

Ethical Concerns with Conflicts of Interest in Partnerships and Collaboration within the Military Health System

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“Medically Ready Force...Ready Medical Force”

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Learning Objectives



At the conclusion of this presentation, participants should be to :

1. Identify potential conflict of interest “hot-spots.”
2. Outline potential conflicts of interest in order to raise the matter to the appropriate subject matter expert (e.g., Chain of Command, Office of General Counsel, Agency Ethics Official, and/or Inspector General).
3. Distinguish how to spot, report, but not directly resolve an ethical issue.

The Law—18 USC Section 208

A Criminal Statute



An executive branch officer or employee who participates ***personally and substantially*** as a Government officer or employee in a **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—Shall be subject to criminal penalties.

- **“Personally”** means to participate directly. Including active supervision of a subordinate in the matter.
- **“Substantially”** means involvement of significance to the matter. Participation may be **substantial** although not determinative of the outcome of a particular matter. However, it requires more than official responsibility.
- **“Particular matter”** Affects the interests of specific persons, or a discrete and identifiable class of persons.

Regulations



5 CFR Part 2635- Subpart D (2635.401-403)--Conflicting Financial Interests

- ☐ An employee is prohibited from participating in an official capacity in any matter in which, to his knowledge, he or any person whose interests are imputed to him has a financial interest, if the matter will have a ***direct and predictable effect*** on that interest.
- ☐ A matter will directly effect a financial interest if there is a close causal link between any decision or action and any expected effect on the financial interest. An effect may be direct even though it does not occur immediately.

Imputed interests. For purposes of 18 USC 208 and this subpart, the financial interests of the following persons will serve to disqualify an employee to the same extent as if they were the employee's own interests:

- ☐ Spouse
- ☐ Minor child
- ☐ **General Partner**
- ☐ An organization or entity which the employee serves as officer, director trustee, ***general partner or employee***
- ☐ A person with whom the employee is negotiating for or has an arrangement concerning prospective employment

Regulations continued...



5 CFR Part 2635

- Subpart E (2635.501-503)--Impartiality in Performing Official Duties
 - Unless he/she receives prior authorization, an employee should not participate in a particular matter involving specific parties which he knows is likely to affect the financial interests of a member of his household, or if a reasonable person with knowledge of the relevant facts would question his impartiality in the matter.

- Subpart H (2635.801-809)--Outside Activities
 - Prohibits outside employment, outside activities and personal financial obligations of employees or any other outside activity that conflicts with the employee's official duties.

Cooperative Agreements



15 U.S. Code § 3710a - Cooperative research and development agreements

- A statutorily permissible outside financial interest for inventors—but only if the laboratory agrees

- ☐ (3) Under an agreement entered into pursuant to subsection (a)(1), a laboratory may...

- ☐ (C) To the extent consistent with any applicable agency requirements or standards of conduct, permit an employee or former employee of the laboratory to participate to commercialize an invention made by the employee or former employee while in the employment or service of the Government.

NOTE: There must be an agreement, so the relationship is both approved and in the open. “Sunlight is the best disinfectant.” - Justice Brandeis.

BEWARE—PAST PROBLEM AREAS



- Inventors who don't disclose an invention (i.e., file a Notice of Invention with the Laboratory), then file a patent on their own. That deprives the government of the choice of whether to file for a patent and, if so, to license the technology.
- Relationships between a government official who is a Cooperative Research and Development Agreement's (CRADA's) proponent, the principle investigator and the collaborator. It should be part of the Department of Defense (DoD) lab's Standard Operating Procedure (SOP) to probe relationships between the government CRADA proponents, the principle investigator and the collaborator.

PAST PROBLEM AREAS continued...



- Beware of disgruntled inventors who think that their value far exceeds their royalty and are undercompensated. They may seek (and, indeed, have sought) compensation on-the-side without disclosure.
- Grants can have the same conflict of interest issues as Federal Acquisition Regulation(FAR) based contracts regarding evaluators with imputed financial interests to entities competing for, or receiving, a grant.

What can be pernicious about partnerships?

