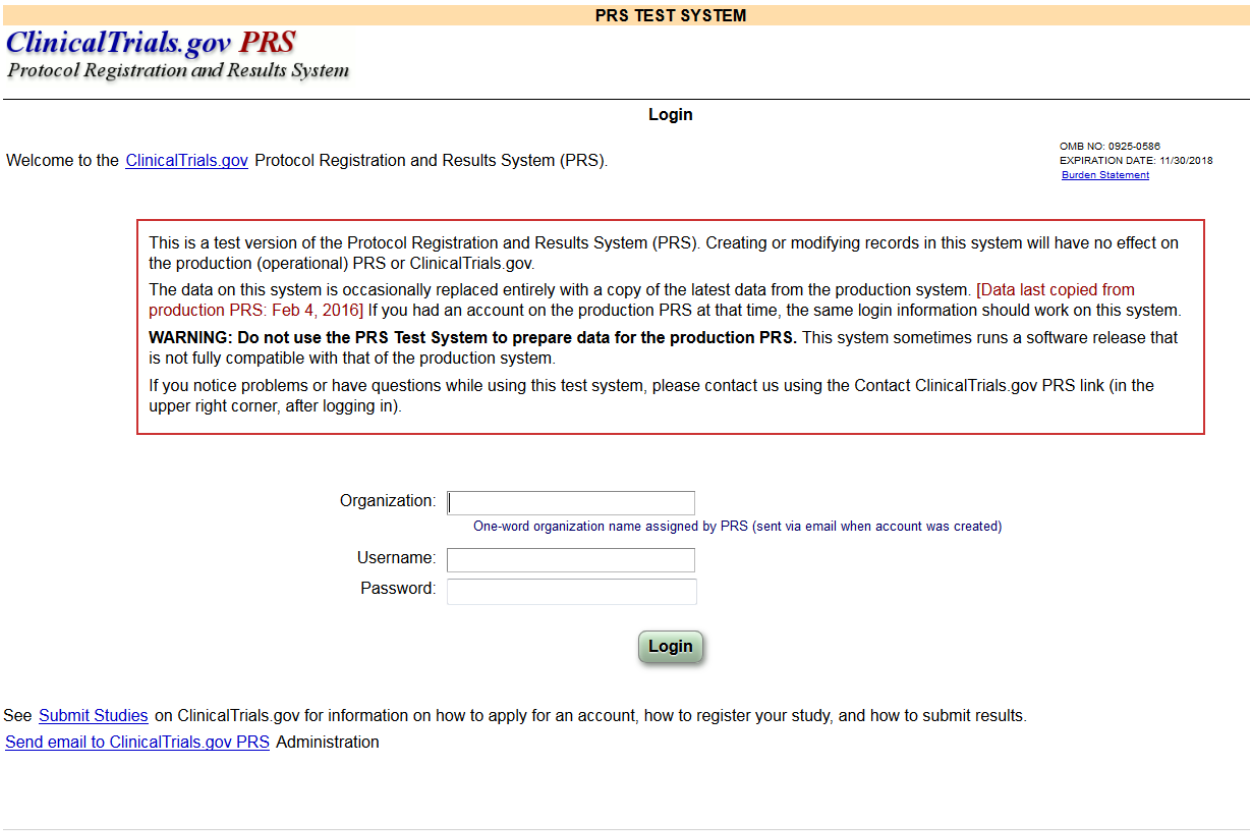
Attachment 2 - ClinicalTrials.gov Registration Data Entry Screen Shots (DRAFT)



PRS TEST SYSTEM

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

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

OMB NO: 0925-0586
EXPIRATION DATE: 11/30/2018
Burden Statement

This is a test version of the Protocol Registration and Results System (PRS). Creating or modifying records in this system will have no effect on the production (operational) PRS or ClinicalTrials.gov.

The data on this system is occasionally replaced entirely with a copy of the latest data from the production system. [Data last copied from production PRS: Feb 4, 2016] If you had an account on the production PRS at that time, the same login information should work on this system.

