

SUBJECT: Participation of Non-Veterans and Non-Eligible Veterans in Research

1. PURPOSE:

The Research and Development Committee is responsible for ensuring that all research in which the facility is engaged is consistent with the VA mission, including research involving non-Veterans or non-eligible Veterans. This policy outlines the approach the Committee follows to evaluate requests to include non-Veterans or non-eligible Veterans in research.

2. DEFINITIONS/ACRONYMS:

ACOS/R: Associate Chief of Staff for Research

dACOS/R: Deputy Associate Chief of Staff for Research

Generalizable knowledge: Information that expands the knowledge base of a scientific discipline or other scholarly field of study.

MVAHCS: Minneapolis Veterans Affairs Health Care System

Operations Activities: Administrative, financial, legal, quality assurance, quality improvement, and public health endeavors that are necessary to support VHA's missions of delivering health care to the Nation's Veterans, performing medical education, and contributing to national emergency response. Operations activities may or may not constitute research.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

RDC: Research and Development Committee

Veteran: As defined in 38 US Code §101(2), a Veteran "...means a person who served in the active military, naval, or air service, and who was discharged or release therefrom under conditions other than dishonorable."

Eligible Veteran: A Veteran who meets VA eligibility criteria for care within the VA system. Please see flowchart "Determining Veteran Eligibility for VA Research," attached below.

Non-Veteran: An individual who does not meet the definition of Veteran above and/or who does not meet VA eligibility criteria for care within the VA system.

3. OVERVIEW:

The Research and Development Committee has multiple oversight responsibilities within the VA research environment. These include ensuring VA research has relevance to the VA's mission and care of Veterans, as well as ensuring the expectations of VA Directive 1200.01 are met regarding the enrollment of non-Veterans. This latter responsibility helps manage risk surrounding research-related injuries. In the case where a study enrolling non-Veterans has a sponsor who does not cover the costs of such injuries, or the study is unfunded, then research-related injuries for that study must be paid out of research, not medical, appropriations.

VHA Directive 1200.01, Paragraph 13.a. describes the specific responsibilities of the RDC when non-eligible Veterans are proposed to be included in VA research. "...The investigator must justify including non-Veterans, and the R&D Committee must review the justification and provide specific approval for recruitment of non-Veterans." Further, if a research study involving VA hospital or outpatient treatment wishes to enroll non-Veterans, this can only happen when there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45, 17.92).

Regardless, non-Veterans may not be entered into VA studies simply because a non-Veteran population is easily accessible to the investigator (1200.01 Paragraph 13.e).

4. **PROCEDURES:**

- a) An MVAHCS investigator proposes a study that includes enrolling non-Veterans.
 - i) This proposal includes a specific form used to help the RDC evaluate this request (currently “Request for Non-Veteran Approval” in IRBNet).
- b) The RDC evaluates the study according to the following:
 - i) For **all** studies requesting to enroll non-Veterans:
 - (1) the study must justify the inclusion of non-Veterans to the satisfaction of the RDC, who then must provide explicit approval for this inclusion.
 - (2) the study cannot enroll non-Veterans into VA studies simply because a non-Veteran population is easily accessible to the investigator.
 - ii) For studies **involving treatment**, either inpatient / hospital or outpatient:
 - (1) The request must clearly state who will pay for research related injuries. Note that medical appropriations cannot be used for non-Veterans, resulting in such costs being borne by the local Research Service. Please see the attached flowchart.
 - (a) If the study is deemed ‘greater than minimal risk’ and is VA funded with an ORD waiver or is industry funded with a usual CRADA, then the RDC may consider allowing such a study.
 - (b) If the study is deemed ‘greater than minimal risk’ and is unfunded, federally (non-VA) funded, or is VA-funded but does not have an ORD waiver, the RDC is unlikely to allow such a study.
 - (2) If possible, the request will be evaluated by the RDC before the Institutional Review Board examines such a study, thus preventing unnecessary review.
 - iii) For studies that **do not involve inpatient or outpatient treatment**, but will generally benefit Veterans and their well-being:
 - (1) it is sufficient to provide justification for non-Veteran enrollment that does not include expediency in the rationale. Examples include surveys of VA providers or caregivers, studies involving Veterans family members, or studies involving active-duty military personnel.
 - (a) If the study is deemed ‘minimal risk’ and is VA funded with an ORD waiver or is industry funded with a usual CRADA, then the RDC will usually allow such a study.
 - (b) If the study is deemed ‘minimal risk’ and is unfunded, federally (non-VA) funded, or is VA-funded but does not have an ORD waiver, then the RDC may consider allowing such a study.
- c) All VA regulations and policies related to Veterans as research subjects apply to non-Veterans entered into VA research, including VHA Handbook 1605.04, Notice of Privacy Practices.

