

Geisinger

CONFLICT OF INTEREST HANDBOOK

Office of Research Compliance

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COI Overview

What is a conflict of interest?

A conflict of interest (COI) is a situation where an interest or relationship with an outside entity can appear to compromise an investigator's professional judgement.

A COI exists if an outside observer might possibly think that a person's judgment or objectivity could be biased by the situation.

What is a Financial Conflict of Interest?

A financial conflict of interest (FCOI) is when an Investigator's financial interest is related to a research project, and could directly or significantly affect the design, conduct, or reporting of the research.

Why are there laws and regulations?

There are laws and regulations to protect research participants, the reputation of investigators, the institution, and the research from potential bias.

Policies and regulations ensure that work is conducted ethically. By fully disclosing interests, it preserves the public's trust and protects human subjects.

What about Geisinger's requirements?

Geisinger has a Policy on Financial Conflicts of Interest in Research. This policy applies to all Investigators who conduct research activities, not just those that are federally sponsored. It also applies to Research Regulatory Committee members, Research Administration staff, and other research positions.

COI Disclosures

How do I report any possible conflicts?

All investigators must complete the annual COI questionnaire. In this questionnaire, you are required to report all relevant payments and financial interests from the previous calendar year. All investigators with a COI Smart account will receive an email to complete the annual questionnaire at the beginning of July.

Do I need to make any disclosures if I'm not an investigator?

Even if you're not an investigator, if you have any financial interests that could create a potential conflict, you must disclose the interest or activity to your supervisor. This is important so that all perceived conflicts can be noted and potentially managed. Supervisors must contact the Office of Research Compliance if the disclosed interest may be related to the employee's work within research.

What do I need to disclose?

The COI Questionnaire will ask a series of questions that detail what needs to be disclosed. These questions include information on:

- Payments from outside work (examples: consulting, speaking)
- Work on outside boards/advisory committees
- Equity Interests, such as owning stock in another company
- Gifts, payments, and entertainment that aren't related to business purposes. This includes travel and lodging, and food & beverage paid for by outside vendors- see below for more details on this
- Financial relationships with foreign vendors or entities (this includes foreign positions, financial interests, foreign investments, and research support from foreign entities)

Don't forget that you also need to disclose the items above for family members too. Family members include your spouse or domestic partner, parents, siblings, children, grandchildren, and great grandchildren.

What do I not need to disclose?

- Payments made by Geisinger to investigators employed by Geisinger
- Intellectual property rights assigned to Geisinger and agreements to share in related royalties
- Income from investments (ex: retirement accounts) when you do not directly control the investment decisions
- Income from service on advisory committees or review panels, or from seminars, lectures, or teaching engagements sponsored by a government agency, institution of higher education, academic teaching hospital, medical center, or not-for-profit research institute.

What is disclosable travel?

Travel expenses, including meals, which are paid for or reimbursed by an outside source must be disclosed within 30 days of reimbursement.

Are any travel expenses excluded from disclosure?

It's helpful to remember that disclosure requirements for travel do not apply to travel that is reimbursed or sponsored by:

- Geisinger
- Federal, state, or local government agency
- Institution of higher education
- Academic teaching hospital, medical center, or research institute that is affiliated with an Institution of higher education

What is considered a significant financial interest & disclosure?

Significant disclosures include:

- Total value of payments received in the preceding twelve months that exceed \$5,000
- Equity interest in a publicly traded company exceeds \$5,000;
- Equity interest, regardless of amount, in a non-publicly traded company
- Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests

What is the solution to a possible COI?

The solution is to identify potential conflicts and implement plans to reduce or eliminate bias.

Disclosure Reviewal Process

When are disclosures reviewed?

ORC Staff reviews all disclosures yearly, when you submit any updated disclosures, and during any grant/contract submissions.

How are conflicts of interest reviewed?

ORC Staff first looks at all disclosures and if a potential conflict is identified as significant, the Research Conflict of Interest Committee (RCOIC) reviews the disclosure and relevant project details. There may be questions for you about your role in the study and with the outside company. If the committee believes there is potential for a conflict, the committee will develop a 'Management Plan' which you will sign.

What is a management plan?

Management Plans are set up to provide transparency and create separation between the investigators interests and Geisinger's.

