR Subpart F. The PHS Awarding Component may determine that imposition of specific award conditions under 42 CFR 75.207, or suspension of funding or other enforcement action under 42 CFR 75.371, is necessary until the matter is resolved.

MAINTENANCE of RECORDS:

Davenport will maintain records relating to all PI/co-PI disclosures of financial interests and Davenport's review of, and response to, such disclosures (whether or not a disclosure resulted in Davenport's determination of a FCOI) and all actions under Davenport's policy or retrospective review, if applicable, for at least three years from the date the final expenditures report is submitted to PHS or, where applicable, from other dates specified in 42 CFR 75.361 for different situations.

ENFORCEMENT MECHANISMS for REMEDIES and NONCOMPLIANCE

Davenport will enforce PI/co-PI compliance through thorough the abovementioned reporting and monitoring processes. When an FCOI is not identified or managed in a timely manner, including failure by the PI/co-PI to disclose an SFI that is determined by Davenport to be an FCOI; failure by Davenport to review or manage the FCOI; or failure by Davenport to comply with a FCOI management plan, Davenport will, within 120 days of the University's determination of noncompliance, complete a retrospective review of the PI/co-PI's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.



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Davenport is required by 42 CFR 50.605(a)(3)(ii)(a) to document the retrospective review and to include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PI or contact PI if a multiple PI model is used;
- Name of the PI/co-PI with the FCOI;
- Name of the entity with which the PI/co-PI has a FCOI;
- 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);
- Findings of the review; and
- Conclusions of the review.

Davenport does not conduct clinical research and, therefore, does not have any current written policies adherent to 42 CFR 50.606(c). If Davenport does move into the realm of clinical research, Davenport will include policies for this section.

SUBRECIPIENT REQUIREMENTS

When Davenport carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), Davenport (awardee Institution) will take reasonable steps to ensure that any subrecipient PI/co-PI complies with 42 CFR Subpart F by:

- Incorporating as part of a written agreement with the subrecipient terms that establish the FCOI policy of Davenport by which the subrecipient will apply to the subrecipient's PIs/co-PIs.
 - All subrecipient's PIs/co-PIs must comply with the subrecipient's FCOI policy and must certify as part of the agreement referenced above that its policy complies with 42 CFR Subpart F. If the subrecipient cannot provide such certification, the agreement will state that subrecipient PIs/co-PIs are subject to the FCOI policy of Davenport for disclosing SFIs that are directly related to the subrecipient's work for Davenport;
 - The written agreement referenced above will specify time period(s) for the subrecipient to report all identified FCOI to Davenport. Such time period(s) will be sufficient to enable Davenport to provide timely FCOI reports, as necessary, to PHS as required by 42 CFR Subpart F;
 - Alternatively, if the subrecipient's PIs/co-PIs must comply with Davenport's FCOI policy, the agreement referenced above will specify time period(s) for the subrecipient to submit all PI/co-PI disclosures of SFIs to Davenport. Such time period(s) will be sufficient to enable Davenport to comply timely with its review, management, and reporting obligations under 42 CFR Subpart F.
- Providing FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient PIs/co-PIs consistent with 42 CFR Subpart F, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.



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G. PUBLIC ACCESSIBILITY REQUIREMENTS

Davenport will maintain an up-to-date, written, enforced policy on FCOIs that complies with 42 CFR Subpart F, and make policy available via a publicly accessible Web site.

Prior to Davenport's expenditure of any funds under a PHS-funded research project, the University will ensure public accessibility, via a written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to Davenport that meets the following three criteria:

- SFI was disclosed and is still held by the PI/co-PI as defined by 42 CFR Subpart F;
- Davenport determines that the SFI is related to the PHS-funded research; and
- Davenport determines that the SFI is an FCOI.

The information that Davenport makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, will include, at a minimum, the following:

- PI's/co-PI's name;
- PI's/co-PI'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 SFI; and
- Approximate dollar value of the SFI 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.

Davenport will update this information at least annually. In addition, Davenport will update within 60 days of the University's receipt or identification of information concerning any additional SFI of the PI/co-PI for the PHS-funded research project that was not previously disclosed, or upon the disclosure of an SFI of PI/co-PI new to the PHS-funded research project, if Davenport determines that the SFI is related to the PHS-funded research and is an FCOI. Responses to written requests for the purposes of this subsection will note 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 Davenport's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFI of an individual subject to paragraph 42 CFR 50.65(a)(5) will remain available, for responses to written requests by Davenport for at least three years from the date that the information was most recently updated.

DEFINITIONS for 42 CFR SUBPART F: FINANCIAL CONFLICT of INTEREST

- **Disclosure of significant financial interests** – a PI/co-PI's disclosure of significant financial interests to Davenport.
- **Financial conflict of interest (FCOI)** - a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.



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- **FCOI report** - Davenport's report of an FCOI to a PHS Awarding Component.
- **Financial interest** - anything of monetary value, whether or not the value is readily ascertainable.
- **HHS** - United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
- **Institution** - 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/Davenport responsibilities** - a PI's/co-PI's professional responsibilities on behalf of Davenport, and as defined by Davenport 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.
- **PI/co-PI** - the project director or principal PI/co-PI or co-principal PI/co-PI 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. The PD/PI is included in the definitions of senior/key personnel and PI/co-PI under 42 CFR Subpart F.
- **Manage** - 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.
- **PHS** - Public Health Service of 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** - organizational unit of PHS that funds the research that is subject to 42 CFR Subpart F.
- **Public Health Service Act or PHS Act** - statute codified at 42 U.S.C. 201 et seq.
- **Research** - systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. It 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 42 CFR Subpart F, 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** - PI/co-PI and any other person identified as senior/key personnel by Davenport in the grant application, progress report, or any other report submitted to the PHS by Davenport under 42 CFR Subpart F.
- **Significant financial interest (SFI):**
 - A financial interest consisting of one or more of the following interests of the PI/co-PI (and those of the PI/co-PI's spouse and dependent children) that reasonably appears to be related to the PI/co-PI's institutional responsibilities:



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- Ownership of or affiliation with publicly traded entities, companies, or organizations with value or remuneration in excess of \$5,000 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 disclosure. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes stock, stock option, or other ownership interest, as determined through public prices or other reasonable measures of fair market value.
 - Ownership of or affiliation with any non-publicly traded entity, companies, or organizations with value or remuneration in excess of \$5,000 received from the entity in 12 months preceding disclosure they hold any equity interest (e.g., stock, stock option, or other ownership interest).
 - Ownership of or affiliation with Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests that meet the following criteria:
 - Reimbursed or sponsored travel (i.e., money paid on behalf of the PI/co-PI but not reimbursed to the PI/co-PI) when related to their Davenport responsibilities. Note: this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency or by Davenport.
- Note: Significant financial interest does not include the following types of financial interests:
- Salary, royalties, or other remuneration paid by Davenport to the PI/co-PI if they are currently employed or otherwise appointed by Davenport, including intellectual property rights assigned to Davenport and agreements to share in royalties related to such rights;
 - Any ownership interest in Davenport held by PI/co-PI, if Davenport is a commercial or for-profit organization;
 - Income from investment vehicles, such as mutual funds and retirement accounts, as long as PI/co-PI does not directly control the investment decisions made in these vehicles; and
 - Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Davenport affiliated with Davenport or income from service on advisory committees or review panels for a Federal, state, or local government agency, or an Davenport that is affiliated with Davenport.
- **Small Business Innovation Research (SBIR) Program** - 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 42 CFR Subpart F, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.