

Disclosure of External Interests for Researchers

Who is required to complete a disclosure for research?

Anyone involved in the conduct of research and listed on the Institutional Review Board submission.

Is the research disclosure different from one I complete annually?

No. There is only one disclosure but individuals with a research role in their account have a few additional questions added to the annual disclosure.

When do I need to complete the disclosure?

The disclosure should be submitted prior to working on any research within MedStar. You should complete the current fiscal year disclosure.

You will also be required to certify the accuracy of the disclosure at the end of the fiscal year (June 30). The certification after the close of the fiscal year should only take a few minutes to complete unless you are updating the disclosure to include new interests not previously disclosed.

Your disclosure should be updated whenever you acquire a new interest, or a previously disclosed interest has changed.

How do I complete the disclosure?

In order to complete the disclosure, you will need an account in COISmart, the online platform where all MedStar disclosures are completed. If you do not have an account, send the following information to Kate Cohen, Research Compliance Director, Katherine.b.cohen@medstar.net:

- Full Name
- Email Address
- MedStar entity you are with
- How long do you anticipate your research lasting?
- Do you have any of the following roles at MedStar? If so, please indicate which ones:
 - o Management Level Full or Part Time Associate/Employee at MedStar
 - o Employed or Contracted Physician at MedStar
 - o Purchasing Committee Member at MedStar
 - o Faculty or Teaching Staff at MedStar
 - o Non-Physician Practitioner (NP, PA, CRNA)

If you have a COISmart account but have not previously participated in research at MedStar, the same information listed above will be required to update your account include your research role.

Once you have an account with a research role, you will be able to go into the system, <https://medstar.coi-smart.com> and complete the current fiscal year disclosure.

I have already done a disclosure, why is the IRB saying I have not completed it?

If you are asked to complete a disclosure but believe that you have already done one, it is possible that you have not completed the research disclosure. You may have an active account and have completed a disclosure for your non-research role within MedStar. You must complete the current fiscal year disclosure, which is only open to researchers during the fiscal year.

Why do I have to certify my disclosure?

Researchers are the only group within MedStar to have access to the questionnaire during the fiscal year so that researchers can update the disclosure in real time. Because MedStar is subject to reporting requirements that are based on our fiscal year, it is important that anyone who completed a disclosure during the fiscal year certify that the information previously entered in the disclosure is accurate and reflects the entire fiscal year. Once the fiscal year closes, researchers who have already completed a disclosure will be required to go into the system and either certify that the disclosure is accurate for the entire fiscal year or make necessary edits so that the disclosure is accurate for the fiscal year.

My research is all reviewed by the Georgetown University IRB. Why are you asking me to complete a research disclosure for MedStar?

The review of conflict of interest disclosures is an institutional responsibility, not an IRB one. Therefore, even if your research is exclusively reviewed by the Georgetown University IRB, it is possible that it is still the responsibility of MedStar Health to review your research conflict of interest disclosure. Some researchers may be required to complete both MedStar disclosures and a Georgetown University general COI disclosure.

How can I tell if I have completed the necessary disclosures?

You can log into your COISmart account and see if you have completed the current fiscal year disclosure (labeled RESEARCH ONLY).

OR

Just ask! Email Kate Cohen, Katherine.b.cohen@medstar.net to check the status of your COI account.

Should I disclose research or grant support that may support my salary?

No. You do not need to disclose any research or grant support that is paid directly to MedStar Health even if it supports your salary. You should only disclose payments by external entities that are made directly to you.

What are my responsibilities related to conflict of interest as a researcher?

A researcher has the following responsibilities related to conflict of interest:

- Familiarize yourself with the applicable COI policies within MedStar Health.
- Ensure you have submitted a current, accurate disclosure in the COISmart system.
- Disclose all external interests and relationships no later than the time of application for PHS funded research and update the disclosure at least annually and no later than thirty (30) days within acquiring a new external interest or relationship.
- Disclose all external interests and relationships, even if the relationship is previously known or approved by your entity's leadership. If you aren't sure what to disclose, seek clarification from research compliance.
- Comply with all management plans issued to you by research compliance.
- For researchers participating in PHS funded research, complete the Conflict of Interest training module through MedStar's subscription to CITI.

What happens if my external interests or relationships change?

You are required to update your disclosure within 30 days of a change to your external interests or relationships.

Why do I need to complete a conflict of interest disclosure?

MedStar Health relies on you to accurately and timely report your external interests and relationships so that the health system can comply with the numerous institutional obligations imposed by agencies that fund MedStar Health research.

Additionally, submission of an accurate and timely disclosure demonstrates your commitment to keep your research objective and free of bias, which preserve the public's trust in MedStar Health and in clinical research.

Will disclosing an external interest or relationship mean I cannot participate in the research?

Most likely no. Not all external interests and relationships are conflicts of interest. It is important that you disclose accurate information on all external interests and relationships so that the Conflict of Interest Official for Research, his/her designee, or the Research Conflict of Interest Committee can review the nature of the relationship/interest and manage the actual or perceived conflict appropriately to comply with applicable federal regulations and MedStar Health policies.

I have no outside relationships or interests to report. Do I still have to complete a disclosure?

Yes. All researchers are required to submit a disclosure, even if there is nothing to report on the disclosure form. Simply answer no to the questions on the disclosure if you do not have anything to disclose.

Reporting for the fiscal year is difficult. Can I report based on the calendar year instead?

No. MedStar's reporting system and conflict of interest policies are based on the MedStar Health fiscal year. MedStar Health utilizes the conflict of interest reporting system to comply with a number of different requirements annually. Many of these reporting requirements are based on our fiscal year. Researchers must complete the disclosures to accurately reflect the fiscal year reporting period and update the disclosure in real time as new interests and relationships are acquired or as previously reported interests and relationships change.