5. **REFERENCES:**

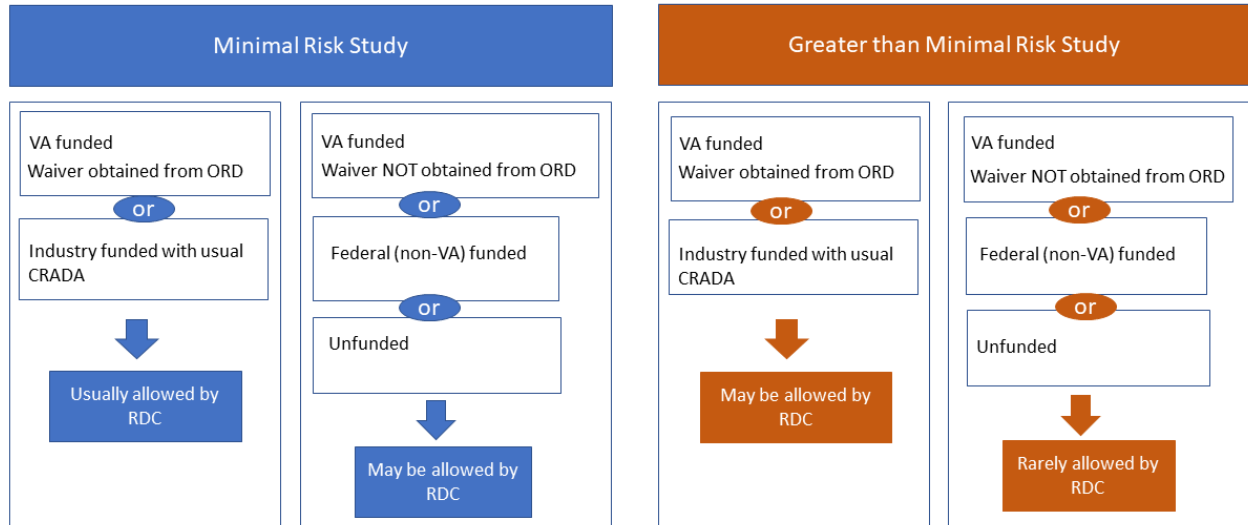
VHA Directive 1200.01 “Research and Development Committee” (24 January 2021)

MVAHCS Research Service SOP R&D-001 “Research and Development Committee”

6. **R&D COMMITTEE APPROVAL:** 17 January 2023
7. **RECISSIONS:** None. This is a new SOP.
8. **EXPIRATION DATE:** N/A
9. **FOLLOW-UP RESPONSIBILITY:** Research and Development Committee

Appendix A: Inclusion of Non-Veterans Flowchart

Inclusion of non-eligible* Veterans or non-Veterans in VA Research Studies



Notes:

*non-eligible refers to Veterans who are NOT eligible for VA care

--Minimal risk studies that are specifically targeted to non-Veterans (e.g. Veterans’ caregivers or VA employees) are almost always allowed

--For projects with source of funding not listed, please discuss with ACOS, deputy ACOS or RDC Chair.

November 4, 2020

Appendix B: Determining Veteran Eligibility for VA Research

