

Department of Veterans Affairs  
CLINICAL SCIENCES RESEARCH AND DEVELOPMENT SERVICE (CSR&D)

**Frequently Asked Questions on the Participation of non-Veterans in  
CSR&D-Funded Studies\***

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**1. Can non-Veterans be enrolled in CSR&D projects?**

CSR&D may allow non-Veterans to be enrolled in some funded projects as long as a non-Veteran enrollment waiver is obtained from the Director, CSR&D. 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.

**2. What is a non-Veteran enrollment waiver?**

A non-Veteran enrollment waiver approves non-Veterans to be enrolled in a CSR&D-funded project. It is endorsed by the Director, CSR&D, 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 CSR&D project?**

The process is to have your ACOS/R send a memo to the Director, CSR&D. The memo should include your name, project title, and the justification for enrolling non-Veterans in your study. You may use the [non-Veteran Enrollment Waiver template](#) for this purpose. Your research office will be notified of the decision.

Once you have obtained CSR&D approval, you must also obtain IRB approval prior to enrolling non-Veterans (see [VHA Handbook 1200.05, Requirements for the Protection of](#)

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

[Human Subjects in Research](#), section on Participation of Non-Veterans as Research Subjects).

#### **4. When should I apply for a CSR&D 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 memo to the Director, CSR&D. You may use the [non-Veteran Enrollment Waiver template](#) 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, Cooperative Clinical Trial Award, or a Merit Review for a clinical trial), the waiver request should be included with the LOI. If the waiver is granted, include the signed waiver with your application in the Letters of Support attachment.
  - 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 Subjects attachment of the proposal. The waiver request will be reviewed by the Director, CSR&D, at the Just-in-Time stage if your project is selected for funding.

#### **5. What factors are considered in an evaluation of a waiver to enroll non-Veterans in a CSR&D 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.
- 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 CSR&D 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 CSR&D 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-CSR&D mailbox ([VHABLRD-CSR&D@va.gov](mailto:VHABLRD-CSR&D@va.gov)), and a staff member will reply.

**REGULATORY AND VHA POLICY REFERENCES:**

[VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research](#), May 2, 2012.

[38 CFR 16, Protections of Human Research Subjects](#)

[VHA Handbook 1200.01, Research and Development Committee](#), June 16, 2009.