

Creating a New Study Record

An Extensive user guide is imbedded in the clinicaltrials.gov system to aid users with navigation and completion.

This document provides institution-specific guidance for UMMS investigators.

Step 1:

1. Go to Website: <https://register.clinicaltrials.gov>
2. Log-in Using Organization Name : **UMass**

Organization:	<input type="text"/>
Username:	<input type="text"/>
Password:	<input type="password"/> Forgot password

Login

Step 2: Under “Standard Functions”, select **New Record**

Standard Functions
Records
New Record
Edit Record
View Record
PRS Review Comments
Problems: Records
Undelete Record

Step 3: Complete required information on “Create New Record” screen

You will be prompted for Unique Protocol ID. At UMass Medical School:

- For grant-funded projects, use the sponsor-issued grant or award number.
- For industry-funded projects, use the sponsor’s protocol ID number
- For all others, if no other unique identifier assigned by funder is available, use IRB docket number.

Step 4: Edit Study Status

Complete all required fields. Guidance and definitions are available on the page.

Step 5. Edit Sponsor/Collaborators

Sponsor: Regardless of funding source, enter the “regulatory sponsor” (individual or organization responsible for creation of the study protocol) for example:

- For industry-initiated trials, name industry sponsor (note: in this instance, verify you are the appropriate responsible party)
- For investigator-initiated trials, enter the name of the Principal Investigator

Responsible Party:

- For investigator-initiated trials without an Investigational New Drug (IND) or Investigational Device Exemption (IDE), select Principal Investigator
- For investigator-initiated trials with an IDE or IDE and you will be the holder of the IND or IDE, select **Sponsor- Investigator**.
- If there is IND or IDE, and the project is investigator-initiated (investigator, not funder, created protocol)

Step 6: Oversight

Under Oversight enter IRB contact information as listed below:

Under FDA Regulated? Enter Yes or No

Under IND/IDE Protocol? Enter Yes or No

Under Review Board:

- Approval Number: enter UMMS IRB Docket Number
- Board Name: Institutional Review Board
- Board Affiliation: UMass Medical School
- Phone: 508-856-4261
- Email: IRB@umassmed.edu

Data Monitoring: Yes or NO

Oversight Authorities: Enter all applicable oversight regulatory authorities (e.g. DHHS, NIH, DOD, DOE, etc)


Helpful Tips:


Record Verification Date: This date refers to current month and year. When updating a record always update the Record Verification Date.


Complete Record by selecting Edit next to each section, and add information as appropriate to your study.

Verify the record is free from errors prior to completing. ***Warning messages may be present to identify possible problems as follows:

 **ERROR** messages indicate serious problems that need to be addressed.

 **WARNING** messages indicate items that are (or may be) required by FDAAA 801.

 **ALERT** messages indicate problems that need to be addressed.

 **NOTE** messages indicate potential problems that should be reviewed and corrected as needed.

Step 7: Once your record has been updated, select **Completed** then the PI will review and **Approve** all changes. Next, the PI will need to select the **Release** command. [be sure to hit “release” or the posting will not be routed for publication]

In Progress | Completed | **Approved** | Released

Step 8: Once released, the record will be reviewed by ClinicalTrials.gov.

If no errors, record will be published.

If errors exist, The PRS system will notify the Owner and Responsible Party. Responsible party will be required to address comments and resubmit for review.

Step 9: To access PRS comments and make necessary corrections:

Log in

Select “**PRS Review Comments**”

Address outstanding issues

Select [**approved, release**]