OFFICE OF RESEARCH AND DEVELOPMENT VETERANS HEALTH ADMINISTRATION

FAQ Topic: "Recruitment Only" Studies

Date: March 12, 2012

Question: Does VA permit its Research and Development (R&D) Committees to approve studies in

which VA's sole involvement is to solicit the participation of Veterans in research that is

conducted entirely by a non-VA entity?

Answer: VA R&D Committees may only approve research that supports VA's mission to advance

the health care of the Nation's Veterans. VA R&D Committees may not approve research that does not support this mission. In addition, approval by a VA R&D Committee makes a study VA research and obligates the VA to provide care for research-related injuries to subjects. VA R&D Committees cannot approve studies that are conducted entirely by

non-VA investigators.

NOTE: This guidance does not preclude VA clinicians, in the normal course of their clinical duties, from discussing specific research studies with their patients where appropriate, and referring them to a non-VA investigator for more information about a non-VA study. However, VA personnel should not provide the non-VA investigator with the names or contact information of Veterans who might be eligible for the study. Instead, the VA clinician should provide the Veteran with the contact information for the non-VA investigator so the Veteran may initiate contact if he/she is interested in participating in the non-VA study. VA personnel should not provide the non-VA investigator with protected health information (PHI) about Veterans who choose to participate in non-VA studies without a signed release form, and a signed HIPAA authorization, and adherence

to local requirements for the release of medical information.

References: VHA Directive 1200 §2.b and §5.tt

VHA Handbook 1200.01 §8.g and §10.a(1) VHA Handbook 1200.05 §3.xxx(note)