WARNING: Do not use the PRS Test System to prepare data for the production PRS. This system sometimes runs a software release that is not fully compatible with that of the production system.

If you notice problems or have questions while using this test system, please contact us using the Contact ClinicalTrials.gov PRS link (in the upper right corner, after logging in).

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

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

OMB NO: 0925-0586
EXPIRATION DATE: 11/30/2018
Burden Statement

Public reporting burden for this collection of information is estimated to average 7.0 hours per response for initial registration, 2.0 hours for each of 8 updates to the registration information during the course of the trial, 25.0 hours per response for initial results submission, 8.0 hours for two substantive updates to the results information. These estimates include the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0586). Do not return the completed form to this address

Create New Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. **Studies may only be registered by the Responsible Party.** The Responsible Party for a clinical study is the Sponsor, Sponsor-Investigator, or Sponsor-designated Principal Investigator who meets specific requirements.
   - When a study is subject to U.S. Food and Drug Administration regulations and conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE Holder is considered the Sponsor or Sponsor-Investigator.
   - When a study is not conducted under an IND or IDE, the entity or single person who initiates the study, by preparing and/or planning the study, and who has authority and control over the study, is considered the Sponsor or Sponsor-Investigator.
2. **Use the PRS account of the Sponsor or Sponsor-Investigator to register the study.** If the Sponsor has designated the Principal Investigator to be the Responsible Party for a study, that study must be registered using the PRS account of the Sponsor.
3. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the Responsible Party (IND/IDE holder or the person or organization who initiates the study and who has authority and control over the study) or its designated principal investigator (PI).
4. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization (or designated PI), as Responsible Party is registering the study.
5. **Refer to the ClinicalTrials.gov Review of Protocol Submissions document** for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.

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 [About Expanded Access Records]

Continue Cancel

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

Edit Study Identification

Help Definitions

* Organization's Unique Protocol ID:

* Brief Title:

[*] Acronym: (if any)

If specified, will be included at end of Brief Title in parentheses.

* § Official Title:

[*] Secondary IDs: (if any)

US NIH Grant/Contract Award Number:

Examples: R01DA013131, U01HL066582, 5R01HL123451-01A2
Tip: Look up the grant/contract number using NIH RePORTER.

Set ID Type × Delete

+ Add Secondary ID

Continue Quit

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

Edit Study Status

Help Definitions

* Record Verification Date:	Month: --Select-- Year:
* Overall Recruitment Status:	Terminated (Halted Prematurely) Tip: Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
* § Why Study Stopped?:	
* § Study Start Date:	Month: --Select-- Day: Year: Type: --Select--
* Primary Completion Date:	Month: --Select-- Day: Year: Type: Month: --Select-- Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: --Select-- Day: Year: Type: --Select-- Final data collection date for study.

Continue Back Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017
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Edit Sponsor/Collaborators

Help Definitions

* Responsible Party:	Principal Investigator Select **Sponsor** unless the Investigator has been designated as Responsible Party per FDAAA.

Investigator Information

Investigator Name [Username]: --Select--
Select the investigator's PRS account.
The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.
Investigator not in list? Incorrect name format?

Investigator Official Title:
Investigator Affiliation:

* Sponsor:	National Library of Medicine Primary organization conducting study and associated data analysis (not necessarily a funding source).
Collaborators:	× Delete + Add Collaborator Organization(s) providing support: funding, design, implementation, data analysis or reporting. Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO) Enter **only the organization name**. ⚠ WARNING: Secondary ID R01DA013131 implies that National Institute on Drug Abuse should be included as a Collaborator.

Continue Back Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017
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Edit Oversight

Help Definitions

* § U.S. FDA-regulated Drug: --Select--
Studying one or more U.S. FDA-regulated drug or biologic products?

