

University of Massachusetts Dartmouth requirements for clinical trials registration and results reporting to ensure compliance with policy requirements.

If your research meets the following definition of a clinical trial and you meet the requirements of the responsible person for registering the trial, then you must register your research with [Clinicaltrials.gov](https://clinicaltrials.gov).

If your study meets ANY ONE of the definitions below, the trial should be registered with [Clinicaltrials.gov](https://clinicaltrials.gov).

- 1. The NIH defines a clinical trial as:**
 - A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions.
- 2. The ICMJE (International Committee of Medical Journal Editors) definition of a clinical trial includes:**
 - 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.
- 3. The FDA (Food and Drug Administration) requires registration for “applicable clinical trials” defined as follows:**
 - For any trials of drugs and biologics: controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation.
 - For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

How do I register with clinicaltrials.gov?

Register a trial before any subjects are enrolled. The International Conference of Medical Journal Editors (ICMJE) requires registration before the first subject is enrolled. To avoid publication restrictions imposed by the ICMJE, register your trial before enrolling the first subject. You may expect each registration to take approximately 1 to 2 hours.

Clinical trials are registered on ClinicalTrials.gov via a web-based data entry system called the Protocol Registration System (PRS). As a PRS user you are responsible for ensuring that the information you provide on your trial is correct, complete, readily understood by the public, and updated in a timely manner.

- 1. Obtain an Individual User Account:** Email akarberg@umassd.edu to obtain an Individual User Account. The UMassD PI is the responsible official for initial registration and for keeping the listing updated. You will receive an e-mail confirmation within two business days when the user account has been created.
- 2. Once you receive your user account login to PRS:** Once your account has been created go to the [ClinicalTrials.gov Registration webpage](https://clinicaltrials.gov). Complete the three fields on the Login screen. See the example below:

Organization: University of Massachusetts Dartmouth

Username: John Doe

Password: 1234

3. **Create a Protocol Record:** A trial is registered in the system by creating a “protocol record.” Click on the Create link under Protocol Records on the Main Menu and fill in a series of data entry screens. Clicking on the various fields will allow you to access instructions for that field. If you still have questions, email: register@clinicaltrials.gov.
NOTE: Using an electronic version of your protocol, you can copy and paste information into the requested data fields.
4. **Review the Protocol Record:** After filing in the last data entry screen, the Edit Protocol screen will appear. Review the information for accuracy and completely and address any ERRORS, ALERTS, WARNINGS, or NOTES in the protocol record. If you fail to do so, you cannot complete the registration process.
5. **Mark the Protocol Record as Complete:** If you fail to mark your record as complete, it will not be approved and released for publication and your trial will not be properly registered.
6. **Keep your Protocol Record Up-To-Date:** An affirmative verification or update of the data in the protocol records that have not been closed or terminated is required every six months. Failing to login to the PRS and confirm or update your record(s) every six months, regardless of whether there has been a change to the trial or not, may result in a loss of funding and/or the inability to publish the results of a trial in an ICMJE associated journal.
NOTE: You will receive a reminder e-mail notification from clinicaltrials.gov once every six months to update your study information.