

VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 4 No. 2
September 30, 2010

Unraveling the confusion about credentialing and Appointment Status for Investigators and Research Staff engaged in research at the VAMHCS

1. ***Credentialing/Privileging and WOC/Employment status ARE NOT the same thing!!!***
2. ***Credentialing/Privileging and WOC/Employment status are two separate requirements that are achieved through two separate application processes!!!***
3. ***Just because you have one does not automatically get you the other!!!!***
4. ***Everyone “engaged in research”* at the VAMHCS must either be a VA employee or have a WOC or IPA appointment.***
**Anyone conducting research activities or collecting information for research purposes. See “Glossary” below.*
5. ***Some** members of the research team must also be credentialed at the VAMHCS.***

***** Any member of the research team who is licensed, registered, or certified for their professions or who are qualified to be licensed, registered, or certified for their professions (whether or not they have the license/registration/certification) must also be credentialed at the VAMHCS through the VetPro system.***

- WOC/IPA appointments and VA employment status: Principal Investigators and members of the research team who are engaged in research at the VAMHCS must either be employed by the VA (receive a VA paycheck) or through an Intergovernmental Personnel Act (IPA), or have a “without compensation” (WOC) appointment.
 - **If you do not have VA “eighths” or do not have an IPA or WOC appointment, you MAY NOT be a VA principal investigator or be a team member engaged in research activities at the VAMHCS.**
 - WOC appointments are obtained through the VA Service or Center most applicable to your team (e.g. Medical Service, Surgical Service, Research Service, GRECC, MIRECC, etc.).
 - The Service then submits the WOC application package to VAMHCS Human Resources (HR) in a process that is similar to an application for employment. This includes items such as a background check, fingerprinting, and security check. This is similar to the credentialing process, but it is an entirely independent process. (See VAMHCS Policy 512-05/HR-021).
 - Your WOC appointment is obtained through Human Resources...NOT through the Medical Staff Office (MSO), the office that performs the

credentialing process). Although correspondence from the MSO may mention WOC status, the MSO itself is not involved with obtaining the WOC appointment for an individual.

- **WOC appointments expire!!!!** A WOC appointment can be active for up to three years. The Service/Center through whom the individual is appointed decides whether the appointment will be for 1, 2 or 3 years.
 - Services/Centers appear to vary with whether the Service/Center reminds you that your WOC is about to expire, whether the Service processes renewals for you or whether it is your responsibility to keep track of your status.
 - Once Human Resources receives all your paperwork (including your completed credentialing [if applicable to you] and your completed and cleared background check), you will receive an appointment letter from HR. This letter needs to be signed by you and a copy returned to HR. The letter shows that you have been appointed for the time period stated in the letter.
 - If your WOC appointment expires, you must halt VA research activities until your status can be finalized.
 - When the Office of Research Compliance conducts audits on VAMHCS studies, the auditor will obtain information on which members of the research team engage in VA activities. Those team members must be VA employees or have a VA appointment or they will be required to halt their VA research activities until their status can be finalized.
 - While this Hot Topic is specifically geared toward research activities, **all of the above also applies to your clinical duties as well:** if you are not a VA employee or if you do not have a IPA or WOC appointment at the VAMHCS, you may not perform clinical duties, access CPRS, collect PHI or otherwise interact with patients at the VAMHCS for research **OR clinical duties** until you have status at the VAMHCS.
- **Credentialing/Privileging:** Principal Investigators and members of the research team who, through their education or training, are or qualify to be licensed, registered or certified in their clinical professions, must also be credentialed at the VA.
- This is the same push to be credentialed that you hopefully heard about and complied with in November 2009-January 2010. By now, all investigators and applicable research staff engaged in research at the VAMHCS MUST be credentialed at the VA.
 - If you are not credentialed but should be (see below), you must stop your research activities at the VAMHCS immediately and contact the VAMHCS Medical Staff Office (MSO) to start the process.
 - Credentialing/privileging is done through the VAMHCS MSO and involves the “VetPro” system.
 - **You must be credentialed at the VAMHCS (through VetPro) if:** If you, by your education or training, are a physician, nurse, physical therapist,

psychologist, pharmacist, dietician, or a member of other professions that require a license, certification or registration in order to practice the profession. You MUST be credentialed through VetPro, even if you do not act in that capacity for your research activities. For example,

- a dietician who does tissue culture in the laboratory and who never sees a patient in her research still needs to be credentialed through VetPro (because dieticians are registered professionals). However...
- a team member with a BS or MS in biology could be a study coordinator (and interact with patients) without being credentialed in VetPro since that team member does not have education/training for a licensed profession. But...
- a nurse employed by the University and with WOC status at the VAMHCS cannot be a study coordinator at the VAMHCS unless she is also credentialed through VetPro (because nurses are licensed).
- This is a VA Central Office directive; the VAMHCS is required to comply with VACO directives.

