OVERVIEW

The ClinicalTrials.gov Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying, and releasing protocol records using the PRS. Records submitted through the PRS (http://register.clinicaltrials.gov) are available to the public at ClinicalTrials.gov (http://clinicaltrials.gov). A guided tour of the PRS and account application information are available at http://prsinfo.clinicaltrials.gov/

The screen shots provided below for your review and assistance are step by step guidance to enter a protocol record.

Color Key Code used on subsequent pages:

- **Green** = Text explanation
- **Orange** = Highlighted information on form
- **RED** = Please take note
Sponsor provided protocol number. This is not the IRB number. If you do not have one, contact your administrator.

Enter the Study “Short Title”; the full title is entered later. The Brief Title put here is to be in lay language and include the condition and intervention evaluated in the study. 300 character limit.

Choose Continue when ready to advance to each next screen. The site will allow you to go forward with incomplete entries as long as all applicable required fields are completed. At the end the system will stop you from filing and will give you an error report that includes anything missing. You will see notes or symbols where there is missing information.
Form section headers are useful for navigation. The section where you are is in **Bold Blue** font.

<table>
<thead>
<tr>
<th>Title</th>
<th>Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title: Short Title of Study</td>
<td></td>
</tr>
</tbody>
</table>

### Unique Protocol ID:
Enter sponsoring organization's unique identifier.

### Brief Title:
**FDAAA**
Use lay language.
Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
Short Title of Study

### Acronym:
If there is an acronym or abbreviation used to identify this study, enter it here.
Example: Phase I Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate
Limit: 14 characters. If you add an acronym, it will be appended to the brief title in parentheses.

### Official Title:
Full title here. Limit 600 characters.

### Study Type:
- *Interventional*
- *Observational*
- *Expanded Access* About expanded access records

### FDA Regulated Intervention?
Choose Yes or No from drop-down list.

### IND/IDE Protocol?
Choose Yes or No from drop-down list.

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**Study Type Expanded Access** includes all types of non-protocol access to experimental treatments: protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access and parallel track.

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This is a smart form - the choices you made on previous screens affect future screens.
FDA screen comes up if you say Yes.

### Section 801 Clinical Trial?
Indicate whether this is an "applicable clinical trial" as defined by US Public Law 110-85, Title VIII, Section 801.

- Select: [ ]

### Delays Protocol Posting?
Indicate whether this is an unapproved or uncleared device trial for which posting to ClinicalTrials.gov should be delayed in accordance with US Public Law 110-85, Title VIII, Section 801.

- Select: [ ]

If you answered Yes above, does this study include a device not previously approved or cleared by US FDA for any use? “Yes” here will delay full posting of the study and the registrant will have to change this selection to “No” to release the record for full publication.

### IND/IDE Grantor:
* CDER, CBER or CDRH

### IND/IDE Number:
* FDA

### IND/IDE Serial Number:
* FDA

### Has Expanded Access?
Indicate whether any protocol exceptions are to be granted for the investigational drug or device.

- Select: [ ]

**About expanded access records**

**If applicable, enter the ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record.**

### Expanded Access Record:
* FDA

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**Required by ClinicalTrials.gov**

Required to comply with US Public Law 110-85, Section 801

May be required to comply with US Public Law 110-85, Section 801

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Controlled clinical investigations other than Phase 1 of an FDA regulated drug or biologic, or controlled trial of FDA regulated device with health outcomes other than small feasibility studies and pediatric post-market surveillance.

IND/IDE Number is assigned by FDA. Serial Number is of the submission in which the protocol for this study was added to the IND or IDE.

If you answer “Yes”, an Expanded Access Record should be created for it.
IRB Approval is required for interventional studies. If Overall Recruitment status is Not Yet Recruiting at the time of registration, the acceptable choices are Submitted, Pending or Request Not Yet Submitted.

Choose “Yes” or “no” from the drop down. If the study has a Medical Monitor but no DMC, the answer is No.

Choose Continue when ready to advance to each next screen. The site will allow you to go forward with incomplete entries as long as all applicable required fields are completed. At the end the system will stop you from filing and will give you an error report that includes anything missing. You will see notes or symbols where there is missing information.
Up to 10 names if applicable to the study. The person who fills in this field is responsible for confirming any Collaborator before listing them here.

Limit 160 characters per name.

Three choices: Sponsor, Sponsor-Investigator or Principal Investigator. If not the Sponsor, additional information will be asked for.

Name of primary organization that oversees implementation of the study and is responsible for data analysis. For applicable trials, Sponsor is defined in 21 CFR 50.3.

