

## NF/SGVHS Research Service

Standard Operating Procedure:

### Financial Conflict of Interest: Instructions for Researchers

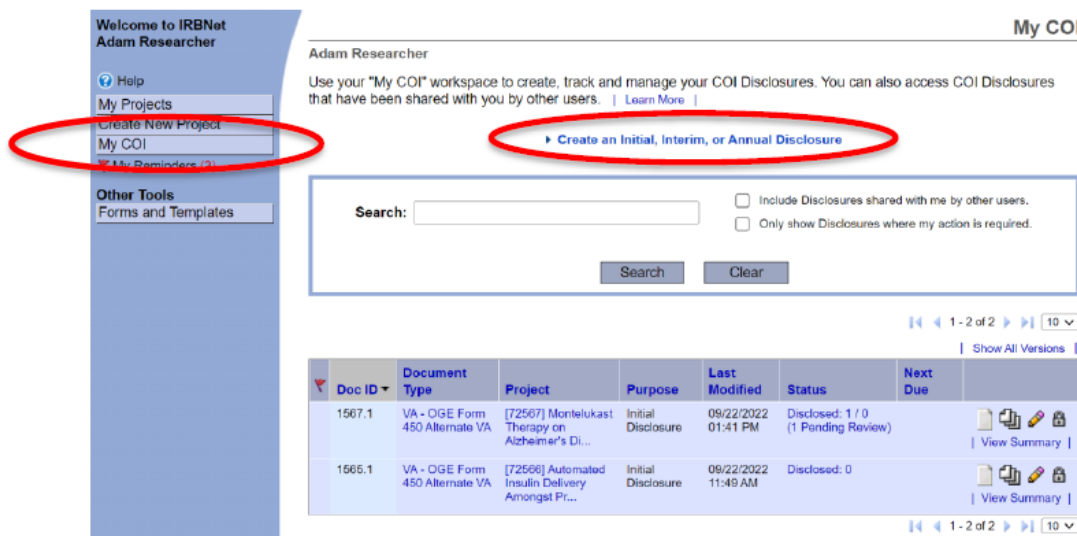
**Updated: 05/25/2024**

The PI and/or Coordinator should ask all Co-Investigators to complete a Financial Conflict of Interest (FCOI) disclosure form in IRBNet/VAIRRS. It is crucial that each investigator has the study “shared” with them in IRBNet (i.e., they must be listed as study staff), and each investigator must be provided the study information shown below in **red font**. If these two requirements are not completed properly, the FCOI disclosure process will not work.

### Instructions to Investigators: Completing a FCOI Disclosure

- 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 or there may be changes in applicable laws.
- 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.

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.”



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

Doc ID	Document Type	Project	Purpose	Last Modified	Status	Next Due	
1567.1	VA - OGE Form 450 Alternate VA	[72567] Montelukast Therapy on Alzheimer's Di...	Initial Disclosure	09/22/2022 01:41 PM	Disclosed: 1 / 0 (1 Pending Review)		View Summary
1565.1	VA - OGE Form 450 Alternate VA	[72566] Automated Insulin Delivery Amongst Pt...	Initial Disclosure	09/22/2022 11:49 AM	Disclosed: 0		View Summary

- The following guidance explains 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 will 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 is responsible for informing the Co-Investigator of what text to use for “Sponsor”. The last page of this document shows the possible options (highlighted in yellow).

**Funding Source:** PI or coordinator is responsible for informing the Co-Investigator of what text to use for “Funding Source”. The last page of this document shows the possible options (highlighted in green).

**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.
- The sections on “Income and Compensation” and “Business Relationships” ask about relationships with “*an entity (including the university affiliate) whose financial interests could be affected by this study*”. The financial interests mentioned here do NOT apply to salary from dual-appointments. Rather, the financial interests must have a close causal link with the research that is being conducted. If there is no such link, answer “No” to these questions.
- 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 complete the submission.