■ Your head is spinning? Where do you go from here?

- Look at your personnel files to check on whether you and your team members are current in employment/WOC status at the VA and are credentialed (if applicable).
- If in doubt, please contact your administrator. If necessary, your Service or Center should start the WOC process immediately.
- For other questions about credentialing please contact Bonnie Huggins, Supervisor, MSO at 410-605-7213 or bonnie.huggins@va.gov.
- For other questions about your WOC status please contact Sandy K. Smith, HR Assistant at 410-642-2411, extension 6687 or by e-mail at Sandra.Smith4@va.gov .

■ Remember, if you are a Principal Investigator, YOU are responsible to ensure that you and your staff have appropriate employment/WOC status at the VAMHCS and are credentialed at the VAMHCS (as applicable).

- You are also responsible for “confirming with the applicable service chief that you have been awarded the appropriate credentials and privileges to conduct research at VA prior to conducting any research” [VHA Handbook 1200.01par 8.a] and for “complying with all applicable personnel and other VA requirements whether the investigator is compensated, WOC, or IPA”. [VHA Handbook 1200.01 par 8.b].
- You are also responsible for confirming that your team members who conduct VA research have the appropriate credentials and employment status.
- If you or a member of your team is out of compliance, please:
 - Have them halt VA research activity IMMEDIATELY.
 - Initiate the WOC or employment process IMMEDIATELY.
 - Initiate the credentialing process IMMEDIATELY

- Self-report to the ACOS/R&D (Dr. Bever) and the Office of Research Compliance.

■ **Glossary for regulatory terms applicable to the Hot Topic:**

- Engaged in research: This term has very specific regulatory meaning:

According to OHRP Guidance (Jan 1999) as well as in the IRB P&P I.1.A., a person or institution is **engaged in research** when:

- The person intervenes with living individuals by performing invasive or noninvasive procedures for research purposes (e.g., drawing blood; collecting other biological samples; dispensing drugs; administering other treatments; employing medical technologies; utilizing physical sensors; utilizing other measurement procedures).
- The person intervenes with living individuals by manipulating the environment for research purposes (e.g., controlling environmental light, sound, or temperature; presenting sensory stimuli; orchestrating environmental events or social interactions; making voice, digital, or image recordings).
- The person interacts with living individuals for research purposes (e.g., engaging in protocol-dictated communication or interpersonal contact; conducting research interviews; obtaining informed consent).
- The person releases, obtains, receives, or possesses private information that is individually identifiable (either directly or indirectly through coding systems) for research purposes (e.g., obtaining private information from medical records and/or research records in an individually identifiable form).

Additionally: A **performance site becomes "engaged" in human participants' research when** its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human participants' research when it receives a direct Federal award to support the research.

The HRPO uses this definition for its requirement as to who must be listed in CICERO as research team members.

- Engaged in VAMHCS research:

A VA **facility** is **engaged** in human subject research (and needs an Assurance) whenever its **employees or agents**:

- Intervene or interact with living individuals for research purposes, *or*
- Obtain, release, or access individually-identifiable private information (or individually-identifiable specimens) for research purposes. [38 CFR 16.102(f)]

A study is VAMHCS research if:

- the research will be conducted completely or partially in VA facilities or at VA approved off-site locations or otherwise utilizes VA resources,
- the research will be conducted by researchers with VA appointments while on official VA duty (including those with WOC status),

- the VAMHCS or its satellites will be recruitment sites for the research project,
- the research is VA-funded, or
- the research involves VAMHCS medical records or VAMHCS databases, or otherwise derives data from intervention or interaction with VAMHCS subjects or tissues.

An “agent” of the VAMHCS is:

Anyone with an appointment to the VAMHCS, whether they are an employee or a “without compensation” (WOC) appointee, and who is engaged in research for the VAMHCS.

▪ [VHA policy statement on credentialing:](#)

All VA research staff conducting any type of VA research, who by virtue of their education and training are or may be eligible to obtain, but do not hold licensure, registration, or certification, are required to have a Scope of Practice Statement and be credentialed, using the VetPro system, under the professional occupational category consistent with their education and training prior to being appointed into a position, or if currently holding an appointment, by January 29, 2010. [[VA Directive 2009-054](#) Par 3]

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

Jessica Mendoza,
Acting Research Compliance Officer
Room 3A-125
410-605-7000 x6512
jessica.mendoza@va.gov

Can't put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website: http://www.maryland.research.va.gov/hot_topics.asp

For comments, complaints or suggestions regarding the Research Service or Office of Research Compliance, contact:

Jessica Mendoza,
Acting Research Compliance Officer
Room 3A-125
410-605-7000 x6512
jessica.mendoza@va.gov