**Instructions**

This form must be used when a VA Investigator is requesting approval to enter non-Veterans into a VA study. This form must be submitted to the R&D Committee in the initial R&D Committee application packet. If a VA Investigator is submitting an amendment to include entering non-Veterans on a previously approved study, this form must be submitted to the R&D Committee with a copy of the amendment.

The VA Principal Investigator must receive documentation of approval from the R&D Committee prior to entering Non-Veterans in the study.

Please note that submission of this form requesting R&D Committee approval for enrollment of non-Veterans into a VA study does not replace any additional committee or subcommittee requirements for approval of the study or study modification/amendment.

 .

1. **Project and Investigator Information**

|  |  |
| --- | --- |
| **Project Number** | Click or tap here to enter text. |
| **VA Facility** | Click or tap here to enter text. |
| **Title of Project** | Click or tap here to enter text. |
| **Principal Investigator** | Click or tap here to enter text. |
| **PI Email** | Click or tap here to enter text. |
| **PI Telephone** | Click or tap here to enter text. |
| **Name of Point of Contact other than PI:** | Click or tap here to enter text. |
| **POC Email** | Click or tap here to enter text. |
| **POC Telephone** | Click or tap here to enter text. |

1. **Non-Veteran Subject Participation Justification**

|  |
| --- |
| 1. **Will the study involve either inpatient or outpatient treatment of non-Veterans or Veterans not eligible for VHA care?**

[ ]  **No** **If No, will this study generally benefit Veterans and their well-being but would**  **not include Veterans as subjects.** [ ]  **Yes**  [ ]  **No (STOP)**[ ]  **Yes** **If Yes, are there an insufficient number of Veterans suitable to be entered into** **the study?**[ ]  **No (STOP)** [ ] **Yes*****Note:*** *A VHA health record and progress note is required for all research subjects who receive research procedures or interventions as inpatients or outpatients at VA medical facilities or at facilities contracted by VA to provide services to Veterans. All people treated at a VHA medical center or contracted medical facility must also be provided a copy of the VHA Notice of Privacy Practices.* |
| **B. Why are non-Veterans required for this study?**        |
| **C. What is the total number of non-Veterans anticipated to be entered into the study?**        |
| **D. What are the proposed recruitment methods for entering non-Veterans into the study?**        |
| **E. What is your assessment of the probability or likelihood that a research-related injury will occur as a result of participating in the study?**        [ ]  None or minimal (less than 5%) [ ]  Low (5% to less than 30%) [ ]  Moderate (30% to less than 50%) [ ]  High (50% and above)**Please provide justification of your assessment:**       |
| **F. Who is the responsible party for providing reimbursement to the VA Medical Center for any research-related injury treatment costs of a non-Veteran or a Veteran not eligible for VHA care participating in the study?”****Please note: the non-Veteran and his or her insurance or third-party payer cannot be a responsible party.** [ ]  No responsible party [ ]  ORD: The study is an ORD-funded study and ORD has approved a waiver to allow for  the inclusion of non-Veterans. [ ]  Industry: The study is an industry-funded study and the CRADA or other agreement outlines the responsibility for research related injury treatment cost reimbursement to the medical center. [ ]  Other: Please list below:            |

1. **Investigator Signature**

|  |
| --- |
| ***The Principal Investigator must sign/date the request below.*** |
|  |
|  | Signature of PI Date |  |