NORTH FLORIDA FOUNDATION FOR RESEARCH AND EDUCATION

Navigating Collaborations within VA Clinical Research*

A Guidebook for
Industry Sponsors,
Contract Research Organizations,
and other Private or Non-Profit Organizations

MAY 1, 2024

***Note**: This guide is adapted from the Guidebook of the National Association of Veterans' Research and Education Foundations (NAVREF), a 501(c)(3) nonprofit membership organization of research and education foundations affiliated with Department of Veterans Affairs (VA) medical centers. These nonprofits, also known as the VA-affiliated nonprofit research and education corporations (NPCs), are authorized by Congress under 38 USC §§7361-7366 to provide flexible funding mechanisms for the conduct of research and education at VA facilities nationwide.

NAVREF

I. Contents

II. Overview and Purpose

The Veterans Health Administration (VHA) is the largest integrated healthcare network in the United States, serving millions of veterans across the country. As such, VHA has access to a large and diverse patient population, well-characterized patient data, specialized facilities, affiliations with various academic medical centers, and expertise focused on veteran-specific health issues. For these reasons, VHA serves as a unique system for collaborative research opportunities.

With such an expansive system, it can be challenging for external organizations interested in working with VHA either on a national or local level to not only get a foot in the door, but also to navigate once inside. Therefore, the primary objective of this document is to provide external organizations with the information necessary to:

- Understand roles and responsibilities of the various stakeholders involved in industry sponsored clinical trials within VHA.
- Identify the appropriate initial entry point to engage VA in a potential research collaboration.
- Guide organizations interested in working with VA on other types of research, such as pilot studies, observational studies, and health outcomes research.

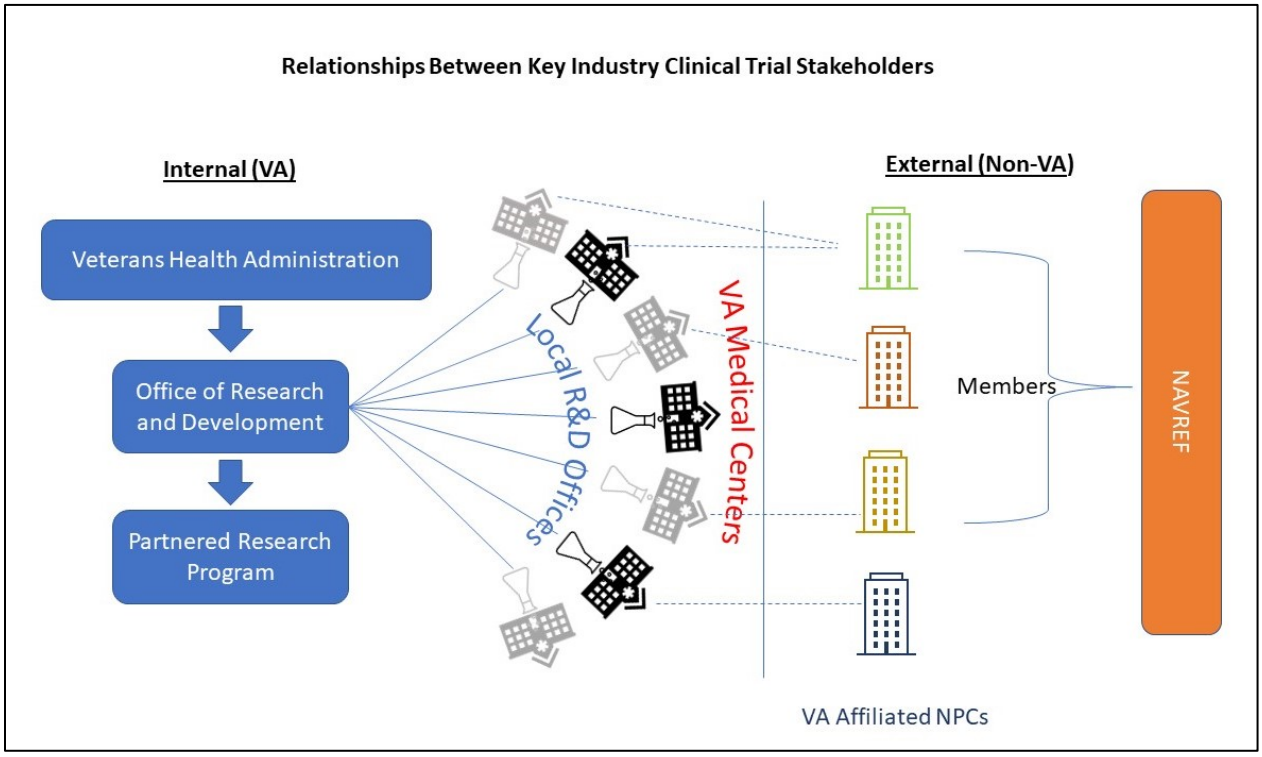
This document is not meant to be a comprehensive resource, but rather provides crucial considerations, steps, and resources to help organizations get started.

