NAVREF
National Association of Veterans' Research and Education Foundations

FREQUENTLY ASKED QUESTIONS:

VA RESEARCHERS & INDUSTRY PARTNERSHIPS

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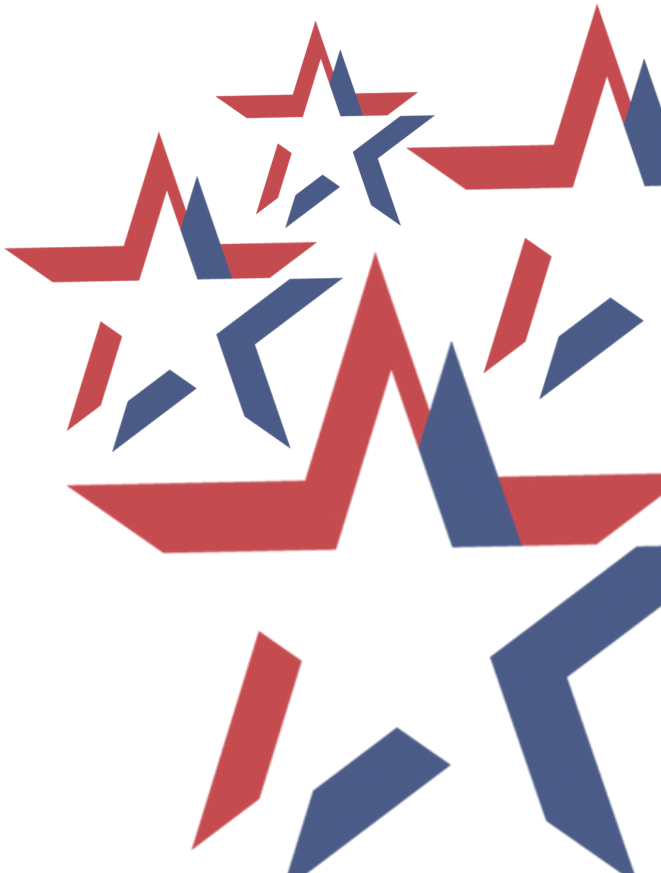
This FAQ document is intended for VA research staff or prospective investigators.



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WHO IS "INDUSTRY?"

In an industry sponsored clinical trial, "industry" refers to a private sector company that may be funding or designing a trial to study a product they are developing. It typically refers to a pharmaceutical, biotechnology, or medical device company. Sponsors refer to companies that are initiating, managing, and paying for the trial.

ARE VA RESEARCHERS ALLOWED TO PARTNER WITH INDUSTRY ON CLINICAL TRIALS?

Yes. VA researchers—also known as VA principal investigators (PIs)—are allowed to collaborate with industry partners on clinical trials, as long as the collaboration supports the VA's mission to improve the health and wellbeing of Veterans.

These collaborations can take different forms, including participating as a site investigator on an industry-sponsored clinical trial or partnering with industry on an investigator-initiated trial. In all cases, the partnership must follow established VA policies and procedures that safeguard scientific integrity, promote transparency, and ensure alignment with VA research priorities.

VA researchers who are interested in these types of collaborations should work closely with their local research office and affiliated nonprofit corporation (NPC), both of which can provide guidance on approvals, funding mechanisms, and compliance requirements.

WHAT IS AN NPC?

A Nonprofit Corporation (NPC) is a congressionally authorized, VA-affiliated organization that facilitates research and education activities at VA medical centers. By statute NPCs can:

- Receive and manage industry funding
- Help negotiate budgets and agreements
- Ensure compliance with federal policies

WHAT ARE THE BENEFITS OF PARTNERING WITH INDUSTRY?

There are numerous benefits for collaborating with industry including (but not limited to):

- Access to cutting-edge therapies and/or technologies that will advance veterans' health
- Additional funding and infrastructure support
- Opportunities for veterans to participate in high impact trials
- Enhanced translational impact of VA research

HOW DO VA PIS FIND INDUSTRY COLLABORATORS?

Many VA researchers connect with industry collaborators at scientific conferences or through introductions made by other VA colleagues. Others reach out directly to industry representatives conducting research relevant to their area of expertise.

Some pharmaceutical and biotech companies have dedicated portals or programs for investigator-initiated trials (IITs), which VA researchers can explore to propose studies that align with their clinical and scientific goals. In addition, local NPCs and organizations like NAVREF may help identify potential opportunities or facilitate introductions based on sponsor interest or emerging trial needs.

HOW DO SPONSORS FIND VA PIS?

VA is a large system, so there is no single pathway for connecting with researchers. However, several effective approaches exist:

1. **Partnered Research Program (PRP)**. PRP is designed for industry sponsors seeking to conduct multisite interventional clinical trials on high-priority topics aligned with VA's mission.
2. **NAVREF and its network of local NPCs.** NAVREF and/or your local NPC will routinely share study opportunities across the system and connect sponsors with investigators based on expertise and interest.
3. Industry sponsors may also reach out directly to individual VA researchers who are publishing or presenting work in relevant areas.

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ARE VA RESEARCHERS ALLOWED TO TALK TO INDUSTRY SPONSORS?

Yes. If a sponsor is interested in talking with a VA investigator about their research or having them participate in an upcoming trial, they may reach out directly. Sponsors are often excited to connect with VA PIs who often possess extensive knowledge in their respective fields.

