Attachment 2 - ClinicalTrials.gov Registration Data Entry Screen Shots

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: 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

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

Public reporting burden for this collection of information is estimated to vary from 2.0 to 8.0 hours per response for registration, 10.0 to 45.0 hours per response results information submissions, and 15 minutes to 2 hours for other submissions including certifications for delay, extension requests, and expanded access. 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 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)

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

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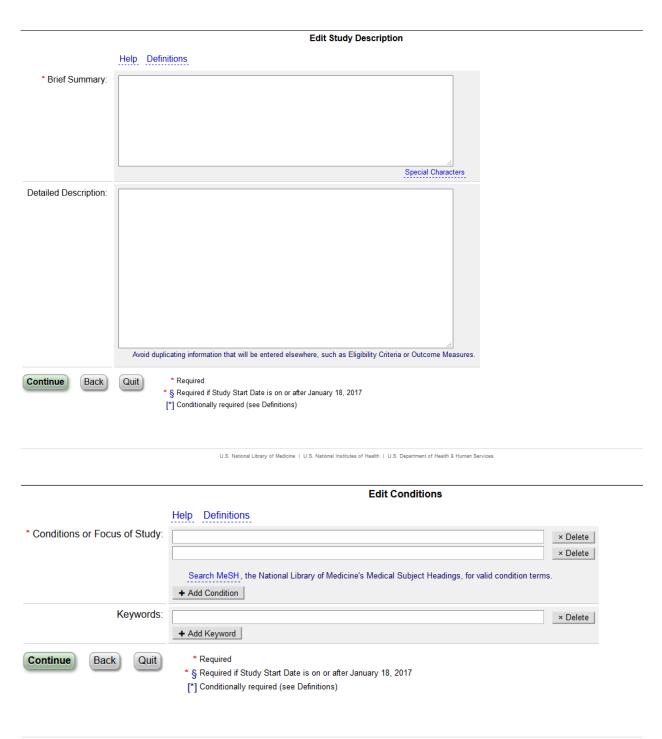- Eligibility
- Contacts/Locations
- References

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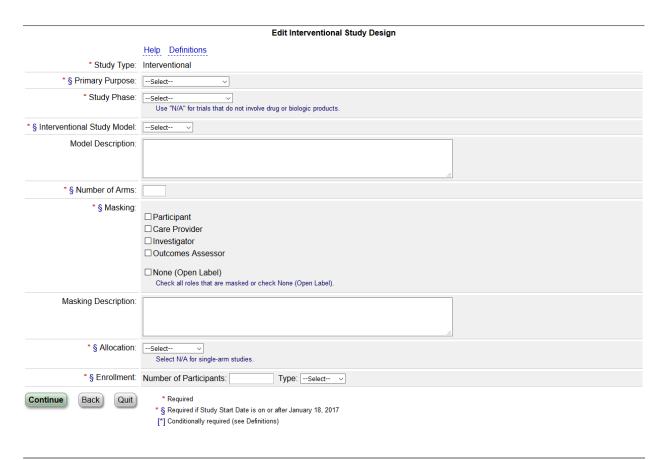
On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.

OK

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)

+ Add Secondary ID

Continue   **Quit**

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

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Edit Study Status

Help   Definitions

* Record Verification Date: Month: October   Year: 2019

* 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.

Continue   **Back**   **Quit**

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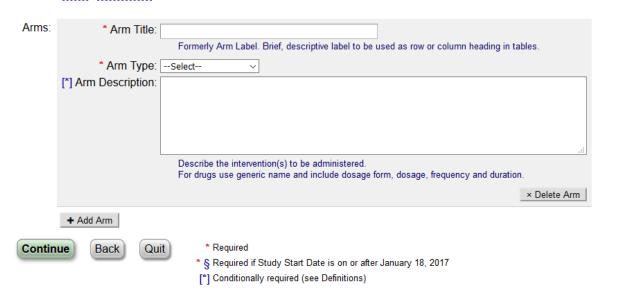[*] Conditionally required (see Definitions)

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Edit Sponsor/Collaborators

Help   Definitions

* Responsible Party: [Principal Investigator ⌄]

Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

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: [   ]

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**.

[Continue]   [Back]   [Quit]

* Required
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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?
For more information see the "Elaboration" in the Applicable Clinical Trial (ACT) Checklist (PDF).

* § U.S. FDA-regulated Device: [Yes ⌄]

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

Unapproved/Uncleared Device: [--Select-- ⌄]

Studying at least one device product that is not yet approved or cleared by the U.S. FDA for any use?
If "Yes" and this is a FDAAA 801 applicable clinical trial (ACT), the study record will not be posted on ClinicalTrials.gov unless posting is authorized.

Pediatric Postmarket Surveillance: [--Select-- ⌄]

Required only if this **study** is a pediatric postmarket surveillance of a device product ordered by the U.S. FDA.

