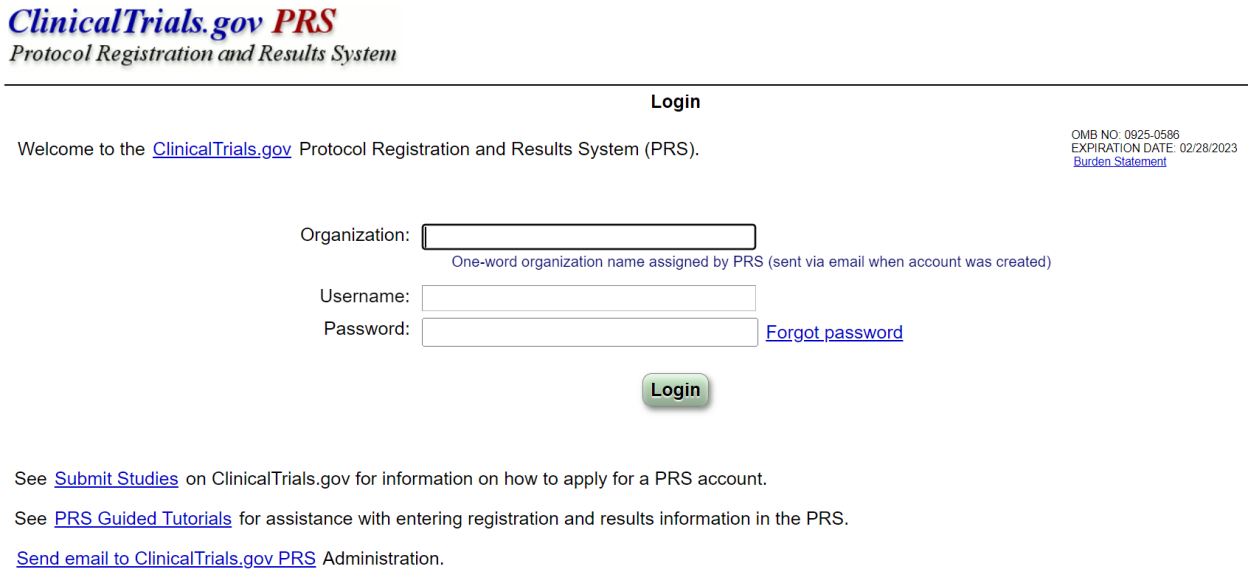
Attachment 2 – Registration Data Entry Forms



OMB NO: 0925-0586
EXPIRATION **DATE: 02/28/2023**
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 for 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)

Help 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)
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
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Edit Study Status

Help Definitions

* Record Verification Date: Month: October Year: 2022

* 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)

Edit Sponsor/Collaborators

Help Definitions

* Responsible Party: Sponsor

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

* 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**.

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?
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: Yes
(Not public)

Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

FDA Center: CDER
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: --Select--

Will any non-protocol access to the investigational drug, biologic or device be provided? [About Expanded Access records]

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

Data Monitoring Committee: --Select--

FDA Regulated Intervention: --Select--

Continue Back Quit

* Required
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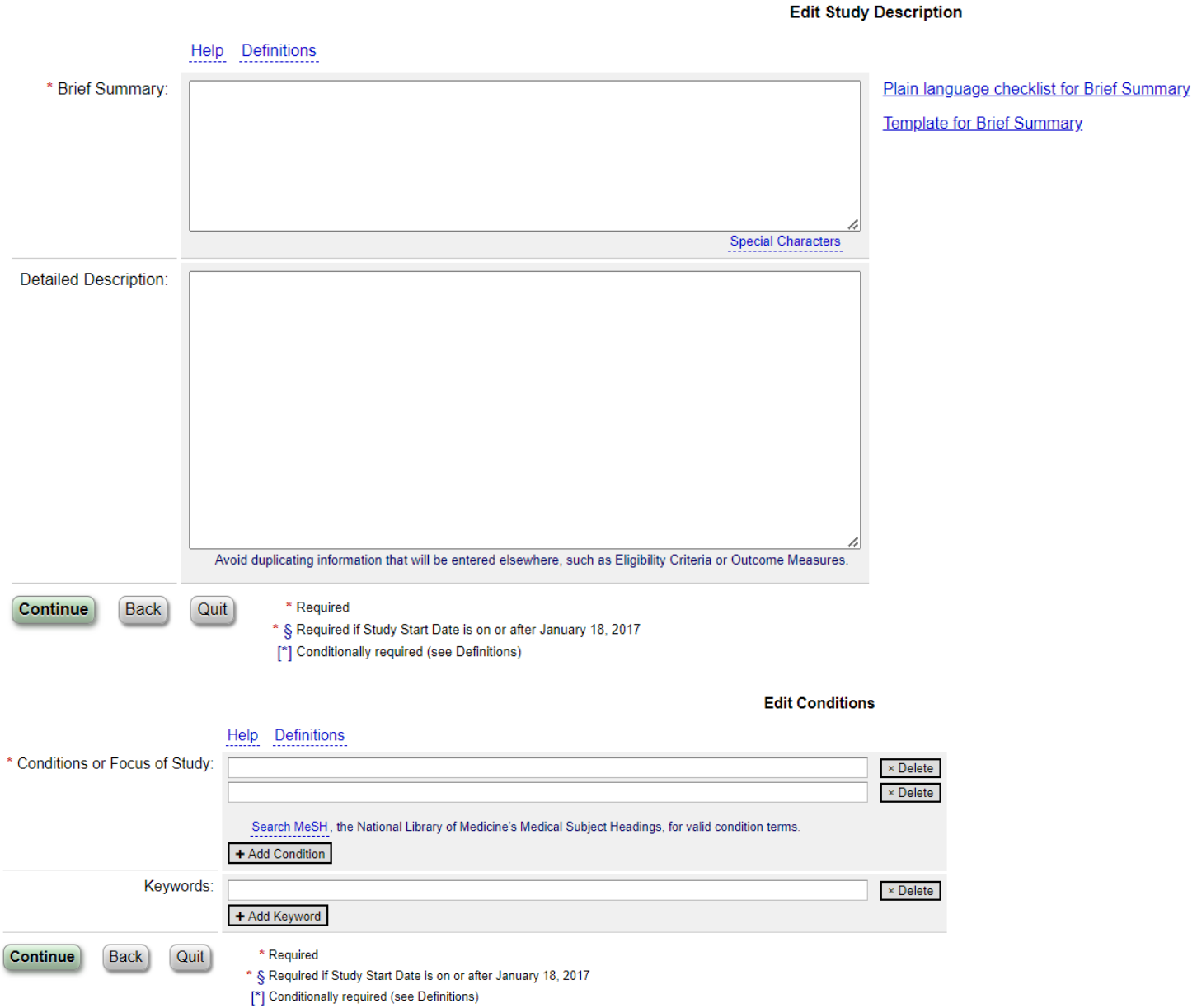

