Clinical Trial Registration:
Initial Registration Entry Guide

Each study must have a single record across all sites and phases. To ensure consistency of records, individuals entering study records under the University of Massachusetts Medical School (UMMS) Protocol Registration and Results System (PRS) account are advised to use the following standards to complete the registration:

The registration record consists of several sections, outlined below, which can be accessed, edited and navigated through in separate units

Contents

I.   Logging In

Enter register.clinicaltrials.gov into the URL bar.

Under "Organization" enter: UMass

Username: enter the username assigned to you at the time of account setup. If you or your colleague need an account, email clinicaltrials.gov@umassmed.edu for assistance.

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 02/29/2020
Burden Statement

Organization: _____
One-word organization name assigned by PRS (sent via email when account was created)

Username: _____

Password: _____   Forgot password

Login

See Submit Studies on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
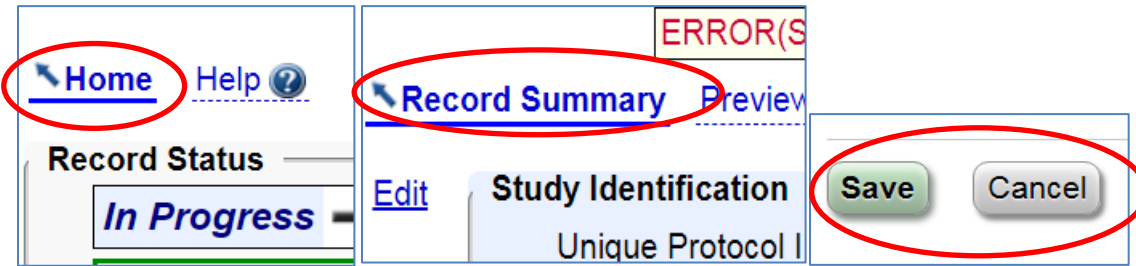
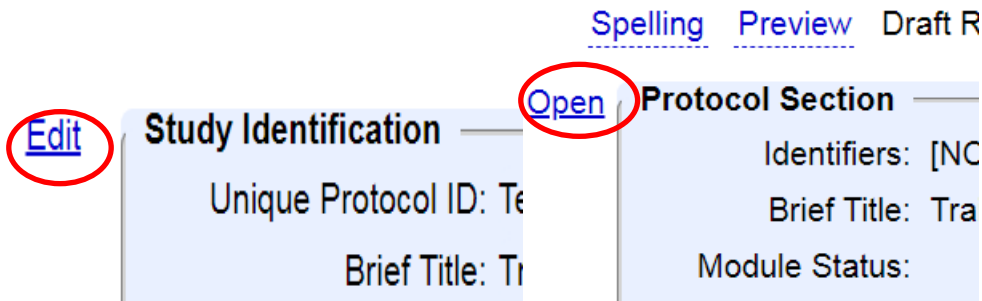Send email to ClinicalTrials.gov PRS Administration

II.   General Navigation

Each component or module of the Clinicaltrials.gov Protocol Registration and Results System (PRS) records can be navigated

Return to the prior screen through use of the return arrows found in the upper left hand corner of your screen or the Save/Cancel buttons within each module

Home Help ?
ERROR(S)
Record Summary Preview
Record Status
In Progress
Edit Study Identification
Unique Protocol I
Save Cancel

Each record module can be accessed through selection of the "Open" or "Edit" hyperlinks

Spelling Preview Draft R
Edit Study Identification
Open Protocol Section
Identifiers: [NC
Unique Protocol ID: Te
Brief Title: Tra
Brief Title: Tr
Module Status:

2

More information about each data element and intended purpose can be found at Definitions

↘Record Summary   Preview   Edit All   Help   (Definitions)

Guidance about registration strategies can be found in Help

↘Record Summary   Preview   Edit All   Help   Definitions

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III. Record Entry

a. Study Identification

Help   Definitions

* Organization's Unique Protocol ID:	
* Brief Title:	
	Special Characters
[*] Acronym: (if any)	
	If specified, will be included at end of Brief Title in parentheses.
* Study Type:	○ Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
	○ Observational participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
	○ Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

Continue   Cancel

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

1. **Organization's Unique Protocol ID**: Use the IRB Docket number (UMMS or otherwise). Do NOT use federal grant or contract number.

2. **Brief Title:** The Brief Title is what displays in the public clinicaltrials.gov record listing. It should be 1) written in language intended for the lay public and 2) should include information on participants, condition(s) being evaluated and intervention(s) being studied, e.g. *Study of the effect of aspirin on pregnancy induced hypertension in pregnant women* or *A phase 2 study of MLPJ-103 on Crohn's Disease in adults*.

