

## VAMHCS RESEARCH SERVICE HOT TOPIC

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### Research Participants Outreach Program

In November, the VA Office of Research and Development (ORD) issued a directive mandating “Research Participants Outreach Programs” (VHA Directive 2008-079; [http://www1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=1805](http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1805)).

The VAMHCS Office of Research Compliance has had a participant outreach program since 2003. However, **the Directive now requires that Investigators be responsible for participant outreach when they interact with the community.**

One of the key features of the outreach program is the distribution of a pamphlet produced by the VA Center for Advice and Compliance help (COACH) entitled **“Volunteering in Research – Here are some things you need to know”**.

Here is what you need to do:

- Obtain “Volunteering in Research – Here are some things you need to know“ from the VAMHCS Office of Research Compliance.
    - The brochures will contain contact information for the VAMHCS Research Compliance Officer (RCO).
    - The ORC may arrange for larger research groups to order the brochures directly from the COACH website and to add the RCO contact information to them.
  - During your recruitment and enrollment activities, make the brochures available to potential research participants in settings where you recruit participants (e.g., clinic waiting areas). Distribute them to each prospective participant (and surrogate where necessary) when they are approached to take part in a project.
    - This requirement applies even if the requirement for written documentation of informed consent has been waived by the IRB.
    - This requirement does not apply if you have received a waiver of informed consent from the IRB.
- NOTE: The Institutional Review Board (IRB) may waive informed consent altogether or it may just waive written documentation of the informed consent but still require that the informed consent process be done with the subject or surrogate.
- Establish procedures to document how you do your outreach activities (for example: how many brochures distributed, reasons why individuals decline the brochure, how many times/schedule a poster is displayed in your clinic area, or some other summary of your efforts). At the time of your triannual audit, the ORC will look for some kind of confirmation that you have made efforts to comply with this program.
  - During the consent process, inform the participant about the IRB and the Office of Research Compliance, in particular that they are independent of the research and are available for expressing questions or concerns.

Details are in a new Research Service SOP, “Research Participants Outreach Program” (HRP 01.16) that will be posted on the Research Service website soon: [www.maryland.research.va.gov](http://www.maryland.research.va.gov).

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

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