ENROLLMENT OF NON-VETERANS

It is expected that all participants enrolled in a CSRD-funded study be Veterans. However, enrollment of non-Veterans may be allowed if a waiver is obtained from the Director. The waiver review will consider relevance to Veterans, feasibility, and risk/benefits. This process may occur at the LOI stage, JIT stage, or if necessary, during the course of the project.

LOI Stage: Clinical Trial and Epidemiology Applications only

A request should be submitted as an addendum to the LOI and must provide sufficient justification for enrollment of non-Veterans and still support the relevance of the trial to the Veteran population. These requests are highly scrutinized for population-based issues, relevance over convenience, risk/benefits, and alternative approaches, e.g., adding a VA recruitment site to meet target comprised of Veterans.

JIT Stage

If non-Veteran enrollment is identified as a JIT issue, then language in JIT will be an element to resolve prior to funding. An approved waiver is required from the Director if the proposed research involves the enrollment of non-Veteran subjects. The process would be for the requirement to be stated; the PI to upload the waiver request; the PM to review according to the criteria of population-based issues, relevance over convenience, risk/benefits, and alternative approaches. If the PM recommends approval, forward to Director, CSRD. A fillable memo template the PI may use is available at https://www.research.va.gov/services/csrd/non-VeteranWaiver.pdf. The waiver request and the approval of the waiver request must be uploaded to satisfy the JIT requirement. The waiver must be approved before any non-Veteran subjects are recruited/enrolled.

During the Project

The investigator sends a memo to the Director via the mailbox, VHABLRD-CSRD@va.gov, requesting permission to enroll non-Veterans. The fillable memo template available at https://www.research.va.gov/services/csrd/non-VeteranWaiver.pdf may be used. The memo template includes language that the investigator understands the research must be focused on improving the quality of healthcare for Veterans and/or medical ailments specifically affecting the Veteran population served by VHA. The PM will review according to the criteria of population-based issues, relevance over convenience, risks/benefits, and alternative approaches. If the PM recommends approval, the request will be forwarded to the Director, CSRD.

Evaluation of Requests Should Consider

- Scientific question and relevance to Veterans (if, for example, enrollment cannot be achieved in Veterans only, and if not, why is the project relevant to our population)
- The inability to meet recruitment objectives with regards to sample size does not constitutes adequate justification but rather a sample of convenience; this would not justify an approval
- Whether study and associated risks are amenable to non-Veteran enrollment. Level of risk to subjects must be considered (because VA must pay for treatment of adverse events)
- Have other alternatives been considered (e.g., adding or changing VA enrollment sites, modifying inclusion/exclusion criteria)

Post Review

- Investigator and his/her Research Office are notified of the decision
- If CSRD approval is in place, IRB approval is needed prior to enrollment of non-Veterans

Sources

- FAQs on the Participation of non-Veterans in CSRD-Funded Studies https://www.research.va.gov/services/csrd/non-VeteransEnrollmentFAQ.pdf

- Memorandum template for requesting a waiver to enroll non-Veterans https://www.research.va.gov/services/csrd/non-VeteranWaiver.pdf
- Just-In-Time (JIT Guidelines)/Miscellaneous/Enrollment of Non-Veteran Subjects
- VHA Directive 1200.05, "Requirements for the Protection of Human Subjects in Research" https://www.va.gov/vhapublications/publications.cfm?pub=1