Limit: 160 characters.
Use lay language. Include a statement of the study hypothesis.

Can cut and paste into this field from a study document. Suggest in from the Informed Consent Form as must use lay language.

5000 character limit.

Provide a more extensive description, if desired.

Avoid duplication of information to be recorded elsewhere, such as eligibility criteria or outcome measures.

This field is NOT asterisked in red, so is optional. May be left blank.

Extended description of the protocol including more technical information as compared to the Brief Summary. Do not include the entire protocol or duplicate information recorded in other data elements of the submission form (such as eligibility criteria or outcome measures). Limit 32,000 characters.
### ClinicalTrials.gov Protocol Registration System

**Title:** Short Title of Study

**Record Verification Date:** January 2012

**Overall Recruitment Status:** Not yet recruiting

**Why Study Stopped:** Limit 160 characters

**Key Trial Dates**

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Start Date:</strong></td>
<td>April 2012</td>
<td></td>
</tr>
<tr>
<td><strong>Primary Completion Date:</strong></td>
<td>April 2015</td>
<td></td>
</tr>
<tr>
<td><strong>Study Completion Date:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Final data collection date for primary outcome measure.**

- **Date:** April 2015
- **Type:** SELECT

**Final data collection date for the study.**

- **Date:** SELECT
- **Type:** SELECT

---

**Update this date when reviewing the record for accuracy and completeness, even when no other changes (besides this date) are made.**

**Choose from the 8 choices on pick-list.**

**Define**

**Date when first participant is enrolled.**

**Date the final Subject was examined or received an intervention for the purposes of final collection of data for the primary outcome.** Choose from: Anticipated and Actual.

**Final date on which study data was (or is expected to be) collected.** Choose from: Anticipated and Actual.
Following this link will provide screens that are specific for Observational.

Choose from the 8 choices on pick-list. If you choose Other, provide a description in the Detailed Description data field.

Choices are N/A (for trials without Phases), 0, 1/2, 2, 2/3, 3, and 4.

At least one of the following is required: Intervention Model, Masking or Allocation. All may be required for some studies.

Choices are Open, Single-Blind, Double Blind. If there is a blind, also check among Masked Roles boxes, which roles will be blinded.

Choose from the 9 choices on pick-list. N/A is an allowed choice. “Other” is not.

Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, you must update this to reflect actual and final total enrollment.
These attributes apply to an "Observational" study. If desired, change the study type to "Interventional".

Temporal relationship of observation period to time of subject enrollment. Choices are Prospective, Retrospective, Cross-sectional, and Other.

Pick list choices are: None Retained, Samples With DNA; Samples Without DNA. If the samples have the potential, then “With DNA” is required.

Specify all types of bio specimens if any are to be retained. Limit: 1000 characters.

Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, update is required.

Enter 1 for a single-group study. Many observational studies have 1 group; case-control studies often have 2.
This is a link to the Tip they are trying to offer you.

Proceed through steps per each outcome measure

Once you make additions, the two Outcomes highlighted areas will become populated. The system will enter these items in the results sections when you begin to access the results section of the registration.

Specific key measurement(s) or observation(s) used to measure the effect of study experimental variables OR for Observational studies, to describe patterns of diseases, traits or associations with exposures, risk factors or treatment.

Other key measures that will be used to evaluate the intervention(s) OR, for observational studies, that are a focus of the study.

Once all Outcomes have been entered, then you will select continue to move on.

The next two pages demonstrate screens you will see once Outcomes Measures has been chosen.
Title is a concise name for the specific measure. Limit, 254 characters. First one listed for observational studies should be the one that receives the most emphasis in assessment.

Or, over what span of time, see example below. (orange box) Limit 254 characters.

Note this is an optional field, available to hold additional information about the outcome measure, if needed for clarification. Limit: 600 characters.

Two examples offered by clinicaltrials.gov:

- **Title:** All-cause mortality  
  **Time Frame:** one year  
  **Safety Issue:** No

- **Title:** Evidence of clinically definite ischemic stroke (focal neurological deficits persisting for more than 234 hours) confirmed by non-investigational CT or MRI  
  **Time Frame:** within the first 30 days (plus or minus 3 days) after surgery  
  **Safety Issue:** Yes

Interventional studies have Arms:
For each Arm, specify the Intervention, see next page.
There are as many boxes here, with the labels you entered, as you told the system the number of arms your protocol has. You'll be filling in a screen for each study Intervention, indicating which Arms receive it.

- **Intervention Type**: *FDAAA*
  - Select:

- **Intervention Name**: *FDAAA*
  - Enter the specific name of the intervention.
  - For a drug, use the generic equivalent name if it has been established.
  - Generic name for drugs, descriptive name for others.
  - Limit: 1000 characters.

