

VAMHCS RESEARCH SERVICE HOT TOPIC

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New VA Research Financial Conflict of Interest (RFCOI) Form

Effective immediately, VA Office of Research & Development (ORD) has issued a new “Research Financial Conflict of Interest Statement” (RFCOI) form that replaces the 2011 form that is currently being used at the VAMHCS.

- WHO must complete the new form:
 - Only VA investigators including Principal Investigators (PI), Co-PIs, Site Investigators, co-investigators, etc. must fill out this form.
 - This applies to VA investigators whether they are compensated, WOC, or IPAs.
 - (Other members of the research team who are not considered investigators do not have to fill out this form.)

- WHAT are the differences and characteristics of the new form:
 - The new form is protocol-specific. Therefore investigators must complete a form for each of their VA protocols.
 - The form contains new questions and re-phrased questions and includes specific queries to the Investigator’s University affiliation.

- WHEN must you submit your new form(s):
 - **Immediately** for NEW protocols The ACOS/R&D Initiation Letter will not be issued from the Research Service until the RFCOI Statement is obtained and reviewed.
 - **Beginning January 2014** for current research projects as their annual updates and/or continuing reviews are brought to R&D Committee throughout the year.
 - **Prior to being added as an Investigator** on any VA protocol
 - **When you have a change in relevant information** that requires you to change an answer on Section I of the Statement to “yes” or that changes the reason for a “yes” answer.

- WHERE can you find the form:
 - See the form attached to this Research Service Hot Topic
 - The new form will be placed on the [R&D Service website](#).
 - VA has purposely **not** made a Word or fillable PDF version of the form available at this time.

- WHY you must file a RFCOI Statement:
 - The duties and responsibilities of your position as a principal investigator, co-principal investigator, investigator (including a collaborator who has a VA appointment), study chair or site principal investigator (hereinafter “Investigators”) require you to file a Research Financial Conflict of Interest Statement (Statement) to avoid involvement in a real or perceived conflict of interest. Federal employees are prohibited from participating personally and substantially in official VA matters affecting their own financial interest or those imputed to them. In addition, in research a real or perceived conflict of interest

occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. This Statement is to assist employees to avoid a conflict between their official duties and private financial interests or affiliations. See VHA Handbook 1200.13 (not yet issued).

- The revision of the 2011 form is a result of collaboration between VA ORD, VA Office of General Counsel (OGC), and the Office of Government Ethics (OGE).

■ HOW to submit the form(s):

- **Read the instructions, definitions, and information on the first two pages of the form.**
- Print out a hard copy and submit as below (there is **no** WORD or fillable-PDF version available at this time).
- Submit the form by either:
 - Sending the completed, signed and dated form to the Research Service in a sealed envelope attached to your submission of a new protocol or annual update/continuing review **OR**
 - Sending a PDF copy of the completed, signed and dated form to the Research Service FCOI contact via an encrypted email: jessica.mendoza@va.gov.

The attachments to this Hot Topic will be posted on the Forms page of the Research Service website:

http://www.maryland.research.va.gov/research/human/human_subject_forms.asp

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, or for comments, complaints or suggestions regarding the Research Service contact:

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Can't put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website:

http://www.maryland.research.va.gov/hot_topics.asp