It should be noted that while this document was developed collaboratively with the VA Office of Research and Development (VA ORD), National Association for Veterans Research and Education Foundations (NAVREF), and VA non-profit corporations (VA-NPCs), it is not an official VA document nor should be viewed as authoritative on behalf of VA. It was produced as a service by NAVREF as part of its mission to support VA research and educational activities.

III. Who's Who: Key Stakeholders in VA Clinical Trials

To navigate the VA clinical trials landscape, it helps to understand who the various stakeholders are- both within and outside of VA. The diagram below illustrates where these organizations sit (within or external to VA) and their relationships to one another. The table provides information regarding their roles and responsibilities.

A. Organizational Relationship Diagram



INTERNAL VA: Within the Veterans Health Administration (VHA), the Office of Research and Development (ORD) is responsible for the execution of VA's research mission. One of ORD's key strategic priorities is increasing recruitment of Veterans into high-quality clinical trials. To help achieve that goal, ORD established the Partnered Research Program (PRP) which serves VA as the preferred entry point for industry sponsored multisite clinical trials and focuses on building relationships with industry partners and VA clinical and research resources, identifying and developing opportunities for standardizing and streamlining clinical trial start up activities. In the case of select trials deemed to be of high priority/wide impact, the PRP may be tasked by ORD to manage trial start up activities.

EXTERNAL VA: NAVREF and VA-NPCs play vital roles in facilitating collaborative research between industry partners and VHA. NAVREF collaborates with industry-partners and the PRP to facilitate the dissemination of study information to all VA-NPCs across the nation. VA-NPCs, in turn, work closely with their respective local medical centers to evaluate the feasibility of conducing a particular study at their site. VA-NPC takes lead in identifying a Principal Investigator and assembling a study team. The VA-NPCs coordinate contract and budget negotiations. If appropriate, NAVREF may also refer the sponsor to PRP.

B. Key Stakeholders Roles and Responsibilities

Key Stakeholders Roles and Responsibilities		
Organization	**Description**	**Roles & Responsibilities**
Non-VA (Extramural) Stakeholders		
National Association of Veterans' Research and Education Foundations (NAVREF)	501(c)(3) nonprofit membership organization to which approximately 76 VA affiliated non-profit corporations (VA-NPCs) belong. The NAVREF Industry Partner Consortium (IPC) is a platform for industry sponsors, VA-nonprofit corporations, and other external stakeholders to maximize efficiencies in recruiting Veterans for cutting-edge clinical trials. The IPC represents stakeholders from all facets of the healthcare industry: pharmaceuticals, medical technology, nonprofit foundations, and other organizations with an interest in VHA research.	• Serves as the primary point of contact for external organizations when: ○ Seeking fast turnaround for short open enrollment periods. ○ Seeking single (1 site) VA engagement in a clinical trial. ○ Seeking VA information in support of a CRO's bid • Bridges a gap between external organizations and the VA affiliated NPCs. • Advocates on behalf of its NPC membership
VA Affiliated Non-Profit Corporations (NPCs)	501(c)(3) nonprofit corporations authorized by Congress under 38 USC §§7361-7366 to provide VA medical facilities with flexible funding mechanisms to support VA-approved research and educational projects. Otherwise known as VA Foundations. NPCs are not owned or controlled by the Federal Government, nor are they an agency or instrumentality of the Federal Government. There are approximately 79 NPCs affiliated with approximately 100 VA medical centers (VAMCs).	• Manage non-VA funds such as funding from industry sponsors or other federal agencies for VA research. • Hire staff, purchase equipment and supplies, reimburse VA facilities for services rendered. • Negotiate and manage study budgets and agreements. • NPCs may enter into contracts and other agreements with individuals and public and private entities for research and educational purposes; however they may not enter into agreements on behalf of VA or that purport to bind VA. • NPCs and VA are both parties to Cooperative Research and Development Agreements (CRADA), the Federal Government's clinical trial agreements, which are subject to review and approval by the VA Office of General Counsel.