3. **Acronym:** If the study has an acronym or abbreviation that is used publicly to refer to the trial, provide it here. Otherwise, skip.

After you complete the initial screen and select "continue", the following message will appear:

The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Interventions
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.

On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.

OK

Continue with data entry of Study Identification:

Edit Study Identification

Help   Definitions

* Organization's Unique Protocol ID:	Test
* Brief Title:	Training Record
	🚫 ERROR: A title this short cannot be sufficiently descriptive.
[*] Acronym: (if any)	TRAIN
	If specified, will be included at end of Brief Title in parentheses.
* § Official Title:	Training record to support PRS education
[*] Secondary IDs: (if any)	✚ Add Secondary ID

Save   Cancel

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

4. **Official Title:** should match the protocol title in eIRB, OnCore (if applicable) and the protocol document, without added acronyms.
5. **Secondary ID:** This applies primarily to federally funded trials and should be the grant or contract number.

b. Study Status

Edit Study Status

Help   Definitions

* Record Verification Date:	Month: May ▾ Year: 2018
* Overall Recruitment Status:	--Select-- ▾
	Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
	Tip: Day is not required for Anticipated dates.
* § Study Start Date:	Month: --Select-- ▾ Day: Year: Type: --Select-- ▾
	Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).
* Primary Completion Date:	Month: --Select-- ▾ Day: Year: Type: --Select-- ▾
	Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: --Select-- ▾ Day: Year: Type: --Select-- ▾
	Final data collection date for study.

Save   Cancel

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

1. **Record Verification Date:** For new entries, confirm that the current month and year is displayed. Update as necessary each time you review or update the record.

2. **Overall Recruitment Status:** Select the status of the study as a whole. For multisite studies, if at least one site is open, it is open to enrollment. Individual site status will be specified in "Locations".

3. **Study Start Date:** If the study has not yet opened to enrollment, enter the date it is anticipated that the study will be open for recruitment and select type "Anticipated". Once the study is opened to enrollment, enter the date the study opened to enrollment or the date on which the first participant is enrolled, and update type to "Actual".

4. **Primary Completion Date:** Anticipated (and then ultimately actual) date that the final participant was or will be examined or receive an intervention for purposes of data collection for the study's <u>primary</u> outcome(s).

5. **Study Completion Date:** Anticipated (and then ultimately actual) date that the final participant was or will be examined or receive an intervention for purposes of data collection for all primary <u>and</u> secondary outcomes measures, as well as adverse events.

c. Sponsor/Collaborators:

1. **Update the Responsible Party field**
   The responsible party field will be defaulted to Sponsor. Use the pull down menu to select Sponsor-Investigator or Principal Investigator:

```
┌─────────────────────────────────────────────┐            ┌──────────────────────────┐
│ Do you hold the IND/IDE for the research?    │──Yes──▶│ Select Sponsor-Investigator │
└─────────────────────────────────────────────┘            └──────────────────────────┘
                      │No
                      ▼
┌─────────────────────────────────────────────┐            ┌──────────────────────────┐
│ Did you design and develop the protocol and/or are you │            │                          │
│ Overall Principal Investigator for research that is externally │──Yes──▶│ Select Principal Investigator │
│ supported through a research assisting funding agreement │            │                          │
│ e.g. grant or sponsored research agreement?  │            └──────────────────────────┘
└─────────────────────────────────────────────┘
                      │No
                      ▼
┌─────────────────────────────────────────────┐            ┌──────────────────────────┐
│ Did you design and develop the protocol and/or are you │            │                          │
│ Overall Principal Investigator for research that is internally │──Yes──▶│ Select Sponsor-Investigator │
│ supported?                                   │            │                          │
└─────────────────────────────────────────────┘            └──────────────────────────┘
                      │No
                      ▼
┌─────────────────────────────────────────────┐
│ Another individual or organization is likely the sponsor and/ │
│ or Responsible Party                         │
└─────────────────────────────────────────────┘
```

2. **Enter Investigator Information**:
   ▪ *Investigator Name*: pull down to select investigator name. If not found, contact
     clinicaltrials.gov@umassmed.edu. Investigator will need a clinicaltrials.gov PRS account.
   ▪ *Investigator Official Title*: Enter Academic title (e.g. Professor, Associate Professor,
     Assistant Professor)
   ▪ *Investigator Affiliation*: verify that affiliation states "University of Massachusetts, Worcester"

   If you selected "Sponsor-Investigator", the Principal Investigator's name will appear in the
   "Sponsor" field. If you selected "Principal Investigator," verify that "University of
   Massachusetts" appears as sponsor.