* § U.S. FDA-regulated Device: Yes
Studying one or more U.S. FDA-regulated device products?
Unapproved/Uncleared Device: Yes
Studying at least one device product that is not yet approved or cleared by the U.S. FDA for any use?
If "Yes," the study record will not be posted on ClinicalTrials.gov unless posting is authorized.
Post Prior to Approval/Clearance: --Select--
Optional. Authorize posting of study record on ClinicalTrials.gov prior to U.S. FDA approval/clearance of device product?
Pediatric Postmarket Surveillance: --Select--
Required only if this a pediatric postmarket surveillance of a device product ordered by the U.S. FDA.

* U.S. FDA IND/IDE Study: Yes
(Not public)
Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?
FDA Center: --Select--
Formerly IND/IDE Grantor
IND/IDE Number:
IND Serial Number:

[*] Availability of Expanded Access: Yes
Will any non-protocol access to the investigational drug, biologic or device be provided? [About Expanded Access records]
Expanded Access Record:
ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record

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

Data Monitoring Committee: --Select--

Plan to Share IPD: --Select--
Indicate if there is a plan to make individual participant data (IPD) available to other researchers.

FDA Regulated Intervention: --Select--

Continue Back Quit

* Required
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Edit Study Description

Help Definitions

* Brief Summary:
Special Characters

Detailed Description:
Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

Continue Back Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017
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Edit Conditions

Help Definitions

* Conditions or Focus of Study: × Delete × Delete

Search MeSH, the National Library of Medicine's Medical Subject Headings, for valid condition terms.

+ Add Condition

Keywords: × Delete

+ Add Keyword

Continue Back Quit

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Edit Interventional Study Design

Help Definitions

* Study Type: Interventional

* § Primary Purpose: --Select--

* Study Phase: --Select--

Use "N/A" for trials that do not involve drug or biologic products.

* § Interventional Study Model: --Select--

Model Description:

* § Number of Arms:

* § Masking:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor
- No Masking

Check all roles that are masked or check No Masking.

Masking Description:

