

**Registration of VA Office of Research and Development (ORD) Sponsored  
Clinical Trials  
Frequently Asked Questions  
Updated August 2015**

- **Why should I register my clinical trial?**

Clinical trials have an important role in advancing scientific knowledge and clinical practice. Registration enables a wide range of stakeholders to know what is being done and ensures greater timeliness in providing relevant details about the study. ORD supports these goals as part of its overall mission and commitment to Veterans and the public. ORD encourages dissemination of the research it supports, including clinical trials. Therefore, to help achieve these goals, ORD requires registration of the clinical trials it funds as a condition of funding. Furthermore, registering a clinical trial may help Principal Investigators (PIs) with meeting other requirements as part of their efforts in conducting the research including the ability to publish the research when it is completed.

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

ORD uses the same definition of a clinical trial as 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 requirements. Also, note that your ORD Service may require registration for observational studies that recruit and consent human participants.

- **How do I register my clinical trial?**

All ORD-funded clinical trials are registered with ClinicalTrials.gov through the VA ART Program Intranet site accessed at <http://art.puget-sound.med.va.gov> (copy and paste this link into your browser). Investigators use a Web-based data entry form to submit all required project information to the ART Program. The ART Program then uploads the information to ClinicalTrials.gov.

If you are the Principal Investigator (PI) on a clinical trial approved for funding and have not received an email from the ART Program with registration instructions, please contact the appropriate ORD Service representative found [here](#). Note that for CSP trials, trial registration, updates and submission of study results are managed by the respective coordinating center.

Although ORD has standardized the registration process, each research service is responsible for ensuring that its respective trials are in compliance with registration requirements.

- **Is ClinicalTrials.gov part of ORD?**

No, ClinicalTrials.gov is maintained by the National Library of Medicine at the National Institutes of Health. However, ORD staff members work directly with personnel at ClinicalTrials.gov to help meet shared goals.

- **When does ORD require a clinical trial to be registered?**

ORD requires PIs to register clinical trials that it funds as a condition of funding. This timing ensures consistency with ICMJE and [Section 801 of the Food and Drug Administration Amendments Act \(FDAAA 801\)](#) requirements. Funds are not released until proof of registration (e.g., posted registration to ClinicalTrials.gov) is available to the ORD service funding the study. Staff members within each ORD service are available to work with investigators to ensure compliance with this policy as needed.

The funding ORD Service initiates the registration process through the Just-In-Time (JIT) system. Once initiated, the PI will receive an email from the VA ART Program with instructions for accessing the ART Website and completing the data collection form.

- **Who can enter the clinical trial registration information on the ART Website (VA intranet site)?**

Registration instructions are sent to the PI. If the PI would like a project staff member to have data entry access to the Website, send a request to the VA ART Program ([ART@va.gov](mailto:ART@va.gov)). If the PI does not have access to the VA network and therefore cannot access the ART Website, the Research and Development Office at the PI Site can assist him or her in submitting the required information.

- **What protocol information must be submitted?**

Protocol information must be consistent with the ClinicalTrials.gov [Protocol Data Element Definitions](#). The information must be clear and informative.

- **Is my study an interventional or observational study type?**

In the Protocol Data Element Definitions document, ClinicalTrials.gov defines the [interventional or observational study types](#) as follows:

- **Interventional:** studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.
- **Observational:** studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

- **What information is required for primary and secondary outcome measures and time frames?**

The primary and secondary outcome measure titles and descriptions (if provided) should be as specific as possible. The outcome measure information should include the name of the specific measure (e.g., Systolic Blood Pressure) and a description of the metric that will be used to characterize the measure (e.g., Change in Systolic Blood Pressure).

Each outcome measure should include a time point at which the outcome is assessed for the specific metric used. Most outcome measures will have one time point. If multiple outcomes are based on the same underlying measure (e.g., Outcome Measure Title “Change from Baseline in Hamilton Depression Rating Scale”) assessed at different time points (e.g., “8 weeks and 12 weeks”), then each unique combination of measurement and time frame should be entered as a separate outcome measure (e.g., “Change from Baseline in Hamilton Depression Rating Scale at 8 weeks” and “Change from Baseline in Hamilton Depression Rating Scale at 12 weeks”).

- **Is the submitted protocol information reviewed by ClinicalTrials.gov?**

ClinicalTrials.gov staff members review protocol information for apparent validity, meaningful entries, logic and internal consistency, and formatting. Information on the [ClinicalTrials.gov review criteria](https://www.clinicaltrials.gov/ct2/info/reviewCriteria.jsp) is intended to assist PIs in preparing for protocol registration.

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

Within 5 business days of submitting your trial information through the ART Intranet site, you should expect to receive an email from the VA ART Program with the ClinicalTrials.gov registration confirmation attached (PDF file). If applicable, an ART Program staff member will alert you to any problems prohibiting the acceptance of your registration. If accepted, the Just-In-Time documentation for the project will automatically be updated to reflect that the registration is complete.

Within 5 business days of receiving confirmation from the ART Program, the registration record should be published to ClinicalTrials.gov.

- **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. Any change to the [recruitment status](#) or the [primary completion date](#) needs to be updated on ClinicalTrials.gov within 30 days of a change. In addition, ClinicalTrials.gov requires PIs to update or verify the protocol information at least every six months while the trial is ongoing. To assist you in this process, the VA ART Program will send you an email reminder when an update or verification is due. Updates are submitted through the ART Intranet site and uploaded to ClinicalTrials.gov.

- **Is the information removed from ClinicalTrials.gov when the trial is completed?**

No, the information is not removed from ClinicalTrials.gov. ClinicalTrials.gov is intended to serve as a long-term public registry. When a trial is registered, it becomes a permanent record. The most recent version of a study record is displayed on ClinicalTrials.gov. When the trial's recruitment status is set to "active, not recruiting" or "completed," the trial is still viewable on ClinicalTrials.gov but contact information for the trial is no longer displayed. A history of changes made to a study record is available on the ClinicalTrials.gov [archive site](#).

- **Do I need to submit additional information when the trial is completed?**

ORD requires the submission of summary results to ClinicalTrials.gov for all ORD-funded clinical trials. Reporting results in a public trial registry helps fulfill ORD's commitment to informing Veterans and the public about its research and helps maximize the impact of the studies it supports. The reporting requirement applies to all ORD trials which includes but is not limited to "Applicable Clinical Trials" as described in [Section 801 of the Food and Drug Administration Amendments Act \(FDAAA 801\)](#).

Results must be submitted no later than 12 months after the trial's [primary completion date](#). This is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was [terminated](#). Results information includes Participant Flow, Baseline Characteristics, all pre-specified Primary and Secondary Outcomes, and Adverse Events. For more information about results submission, please refer to the information on the [Results Submission Process](#) on the ORD Website.

- **What do I do if ORD classified my study as a clinical trial but I do not think it meets the definition of one?**

Please contact your research service's [Clinical Trials Program Manager](#).