Key Stakeholders Roles and Responsibilities		
Organization	**Description**	**Roles & Responsibilities**
Internal (Inside of VA) Stakeholders		
Office of Research and Development (ORD)	Office within the Veterans Health Administration responsible for carrying out the strategic mission of VA research. Led by the Chief Research and Development Officer (CRADO)	• Issues policies for how research is done within VHA. • Supports VA investigators and research offices across the nation. • Maintains key research enterprise resources that help advance its strategic priorities.
Partnered Research Program (PRP)	Program within ORD dedicated to the enterprise-based approach to developing long-term relationships with external organizations committed to Veteranss health and one of ORD's strategic goals to enhance recruitment of Veterans to high-quality multisite clinical trials. PRP focuses its activities on: • **Clinical Trial Partnerships and Relationship Building** with external organizations and internal stakeholders committed to improving recruitment of Veteran into clinical trials. • **Clinical Trial Standardization and Quality** to ensure that start up procedures be well-defined and standardized across VA when possible. • **Clinical Trial Facilitation of** key study start up activities such as: CDA negotiation and execution, site identification, feasibility and selection, budget and contract timelines, submission and approval timelines. Additional information about the PRP can be found on its webpage.	• Serves as the *VA preferred* initial entry point for all industry sponsored multisite clinical trials. • Improves stakeholders' understanding of VA research and serve as the primary resource for the conduct of industry sponsored multisite trials within VA. • Identify opportunities to improve clinical trial start up activities as well as to identify, develop and/or disseminate tools & resources that support high quality and efficient processes. • Provide guidance and support related to key study start up activities.
VA Medical Centers	VAMCs are the primary sources of care that also carry out VA missions related to research and education. The VAMCs range in levels of complexity and can provide state-of-the-art	VA Principal Investigator and study team conduct the clinical trial at the VAMC.

Key Stakeholders Roles and Responsibilities		
Organization	**Description**	**Roles & Responsibilities**
VA Medical Centers	technology and a range of services such as education and research. Wide ranging VA services include traditional hospital-based services such as surgery, critical care, mental health, orthopedics, pharmacy, radiology, and physical therapy. In addition, most VAMCs offer additional medical and surgical specialty services including audiology and speech pathology, dermatology, dental, geriatrics, neurology, oncology, podiatry, prosthetics, urology, and vision care. Some VAMCs also offer advanced services such as organ transplants and plastic surgery. Approximately 100 VAMCs maintain research programs that are under the purview the VAMC Research Service, which is led by the Associate Chief of Staff for Research (ACOS/R). From a research regulatory standpoint, each facility is an independent entity with the VAMC Director serving as the institutional official.	VA Principal Investigator and study team conduct the clinical trial at the VA medical center.

IV. Foot in the Door – Where Does Industry Begin?

A. Determining Entry Point

The Veterans Health Administration is a multifaceted organization that requires a tailored approach when it comes to engaging in research activities. A one-size-fits-all approach simply wouldn't be feasible due to the complexity and diversity of the system. Therefore, it is important that external organizations be familiar with the various ways they can engage VA and the strengths and limitations of each. This will allow organizations to more efficiently navigate the system y based on their needs and desired outcomes.

Let's explore each of these entry points in more detail.

1. VA Partnered Research Program

a) What is the Partnered Research Program?

The PRP serves as *VA's preferred* starting point for external organizations seeking to collaborate with VA Research around industry sponsored multisite interventional clinical trials.

b) *How Does Industry Initiate Contact with the PRP?*

Study Sponsors and Contract Research Organizations (CROs) are encouraged to visit the PRP's webpage to learn more about the PRP. Organizations interested in engaging with VA around clinical trial collaborations should visit the PRP's Engagement Decision Tool to determine whether a submission to the PRP is appropriate or if they may be better served by another internal or external entity. The Decision Tool walks organizations through a series of yes/no questions focused on the nature of the proposed collaboration. With each response, users are either directed to the next question or provided with the appropriate point of contact. Potential collaborations that meet criteria for submission will be directed to submit a Request for Collaboration to the PRP.

c) *Key Considerations Before Submitting to the PRP*

VA prioritizes those opportunities designed to address the needs of Veterans and for which VA is best positioned to be successful. Companies best served by the PRP are:

- Committed to placing multiple trials within VA
- Interested in VA feedback/input into trial design
- Wiling to exchange information related to challenges and best practices

This relationship building and engagement process takes time- often a period of 3-6 months. This allows the PRP to review your submission, connect with the appropriate clinical and research leads/experts, get the necessarily agreements in place, identify interested sites and when appropriate, identify a VA Champion to work with your study team. Therefore, early engagement (at least 6 months prior to VA enrollment is key).

Please note that the PRP is not purely a clinical trial matchmaking service. If an organization is seeking rapid identification of interested VA sites/investigators to onboard sites quickly, please refer to the decision tool and follow the given guidance.

d) *What Happens After My Organization Submits to the PRP?*

The PRP reviews all Requests for Collaboration that it receives and will provide a response typically within 3 business days. The purpose of the PRP review is to determine if a given request is a) complete (meaning does the PRP have enough information in order to move it forward) and b) appropriate (meaning does the information outlined in the request meet criteria for submission as outlined in the decision tool). The organizational POC will be contacted by email with the outcome of this review and next steps will be detailed.