* § Allocation: --Select--

Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type: --Select--

Continue Back Quit

* Required

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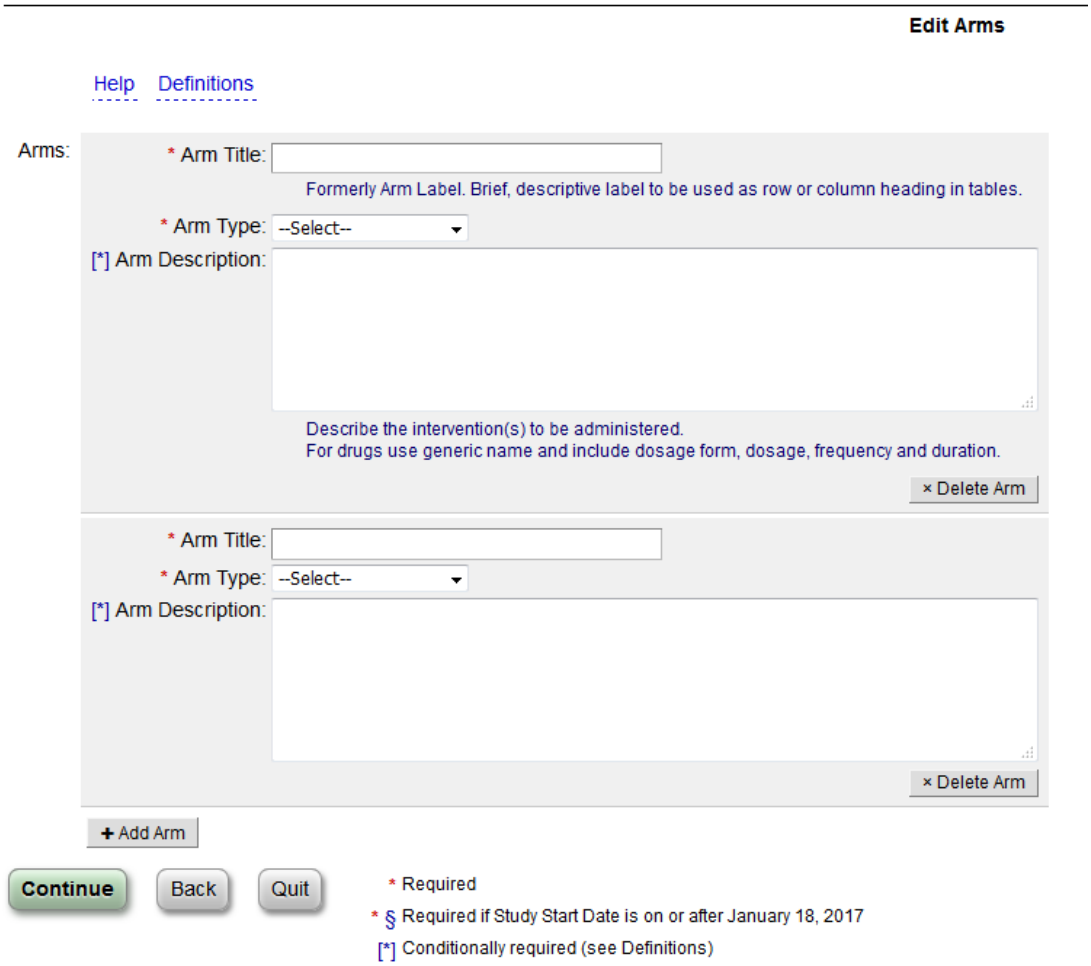
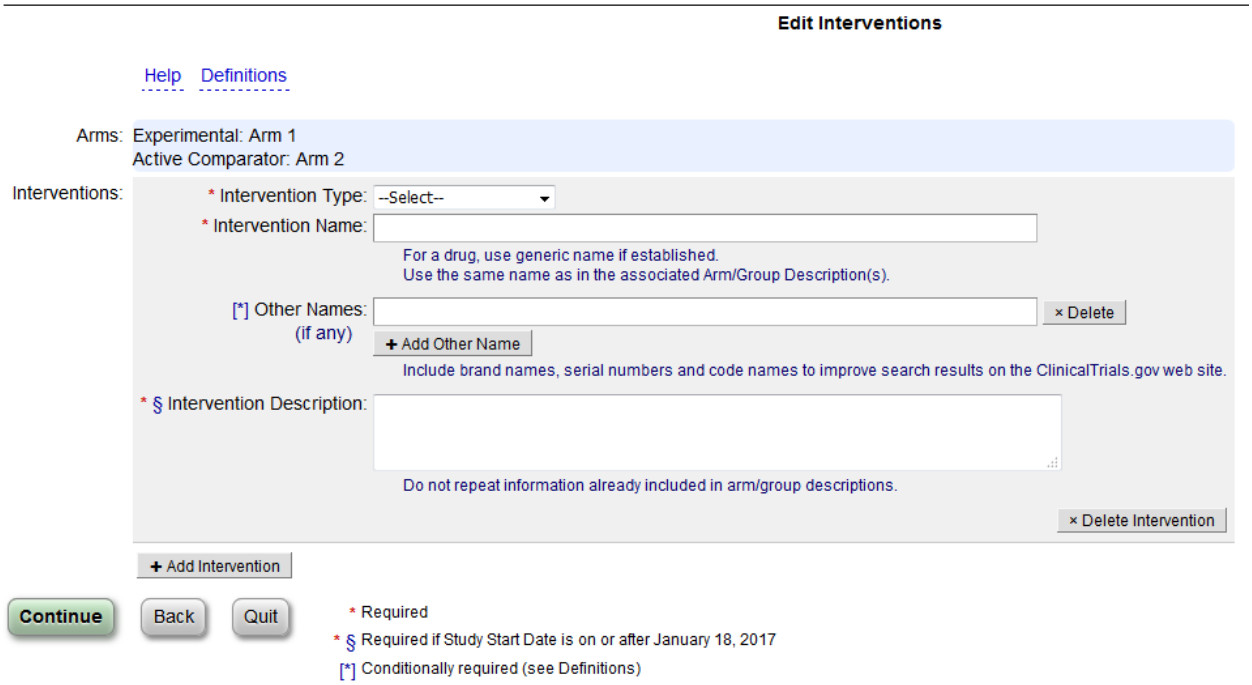