A management plan will provide an overview of the conflict and include steps to address it. Common ways to manage a conflict are:

- Disclosure of the COI in presentations and publications
- Disclosure of the FCOI to human participants, if applicable
- Modification of the Research plan, including change in personnel
- Disqualification of personnel from participation in all or a portion of the Research
- Reduction or elimination of the SFI (e.g., sale of an equity interest)
- Eliminating the relationship giving rise to the FCOI.

Are there penalties for not disclosing?

If you don't complete the COI questionnaire you will not be approved to be an investigator on any grant or IRB submissions.

Also, not completing the annual questionnaire could result in:

- Communication sent from the Research Compliance Committee to the investigator, PI, and/or supervisor
- Removal of the investigator from study
- Recommending IRB suspension of the study until the investigator completes COI reporting requirements

Additionally, physician investigators who do not complete their annual COI questionnaire could be subject to discipline at Geisinger.

FAQs and COI Examples

What are some common situations that could be a potential conflict?

Some common potential COIs include:

- Working as a consultant for a company that is also the sponsor of a study
- Having a financial relationship with a company whose drug or device is being studied, regardless of if they are the sponsor or not
- Owning stock in a company that's sponsoring the study or whose drug/device is being studied
- Acting as a PI and also serving on an adjudication committee for the sponsor of the study

I received \$3,000 for consulting work from an outside company. I expect to receive another \$1,000 for a speaking engagement with the same company. I already disclosed the \$3,000 I received. Am I required to report the \$1,000, even if I haven't received it yet?

Yes, you should report all compensation received, and also anticipated compensation. You should update your disclosures at any time during the year, not just when the questionnaire opens.

I am not considered an investigator but work on a research study. My spouse works for the sponsor of the study. Should I disclose this?

Even though you are not considered an investigator, you should report this conflict to your immediate supervisor. This is a requirement in the policy to protect the integrity of the research.

I received grant funds for research I am conducting. These grant funds are also listed on CMS open payments. Do I have report this?

No, any grant funds received for research purposes are not required to be disclosed.

I am a Co-Investigator, and my spouse works for an outside company that provides supplies to Geisinger. Am I required to report this even though they are not a Geisinger employee?

Yes, per the policy you should report any financial interest received by a spouse.

I hold stock in an outside medical device company that I was previously employed with. Is this reportable?

Yes, stock ownership is considered a financial interest.

I'm positive that I don't have any external financial interests. Do I still need to fill out a COI Smart questionnaire?

Yes, its required by all investigators regardless of any financial interests. If there aren't any disclosures to report, you can answer "no" to all questions in the disclosure form.

My information is already on CMS open payments. Do I still have to fill out the questionnaire?

Yes! You should disclose all payments at the time they are received. In the annual questionnaire, you should confirm that the CMS open payments data is accurate. Although CMS payments shows information, some isn't included that we still need to know about. Examples of this include your participation on any outside committees or boards, and family member SFIs.

How to Report Disclosures

1. Go to <https://geisinger.coi-smart.com>. The Login screen appears
2. Enter your Username
3. Enter your Password. If you do not remember your password, click on the “Forgot Password” link, and enter your email address. Check your email for a message from noreply@geisinger.edu and follow the instructions
4. Click Login. The Home page appears



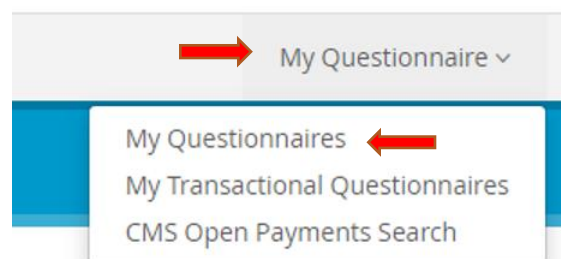
Need help? [Click here for our Quick Reference Card](#)

Login ID:

Password:

[Login](#) [Forgot Login ID or Password?](#)

5. Click My Questionnaire at the top of the page, then select My Questionnaire



6. Select the appropriate questionnaire and click "Start the Questionnaire"

My Questionnaires

Home > My Questionnaires

VIEW TRANSACTIONAL QUESTIONNAIRES

Click on **Start the Questionnaire** to begin answering a new questionnaire.
If you wish to **Revise** your answers to a previously submitted questionnaire, click on the questionnaire you wish to edit. An **Options Menu** will appear under the list giving you the option to revise it.

