



**U.S. Department of Veterans Affairs**

North Florida / South Georgia Veterans Health System

## NF/SGVHS Research Service

Standard Operating Procedure:

### Financial Conflict of Interest: Instructions for Researchers

**Updated: 01/22/2023**

**This SOP documents contains two sets of instructions.** The first set of instructions with the light blue background are for Co-Investigators who have been asked to complete a Financial Conflict of Interest Form. The second set of instructions with the light green background are for the PI and/or Coordinators who lead the study and are managing the submission.

The first step is for the PI and/or Coordinator to reach out to Co-Investigators and ask them to complete a Financial Conflict of Interest form. When doing so, **be sure to include the information shown below in red font so the Co-Investigator will fill in the correct information for the correct study.**

#### Instructions to Co-Investigators

- All investigators (PI and Co-Is) must complete a Financial Conflict of Interest (FCOI) disclosure form at initial submission of a new project and annually thereafter. The disclosure form is called “OGE 450 Alt”. Annual submission is required whether or not a FCOI actually exists, and whether or not a FCOI has previously been cleared by the Office of General Counsel (OGC). This is because the nature of FCOIs may evolve over time and there may be changes in federal or state law.
- Log in to IRBNet at: <https://gov.irbnet.org/release/home.html>
- Once logged into your account, click on “My COI” and then “Create an Initial, Interim, or Annual Disclosure” as shown in the screenshot below.
- Here is guidance on how to fill in some of the fields:

**Select a Project:** It is important to choose the correct project from the drop down list. The PI or Coordinator should tell you which project to choose. If you do not see the correct project listed, then you may not have been added as study staff by the PI or Coordinator. Please contact the PI or Coordinator and request that they “Share” the project with you in IRBNet.

**Duty Station:** North Florida/South Georgia Veterans Health System

**Telephone:** your business phone number

**VA Email:** VA or UF email address is acceptable

**Sponsor of Study:** PI or coordinator should tell you this information

**Funding Source:** PI or coordinator should tell you this information

**Cooperative Studies Program Study?:** “CSP Study” refers to a VA funding mechanism for multi-site research. If you are part of a CSP Study you are likely aware of it. Otherwise the answer is “No”.

- The website will walk you through a series of questions for the COI disclosure.
- After you have completed the COI form you will see the status as “not submitted”. That’s OK, the Principal Investigator or Research Coordinator will take care of the submission.

The “My COI” page lists each of the disclosure forms that you have created so far. To create a new OGE 450 form, simply click “Create an Initial, Interim, or Annual Disclosure.”

Welcome to IRBNet  
Adam Researcher

My COI

Adam Researcher

Use your "My COI" workspace to create, track and manage your COI Disclosures. You can also access COI Disclosures that have been shared with you by other users. | [Learn More](#) |

[Create an Initial, Interim, or Annual Disclosure](#)

Search:   Include Disclosures shared with me by other users.  
 Only show Disclosures where my action is required.

Search Clear

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Doc ID	Document Type	Project	Purpose	Last Modified	Status	Next Due	
1567.1	VA - OGE Form 450 Alternate VA	[72507] Montelukast Therapy on Alzheimer's Di...	Initial Disclosure	09/22/2022 01:41 PM	Disclosed: 1 / 0 (1 Pending Review)		<a href="#">View Summary</a>
1565.1	VA - OGE Form 450 Alternate VA	[72566] Automated Insulin Delivery Amongst Pr...	Initial Disclosure	09/22/2022 11:49 AM	Disclosed: 0		<a href="#">View Summary</a>

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## Instructions to Principal Investigators and/or Research Coordinators









- Open a new package within the IRBNet project, which will be used ONLY for the COI submission. A separate package will be used for submitting other study documents, if applicable.

## Step 2: Link Disclosure Forms for Submission

In IRBNet, research projects are organized into “packages” of documents that can be submitted for review. To get the OGE 450 forms for you or your team ready for submission, first link the completed forms to a package using the Designer (you must have Full or Write access to the project):

1. Select your project from the My Projects page.
2. Make sure all research team members have been provided access to the project on IRBNet (otherwise you won't be able to link their OGE 450 forms).
3. Click the Designer button on the left menu.
4. Click “[Link / Un-Link COI Disclosures](#)”.

Documents in this Package:

Document Type	Description	Last Modified	
Budget	Budget.docx	09/28/2022 03:09 PM	   
Protocol	Protocol.docx	09/28/2022 03:09 PM	   

There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |  
There are **2 COI Disclosure records** linked to this package. | [View All Links](#) | [Link / Un-Link COI Disclosures](#) |

5. You will be presented with a list of disclosures for every study team member with access to the project. Select the OGE 450 forms that you want to submit, and click Save.

- Before submitting the package, ensure that ALL co-investigators have completed their COI disclosures. You can tell the status by viewing the list of project staff and observing the colored triangle next to each person's name in the “COI” column.
  - All investigators should have a green triangle with a checkmark, which means the COI disclosure was properly linked to the package, and review is complete. To continue on with submission of the package, all investigators must have a green triangle.
  - If there is a yellow triangle with a question mark, the COI disclosure was submitted but is still under review.
  - If there is a gray triangle with a question mark, no COI disclosure was submitted. A gray triangle is OK for staff who are not project investigators.

After all required disclosure forms are linked to the package, click the “Submit this Package” button, and select your facility's COI workspace. Packages containing disclosure forms should **only** be submitted to the COI workspace. It is the responsibility of the project owner (someone with “Full” access) to submit the package. Always follow local COI SOPs.

### Submit Package

[72653-1] Interventional Study of VNM-573 in Chiroptera Pteropodidae to treat rabies

IRBNet supports multiple models of review. Using the “Submit” feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Only show My Default Boards

- Lake Wobegon VA Research Administration, Lake Wobegon, MN
- Lake Wobegon VA Conflict of Interest, Lake Wobegon, MN
- VA Central IRB Office, Washington, DC

Select a Board \*

\* required fields