3. **Collaborators**:
   Ensure funding sources/organizations are listed in addition to institutions of collaborating
   individuals.

d. Oversight

Edit Oversight

Help   Definitions

* § U.S. FDA-regulated Drug: --Select-- ▾
  Studying one or more U.S. FDA-regulated drug or biologic products?
  For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).

* § U.S. FDA-regulated Device: --Select-- ▾
  Studying one or more U.S. FDA-regulated device products?
  For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).

* U.S. FDA IND/IDE: --Select-- ▾
  (Not public)   Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

* Human Subjects Protection Review: Board Status: --Select--   ▾

Data Monitoring Committee: --Select-- ▾

FDA Regulated Intervention: --Select-- ▾

[Save] [Cancel]   * Required
                    * § Required if Study Start Date is on or after January 18, 2017
                    [*] Conditionally required (see Definitions)

1. FDA Oversight

Answer all questions related to FDA regulation of drugs or devices.
Note: Answer "yes" to US FDA Regulated Drug if the drug being studied is FDA approved or under an IND, and answer "yes" to US FDA Regulated Device if the device being studied is FDA cleared/approved or under an IDE.

If the study involves a test article under a US FDA IND or IDE, select "yes" and enter all required information as prompted.

2. Human Subjects Protection Review:

- If UMMS IRB:
  - Enter docket number (without extensions but including all letters and leading zeroes e.g H00001234)
  - Enter Board Name: University of Massachusetts Medical School IRB
  - Affiliation: University of Massachusetts Medical School
  - Phone: (508) 856-4261, email: irb@umassmed.edu, Address: 55 Lake Ave N Worcester MA 01655.
- If other than UMMS IRB (e.g. WIRB or single IRB review by other IRB)
  - Full identifying number
  - Board name
  - Affiliation
  - Main office phone, email and address.

3. Data Monitoring Committee: Answer yes or no

4. FDA Regulated Intervention: Answer yes or no

5. Section 801 Clinical Trial: Displays only if US IND/IDE and/or FDA Regulated Intervention is answered "Yes", above. If displays, answer yes or no

e. Study Description

1. **Brief Summary:** Provide a short description of the study, including a brief statement of the study's hypothesis written in lay language.

2. **Detailed Description (optional):** Permits study teams to provide an extended description of the protocol. Do NOT include the entire protocol, or duplicate information found in other data elements e.g. eligibility criteria or outcome measures. For patient registries, there are special requirements for entry of registry procedures and quality assurance.

f. Conditions

1. **Primary Disease or Condition:** Use MeSH (embedded link provided)
2. **Keywords**: USE NLM's MeSH controlled vocabulary terms where appropriate. Avoid acronyms and abbreviations.

g. Study Design, Arms and Interventions and Outcomes Measures

These all should be clear, well-defined and consistent with the protocol/ISP. Use the embedded system resources to build out arms, interventions and outcomes

1. **Study Design:** Verify the Study Type is correct, and enter the Primary Purpose, Phase (if non-drug study: enter N/A) or , Study Model, number of arms, Masking, Allocation and anticipated enrollment (selecting Type as "Anticipated'

2. **Arms and Interventions:** Enter information about the arms and interventions under study
   a. Arms: Add arms for each arm of the study
      i. provide arm titles for each arm. The titles should be short but descriptive to the role in the clinical trial and also provide additional descriptive information, including information about the interventions administered in that arm. Continue to add arms until each arm is built out. Additional detail can be provided in "Arm Description"
      ii. Select the applicable arm type
   b. Interventions: Enter each intervention used in the study
      i. Select Intervention type
      ii. Enter Intervention name
         1. Tips: the intervention name must match with arm/group description
         2. For drugs, use generic name, and provide brand name for "Other Intervention Names (if any)"
         3. Other Intervention Name: Other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), or serial numbers.
      iii. Provide a description of the intervention sufficient to distinguish it from other interventions studied in the same study. Interventions involving drugs may include dosage form, dosage frequency and duration.
      Note: If the same intervention is associated with more than one arm or group, provide the information once and use the Arm or Group/Intervention Cross-Reference to associate it with more than one arm or group.

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    c. Arm or Group/Intervention Cross-Reference
          i. Assign interventions to each arm/group using the cross-reference checkboxes.
    NOTE: Interventions are the ACTIONS, and Arms are the COMBINATION of actions.

