Registration of Department of Veterans Affairs Sponsored Clinical Trials
Frequently Asked Questions

- **What is the definition of a "clinical trial"?**

The VA Office of Research & Development (ORD) currently uses a definition for clinical trials that is similar to that used by the International Committee of Medical Journal Editors (ICMJE) and the World Health Organization. This definition is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." If your study meets this definition, then it needs to be registered in order to meet ORD and ICMJE requirements.

The Cooperative Studies Program also requires registration of observational studies that recruit and consent human participants.

- **When does a clinical trial need to be registered?**

ORD requires Principal Investigators to register clinical trials that it funds upon notification of funding or shortly thereafter. Funds are not released until proof of registration is submitted. The notice of funding will provide instructions for registering and trial and ORD staff will be available to work with investigators to ensure compliance with this policy.

- **How do I know if my clinical trial is registered?**

If you have an on-going ORD funded clinical trial, it is already registered it at the National Library of Medicine's clinicaltrials.gov registry. However, you should check to see if your trial is listed and has complete and accurate information.

If you have a clinical trial funded by another organization (e.g., NIH or industry), you will need to check with the sponsor to determine whether it is registered and/or pursue registration efforts on your own.

- **How does my clinical trial get registered?**

All ORD-funded clinical trials are registered through the HSR&D ART Program Intranet site (http://art.puget-sound.med.va.gov). ART Program staff work with investigators to ensure that the clinical trials are registered with *ClinicalTrials.gov.* Investigators use a Web-based data-entry form to submit all required project information to the ART Program.

If you are the Principal Investigator on a newly approved clinical trial and have not received an email from ART with registration instructions, please contact the ART Program at ART@va.gov.

Although ORD has standardized this process, each research service will continue to be responsible for ensuring that its respective trials are in compliance with registration requirements.

- **How will I be notified that my registration is complete?**

Within 2 to 3 business days of submitting your trial information through the ART Intranet site, you should expect to receive an email from ART with the *ClinicalTrials.gov* registration attached (PDF file). ART staff will alert you to any problems or deficiencies in the data you submitted. This PDF file is to be submitted with your other Just-In-Time documentation.

Within 2–5 business days of receiving confirmation from ART, you should be able to view your study's registration record on *ClinicalTrials.gov*.

- **After I register with *ClinicalTrials.gov*, can I register the trial with other registries?**

After completing the *ClinicalTrials.gov* registration, you may register the trial in other registries; however, you must do so on your own. ORD does not facilitate the registration process for other registries.

- **How do I keep the study's *ClinicalTrials.gov* registration up-to-date?**

It is important to keep your registration updated, especially with regard to the trial's recruitment status and contact information. This information is important for members of the public who are accessing your trial information. In addition, *ClinicalTrials.gov* requires that registrations be updated at least every six months. To assist you in this process, when an update is due, the ART Program will send you an email reminder. Updates, like the initial registration information, are collected through the ART Intranet site and uploaded to *ClinicalTrials.gov*.

- **When the trial is completed, is the information deleted from *ClinicalTrials.gov*?**

The information is not deleted. *ClinicalTrials.gov* is intended to serve as a long-term public registry. As soon as the trial is registered in the *ClinicalTrials.gov* system, it becomes a permanent record. Once the trial's recruitment status is set

to “no longer recruiting” or “completed,” it will be listed as an inactive trial, but will still be viewable on the Website. Contact information will no longer be displayed.

- **My study is completed, why do I continue to receive requests for citations?**

Although your trial is completed, the data analysis and dissemination of results are likely to continue. ORD encourages investigators to submit citations to *ClinicalTrials.gov* that include results from the clinical trial. Providing up-to-date information on publications helps ensure that veterans and the general public are receiving the full benefit of the research investment that was made.

With the inclusion of citations, the registry is an open source of information about trial results for patients, the public and other health professionals. This information may improve access to new evidence on health care and medical practice. Submission of results to *ClinicalTrials.gov* may also reassure the public and professionals that all clinical trial results are reported, including those with adverse or negative findings.

Sources
ClinicalTrials.gov. http://ClinicalTrials.gov (August 23, 2007.)
National Institutes of Health. http://nih.gov (August 23, 2007.)
Australian Clinical Trials Registry. http://www.actr.org.au/ (August 21, 2007.)