**OFFICE OF RESEARCH AND DEVELOPMENT (ORD)**

**VETERANS HEALTH ADMINISTRATION (VHA)**

**ORD Guidance on Non-affiliated Institutional Review Board (IRB) Members**

**Date: April 16, 2015**

**SCOPE:** The Common Rule and VHA Handbook 1200.05 §6.d require that each IRB include at least one voting member who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution. For purposes of this guidance, institution refers to the VA facility or the VHA Central Office Human Research Protection Program. The previous Handbook dated May 2, 2012, annotated considerations for determining who could be considered non-affiliated IRB members. This guidance provides more information about considerations to guide VA institutions in selecting and managing non-affiliated IRB members in compliance with the November 12, 2014, version of VHA Handbook 1200.05.

1. Who is a non-affiliated individual?
2. What does academic “affiliation” mean for the purposes of this Guidance document?
3. Are employees of the academic affiliate considered affiliated with VA for purposes of the Guidance document?
4. Are Veterans receiving care at the VA considered to be affiliated?
5. Are Veterans who volunteer at the VA considered to be affiliated?
6. Are VA retirees considered affiliated for purposes of the Guidance document?
7. What does receiving a without compensation (WOC) appointment mean?
8. Should a non-affiliated IRB member be given a WOC appointment?

**1. Who is a “non-affiliated individual?”?**

“Non-affiliated individual” means an individual who has no discernable ties, ongoing relationship, or association with the VA facility (but see paragraphs 3 and 4 below). An immediate family member (parent, spouse, child, sibling) of an affiliated person may not be considered a “non-affiliated individual.”

**2. What does academic “affiliation” mean for the purposes of this Guidance document?**

An “academic affiliate” means an academic institution that has a relationship for the purpose of education, research, or enhanced patient care with a VA facility documented by an executed Affiliation Agreement in conformance with VA requirements. In addition, special purpose agreements documented by a memorandum of understanding approved by the Chief Research and Development Officer may be developed in research and development (R&D) areas, such as health services or rehabilitation R&D.

**3. Are employees of the academic affiliate considered affiliated with VA for purposes of this Guidance document?**

Employees of the academic affiliate are considered non-affiliated for purposes of determining membership eligibility on a VA IRB if they do not have an appointment (i.e., compensated, Intergovernmental Personnel Act (IPA), or WOC) at the VA, any discernable ties, ongoing relationship, or association with the VA.

**4. Are Veterans receiving care at the VA considered to be affiliated?**

Veterans whose only relationship with VA is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration are not considered to be “affiliated” for the purpose of being an IRB member.

**5. Are Veterans who volunteer at the VA considered to be affiliated?**

Individuals who perform occasional volunteer activities at VA without a WOC appointment are not considered “affiliated” for purposes of this Guidance document. However, those who hold a WOC appointment for volunteer activities other than IRB service are considered to be affiliated.

**6. Are VA retirees considered “affiliated” for purposes of this Guidance document?**

Individuals who have retired from VA are considered affiliated for purposes of determining membership eligibility on a VA IRB only if they are receiving VA retirement benefits.

**7. What does receiving a WOC appointment mean?**

A WOC is an individual that has an official VA appointment, but does not receive any salary or benefits from VA (38 U.S.C. §§ 513, 7405(a)(1)). This appointment may allow the individual to support VA’s research program in various capacities including, but not limited to, investigator, research coordinator, and administrator while at VA for a defined period of time.

WOCs are subject to all laws and regulations pertaining to government personnel, including, but not limited to, government ethics laws and standards of conduct and VHA’s credentialing and privileging policy. A WOC is considered a VA employee.

***NOTE:*** *A WOC**may be an employee of a university affiliate or other nonprofit organization and is not under an IPA. An IPA is also a VA appointment that allows an individual to serve as a VA employee, therefore, an IPA does not require a WOC appointment.*

**8. Should a nonaffiliated IRB member be given a WOC appointment?**

A nonaffiliated VA IRB member should, but is not required to, obtain a WOC appointment. The WOC appointment provides the best protection from unexpected liability and the best likelihood for the Department of Justice (DOJ) to represent that individual as a VA "employee" and thus, be immune from personal liability for negligence. The WOC appointment for purposes of liability coverage does not change the affiliation status of the IRB member. *NOTE: If a nonaffiliated IRB member chooses not to obtain a WOC appointment for purposes of being on the IRB, he/she is still bound to all VA requirements on confidentiality and conflict of interest.*

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| **A VA WOC Appointed IRB Member** | **A VA Non-WOC Appointed IRB Member** |
| Best likelihood for DOJ representation | Least likelihood for DOJ representation |
| Immunity from personal liability | Personally liable for negligence so should consider a professional liability insurance policy |
| If injured on VA premises, relief is sought first through Federal Employees’ Compensation Act, then potentially through Federal Torts Claim Act (FTCA) | If injured on premises, relief is sought through FTCA |

**REGULATORY AND VHA POLICY REFERENCES:**

* VHA Handbook 1200.01, Research and Development Committee.
* VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.
* VA Handbook 5005, Part II, Chapter 3, Section G, paragraph 7, Staffing.