## Instructions to the Principal Investigator and/or Research Coordinator responsible for submitting the package in IRBNet

- Please re-read the first paragraph of this document (“The PI and/or Coordinator should ask all Co-Investigators...”).
- From the “Project Overview” page, create a new package. FCOIs must be submitted in a package that is separate from the package used to submit study documents (e.g., protocol, consent forms, etc.). This is because each package will be submitted to a different review board. The FCOI package will be submitted to the “NF/SGVHS Conflict of Interest Board”. The study document package will be submitted to the “NF/SGVHS Research Administration Members Board”.
- You can only have one new unsubmitted package open at a time within your IRBNet project. If you already have a package open for your study documents, you will need to wait until it is submitted before you can create your FCOI package (or vice versa). If this is preventing progress (e.g., a Co-I is not responding to your requests to complete the FCOI disclosure), then a workaround is to submit your incomplete package, then inform the IRBNet administrator that you are not actually done and ask for your package to be unlocked. This works because once a package has been submitted (even if unlocked again), it clears the way for a new package to be created.
- The following instructions explain how to link FCOI disclosures to the package:

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 FCOI disclosures and that all are linked to the package. To submit, follow the instructions below and make sure to choose “NF/SGVHS Conflict of Interest Board”.

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

After you submit the package, you will be able to view the status of the FCOI review from the “Project Overview” page in IRBNet. The list of study staff on this page has a column for “COI” where you can view the status by observing the colored triangle next to each person’s name.

- 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.
- If there is a yellow triangle with a question mark, the COI disclosure was submitted but is still under review.
- If there is a green triangle with a checkmark, the COI disclosure was reviewed and approved.

# For the purposes of Financial Conflict of Interest (FCOI) Reporting:

Use yellow highlighted text for "Sponsor"

Use the green highlighted text for "Funding Source"

## FUNDING SOURCE CODES

### 1. Department of Veterans Affairs (Use only Administrative Code 02)

[9002] BLR&D Research Advisory Group (CC 103)	[9009] BLR&D Other Designated Research (CC 109)	[9024] Health Services R&D (Prog 824)
[9003] BLR&D Merit Review (CC 103)	[9010] BLR&D Research Career Scientist (CC 110)	[9025] Cooperative Studies (Prog 825)
[9006] BLR&D Special Research Initiatives (CC 106)	[9022] Rehabilitation R&D (Prog 822)	[9026] Million Veteran Program (Prog 826-CC160)
[9008] BLR&D Career Development (CC 108)	[9023] Agent Orange & Related Herbicides	[9050] Clinical Science R&D
[9092] Musculoskeletal Research		

### 2. National Institutes of Health and Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)

[9103] National Cancer Institute	[9117] Natl Inst of Environmental Health Science	[9129] Natl Inst on Arth, Musculo & Skin Dis
[9105] National Eye Institute	[9119] Natl Inst of General Medical Sciences	[9131] Natl Inst on Deafness & Other Commu Dis
[9107] National Heart, Lung & Blood Inst	[9121] Natl Inst of Neurological Disor & Stroke	[9133] Natl Inst on Drug Abuse
[9109] Natl Inst of Allergy & Infectious Dis	[9122] Natl Human Genome Research Institute	[9135] Natl Inst on Mental Health
[9111] Natl Inst of Child Health & Human Dev	[9123] National Institute of Nursing Research	[9137] Natl Center for Research Resources
[9113] Natl Inst of Dental and Craniofacial Research	[9125] National Institute on Aging	[9138] Natl Inst of Biomedical Imaging and Bioengineering
[9115] Natl Inst of Diabetes, Digest, & Kidney	[9127] Natl Inst on Alcohol Abuse & Alcoholism	[9143] Natl Inst of Health (Inst not known)
[9144] Natl Inst of Disability & Rehabilitation Research		

### 3. Other United States Federal Government Agency

[9202] Centers for Disease Control	[9213] Environmental Protection Agency	[9225] National Library of Medicine
[9203] Dept of Defense	[9215] Food and Drug Administration	[9227] National Science Foundation
[9205] Dept of Education	[9217] Health Resources & Svcs Admin	[9229] Rehabilitation Services Admin
[9207] Dept of Energy	[9219] Natl Inst of Occupational Safety	[9235] U.S. Public Health Service
[9209] Dept of Health & Human Services	[9221] Natl Aeronautics & Space Admin	[9237] Natl Inst of Disability Rehab. Research
[9211] Dept of Labor	[9223] Agency for Health Care Policy Research	[9299] Other Federal Government Agency