CAN A VA RESEARCHER INITIATE CONTACT WITH AN INDUSTRY SPONSOR?

Yes. VA researchers may reach out to or respond to inquiries from industry sponsors. Any resulting collaboration must follow VA policies (your local R&D Office or NPC can help!)

CAN VA RESEARCHERS BE PAID DIRECTLY BY INDUSTRY?

No. VA researchers CANNOT be directly paid by industry for work conducted as a part of their VA duties. However, industry funding and support can flow through VA's network of nonprofit corporations (NPCs). To find your local NPC, please visit https://navref.org/directory.

WHY ARE CONFIDENTIAL DISCLOSURE AGREEMENTS (CDAS) OR NON-DISCLOSURE AGREEMENTS (NDAS) NEEDED?

CDAs (also known as NDAs) are used to protect confidential or proprietary information shared between parties during early discussions about potential research collaborations or clinical trials.

For VA research, a CDA ensures that sensitive information—such as study protocols, investigational product details, or unpublished data—is not disclosed or used inappropriately. This protects both the sponsor's intellectual property and the VA's interests, while allowing for open, informed conversations about feasibility, study design, or partnership potential.

While some investigators might initially view CDAs as a barrier, it's important to understand that they safeguard researchers' contributions. For example, if an investigator contributes to the development of an investigational product or a novel research idea, those contributions may qualify for royalty payments or intellectual property rights. CDAs help ensure that any potential future benefits, including recognition and financial rewards, are properly tracked and protected.

WHEN IS A CDA NEEDED AND WHO SIGNS IT?

A CDA is typically needed before sharing any proprietary, confidential, or non-public information between a sponsor and a VA researcher or NPC. They are typically put into place:

- **Before Feasibility Discussions:** If a sponsor wants to explore whether a VA site or investigator is a good fit for a trial and will share a protocol, investigational product information, or other sensitive materials, a CDA should be in place first.
- **Before Budget or Contract Negotiations:** When proprietary trial details or pricing structures may be discussed between a sponsor and an NPC or VA investigator, a CDA may be needed to protect the confidentiality of both parties.
- **Before Sharing Unpublished Data:** If unpublished study results or scientific data will be shared for collaborative planning, a CDA ensures that this information is protected.

Importantly, VA investigators cannot independently sign a CDA—they may acknowledge it, but the actual execution must come from either the local NPC or the Partnered Research Program (PRP), depending on the structure of the collaboration. In contrast, CDAs are generally not needed for preliminary conversations about public studies, general research interests, or VA capabilities.

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WHAT KINDS OF COSTS CAN BE COVERED BY AN INDUSTRY SPONSOR?

Industry can cover:

- Study staff salaries (via the local NPC)
- Participant stipends
- Research-related procedures
- Data management
- Facilities & Administrative Costs

Your NPC can help you with building a compliant and fair budget.

CAN I ACCEPT LUNCH OR A SMALL GIFT FROM A POTENTIAL RESEARCH FUNDER?

Federal ethics rules allow VA employees to accept unsolicited gifts of modest value in certain circumstances. Specifically:

- Accepting a gift valued at $20 or less: You may accept gifts, including meals, with a market value of $20 or less per occasion.
- Annual Limit: However, the total value of gifts from a single source in a calendar year cannot exceed $50.
- No Cash or Influence: You can never accept cash or anything of value in exchange for taking a specific official action.

That said, pharmaceutical and device companies are considered “prohibited sources” under federal ethics rules—and under the Sunshine Act, they are required to publicly disclose most payments to healthcare providers, including meals.

In the event of any questions, please reach out to your local ethics officer, R&D Office, or NPC for guidance—or review 5 U.S. Code § 7351.

FOR EARLY-CAREER VA RESEARCHERS, WHAT IS THE BENEFIT OF WORKING WITH INDUSTRY?

For early-career VA researchers, participating in industry-sponsored clinical trials offers valuable professional development—particularly in understanding clinical trial operations, regulatory processes, and sponsor expectations.

Initially, early-career investigators may serve as a co-investigator or sub-investigator; these roles provide opportunities for hands-on experience, and increased visibility within the research community. Over time, such involvement can help build the track record and expertise needed to lead future studies.

DOES PARTNERING WITH INDUSTRY COMPROMISE SCIENTIFIC INTEGRITY?

Not if managed properly! VA has strong safeguards to ensure that ALL research – regardless of funding source – meets high standards of scientific rigor, transparency, and ethics.

WHAT AGREEMENTS ARE NEEDED TO WORK WITH INDUSTRY?

VA researchers typically need:

- A CRADA (Cooperative Research and Development Agreement) for collaboration. CRADAs ensure compliance with federal ethics and research regulations.
- VA R&D Committee & IRB Approvals. Your local research office and NPC can help you navigate these approvals
- CDA – Confidential Disclosure Agreement
  - VA PIs can sign but only acknowledge the agreement and abide by the terms applicable to the PI.
  - CDAs must be reviewed and signed by authorized officials, typically your NPC or VA Office of General Counsel

WILL PARTNERING WITH INDUSTRY ADVERSELY IMPACT A VA RESEARCHER'S VA (OR ACADEMIC) PROMOTION?

No. In fact, industry collaboration can enhance a Researcher's portfolio, especially if the trial results in high-quality research, publications, and leadership roles. Transparency about funding sources and independence in publications are key to maintaining academic integrity.