IMPUTATION OF THE PARTNERS'/PARTNERSHIP'S FINANCIAL
INTEREST TO THE GOVERNMENT OFFICIAL PARTNER

Let's Discuss Situations You May Encounter



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Polling Question #1



A scientist at a DHA laboratory is frustrated because CRADA approval takes so long that, by the time the CRADA is approved, the state of the art has moved on and the research is outdated. So, the scientist teams with a collaborator outside official channels, conducting the research on government time at the DHA laboratory. When you learn this, you:

- A. Notify the lab director
- B. Notify lab counsel
- C. Either or both above; or
- D. Commiserate with the scientist and offer to assist with the research

Polling Question #2



The scientist is working “off-the-books” with a collaboration invents something. That scientist should:

- A. File privately for a patent without disclosing the invention to the government because, after all, if the government truly wanted to participate it wouldn't have dithered regarding the CRADA; or
- B. Disclose the invention under the lab's invention disclosure procedures, thereby bringing to the lab director's attention the scientist's off-the-books research; or
- C. Something else?

Polling Question #3



You learn about the scientist's invention in your DHA lab, but curiously you never hear anything more. In a casual conversation with the lab's patent counsel, you get the impression that patent counsel is unaware of the invention. You are not a member of the lab's committee that reviews whether the government should pursue a patent for inventions. You should:

- A. Leave this to others;
- B. Mention this to the lab director;
- C. Mention this to your supervisor; or
- D. Mention this to lab counsel.

Polling Question #4



The scientist in the previous questions obtains a patent privately without disclosing that invention and licenses the technology.

You are the Lab's Ethics Counsel. What might the scientist have violated?

- A. Nothing because this research wasn't approved by the laboratory—it was off-the-books
- B. Agency and laboratory Technology Transfer procedures
- C. 5 CFR Part 2635 Part H--Outside Activities
 - A. Prohibits outside employment, outside activities and personal financial obligations of employees or any other outside activity that conflicts with the employee's official duties.
- D. 5 CFR 2635 Part H is inapplicable here because the private filing of the patent does not conflict with the scientist's official duties.

Polling Question #5



The scientist discloses the invention, the government obtains a patent, the lab tries to license the invention to a third-party, but the potential licensee will only enter into the license if the inventor serves as a paid technical advisor. (FYI—this request is not unusual.) The scientist doesn't want to leave his government job.

- A. This cannot be done because of 18 USC 208—the scientist was personally and substantially involved in the invention and would have an illegal financial interest with the licensee.
- B. This can be done while the scientist remains a lab employee IF the lab director permits the scientist-inventor to help the licensee commercialize the technology. *See 15 USC 3710a(b)(3)(C)

Polling Question #6



An employee of the Defense Health Agency has just been asked to serve on the technical evaluation panel to review grant proposals. Acme Immune Corporation, a closely held company in which he and his wife own majority of stock, has submitted a proposal.

- A. Because this is a grant, the FAR and its conflict of interest provisions don't apply and, moreover, there's rarely litigation with grant awards. Don't worry, be happy.
- B. Because award of the grant to Acme or to any other offeror will have a direct and predictable effect on both his and his wife's financial interests, the employee cannot participate on the technical evaluation team unless his disqualification has been waived—and this would violate 18 USC 208 because the evaluator is personally and substantially involved in the evaluation.

Polling Question #7



Upon assignment to the technical evaluation panel, the government employee in the preceding example (#6) finds that Acme Immune Corporation has not submitted a proposal. Rather, Roadrunner Corporation, with which Acme competes for private sector business, is one of six offerors.

- A. This still violates 18 USC 208 because the government employee is personally and substantially involved in the evaluation and the result will affect his financial interest.
- B. The employee is not disqualified from serving on the technical evaluation panel because any effect on the employee's financial interests as a result of the agency's decision to award or not award the systems contract to Roadrunner Corporation would be indirect and speculative.

