**Office of Research and Development (ORD)**

**Partnered Research Program (PRP)**

**Guidance for External Organizations Seeking to Engage VA Research**

1. **Purpose**

This document provides general information and guidance for external organizations interested in working with the U.S. Department of Veterans Affairs (VA) on industry-sponsored multisite clinical trials. Additionally, it provides some basic information for those organizations seeking collaboration with VA outside of the clinical trial landscape (e.g., pilot studies, health outcomes research, observational studies, etc.). The information provided is not intended to be comprehensive, but rather, provides key consideration, steps and available resources to ensure that organizations are guided appropriately and that the scope of the Partnered Research Program is clear. Questions can be directed to PartneredResearch@va.gov .

1. **Partnered Research Program Role and Scope.**

The Partnered Research Program (PRP) was established in 2020 in response to ORD’s commitment to streamlining and standardizing clinical trial start up practices across VA. Since its implementation, the PRP has been working with internal and external stakeholders to achieve this objective. A complete listing of PRP’s services can be found on its [webpage](https://www.research.va.gov/programs/partnered_research/default.cfm).

1. **Determining When and How to Contact the Partnered Research Program**

The PRP serves as the entry point for all external organizations seeking to engage VA in discussions around industry sponsored multisite clinical trials. In order to ensure that an inquiry is managed appropriately, organizations are encouraged to review the “PRP Engagement Decision Tool” prior to submitting a request for collaboration and/or contacting the PRP directly.

1. **Guidance for Organizations for Whom a Request for Collaboration is Not Appropriate**

The PRP’s primary objective is to ensure that we are able to triage requests in a timely manner, and often a rate limiting factor is that the request is outside of the scope of the program and/or is not complete. The guidance below is designed to aid such inquiries.

1. **Organizations Seeking to Sell or Market their Product or Service to VA**

As a Federal Agency, there is a specific pathway for VA acquisitions which PRP cannot and does not manage. Organizations wishing to conduct business with VA as described below must visit the Office of Acquisitions and Logistics for additional information (<https://www.va.gov/opal/fo/dbwva.asp>).

* Entering into a contract or other agreement in order for VA to purchase a product or service for use in clinical care
* Entering into a contract or other agreement in order for VA to purchase a product or service for use in research (e.g., recruitment platforms, Clinical Trial Management System, etc.)

Organizations seeking to engage a specific VAMC are encouraged to contact that facility directly. A listing of VA Medical Facilities can be found at: <https://www.va.gov/directory/guide/rpt_fac_list.cfm>

1. **Contacts by Organizations other than a Sponsor/Funder or Contract Research Organization**

Organizations contacting PRP should represent the final decision maker regarding any partnership with VA, when at all possible. PRP will accept requests for collaboration from Contract Research Organizations that have been contracted by the sponsor to act on their behalf provided that other criteria outlined in the decision tool have been satisfied. Organizations interested in engaging VA that do not represent the study sponsor/funder and do not represent the CRO are encouraged to verify that the sponsor is interested in engaging with VA before proceeding.

1. **Organizations Seeking to Obtain Information in Support of a Contract Bid/Not Yet Awarded Opportunity**

Organizations seeking information in support of a CRO’s application on a sponsor’s contract should not contact PRP. In such an instance, organizations are encouraged to contact the National Association of Veterans Research and Education Foundations (NAVREF). This organization may be able to provide support for general requests for information regarding not yet awarded projects. Inquiries should be directed to pwest@navref.org.

Should an organization later be awarded the trial, please visit the decision tool and if appropriate, submit a [Request for Collaboration](https://www.research.va.gov/programs/partnered_research/request.cfm).

1. **Organizations Seeking to Fund/Support Less than 3 VA Sites**

Given PRP’s focus on multisite trials many of the efficiencies that VA has identified and/or developed are not optimal for studies that involve a small number of VA sites. PRP will accept requests for collaboration for which the sponsoring organization plans to fund/support at least 3 VA sites, however prioritization will be given to those organizations for which there is an interested in engaging 5 or more VA sites. Organizations which plan to fund/support only 1-2 VA sites are encouraged to contact the National Association of Veterans Research and Education Foundations (NAVREF) for help identifying sites that may have interest in the opportunity. This service utilizes the VA affiliated non-profit corporations as a source for identifying VA investigators that may be interested in an opportunity. Inquiries should be directed to pwest@navref.org .

1. **Guidance for Organizations for Whom a Request for Collaboration is Appropriate**

1. **Organizations Seeking to Engage VA in Clinical Trial Collaborations:**
2. Initiating a Request: Upon verification that a Request for Collaboration is appropriate, the next step is submission of the completed [Request for Collaboration Form](https://www.research.va.gov/programs/partnered_research/request.cfm). The form is designed to capture high level information related to a potential partnership/trial opportunity and ensures that the PRP staff can route the request appropriately.
3. Information Needed: Organizations should only complete all sections of the form. more complete the application the more quickly it will be processed. The information requested should not warrant a CDA be executed. If for some reason your organization will not provide the requested information, without a CDA, please notate this on the form and the PRP staff will follow up regarding appropriate next steps.
4. Supplemental Information: Prospective collaborators organizations are encouraged to provide additional, relevant information if possible, such as a protocol synopsis. This information can be submitted via email to PartneredResearch@va.gov AFTER the Request for Collaboration has been sent (please include the reference to your request in the email).
5. The information below is provided to help external organizations understand VA’s priorities related to clinical trial collaborations:
	1. Timing: VA encourages external organizations to initiate partnerships as early as possible. Therefore, we want to ensure that the trials that best align with our priorities and mission are afforded adequate time for evaluation, discussion and planning. Organizations can demonstrate this by:
		* Engaging VA in discussions regarding clinical trials for which there are 6 or more months until VA site initiation is expected; or
		* Engaging VA in discussions regarding clinical trials for which there are at least 12 months of study enrollment remaining.