### 4. Other Government, Private Donor, or Academic Institution

[9301] Affiliated University	[9307] State Government	[9360] VA Medical Care Supported Mgmt. Studies
[9303] Private Donor	[9309] Foreign Government	[9399] Other Government or Academic
[9305] Local Government	[9311] SWOG	

### 5. Private Proprietary Company

[9701] A.H. Robins	[9723] Cytogen	[9752] Lorex	[9779] Rhone-Poulenc Rorer
[9703] Abbott	[9725] Du Pont	[9754] Marion-Merrell Dow	[9781] Ross
[9705] Adria	[9729] E.R. Squibb	[9756] Mc Neil	[9782] R.W. Johnson Pharm
[9706] Aventis Pharmaceuticals	[9731] Eli Lilly	[9758] Mead Johnson	[9783] Sandoz
[9707] Alpha Therapeutic	[9732] Fujisawa	[9760] Merck & Co.	[9784] Schering
[9708] American Cyanamid	[9733] G.D. Searle	[9762] Merrell-Dow	[9785] SmithKline Beecham
[9709] Ayerst	[9734] G.H. Besselaar	[9764] Miles	[9787] Sanofi-Aventis
[9710] Amgen	[9736] Genentech	[9765] Novartis	[9789] Stuart
[9711] Beecham	[9738] Glaxo	[9766] Proctor & Gamble	[9790] Takeda
[9712] Berlex	[9740] Hoechst-Roussel	[9768] Organon	[9791] Syntex
[9713] Boehringer Ingelheim	[9742] Hoffman-La Roche	[9770] Ortho	[9792] TAP Pharm
[9715] Boots	[9744] Hybritech	[9773] Parke-Davis	[9793] Upjohn
[9717] Bristol-Meyers Squibb	[9745] Immunomedics	[9775] Pfizer	[9795] Warner-Chilcott
[9719] Burroughs Wellcome	[9746] Janssen	[9776] Purdue Frederick	[9797] Wyeth-Ayerst
[9720] Centocor	[9748] Knoll	[9777] Roberts Pharm	[9798] Zeneca
[9721] Ciba-Geigy	[9750] Lederle	[9778] Roche	[9799] Other Private Proprietary Company

### 6. Voluntary Agency/Foundation (For Local Chapters of National Organizations, use Agency/Foundation code)

[9803] Alzheimer's Dis & Related Dis Assoc	[9823] Arthritis Foundation	[9863] National Dairy Council
[9805] American Cancer Society	[9827] Council for Tobacco Research	[9867] Natl Foundation Ileitis & Colitis
[9809] American Diabetes Association	[9831] Cystic Fibrosis Foundation	[9871] National Kidney Foundation
[9811] American Fed for Aging Research	[9833] Deafness Research Foundation	[9875] National Multiple Sclerosis Society
[9812] American Fndn for AIDS Research	[9837] Dermatology Foundation	[9879] Paralyzed Veterans of America
[9813] American Heart Association	[9839] Disabled American Veterans	[9883] Robert Wood Johnson Foundation
[9815] American Kidney Foundation	[9843] Epilepsy Foundation of America	[9885] Scleroderma Foundation
[9817] American Legion	[9847] Juvenile Diabetes Foundation	[9887] Smokeless Tobacco Research Council
[9819] American Lung Association	[9851] Lupus Foundation of America	[9891] Spinal Cord Society
[9821] American Narcolepsy Association	[9855] March of Dimes	[9895] Va Private Research Corporation
[9822] Amer Parkinson Disease Assoc	[9859] Muscular Dystrophy Association	[9899] Other Voluntary Agency/Foundation

### 7. None (Enter 0000) (Use only Administrative Code 01.)

## ADMINISTRATIVE CODES

[01] No Funding (Valid only for Funding Code 0000)	[06] VA - Private Research Corporation
[02] VA Funds (Valid only for Funding Codes beginning with 90)	[07] Affiliated University
[03] VA - Reimbursed from another Federal Agency*	[08] Other
[04] VA - Direct Grant	[09] Med Care-Supported Studies*
[05] VA - General Post Funds	

\*Administrative Code 03 is valid only for Funding Codes beginning with 91 and 92.

\*Administrative Code 09 is valid only for Funding Code 9360.