3. Outcome Measure(s)
    a. Enter information about the Primary Outcome and any Secondary Outcome measures.
    b. Outcome measures must describe what is being measured, not why.
    c. Outcome measures using instruments must name the instrument. Spell out all acronyms with the first usage.
    d. Time frame must describe the time point(s) at which the measure is assessed for the specific metric used. Generally this is a specific duration of time or time to event.
    e. Spell out acronyms

Good results reporting starts with the construction of clear, well-defined outcome measures.
Example:

Example

Outcome Measures

Primary Outcome Measure:
1. 4-Item Pain Intensity Measure (P4)
    Self reported pain intensity in the morning, afternoon, evening and with activity over the past 2 days. Each item is scored 0-10 (0 = no pain; 10 = pain as bad as can be), yielding a total between 0 and 40.
    [Time Frame: 2 days]
Secondary Outcome Measures:

2. Recurrence of Pain
    Return of any migraine headache pain during the specified post-dose period, following a pain-free response at 2 hours.
    [Time Frame: 24 and 48 hours]
3. Sustained Freedom from Migraine
    Pain free, with no migraine associated symptoms (photophobia, phonophobia, nausea) at the time of assessment, following a symptom-free response within 1 day of initial dose.
    [Time Frame: 7 days]

h. Eligibility

The information entered should be clear and consistent with the protocol/ISP, and be formatted correctly (inclusion and exclusion criteria in a bulleted list.
Note: To get bullets in the entry field, type two spaces and a dash "##-#"

i. Contacts/Locations

1. Contacts:
    a. **Central Contact Person:** Enter the name of the individual who can answer questions about the study. This will typically be the PI or designated study team member. Also include a Central Contact Backup. It is recommended that these individuals also be listed on the record access list.
    b. **Study Official:** This is required by World Health Organization (WHO) policy.   Enter the PI/Responsible Party as "Study Official" and enter academic title.

2. Locations:
    Select: Add Location (enter EACH site/institution where research will be occurring)

- **Facility Name:** Facility name(s) should match to listing(s) on 1572
- **Site Recruitment Status**: enter the recruitment status for the individual location
- **Facility Contact:** enter the name or title (if using title, enter in "Last Name" space and leave First Name and MI spaces blank), telephone number and email address of a person to whom questions about the study and enrollment at the site can be addressed.
- **Investigators:** Add Investigators at site (used for multisite research)

j. IPD Sharing Statement

Indicate whether there is a plan to make individual participant data (IPD) collected in this study available to others. Per ICMJE policy, Manuscripts submitted to ICMJE journals that report results of clinical trials must contain a data sharing statement. Clinical trials that begin enrolling participants on or after January 1 2019 must include a data sharing plan in the trial's registration. More information, including examples of IPD statements, is available at http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html#two

If there is a plan to make individual participant data and related data dictionaries available to others:
- Select yes, and 1) describe what specific data sets are to be shared 2) upload supporting information including: study protocol, statistical analysis plan, informed consent form (unsigned), clinical study report and analytic code and 3) specify IPD sharing time frame.

If there is not a plan to make individual participant data available or if study team is undecided, provide explanation as to why.

IV.   Next Steps

Once the registration record has been completed by the study team/investigator (and all Errors/Warnings have been addressed), the "Entry Complete" button on the Record Summary screen will show as green.

Click the "Entry Complete" button to route the record for administrative QA review by the UMMS PRS Administrator.
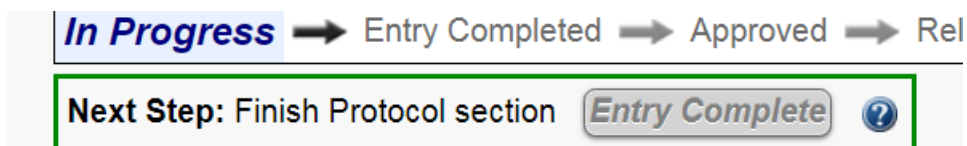
The system will send an automated message to the Record Owner, PRS Administrator and Responsible Party.

Once the Entry is completed, and the Record has received approval for release by the PRS Administrator, the "Release" button will be highlighted. The Responsible Party must release the record by clicking on the "Release" button.

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From there, the record will be reviewed by the central PRS administrators and either posted and assigned an NCT number, or returned for corrections.

V.   Questions & Additional Guidance

Have questions or need additional guidance?

Contact the UMMS PRS Administrator at clinicatrials.gov@umassmed.edu