General questions about the Partnered Research Program should be directed to PartneredResearch@va.gov

2. NAVREF

NAVREF can offer support to external organizations to help identify interested investigators and sites. To initiate a request for NAVREF support, kindly send an email inquiry to info@navref.org . In the email, please include relevant study information such as a non-confidential summary of the protocol or a link to the ClinicalTrials.gov listing. Please note that any CDA executed between VA and your organization is not applicable to NAVREF and any CDA between NAVREF and your organization is not applicable to VA. NAVREF can help support site identification in the following ways:

a. NAVREF can distribute a bulk email to all its network of Participating Clinical Sites (NPCs) that provides details about the study opportunity, including as much publicly available information as possible or a reference to the ClinicalTrials.gov listing. The email will request that interested sites reach out to the sponsor/CRO for further information or to express their interest in participating as a study site.

b. NAVREF can publish the study opportunity on a secure, members-only section of its website that is dedicated to listing clinical trial opportunities. This listing will include general information about the study, such as a link to the ClinicalTrials.gov listing, and the contact details for obtaining additional information.

c. To the fullest extent of its capabilities, NAVREF can suggest sites that are suitable for the study based on their research focus and patient demographics. The organization will provide specific contact information for the sponsor/CRO to directly connect with the potential sites.

Please note: It is not advantageous to any organization to submit to both NAVREF and PRP and such activity could negatively impact efforts being undertaken to assist you. The two entities will, when appropriate, consult with each other and make referrals to one another when necessary. If an organization is unclear as to how to proceed after reviewing the decision tool and guidance, they should initiate contact via the PRP which will then provide further instruction.

3. VA-NPCs

VA-NPCs operate within VAMCs and facilitate research, education, and other programs that support the VA Healthcare System's mission. They offer a range of resources and expertise, making them attractive entry points for sponsors seeking research collaborations within specific medical centers. Overtime, sponsors develop relationships with different VA-NPCs. It is not uncommon for a sponsor to contact a VA-NPC's executive director to determine if their site or others have an interest in collaborating on a study, especially if they have

collaborated on prior successful studies. If the sponsor is only looking for a single site, then the VA-NPC may be the best place to initiate a conversation around site participation.

4. Principal Investigators

Within the VHA, there are numerous experienced and dedicated principal investigators (PI) leading research initiatives. Sponsors can directly reach out to these investigators, who possess extensive knowledge in their respective fields. For example, a sponsor may meet a physician-scientist at a scientific conference and initiate discussions on study collaborations. Alternatively, a sponsor may have had prior successful collaborations with a physician-scientist. Collaborating with principal investigators can provide sponsors with valuable expertise and access to a wide range of resources within the VA system.

If a sponsor has an established relationship with a PI and is interested in having that investigator participate as a single site, the sponsor can contact that PI directly. VA investigators may also be approached for various other types of research activities. Such important relationships should continue. If at any point the sponsor, or CRO determines that they wish to expand the study beyond a single site, they can and should be referred to NAVREF or the PRP as appropriate.

V. Key Activities in Site Selection & Study Start-Up (VA-NPC Entry Point)

As highlighted in this guide, the VA healthcare system offers several entry points for conducting research. Sponsors seeking to collaborate with multiple VA sites have the option to engage with PRP or NAVREF. These avenues provide opportunities to establish partnerships and facilitate research across various locations within the VA system.

It's important to note that depending on the chosen entry point and the stage of study development, the processes for feasibility assessment and negotiation of clinical trials may differ. Each entry point may have specific guidelines and procedures to follow, ensuring a streamlined and efficient research process within the VA healthcare system.

This section of the guide provides general guidance when utilizing the VA-NPC as the entry point. These instructions will outline the general steps and procedures to be followed for feasibility assessment, negotiation, and successful implementation of the research study within the VA system. Procedures related to other entry points may vary and should be discussed with the appropriate point of contact.

By understanding the different entry points available and the varying processes associated with each, sponsors can navigate the VA healthcare system more effectively and engage in research collaborations that align with their objectives.

A. CDA

In the VA healthcare system, confidential disclosure agreements (CDAs) are normally specific to each study and are vital for ensuring the protection of confidential information. The CDA negotiation process ensures that all parties involved in the research study, including the sponsor and the VA sites, adhere to the agreed-upon terms

regarding the protection and confidentiality of sensitive information. It is important for sponsors to understand that the specific CDA negotiation and signature routing procedures may vary depending on the entry point. Therefore, it is crucial to follow the instructions provided by the PRP or VA-NPC to ensure compliance with the VA healthcare system's requirements and guidelines regarding CDAs.