Organizations contacting PRP regarding multisite clinical trials for which there are less than 6 months until VA site initiation or for which there are less than 12 months of study enrollment remaining should still initiate a request but may be directed to other resources and options.

* 1. Trial Indication: VA is committed to participating in high quality clinical trials that offer our Veterans opportunities to improve their health and/or contribute to trials of significant national importance. PRP engages with VA’s scientific and clinical experts to ensure that VA’s research portfolio includes clinical trials designed to meet the needs of Veterans. Examples, include but are not limited to:
		+ Precision Oncology (particularly in lung and genitourinary cancers)
		+ Mental Health (Suicide Prevention, Depression, PTSD)
		+ Brain Health (TBI, Alzheimer’s Disease)
		+ Combat Related Exposures
		+ Infectious Diseases

Requests for Collaboration in other therapeutic areas can and should continue to submitted, however they may be referred to other internal or external resources depending upon the specific area.

* 1. Phase of Trial: VA is committed to participating in clinical trials that may offer our Veterans opportunities to improve their health. As such, we emphasize partnerships on Phase II- IV trials. Organizations that contact PRP regarding Phase I trials may be directed to other resources.
	2. Partnership Expectations/Level of Engagement Partnerships should center around research that aligns with VA priorities and with the mission of VA. VA has a wide range of capabilities and clinical research resources. However, VA’s primary commitment to the care and well-being of our Veterans and stewardship of resources require that VA carefully consider those partnerships that are most beneficial towards its mission. Therefore, VA will prioritize relationships with organizations that demonstrate:
		1. A commitment to communication and collaboration. Key tenets of the collaboration include:
			+ Identification of a central contact within both organizations through whom all information flows.
			+ Sharing metrics, best practices, and opportunities for process improvement.
			+ Identifying issues and challenges and proactively working together to resolve them.
		2. A vested interest in conducting research addressing the needs of Veterans. This may be demonstrated by:
			+ A portfolio of trial opportunities in areas of particular interest/concern to Veterans.
			+ Willingness to engage VA in thoughtful conversations regarding trial or program design to ensure that efforts are focused on quality and identification of those opportunities that best utilize the strengths of both organizations.

Organizations that are not seeking to engage VA as a partner, but rather are seeking support solely to identify individual investigators/study sites may be directed to additional internal or external resources.

Additional information regarding the management of Requests for Collaboration can be found in Section VI below “What Happens After a Request for Collaboration for a Multisite Clinical Trial is Submitted to the PRP?”

1. **Organizations Seeking to Engage with VA on Other Types of Research Collaborations (e.g., health outcomes research, real world evidence, observational research, VA funded research).** The Partnered Research Program’s current scope is centered on supporting externally funded investigational drug and device clinical trials. While VA recognizes and appreciates that external organizations may be interested in partnering on these other types of trials, PRP’s services in this area are limited. Organizations seeking these types of collaborations, should not submit a Request for Collaboration, but instead submit a written summary to the PRP mailbox (PartneredResearch@va.gov) which includes the following:
	1. Email subject line: Request for Other Type of Research Collaboration
	2. Body of Email must include the following:
		1. Name of Requesting Organization:
		2. Name, Email Address and Role of Requestor:
		3. Description of the Requesting Organization:
		4. Proposed type of research collaboration(s) that you are seeking
		5. Aims of any collaboration
		6. Timeline(s) for the proposed collaboration(s) to begin
		7. Funding source(s) available/being sought. Do you have funding to support these collaborative activities or are you seeking funding?
		8. Why is your organization specifically interested in working with VA research?
		9. What, if any, longer term objectives or goals is your organization hoping to accomplish with VA?
		10. Has your organization had previous experience working with VA? If yes, please provide additional details regarding the scope of those engagements

Requesting organizations should note that the PRP will attempt to match your request with a corresponding service or interested party. However, it is possible that your request will not be matched.

1. **What Happens After a Request for Collaboration for a Multisite Clinical Trial is Submitted to the PRP?**

PRP Administrative Review: The PRP Staff will perform an administrative review of the information submitted. The purpose of this review is to evaluate the following:

* Is the request appropriate? Meaning:
	+ Is it related to a clinical trial?
	+ Is the request for a Phase II- IV clinical trial?
	+ Is there at least 6 months until FPI OR 12 months of enrollment remaining?
	+ Is the organization seeking at least 3 VA sites?
* Does the request include enough information to proceed with a SME consult?

Any request that lacks enough information will be followed up by staff to gather additional information. Organizations will have 10 business days to respond. In the case of an inappropriate request, the requestor will be contacted by PRP staff by email with an explanation as to why the request is inappropriate and possible referral options.

In the case that the review satisfies the criteria above, the PRP staff will contact the requestor, providing the results of the administrative review and detailing potential next steps. In the case of ANY new organization, an introductory call will be established to clarify roles and options before proceeding with an SME consult.