- **Intervention Description**: *(FDAAA)*
  - Key details, e.g., for drugs include dosage form, dosage, frequency and duration.
  - Limit: 1000 characters.

- **Arms**: *(FDAAA)*
  - : 
  - : 
  - : 

- **Other Names**: *(One per line)*
  - Other names used to identify the intervention, past or present.
  - These names will be used to improve search results. Limit: 160 characters per name.

**9 item Pick List, select one per intervention:**

- Generic name for drugs, descriptive name for others.
  - Limit: 1000 characters.
For a single group study, both of these items are optional.

Note relationship to later posting of results. Limit: 62 characters.

Explanation of the nature of the study group, e.g. those with a condition or those without a condition; those with an exposure or those without an exposure. Note that the overall population is described under Eligibility; here put the specifics that cause eligible participants to be in the indicated study group. Limit: 1000 characters.

**Group/Cohort Label Noes and examples from clinicaltrials.gov:**

If the Number of Groups/Cohorts field on the Study Characteristics page is specified as 2 or greater and no groups have yet been defined, that number of groups is created automatically.

IMPORTANT: A single intervention can be assigned to multiple groups, so that the intervention need not be specified redundantly. If the same intervention applies to multiple groups, but with different dosages or other differences, the group descriptions can be used to indicate those differences.

For all studies and for expanded access-related registrations, specify the associated interventions in the group label and description. Describe the nature of the group or cohort. Note that for observational studies where interventions are specified, intervention information will be displayed with the associated group(s).

**Examples:**

- Statin dose titration
- Chronic kidney disease, no anemia
- No treatment
Avoid dashes and bullets, or risk being tripped up at final automated data check.

Be sure to use standardized terms here.

Words or phrases that best possible describe the protocol. Keywords help users find studies in the database. Use MeSH controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

Observational studies have Groups/Cohorts
Sampling Method selection is for Observational studies only. Pick list choices are Probability Sample and Non-Probability Sample.

Physical Gender. Choices are Male, Female, Both

If there is a limit, provide a number and select the corresponding unit. Age unit choices are minutes, hours, days, weeks, months, years. Blank with selection of N/A (No Limit) is allowed for minimum, maximum or both.

Limit 15,000 characters. List criteria with Hyphen, then space, then text in words, phrases or sentences.
This section begins illustration for completing Contact/Facility Information, next 7 pages.

<table>
<thead>
<tr>
<th>Title</th>
<th>Oversight</th>
<th>Sponsor</th>
<th>Summary</th>
<th>Status</th>
<th>Design</th>
<th>Interventions</th>
<th>Conditions</th>
<th>Eligibility</th>
<th>Locations</th>
<th>Citations</th>
<th>Links</th>
<th>ID: Text?</th>
</tr>
</thead>
</table>

Specify the Central Contact * (F003A) with overall recruiting responsibility for this study.
Specify the Study Officials/Investigators with overall scientific responsibility for this study.
Add a location * (F003A) to this Study.
Copy locations from a master list, extracted from this organization's records.

Locations: *
There are no Locations currently listed for this study.

* Required by ClinicalTrials.gov
(Required to comply with US Public Law 110-85, Section 801)
May be required to comply with US Public Law 110-85, Section 801
Study officials, including the principal investigator, are the persons responsible for the overall scientific leadership of the protocol.

Study Official is the person with overall scientific leadership of the study. Select this and you get the next page.

NOTE: Study Official is required by the WHO and ICMJE.

ICJME: International Council of Medical Journal Editors. This item relates to your ability to publish the study results.
Pick list choices are: Study Chair, Study Director, Principal Investigator.

Once OK is selected here, the system will return you to the first Locations page. If "Add Location" is chosen the next screen shot will appear.
These are the picklist choices for Recruitment Status.

Facility Contact information on this page is required only for locations with status of Recruiting or Not Yet Recruiting.

Tip from Clinicaltrials.gov:
When a trial’s overall status changes to Active, not recruiting, it is not necessary to change recruitment status for each location. Location recruitment status is shown on clinicaltrials.gov only when Overall Status is “Recruiting”.

Repeat of previous page, to illustrate boxes covered by the pick list.
After you fill in Location you then have the opportunity to Add one or multiple Investigator(s) at this location. (See next page).

### Facility

*Required

<table>
<thead>
<tr>
<th>Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>City:</td>
<td></td>
</tr>
<tr>
<td>State/Province:</td>
<td>Postal Code:</td>
</tr>
<tr>
<td>Country:</td>
<td></td>
</tr>
</tbody>
</table>

### Recruitment Status

*Required

Location recruitment status is required when Overall Status is "Recruiting". If Overall Status is anything other than Recruiting, location status is not displayed on ClinicalTrials.gov.

