

Purpose: It is CFVHS's IRB obligation to ensure research participant protections, the integrity of IRB review, and the conduct of research is not jeopardized by an unidentified or unmanaged conflict of interest. Use this form to disclose financial conflicts of interest or other interests that are/or may be perceived to be related to the research.

Instructions:

This form must be completed individually by the Principal Investigator (PI) and each person having responsibility for the design, conduct, and/or reporting of the research. This form should be submitted with the initial appropriate *IRB Protocol Application Form*. Individuals are responsible for notifying the PI of any changes to their IRB Conflict of Interest (COI) Form.

- The PI must keep completed copies of all protocol investigator's IRB COI forms for their records.
- Following the IRB review and approval of the research protocol, the PI must review, at least annually, this form with all applicable personnel and promptly report any changes to the IRB.
- The PI must submit this form only for:
 - New research personnel who have ***identified*** a real, perceived, or potential conflict of interest on their form. Submit the form(s) with either the appropriate *Protocol Application Form* or the Amendment Submission Form.
 - Existing personnel who have ***identified*** a change to a relay, perceived, or potential conflict of interest on their form. Submit the form(s) with an *Amendment Application Form*.

Additionally, if the research is federally, federally passthrough (federal funding routed through a local, state, or institution), and/or externally funded, federal regulations require a separate Financial Conflict of Interest (FCOI) declaration submitted for all researchers responsible for the design, conduct, or reporting of externally funded research.

- The FCOI declaration should be submitted prior to filling out this form.
- Any change to FCOI declaration information requires a re-submission within 30 days of the change.
- Complete all parts of this form, for Part III answer only question 1.

Save this form to your computer before proceeding.

For more information on federal regulations contact the IRB Office.

-CONTINUE TO THE NEXT PAGE-

Part I: Project Title and Researcher Information

Project Title:

Protocol Number (if known):

Principal Investigator:

Your Name:

Your Email:

Are you submitting this as a result of any change(s) to your previously disclosed financial conflict of interest?

Yes No

Part II: General Conflicts of Interest

1. Do you have a pre-existing relationship or affiliation with any of the external entities or their staff, or subjects (or potential subjects) affiliated with this research?

Yes No If "Yes", explain

2. Have you been involved with the development of any materials or products affiliated with this research?

Yes No If "Yes", explain:

3. Have you benefited or do you stand to benefit from the research or commercialization of its findings?

Yes No If "Yes", explain:

4. Is there anything about your involvement with this research that may appear to outsiders to be a conflict of interest?

Yes No If "Yes", explain:

5. If you have answered "Yes" to questions 1-4 in Part II above, please explain your research role?

Yes No If "Yes", explain:

Part III: Financial Conflicts of Interest

This section is related to financial interests that belong to you, your spouse, your domestic partner, or your dependent children and are related to this research protocol. Financial interests that are unrelated to research do not need to be disclosed.

1. If this is federally funded or Public Health Sponsored (PHS) research have you completed a CFVHS FCOI in Research Disclosure Form with the within the last 365 days?
 - Yes If "Yes", skip the remainder of this section and proceed to Part V: Investigator Confirmation.
 - No If "No", contact OSPR immediately.
 - NA If "NA", complete questions 2-7 below before proceeding to Part IV: Conflict of Interest Training.
2. Do you, your spouse, your domestic partner, or your dependent children have or plan to have compensation and/or other payments for service that exceeds \$5000?
(Do Not Disclose: compensation received less than \$5000, as well as any compensation received for lectures, seminars, teaching engagements, or service on advisory committees or review panels relating to federal, state, or local government agencies, an institution of higher education as defined in 20 U.S.C. 1001(s), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education, and compensation received from CFVHS funds.)
 - Yes No If "Yes", explain:
3. Do you, your spouse, your domestic partner, or your dependent children have or plan to have equity interests in a publicly-traded entity that exceeds \$5000?
(Do Not Disclose: Interests in publicly-traded entities valued at less than \$5000 as well as interests in any entity through personal retirement accounts and mutual funds.)
 - Yes No If "Yes", explain:
4. Do you, your spouse, your domestic partner, or your dependent children have or plan to have equity interests in a non-publicly-traded entity that exceeds 0?
(Do Not Disclose: Interests in any entity through personal retirement accounts and mutual funds.)
 - Yes No If "Yes", explain:
5. Do you, your spouse, your domestic partner, or your dependent children have or plan to have intellectual property rights and interests upon receipt of income related to such rights and interests that exceeds \$5000?
(Do Not Disclose: Royalties received from CFVHS funds, and unlicensed intellectual property that does not generate income.)
 - Yes No If "Yes", explain:
6. Do you, your spouse, your domestic partner, or your dependent children have or plan to sponsored or reimbursed travel that exceeds \$5000?
(Do Not Disclose: Travel administered through CFVHS funds, and travel reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of high education.)
 - Yes No If "Yes", explain:

7. If you have answered "Yes" to questions 2-6 in Part III above, please explain your research role:

N/A Role in Research:

Part IV: Conflict of Interest Training (for federally funded projects only)

1. Have you completed CFVHS Conflict of Interest Training and received your certification of training?

- Yes No If "Yes", please attach COI verification/certificate of training when submitting this form.
If "No", certification of COI training must be completed prior to submitting this form.

Part V: Investigator Certification

I hearby affirm:

- *I have declared an FCOI with the IRB Office, if applicable;*
- *I have completed COI training and certification, if applicable;*
- *The information I have provided in this Form is complete and accurate to the best of my knowledge.*

Researcher Signature

Date

- *Electronic signatures are acceptable. You may type in your name.*
- *Attach this form to your appropriate Protocol Application Form or Amendment Application Form.*