

FINANCIAL CONFLICT OF INTEREST (FCOI) and 208 waivers

VA researchers as Federal employees need to be mindful of 18 U.S. Code § 208 - Acts affecting a personal financial interest, (which are differ from the rules in academia.)

18 U.S. Code § 208 states: *“Except as permitted by subsection (b) hereof, whoever, being an officer or employee of the executive branch of the United States Government ..., participates personally and substantially as a Government officer or employee, through decision, approval, disapproval, recommendation, the rendering of advice, investigation, or otherwise, in a judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which, to his knowledge, he, his spouse, minor child, general partner, organization in which he is serving as officer, director, trustee, general partner or employee, or any person or organization with whom he is negotiating or has any arrangement concerning prospective employment, has a financial interest”*

- These rules, in simple terms, prohibit Federal employees from participating in official VA matters (e.g. research) if the employee has a personal financial interest or relationship that might affect their service to the Government – do they appear to have a “dog in the fight” that might affect their objectivity in performing their duties – are they acting in the best interest of the public, Veterans and the Department or is there some element of benefitting themselves or others.
- For the VA employee, the close relationship with the university affiliate only increases the potential to have an outside interest that might disqualify someone from conducting research at VA.
- One caveat – the mere existence of an outside interest does not automatically disqualify someone from a particular study – the determination is fact-driven and existence of an outside interest might mean that a consult with OGC Ethics Specialty Team (EST) is in order. OGC has tools to manage some interests that would otherwise be disqualifying. [By the way, a double-blind study does not resolve these types of financial or relationship-based conflicts of interest.]

Interests and relationships that might signal a need to contact VA OGC Ethics Team include:

- An outside entity that is funding/sponsoring the study or that owns or has licensed rights to inventions that are involved in or affected by the study (“affected” should be initially thought of in a very broad sense) – if the researcher or his spouse or minor child:
 - o has a financial interest in the company through ownership, stock holdings (including publicly-traded companies), being general partner;
 - o has a fiduciary responsibility toward the company because of service as officer/director/trustee (usually on the board of directors);
 - o is an employee, consultant, contractor, agent, or otherwise does business with the outside entity (e.g. speaker’s bureau, member of scientific advisory board, consultant) (or if the researcher has held such a position within the past year); or
 - o is negotiating or has an agreement for future employment with the entity
- Inventions are involved in the study – either the study is further research into the invention or will affect the value of the invention (e.g. make it more or less likely to be commercialized) and the invention is:
 - o made by the researcher,

- o owned by the researcher, or
- o owned by someone or some entity other than VA (including if that entity is the university affiliate)

How do you obtain an ethics consultation?

Email:

- OGCNorthAtlanticEthics@va.gov
for CT, DC, DE, MA, MD, ME, NC, NH, NJ, NY, PA, RI, VA, VT, WV
 - OGCSouthEastEthics@va.gov
for AL, FL, GA, KY, Puerto Rico, SC, TN
 - OGCMidwestEthics@va.gov
for IA, IL, IN, KS, MI, MN, MO, NE, ND, OH, SD, WI
 - OGCContinentalEthics@va.gov
for AR, CO, LA, MS, MT, OK, TX, UT, WY
 - OGCPacificEthics@va.gov
for AK, AZ, CA, Guam, HI, ID, NM, NV, OR, Philippines, WA
- Additional information on VA ethics can be found at <https://vawww.ogc.vaco.portal.va.gov/law/ethics/SitePages/Home.aspx>

How can a researcher commercialize their inventions?

- The Federal Technology Transfer Act at section 3710a, subparagraph (b)(3)(C), of title 15 United States Code, permits a Federal employee, under a Cooperative Research and Development Agreement (CRADA), to participate, as part of official duty, in an effort to commercialize an invention made by the researcher while in the employment or service of the Government.
- This means that with supervisory approval and after putting in place a CRADA, and if necessary a waiver of the criminal conflict of interest statute (208 waiver through EST), a VA researcher who has made an invention may assist the outside company that has licensed the invention in the commercialization effort by providing scientific and/or technical expertise or serving on the scientific advisory board.
- However, such assistance does not extend to activities related to the management of the outside company or to the promotion and/or marketing of its products to the general public

How to obtain a 208 Waiver

- It may be possible to obtain a 208 waiver and authorization which allows the researcher to participate in research from which they would otherwise be disqualified, absent such a waiver, because of their financial interest in the matters.
- The financial conflict of interest does not occur until there is a flow of royalties coming from a non-VA source (such as the academic affiliate) so consult with your VA Ethics official regarding whether and when a waiver is needed.
- The researchers will submit the information below to their VA Ethics official who will work with them on a waiver. If approved by the Federal Government Office of Government Ethics, the waiver will be processed through the ACOS for Research and signed by the MCD.
- The request for a 208 waiver includes the following:
 1. Your full VA title; whether you are Part time or Full time VA.

2. What is your “Area of Research” at VA? Please define this as broadly as possible in a sentence or two.
3. Please list all patents that you own or are listed as an inventor on. For each, please state:
 - a. Who owns the patent at issue - VA solely or Jointly owned by VA and the University?
 - b. Patent # if applicable
 - c. Date issued or any other relevant dates
 - d. any other information relevant to the patent(s)
4. State in layman’s terms: Your proposed study and how it will affect this IP.
5. Does your spouse work for the VA or a hold a University appointment? Please describe and if so, does he/she have any interest in the IP at issue?
6. Is there an outside company that is interested in licensing the IP?
7. If so, do you, your spouse, minor child, have any equity interest in the company, now or in the future?
8. Are you (spouse, minor child) an employee of the company licensing the IP or do you consult for the company or have any other financial interest in the company?

Remember to indicate invention disclosures in the Financial Conflict of Interest Form

- Currently the FCOI disclosure form can be found on ORD’s Tech Transfer Program website (Research Financial Conflict of Interest Statement located at http://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm)
- Question 3 in Section 1 asks:
 3. INTELLECTUAL PROPERTY. With respect to intellectual property that could be affected by this study, are you, your spouse, dependent child, general partner, or outside employer:
 - (i) listed as the inventor on an invention disclosure or a patent application;
 - (ii) the owner of any intellectual property;
 - (iii) the holder of a license of a patent, copyright, software or other intellectual property;
 - (iv) entitled to earn royalties now or in the future;
 - (v) the author of written materials that are, or are going to be, commercialized;
 - (vi) otherwise earning compensation from, or have a financial interest in, intellectual property (not covered elsewhere in this form); OR
 - (vii) holding any other financial relationship not covered elsewhere in this form?
- Question 3 in Section II, the researcher provides additional information including whether the invention is held jointly with an outside entity such as the academic affiliate.