Typically, VA-NPC will route approved CDA(s) for local site signatures, which include the medical center director or their designated representative, the Associated Chief of Staff for Research (ACOS/R).

Please note that any CDA executed between VA and your organization is not applicable to NAVREF and any CDA between NAVREF and your organization is not applicable to VA.

B. Feasibility

The VA-NPC Executive Directors and/or principal investigators (PI) the receive notifications about clinical trial opportunities to be conducted at VA sites. If a principal investigator (PI) has not been designated, the VA-NPC will search for a suitable PI with an interest in the study opportunity. The VA-NPC will work with the sponsor and PI to complete the preliminary feasibility questionnaires.

C. Site Identification

After receiving the site acceptance notification from the sponsor or CRO, the VA-NPC will confirm the site's participation. The negotiations for the Cooperative Research and Development Agreement (CRADA) and budget begin. The VA and VA-NPC procedures determine whether the regulatory and contract negotiations take place concurrently or in sequence.

D. Contracting

The Cooperative Research and Development Agreement (CRADA) serves as the document utilized by VAMCs when conducting clinical trials. It is a federal equivalent to a clinical trial agreement and enables all parties involved to achieve their goals while serving veterans. The terms of the CRADA can be tailored to meet the specific needs of the collaborating partner. One advantage of using the CRADA is that it can be swiftly executed if no modifications are required, but if changes are necessary, it will undergo additional review by Regional Counsel.

To further expedite CRADA negotiations, a sponsor who has an established relationship with the VA (e.g., has conducted several prior clinical trials), can negotiate a MASTER CRADA. By establishing a master CRADA, sponsors can save time and effort by leveraging a unified agreement for their studies, while still adhering to the specific requirements of each individual trial. For further information, please contact Partnered Research Program at PartneredResearch@va.gov.

E. Budget Development

The VA-NPC serves as the main point of contact for budget development of clinical trials. Upon receiving the budget proposal from the sponsor, the VA-NPC adjusts it to account for the expenses of study personnel, medical tests and procedures specific to the study, and any other relevant administrative or subject costs. The VA-NPC also assesses the schedule of payments for the study, including upfront payments and payments for

ongoing triggers, to guarantee that there is adequate financial support for the study staff. Finally, the VA-NPC engages in negotiations with the sponsor to arrive at an agreement that meets the needs of both parties, potentially through multiple rounds of communication.

F. Regulatory Support

The site is responsible for ensuring all regulatory approvals and related paperwork are in order. They prepare submissions for the IRB of record (local, VA Central or Commercial Independent) and any other local review bodies. The site also gathers necessary documents to maintain regulatory compliance, including 1572 forms, training certificates, and CVs.

G. Committee Approvals

The site is accountable for obtaining all required VA approvals before launching a clinical trial. This approval process involves multiple committees, commencing with the sub-committees (e.g., IRB, and Biosafety) and concluding with the VA Research and Development (R&D) Committee. Approval from all relevant sub-committees must be secured before the study can be considered by the R&D Committee. After R&D Committee approval, the Associate Chief of Staff for Research (ACOS/R) will issue a formal letter indicating that the study can commence. The schedules for these committee meetings may differ among different VA facilities.

H. IRB Reviews

The VA healthcare system has traditionally relied on its local Institutional Review Boards (IRBs) to review and provide oversight for research protocols. However, in recent years, the VA has recognized the benefits of utilizing central IRBs to streamline the research review process. As part of this effort, the VA now allows the use of several central IRBs, including the VA Central IRB, WCG (formerly Western Institutional Review Board), Advarra and Sterling.

Privacy and Information System Security Officers' Review

The VA requires review and approval by the facility Privacy Officer (PO) and Information System Security Officer (ISSO) to ensure that research studies conducted within the VA healthcare system comply with all applicable privacy and data security requirements.

The PO conducts both a pre-review and as post-review of the research study to ensure that the research activities adhere to the privacy regulations and guidelines set forth by laws such as the Health Insurance Portability and Accountability Act (HIPAA) and the VA's own privacy policies. The pre-review is conducted prior to IRB review. During this review, the PO reviews the research protocol and associated documents to assess any potential risks to patient privacy and ensures that appropriate measures are in place to protect patient information. The post-review is conducted after IRB approval to ensure that any changes made to the research protocol does not alter compliance to privacy regulations.

The ISSO is responsible for managing and maintaining the security of information systems within the VA facility. They evaluate the technical safeguards in place to protect the confidentiality, integrity, and availability of research data. The ISSO reviews research protocols to identify any potential vulnerabilities or risks to data

security. They also ensure that proper data protection measures, such as encryption and access controls are implemented to safeguard sensitive information.

