

AVAMC Research Policy for Referring Veteran patients to non-VA Research Projects

VA regulations do not prevent a VA provider discussing treatment options with VA patients, including options that may be only available in the research environment. However, there is a clear line between a VA provider giving VA patients information about options that may include research and the VA provider acting as an agent of individual non-VA studies, thus engaging the VA and the referring clinician in human subjects research. When unsure if referrals to non-VA research projects are allowed, please contact the VA Research Office.

Specific criteria for this referral to be compliant:

- VA cannot refer VA patients for affiliate studies in which the VA physicians are conducting those same studies during their affiliate duties, yet the VA is not engaged in the research. A federal employee cannot use his or her federal employment to benefit his or her non-Federal position. This is an ethics violation as well as an inappropriate mechanism to circumvent the Common Rule regulations involving requirements for institutions engaged in human subjects research.
- A VA provider cannot review the medical records of VA patients to screen these VA patients for non-VA studies because the authority to access a VA patient's PHI for treatment, payment, and health care operations does not cover research purposes without research authority. VA providers cannot screen VA patients' medical records for non-VA studies for research purposes as part of clinical care.
- The VA provider cannot act as an agent of the non-VA investigator. If the VA provider is discussing the study in a detailed manner that would make the VA provider an agent of the study, then the VA institution would be engaged in the research.
- VA providers cannot determine if the veteran patients are eligible for the study. VA providers must refer any patients that express interest in the non-VA research. The non-VA research staff can assess the patient for study eligibility.
- A VA provider in the course of his or her clinical duties talking with a VA patient about options for treatment and/or giving the VA patient basic information about the study and contact information (similar to the basic level found in an advertisement), is allowable.
- If a VA patient chooses to allow a VA provider to give his or her contact information to a non-VA provider, there has to be permission to do so. If a VA patient informs a VA provider that he or she wishes the VA provider to contact the study coordinator at a non-VA facility, there must be clear documentation (ex. in CPRS) from the patient and the VA provider that the VA patient has given permission for the VA provider to give the VA patients' contact information to the non-VA facility.
- In addition, PHI cannot leave VA for research purposes without a written authorization; the information that can be given by a VA provider to a non-VA research study team is limited to contact information (name and telephone number).