Locate a specific answer to a question:

Include Hidden Questionnaires

Show entries

My Questionnaires				
Questionnaire Name	Status	Due Date	Last Activity Date	
2018 Research Conflict of Interest Questionnaire	Closed	12/31/2018		
2019 Research Conflict of Interest Questionnaire	Closed	12/31/2019		
2020 Research Conflict of Interest Questionnaire	Closed	12/31/2020		
2021 Research Conflict of Interest Questionnaire	Closed	12/31/2021		
CY2021 Conflict of Interest Questionnaire	Closed	07/21/2022		
2022 Research Conflict of Interest Questionnaire	Closed	12/31/2022	11/02/2022	
2023 Research Conflict of Interest Questionnaire	Start the Questionnaire	12/31/2023		

Showing 1 to 7 of 7 entries

7. A new page will appear with instructions. Click "Continue"

2023 Research Conflict of Interest Questionnaire

Home > My Questionnaires

2022 Research Conflict of Interest Questionnaire

Welcome to Geisinger COI SMART.

Investigators are required to disclose financial interests related to their work at Geisinger (per *Geisinger Policy on Financial Conflicts of Interest (COI) in Research*, located in PolicyManager).

The **2022 Research Conflict of Interest Questionnaire** is available for two purposes:

- All investigators new to research at Geisinger must complete the **2022 Research Conflict of Interest Questionnaire**.
- Investigators who previously completed the COI questionnaire must update disclosures in the **2022 Research Conflict of Interest Questionnaire within 30 days** if any of the following occur:
 - You travel related to your institutional responsibilities, and your travel/lodging is paid for or reimbursed to you by an outside entity;
 - You acquire a different type or nature of significant financial interest (SFI) (e.g., royalty payment versus consulting fees) than what was previously disclosed from the same entity; or
 - You acquire the same type or nature of SFI (e.g., royalty payment) from a different entity (e.g., company A versus company B).

If you experience any technical issues or would like additional information, please contact Christine Gleave (570-214-9628, cmgleave1@geisinger.edu) or Brenda Cook (570-214-1635; bcook@geisinger.edu) in the Office of Research Compliance (ORC) or orc@geisinger.edu.

Your cooperation is greatly appreciated.

8. Type or select your responses to each question set. For questions that allow more than one disclosure, a green “+” sign appears, which allows you to add additional disclosures
9. Click “Save and Continue” to go to the next question(s).

Home > My Questionnaires

< 1 2 3 4 >

Financial Interests/Relationships

In the last twelve (12) months, did you or a **FAMILY** member, to the best of your knowledge, have a direct or indirect **FINANCIAL INTEREST** with, or, perform, render, or provide any type of services (paid or unpaid) to any vendor, **ENTITY** or person that (a) does business with Geisinger, (b) supplies products or technologies to GHS or (c) competes with Geisinger?

This includes attending any conferences, promotional or professional events, or trips related to your Geisinger Professional Responsibilities paid for or reimbursed by an outside source (profit or non-profit).
By way of example only, this would include acting as an officer, director, manager, employee, consultant or speaker for a vendor or other **ENTITY**, attending an investigator meeting or owning stock in another company.
This excludes, however, income from investment vehicles, such as mutual funds and retirement accounts where you do not directly control the investment decisions made.

1

Indicate Yes or No

Yes

No

To disclose another financial interest/relationship, please click the green “+” sign below.

+ Click here if you have another disclosure for this question (NOTE: Clicking this link will also save your current progress)

Supporting Documentation

Choose File No file chosen

UPLOAD (10 MB Limit)

SAVE & CONTINUE CANCEL AND EXIT

10. Upon completing all questions, a submission page appears. Type the word *submit*, then click “Finish”

Submit Questionnaire

Attestation

I acknowledge that all information that I have provided is correct and complete to the best of my knowledge and I understand that I am required to update the disclosure as changes occur.

I agree to abide by all applicable Geisinger Conflict of Interest policies.

You have completed all of the questions for this questionnaire.
Type the word **submit** in the text box below before clicking the “FINISH” button to indicate that you are ready to submit your completed questionnaire.

Type submit:

FINISH CANCEL

Contacts

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