I. Research and Development (R&D) Committee

The R&D Committee oversees research at each VAMC. The Committee is accountable to the Chief of Staff and the Director of the medical center, with the goal of maintaining high standards in the R&D program. These standards include ensuring the scientific validity of the R&D projects, safeguarding human rights, promoting laboratory safety, and protecting animal welfare in research activities. The Committee provides guidance to the Director on the professional and administrative aspects of the R&D program. All R&D activities conducted within the facility, funded or unfunded, fall under its jurisdiction. After R&D Committee approval, the Associate Chief of Staff for Research (ACOS/R) will issue a formal letter indicating that the study can commence.

VI. Appendix

A. Key Terms and Definitions

1. Confidential Disclosure Agreement/ Non-Disclosure Agreement

Confidential Disclosure Agreements (CDAs) may be used where VA and/or a third party wish to share confidential information in anticipation of a future relationship. For example, a CDA may be used to allow for the sharing of information needed to determine whether a CRADA is feasible. Unmodified VA CDAs may be approved locally and signed by the Medical Center Director or Associate Chief of Staff for Research (ACOS/R), where such authority has been delegated. VA has three types of general CDAs:

- Bi-directional
- VA – receiving only
- VA – sending only

If a sponsor intends to conduct multiple clinical trials within the VA system, a master CDA can be developed to streamline the process and facilitate the efficient execution of these agreements.

Please note that any CDA executed between VA and your organization is not applicable to NAVREF and any CDA between NAVREF and your organization is not applicable to VA.

2. Cooperative Research and Development Agreement (CRADA)

A Cooperative Research and Development Agreement (CRADA) is required format for research contracts between the VA and for-profit entities. The CRADA must be used in place of the industry's clinical trial agreement.

The CRADA is an agreement established pursuant to 15 U.S.C. 3710a between VA and one or more non-Federal parties under which VA may accept, retain, and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the other party, as well as provide personnel, services, facilities, intellectual property, equipment or other resources, excluding funding, toward the conduct of specified research and development that is consistent with VA's mission.

Once a CRADA is negotiated for an individual study at one VA facility, it can be used across all other VA sites, but it is important to note that the agreement is specific to that particular study. In other words, the CRADA applies only to the agreed-upon research project and does not automatically grant permission for other unrelated studies.

However, if a sponsor intends to conduct multiple clinical trials within the VA system, a master CRADA can be developed to streamline the process and facilitate the efficient execution of these trials. By establishing a master CRADA, sponsors can save time and effort by leveraging a unified agreement for their studies, while still adhering to the specific requirements of each individual trial.

3. VA Investigator

A VA investigator is an individual who conducts research approved by the Research and Development (R&D) Committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970 (5 U.S.C. 3371 *et seq*.). As a VA investigator, that individual represents the interests of the VA in conducting the study. *NOTE: Individuals working under a contract with VA cannot be given a WOC appointment to conduct research on their contract time*. *Contractors can provide clinical services or other activities in support of VA research in accordance with their contract.*

4. VA Research

VA research is research conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. The research must be approved by the R&D Committee before it is considered VA research and before it can be initiated.

B. FAQs

1. Can industry use their own CDA?

Yes. However it is advisable to use the VA's template or a Master CDA agreement to streamline negotiations.

2. Can industry use their own clinical trial agreements?

No. Federal Government must use the CRADA agreement.

3. Who are parties to a CDA?

For CDAs that are initiated at the VA-NPC entry point, the sponsor and the VA medical facility must sign the CDA. The PI may sign in acknowledgement.

If another party (e.g., CRO) is signing instead of and not as a Sponsor, VA requires a Letter of Authorization (LOA) from Sponsor on Sponsor's letterhead for the specific study delegating to CRO authority to sign the CDA and to disclose Sponsor's Confidential Information to VA. The LOA must be signed and dated by an authorized Sponsor company official.

4. How can a CRO obtain pre-award information in support of a contract bid?

Organizations looking for information to support a CRO's application on a sponsor's contract should not contact the PRP. Instead, they are advised to reach out to the National Association of Veterans Research and Education Foundations (NAVREF) for assistance with general requests for information on unawarded projects. Inquiries can be sent to info@navref.org. If the CRO is awarded the trial, they should be working directly with the sponsor to determine if the VA has been or will be approached for consideration. If the sponsor is interested in approaching VA, the

PRP Engagement Tool should be reviewed, and if directed, a Request for Collaboration can be submitted to the PRP.

