

**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

FAQ Topic: Recruitment of Non-Veterans for VA Research

Date: March 12, 2012

Question: The VA investigator for an industry-sponsored, multi-site investigational drug study relevant to the Veteran population has been unable to find enough Veterans who meet the study's inclusion criteria. The investigator wants to recruit non-Veterans by posting fliers in the community informing potential subjects about the trial and instructing them to contact the VA investigator for additional information. Is this form of recruitment permissible?

Answer: A VA facility's IRB of record may permit the recruitment of non-Veterans into VA research only if there is a compelling argument for their inclusion (e.g., a study-wide shortage of eligible Veterans) and the research is relevant to the care of Veterans or active duty military personnel. Non-Veterans cannot be recruited into VA research if the research is not relevant to the care of Veterans or active duty military personnel. The IRB must specifically document in the IRB meeting minutes or IRB protocol file its determinations regarding participation of non-Veterans in the study. The IRB should also review and approve any proposed recruitment materials to be used for the study.

Question: A VA facility is considering participating in a multi-center, industry-sponsored clinical trial. The industry sponsor wants to post national ads soliciting prospective subjects to call a national 1-800 number staffed by the sponsor. The prospective subject would provide health information to the sponsor for initial screening, and if eligible, would be instructed to contact the nearest study site, which could be the VA. Can the VA facility participate in a study with this recruitment procedure?

Answer: A recruitment strategy using a sponsor's 1-800 call center to refer potential subjects to a VA study site could be acceptable to VA under certain conditions. However, additional information is needed before a determination can be made about the acceptability of this study for VA. In order to determine whether all requirements for VA research have been satisfied, the VA facility's IRB of record would need to review not only the complete protocol and clinical investigators' brochure, but also (a) a detailed justification for the VA investigator to enroll non-Veterans, (b) the proposed sponsor protections at the call center and elsewhere to ensure the privacy of subjects and the confidentiality of subjects' health information, and (c) the proposed recruitment procedures, including the text of the proposed ads.

References: *VHA Handbook 1200.05 §27.c and §58*

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FAQ – Non-Veterans in Research