* U.S. FDA IND/IDE: [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: [   ]

4 digit number entered on the U.S. FDA IND application, Form 1571, if any.

[*] 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-- ⌄]

FDA Regulated Intervention: [--Select-- ⌄]

[Continue]   [Back]   [Quit]

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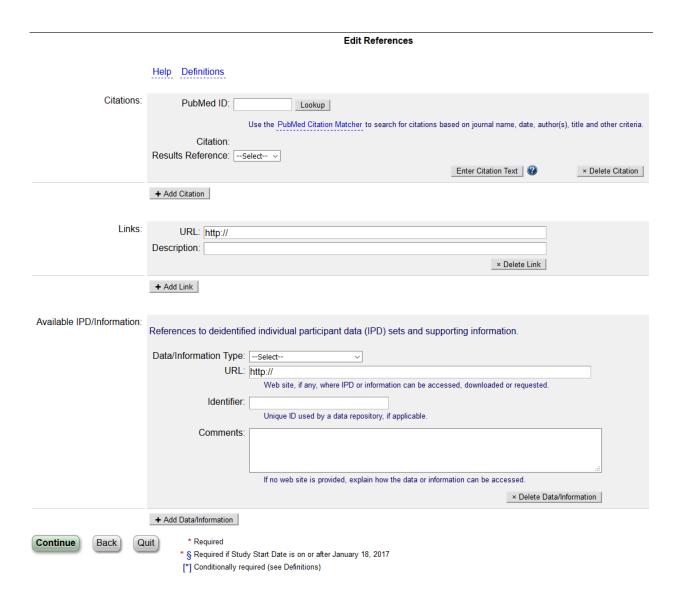[*] Conditionally required (see Definitions)

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)

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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

☐ None (Open Label)
Check all roles that are masked or check None (Open Label).

Masking Description: [   ]

* § Allocation: [--Select-- ▾]
Select N/A for single-arm studies.

* § Enrollment: Number of Participants: [   ]   Type: [--Select-- ▾]

[Continue] [Back] [Quit]

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

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]

[+ 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: [No Arms have been specified.]

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 Intervention Names: [   ]   × Delete
(if any)

+ 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: Intervention 1	Drug: Intervention 2
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: [   ]

[+ Copy Outcome] [Change Type] [× Delete Outcome]

[+ Add Primary Outcome]

[*] Secondary Outcome Measures:
(if any)

Outcome 2

Title: [   ]

Description: [   ]

Time Frame: [   ]

[+ Copy Outcome] [Change Type] [× Delete Outcome]

[+ Add Secondary Outcome]

Other Pre-specified Outcomes:

[+ Add Other Outcome]

[Continue] [Back] [Quit]

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

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Edit Overall Contacts

Help   Definitions

* Central Contact Person:

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).

Central Contact Backup:

First Name: [   ]   MI: [   ]   Last Name: [   ]   Degree: [   ]

Phone: [   ]   Ext: [   ]   Email: [   ]

Overall Study Officials: [+ Add Study Official]

[Save]   [Cancel]

* Required
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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: [+ Add Investigator]

[Save]   [Cancel]

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

Edit IPD Sharing Statement

Help   Definitions

Plan to Share IPD: [Yes   ⌄]
             Indicate if there is a plan to make individual participant data (IPD) available to other researchers.

Plan Description:
```
[                                                    ]
```
             Describe the IPD sharing plan, including what IPD are to be shared with other researchers.

IPD Sharing: Supporting Information:

             Check all types of supporting information that will be shared.

       ☐ Study Protocol
       ☐ Statistical Analysis Plan (SAP)
       ☐ Informed Consent Form (ICF)
       ☐ Clinical Study Report (CSR)
       ☐ Analytic Code

Time Frame:
```
[                                                    ]
```
             Describe when the data will become available and for how long.

Access Criteria:
```
[                                                    ]
```

URL: [http://   ]
             Web address (if any) with additional information about the plan to share IPD.

[Continue]   [Back]   [Quit]

    * 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 IPD/Information:

References to deidentified individual participant data (IPD) sets and supporting information.

Data/Information Type: [--Select-- ˅]
URL: [http://]
Web site, if any, where IPD or information can be accessed, downloaded or requested.

Identifier: [   ]
Unique ID used by a data repository, if applicable.

Comments: [   ]

If no web site is provided, explain how the data or information can be accessed.

[× Delete Data/Information]

[+ Add Data/Information]

[**Continue**] [Back] [Quit]

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

You have finished data entry for the Protocol Section.

Review any Errors, Warnings or Notes and make changes as needed. Select Preview to see a rough approximation of how the record will appear on ClinicalTrials.gov.

Select the "Record Summary" link in the top left corner of the page to see next steps for finishing the record submission process.

[**OK**]