5. How does a sponsor initiate a relationship with the VA?

Organizations looking to collaborate with VA research, may initiate a request through the Partnered Research Program. A request can be specific to a particular study or may be a broader request, such as a desire to discuss a clinical portfolio or the organization's pipeline. All requests should be initiated by reviewing the "PRP Engagement Decision Tool" and Guidance for External Organizations Seeking to Engage VA Research. Upon receipt the PRP staff will follow up with the requesting organization to learn more about the nature of the request and if appropriate begin to facilitate connections with appropriate VA thought leaders.

6. What is a "long-term relationship with the VA"?

Many relationships between VA and external organizations develop over a period of time. An external organization may initially reach out to VA regarding a particular trial and through various connections made, determine that they wish to continue working with VA. Conversely, other organizations, may have a portfolio of trials that are relevant to the concerns of Veterans or have a strong interest in conducting research that addresses the needs of Veterans. Therefore, collaboration entails engaging in meaning discussions with VA regarding the design of trials or programs. Such discussions should aim to ensure that efforts are focused on quality and to identify the best opportunities that make use of the strengths of both organizations. Key features of such partnerships may include:

a. Meeting on a regular basis (e.g., monthly, quarterly)
b. Sharing information regarding the organizations' trials that are being planned or conducted across VA.
c. Identifying opportunities for learning and process improvement.

C. Acronyms

AAHRPP: Association for the Accreditation of Human Research Protection Programs

ACOS: Associate Chief of Staff

ADR: Adverse Drug Reaction

AE: Adverse Event

AHIC: American Health Information Community

AO: Administrative Officer

AVMA: American Veterinary Medical Association

BAA : Business Associate Agreement

CBOC: Community Based Outpatient Clinic

CDC: Centers for Disease Control and Prevention

CEO: Chief Executive Officer

CER: Comparative Effectiveness Research

CFR: Code of Federal Regulations

CIO: Chief Information Officer

CIOMS: Council for International Organizations and Medical Science

CIP: Certified IRB Professional

CIRB: Central Institutional Review Board

CITI: Collaborative IRB Training Initiative

CLIA: Clinical Laboratory Improvement Amendment

CO: Central Office

COACH: Center on Advice & Compliance Help

COI: Conflict of Interest

COS: Chief of Staff

CPA: Cooperative Project Assurance

CPRS: Computerized Patient Record System

CRADA: Cooperative Research and Development Agreement

CRADO: Chief Research and Development Officer

CRF: Case Report Form

CRO: Contract Research Organization

CSP: Cooperative Studies Program

CT: Clinical Trial

CTAA: Cooperative Technology Administration Agreement

CVMO: Chief Veterinary Medical Officer

CY: Calendar Year

CYA: Call Your Attorney

DAEO: Designated Agency Ethics Official

DARPA: Defense Advanced Research Projects Agency

DCC: Data Consent Committee (HIPAA abbreviation)

DHHS: Department of Health and Human Services

DHS: Department of Homeland Security

DMC: Data Monitoring Committee

DoD: Department of Defense

DOR: Determination of Rights

DSL: Digital Subscriber Line

DSMB: Data Safety Monitoring Board

DSMO: Designated Standard Maintenance Organization (HIPAA abbreviation)

DUA: Data Use Agreement

DUSH: Deputy Under Secretary for Health

ECFVG: Educational Commission of Foreign Veterinary Graduates

FAQ: Frequently Asked Question

FASB: Federal Accounting Standards Board

FCOI: Financial Conflict of Interest

FDA: Food and Drug Administration

FDAAA: FDA Amendments Act of 2007

FFP: Fabrication, Falsification, and Plagiarism

FIPS: Federal Information Processing Standard

FISMA: Federal Information Security Management Act

FMS: Financial Management System

FOIA: Freedom of Information Act

FRAC: (VA) Field Research Advisory Committee

FTEE: Full-time Employee Equivalent (FTE)

FWA: Federal-wide Assurance

FY: Fiscal Year

GAO: Government Accountability Office

GCP: Good Clinical Practice

GenIsis: The Genomic Informatics System for Integrative Science

GMPAC: Genomic Medicine Program Advisory Committee

GPPC: Genetics and Public Policy Center

HCP: Health Care Provider

HHS: Department of Health and Human Services

HIPAA: Health Insurance Portability and Accountability Act

HIPDB: Health Integrity and Protection Data Bank

HITECH: Health Information Technology for Economic and Clinical Health

HPA: Human Protections Administrator

HRP: Human Research Protection

HRPP: Human Research Protection Program

HSRS: Human Subjects Research Subcommittee (of the Committee on Science, White House National Science and Technology Council)