Edit Arms
Help Definitions
Arms:
* Arm Title:
Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables.
* Arm Type: --Select--
[*] Arm Description:
Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.
× Delete Arm
* Arm Title:
* Arm Type: --Select--
[*] Arm Description:
× Delete Arm
+ Add Arm
Continue
Back
Quit
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)


Edit Interventions
Help Definitions
Arms:
Experimental: Arm 1
Active Comparator: Arm 2
Interventions:
* Intervention Type: --Select--
* Intervention Name:
For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).
[*] Other Names: (if any)
× Delete
+ Add Other Name
Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.
* § Intervention Description:
Do not repeat information already included in arm/group descriptions.
× Delete Intervention
+ Add Intervention
Continue
Back
Quit
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Arm/Intervention Cross-Reference

Help Definitions

* Cross-Reference:

Arms	Interventions	
	Drug: Drug ABC	Drug: Drug XYZ
Experimental: Arm 1	☐	☐
Active Comparator: Arm 2	☐	☐

Check boxes for Interventions associated with each Arm in the study.

Continue Back Quit

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

Edit Outcome Measures

Help Definitions

* Primary Outcome Measure:

Outcome 1
Title:
Description:
Time Frame:
× Delete Outcome

+ Add Primary Outcome

[*] Secondary Outcome Measures: (if any)

Outcome 2
Title:
Description:
Time Frame:
+ Copy Outcome × Delete Outcome

+ Add Secondary Outcome

Other Pre-specified Outcomes:

+ Add Other Outcome

Continue Back Quit

* Required
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Edit Eligibility

Help Definitions

* Sex: --Select--
Biological sex of eligible participants.

[*] Gender Based: --Select--
If applicable, indicate if participant eligibility is based on self-representation of gender identity.

* Age Limits: Minimum: Years Maximum: Years

* § Accepts Healthy Volunteers?: --Select--

* Eligibility Criteria:

Inclusion Criteria:
-

Exclusion Criteria:
-

Special Characters

Continue Back Quit

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

Edit Overall Contacts

Help Definitions

* Central Contact Person: First Name: MI: Last Name: Degree:
Phone: Ext: Email:

Central Contact Backup: First Name: MI: Last Name: Degree:
Phone: Ext: Email:
Either Central Contact or Facility Contacts are required.
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Overall Study Officials: First Name: MI: Last Name: Degree:
Organizational Affiliation:
Official's Role: --Select-- × Delete
+ Add Study Official

Save Cancel

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

Edit Location

Help Definitions

* Facility:
Name:
City:
State/Province: Maryland ZIP/Postal Code:
Country: United States

* Site Recruitment Status: --Select--
Recruitment status for this individual location.

* Facility Contact: First Name: MI: Last Name: Degree:
Phone: Ext: Email:

Facility Contact Backup: First Name: MI: Last Name: Degree:
Phone: Ext: Email:

Either Central Contact or Facility Contacts are required.
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Investigators:

First Name	MI	Last Name	Degree	Role	
				--Select--	× Delete

+ Add Investigator

Save Cancel

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

Edit References

Help Definitions

Citations: PubMed ID: Lookup
Use the PubMed Citation Matcher to search for citations based on journal name, date, author(s), title and other criteria.
Citation:
Results Reference? --Select--
Enter Citation Text × Delete Citation

+ Add Citation

Links: URL: http://
Description:
× Delete Link

+ Add Link

Available Study Data/Documents: Type: --Select--
URL: http://
Web site where study data or document can be accessed, downloaded or requested, if applicable.
Identifier:
Unique ID used by a data repository, if applicable.
Comments:
× Delete Data/Document

+ Add Data/Document

Continue Back Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017
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