- Select: -

### Facility Contact

*Required

Facility contact is required for locations that are recruiting, but may be omitted if a Central Contact is provided for the trial. At a minimum, last name and either phone or email are required.

If Overall Status is anything other than Recruiting, facility contact information is not displayed on ClinicalTrials.gov.

<table>
<thead>
<tr>
<th>First:</th>
<th>MI:</th>
<th>Last:</th>
<th>Degree:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td>Ext:</td>
<td>Email:</td>
<td></td>
</tr>
</tbody>
</table>

### Facility Contact Backup

<table>
<thead>
<tr>
<th>First:</th>
<th>MI:</th>
<th>Last:</th>
<th>Degree:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td>Ext:</td>
<td>Email:</td>
<td></td>
</tr>
</tbody>
</table>

Office phone **OR** email is required. In the US and Canada, phone number should include area code and be in the format 123-555-5555. Otherwise, include the country code. Extension can be left blank if not needed.

A Backup for the Facility Contact is not required.

Multiple locations may be specified by invoking this page more than once.
The Facility name and address that you added is brought into this area for you.

Choose this Add button and the following screen comes up.

Investigators: There are no Investigators currently listed for this location.
This OK brings up the screen illustrated on the next page.

Multiple Investigators may be specified by invoking this page more than once.

2 Pick list choices: Site PI or Site Sub-I.
You can attach additional Investigators or additional Locations from here. Choose Continue button to the left if you are finished adding both Investigators and Locations for the study.

Information you previously added populates here for you to review. The system provides Edit and Delete links for your convenience just to the left of these entries.

<table>
<thead>
<tr>
<th>Facility:</th>
<th>Information you previously added populates here for you to review. The system provides Edit and Delete links for your convenience just to the left of these entries.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment Status:</td>
<td></td>
</tr>
<tr>
<td>Contact:</td>
<td></td>
</tr>
<tr>
<td>Contact Backup:</td>
<td></td>
</tr>
<tr>
<td>Investigators:</td>
<td>Francisco K Fermata, MD Role: Site Sub-Investigator</td>
</tr>
</tbody>
</table>

* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
FDAAA May be required to comply with US Public Law 110-85, Section 801
Phone if given for Central Contact (and Central Contact Backup if one is entered), must be a toll-free number. Phone format in the US and Canada to be used is 800-555-5555. Otherwise, provide the country code. Extension may be left blank.
Once a citation is added, it will show here when you are brought back to this screen to be able to add more.

As always select Continue to leave this screen (when you have added as many citations as you wish to). Adding Citations is encouraged.

Choose this Add link and the screen on the next page comes up.
Provide the unique PubMed Identifier (PMID) for the citation.

Search for a citation in MEDLINE, using the PubMed browser.

<table>
<thead>
<tr>
<th>MEDLINE Identifier</th>
<th>Enter PubMed Identifier (PMID)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Results Reference</th>
<th>Does the publication report on results of this study?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Select: Yes or No.</td>
</tr>
</tbody>
</table>

If the publication was not found in MEDLINE, enter the citation text.

This OK will take you back to the screen on the previous page, where you confirm that you are done adding citations by choosing Continue.
Once one is added, it will show here and you are brought back to this screen to be able to add more, up to 5 allowed.

Cautionary Tip from Clinicaltrials.gov:

*Do not include sites whose primary goal is to advertise or sell commercial products or services.*
<table>
<thead>
<tr>
<th>URL</th>
<th>http://</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Enter desired link text. Default: Related Info</td>
</tr>
</tbody>
</table>

Complete URL, Limit 254 characters, includes the http://.

Limit: 254 characters.
Typographical errors may be easily picked up at this review stage. There is a spelling tool on the View Protocol Record page.

The OK button invokes an automated check of the registration form fields. The system will return errors to be corrected and omissions where it recognizes that additions are needed. The programming indicates what is needed based on the entries you have made.

On your final pass, when the automated checks indicate all is well, selecting this OK means your Administrator will be notified and will be required to do a QC check prior to releasing your registration for posting into the system. Your Administrator is ClinicalTrials.gov's UC contact person of record. **Even after your Administrator has approved and released, the QA review done by clinicaltrials.gov personnel may return additional questions to be resolved before your study actually becomes posted.**

**Holding off on enrollment start until after you see your study fully posted on ClinicalTrials.gov assures your ability to publish the study results.**