IAA: Inter-Agency Agreement

IAP: Information Access and Privacy

IC: Information Custodian

ICD: Informed Consent Document

ICF: Informed Consent Form

ICH: International Conference on Harmonisation

IDE: Investigational Device Exemption

IG: Inspector General

IND: Investigational New Drug

IO: Institutional Official

IPA: Intergovernmental Personnel Act

IRB: Institutional Review Board

IRM: Information Resources Management

ISBER: International Society of Biological and Environmental Repositories

ISO: Information Security Officer

IT: Information Technology

ITOC: Information Technology Oversight and Compliance

LAR: Legally Authorized Representative

LDS: Limited Data Set

LOI: Letter of Intent

LSI: Local Site Investigator

MAVERIC: Massachusetts Veterans Epidemiology Research and Information Center

MCD: Medical Center Director

MOU: Memorandum of Understanding

MPA: Multiple Project Assurance; obsolete - refer to FWA

MT: Material Transfer

MTA: Material Transfer Agreement

MVP: Million Veteran Program

NAVREF: National Association of Veteran Research and Education Foundations

NBAC: National Bioethics Advisory Commission

NCI: National Cancer Institute

NCQA: National Committee for Quality Assurance

NEAVS: New England Anti-Vivisection Society

NHGRI: National Human Genome Research Institute

NHPP: National Health Physics Program

NIH: National Institutes of Health

NIST: National Institute of Standards and Technology

NLB: National Leadership Board

NPC: Nonprofit Corporations

NRAC: (VA) National Research Advisory Council

NRC: Nuclear Regulatory Commission

NSF: National Science Foundation

NSR: Non-Significant Risk (device studies)

OBA: Office of Biotechnology Activities

OEF: Operation Enduring Freedom

OER: Office of Extramural Research

OGC: Office of General Council

OGE: Office of Governmental Ethics

OHRP: Office for Human Research Protections (HHS)

OI&T: Office of Information and Technology

OIF: Operation Iraqi Freedom

OIG: Office of the Inspector General

OMB: Office of Management & Budget

ORD: Office of Research and Development (VHA)

ORI: Office of Research Integrity (HHS)

ORO: Office of Research Oversight (VHA)

ORO RO: Office of Research Oversight Regional Office

ORPP&E: Office of Research Protections, Policy,

and Education

OSHA: Occupational Safety & Health Administration

PA: Privacy Act

PB: Privacy Board

PDUSH: Principal Deputy Under Secretary for Health

PHI: Protected Health Information

PHRP: Partnership for Human Research Protection

PHS: Public Health Service

PI: Principal Investigator

PO: Privacy Officer

PRIM&R : Public Responsibility in Medicine & Research

PTSD: Post Traumatic Stress Disorder

PVTS: Privacy Violation Tracking System

QA: Quality Assurance

QI: Quality Improvement

QUERI: Quality Enhancement Research Initiative

R&D: Research and Development

RACO: Research Assurance & Compliance Officer (VISN Level)

RAMS: Research Administrative Management System

RC: Regional Council

RCO: Research Compliance Officer (Facility Level)

RCR: Responsible Conduct of Research

RCS: Records Control Schedule

RFA: Request for Application

RIO: Research Integrity Officer

RIPP: Research Information Protection Program

RO: Regional Office

SACHRP: Secretary's Advisory Committee on Human Research Protections (HHS)

SAE: Serious Adverse Event

SAS: Statement on Accounting Standards

SC: Study Chair

SIA: System Interconnection Agreement

SMART: Site Mentoring Advice and Resource Team

SME: Subject Matter Expert

SMI: Serious Mental Illness

SNC: Serious Noncompliance

SOP: Standard Operating Procedure

SOP: Scope of Practice

SOR: Systems of Record

SOW: Statement of Work

SPA: Single Project Assurance; obsolete - refer to FWA

SR: Significant Risk

SRS: Subcommittee on Research Safety

SSN: Social Security Number

TBI: Traumatic Brain Injury

TTP: Technology Transfer Program

UAE: Unanticipated Adverse Event

UAP: Unanticipated Problem

URL: Universal Resource Locator

USC: United States Code

US-CERT: United States Computer Emergency Readiness Team (Department of Homeland Security)

USDA: United States Department of Agriculture

USH: Under Secretary for Health

VA: Department of Veterans Affairs

VAMC: VA medical center

VACO: VA Central Office

VAPI: VA Protected Information

VASI: VA Sensitive Information

VA-SOC: VA Security Operations Officer

VHA: Veterans Health Administration

VINCI: Veteran's Informatics and Computing Infrastructure

VISN: Veterans Integrated Service Network

VistA: Veterans Health Information Systems & Technology Architecture

VMU: Veterinary Medical Unit

VSO: Veterans Service Organization

WOC: Without Compensation