

Date:

From:

Subj:

To: Director, Clinical Science Research and Development (14RD)

Approval of a non-Veteran waiver requires the Clinical Science Research and Development Service to take on financial responsibility for any research-related injuries to the non-Veteran. Only minimal risk studies will be considered for a non-Veteran waiver.

1. I am the principal investigator on the [funded / proposed] project entitled:
2. I am requesting permission to enroll non-Veterans in this research study.
3. I understand that research funded by CSRD must be focused on improving the quality of healthcare for Veterans and/or medical ailments specifically affecting the Veteran population served by VHA. For all studies we require a IRB determination of risk to be included in the justification. For projects requesting this waiver prior to IRB determination (e.g., Letter of Intent stage), the decision will be conditional on final IRB determination. My justification for enrolling non-Veterans in this protocol is as follows (including IRB risk determination):
4. I understand that if the Director, CSRD, approves this request, I must also obtain approval from my facility R&D Committee to enroll the proposed non-Veteran research subjects.

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Principal Investigator Signature

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Assoc. Chief of Staff for Research Signature

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Investigator Name/Degrees

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ACOS/R Name/Degrees

July 6, 2022

RE:

Enrollment of non-Veterans in this study is:      Approved      Disapproved      Conditionally Approved

ORD Comments:

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Written Justification (and IRB risk assessment) continued (if applicable):

July 6, 2022