Polling Question #8



Dr. Bambi Doe is the Principle Investigator on a CRADA with Collaborator X. The research results are disappointing. Dr. Doe is considering whether to reassign government manpower and equipment to other research. Collaborator X's president meets with Dr. Doe to inform her that they just received promising results—a breakthrough may be just around the corner! Dr. Doe, skeptical, nonetheless decides to continue the lab's level of support for another month. Dr. Doe's husband, Buck Doe, is an accountant. When Collaborator X formed as an undercapitalized start-up years ago, Collaborator X struck a deal with Buck Doe: He received a very small partnership share of Collaborator X in return for charging reduced rates on keeping the Collaborator X's books. Collaborator X has never had a profit.

- A. Everything is fine because Buck Doe has nothing whatsoever to do with the research.
- B. Everything is not fine because Dr. Bambi Doe is personally and substantially involved in this matter of which her husband is a general partner of Collaborator X, he has a financial interest, and Buck Doe's financial interest is imputed to his spouse, Principle Investigator Dr. Bambi Doe.

*See also 5 CFR Part 2635 and 5 CFR Part 2635 Subpart E for other bases for this being not fine.

Polling Question #9



A superstar Navy M.D. is part of your lab. He is a prolific inventor. He recently outdid himself by inventing a drug that reverses the effects of frostbite. Shortly thereafter, the Navy doc started grumbling incessantly as to how he isn't appreciated and is not compensated to his full value. Around that same time, he started closing his usually open office door and the doc seemed perpetually busy on other matters of which you and your colleagues were unaware what they may be. Yesterday he drove a new Ferrari into the lab parking lot. You should:

- A. Ask for a ride in the Ferrari;
- B. Mention to the lab director, lab counsel, or your supervisor that something seems unusual.
- C. All the above.

Polling Question #10



Joe Doaks, who handles the lab's Communications/Public Affairs, suggests a CRADA with the local minor league ice hockey team to study traumatic brain injury by adding sensors to the hockey helmets and padding. Joe makes the connection with the hockey team, which is amenable to collaborate on the CRADA. Joe Doaks' wife, a salesperson for Acme Sensors who works on commission, sells the type of sensors and data collection devices to be used in the research. She sells the sensors to the hockey team, which supplies them for the CRADA.

- A. No problem because Ms. Doaks doesn't work for the lab or for the collaborating hockey team.
- B. This violates 18 USC 208 and 5 CFR Part 2635 Subpart D (2635.401-403).
- C. This may not violate that statute and regulation depending on, whether, as a factual matter, Joe Doaks is personally and substantially involved with the CRADA (that seems doubtful) and whether the benefit to his financial interest was direct and predictable (also doubtful).
- D. This may well violate 5 CFR Part 2635 Subparts Subpart E (2635.501-503)--Impartiality in Performing Official Duties, and Subpart H (2635.801-809)--Outside Activities
- E. Doaks should have disclosed to the lab director that his wife sells the type of sensors needed by the hockey team under the CRADA.

Key Takeaways



1. **Conflicts of Interest (COI) happen.** This is not hypothetical or only happens to others.
2. **Be Diligent.** If a COI happens, let it be DESPITE your diligence (e.g., an SOP to examine financial interests between the principle investigator and CRADA proponent and the collaborator), not because of your laxity. Know what scientists in your lab are inventing and whether inventions are disclosed. If something seems “off,” it may well be (e.g., a superstar inventor disgruntled for not receiving more money).
3. **Involve your subject matter experts.** As stated earlier, your role is to issue-spot, not resolve potential COIs singlehandedly.

References



Acts Affecting a Personal Financial Interest, 18 U. S. C. § 208 (2012),

<https://www.govinfo.gov/content/pkg/USCODE-2012-title18/html/USCODE-2012-title18-part1-chap11-sec208.htm>

Cooperative research and development agreements, 15 U.S.C. § 3710a(b)(3)(C) (2012),

<https://www.govinfo.gov/content/pkg/USCODE-2011-title15/pdf/USCODE-2011-title15-chap63-sec3710a.pdf>.

Standards of Ethical Conduct for Employees of the Executive Branch. 5 CFR Part 2635, Subpart D, E, H

(2011), <https://www.govinfo.gov/content/pkg/CFR-2011-title5-vol3/pdf/CFR-2011-title5-vol3-part2635.pdf>

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