

Department of Veterans Affairs
CLINICAL SCIENCE RESEARCH AND DEVELOPMENT SERVICE (CSRSD)

**Frequently Asked Questions on the Participation of non-Veterans in
CSRSD-Funded Studies***

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1. Can non-Veterans be enrolled in CSRSD projects?

CSRSD may allow non-Veterans to be enrolled in some funded projects as long as a non-Veteran enrollment waiver is obtained from the Director, CSRSD. Evaluation of the request will take into consideration the scientific question and the relevance to Veterans (if, for example, enrollment cannot be achieved in Veterans only), as well as the level of risk to the subject (because VA must pay for treatment of adverse events).

2. What is a non-Veteran enrollment waiver?

A non-Veteran enrollment waiver approves non-Veterans to be enrolled in a CSRSD-funded project. It is endorsed by the Director, CSRSD, at the Letter of Intent (LOI) stage, Just-in-Time stage, or, if necessary, during the course of the project.

3. What is the process to obtain a non-Veteran enrollment waiver for a CSRSD project?

The process is to have your ACOS/R send a request to the Director, CSRSD. This request should use the fillable memorandum template ([Non-Veteran Waiver form \(va.gov\)](#)) for this purpose. Your research office will be notified of the decision.

Once you have obtained CSRSD approval, you must also obtain R&D approval prior to enrolling non-Veterans.

* May differ from the other Office of Research and Development Services.

4. When should I apply for a CSRD non-Veteran enrollment waiver?

You should apply for a waiver as soon as you determine that you may need to enroll non-Veteran subjects.

- A. If this is during the course of the project when changes to the enrollment plan are needed, you should have your ACOS/R to send a request to the Director, CSRD. The fillable memorandum template ([Non-Veteran Waiver form \(va.gov\)](#)) should be used for this purpose. Your research office will be notified of the decision.
- B. If this is before you have applied for funding, the timing of applying for a non-Veteran enrollment waiver depends on the type of award.
 - i. For awards that require a Letter of Intent (LOI) prior to submission of the full application (Career Development Award, Clinical Trial Merit Award), the waiver request must be requested during the LOI stage. If the waiver is granted, include the signed waiver with your application.
 - ii. For Merit Review applications, you should apply for a waiver to enroll non-Veterans when you submit your Merit Review or other proposal. This request should be clearly stated within the Human Research Subjects section of the proposal. The waiver request will be reviewed by the Director, CSRD, at the JIT stage if your project is selected for funding (station will need to upload waiver into JIT for review).

5. What factors are considered in an evaluation of a waiver to enroll non-Veterans in a CSRD study?

- Whether the overall focus of the request maintains relevance to our mission and is focused on Veterans' health.
- Whether the study and its associated risks are amenable to non-Veteran enrollment. The IRB determination of risk must be included with the waiver request. Studies that are minimal risk only will be considered, as greater than minimal risk studies add liability risk to ORD.
- Whether the inability to meet recruitment objectives with regards to sample size constitutes adequate justification.

6. I am unable to achieve my recruitment objectives, can I enroll non-Veterans?

A waiver for non-Veteran enrollment may be considered in this case; however, other alternatives should also be evaluated (e.g., adding or changing enrollment sites, modifying inclusion/exclusion criteria).

7. I obtained a waiver to enroll non-Veterans in my CSRD study; I had previously been enrolling only Veterans. Do I need to inform my IRB of that change?

Yes, anytime there is a modification to the population being enrolled in a CSRD study, all research oversight committees must be informed, and in some cases (e.g., IRB) their approval must be obtained.

8. Who do I contact if I have questions?

Send an e-mail with your questions to the VHA BLRD-CSRD mailbox (VHABLRD-CSRD@va.gov), and a staff member will reply.

REGULATORY AND VHA POLICY REFERENCES:

VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research

38 CFR 16, Protections of Human Research Subjects

VHA Directive 1200.01, Research and Development (R&D) Committee