Edit Study Description

Help Definitions

* Brief Summary:

Special Characters

Plain language checklist for Brief Summary

Template for Brief Summary

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)

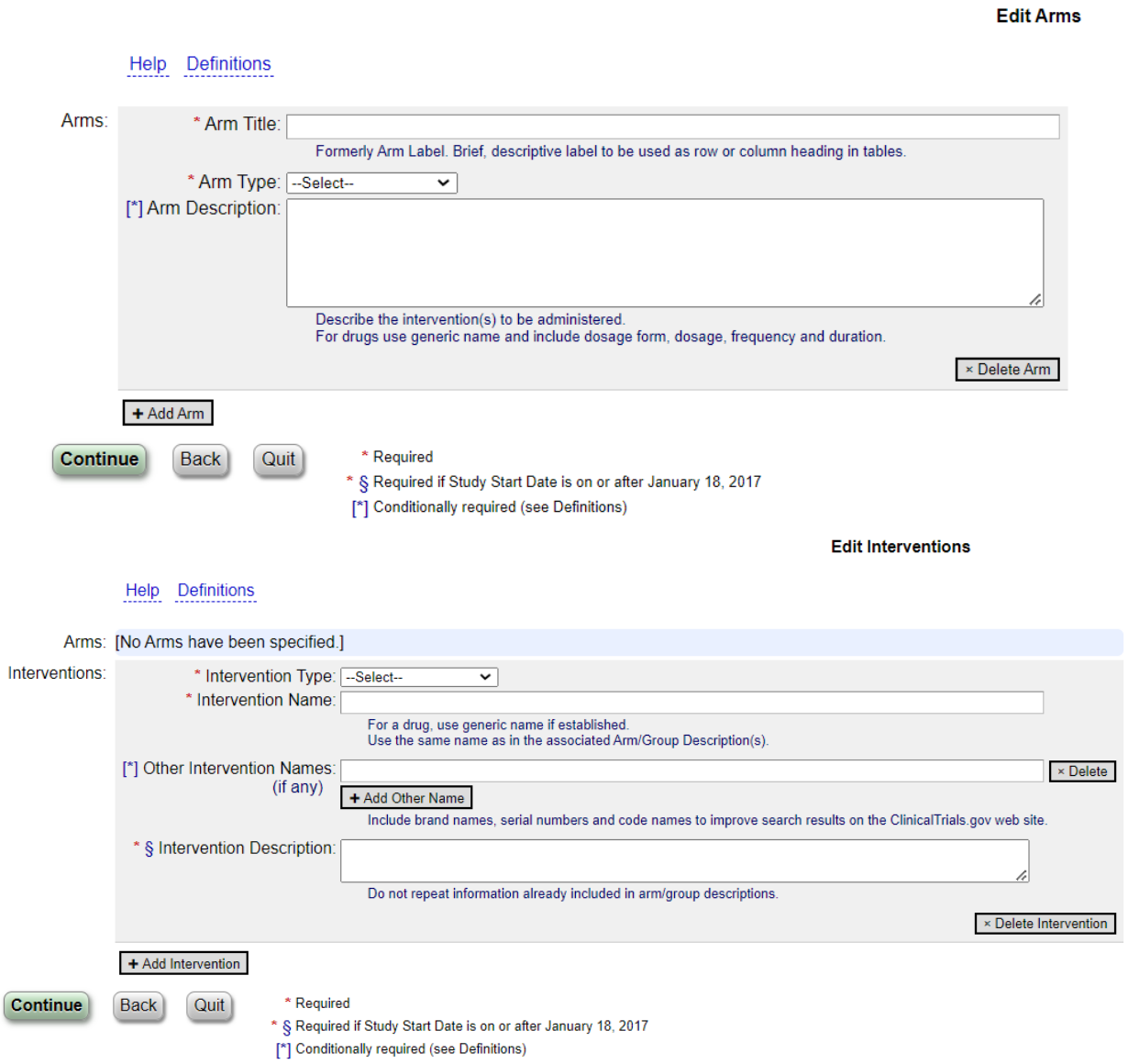
Edit Interventional Study Design

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 ☐ 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: (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: 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
[*] Conditionally required (see Definitions)

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: --Select-- Maximum: --Select--
* § 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:

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:

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
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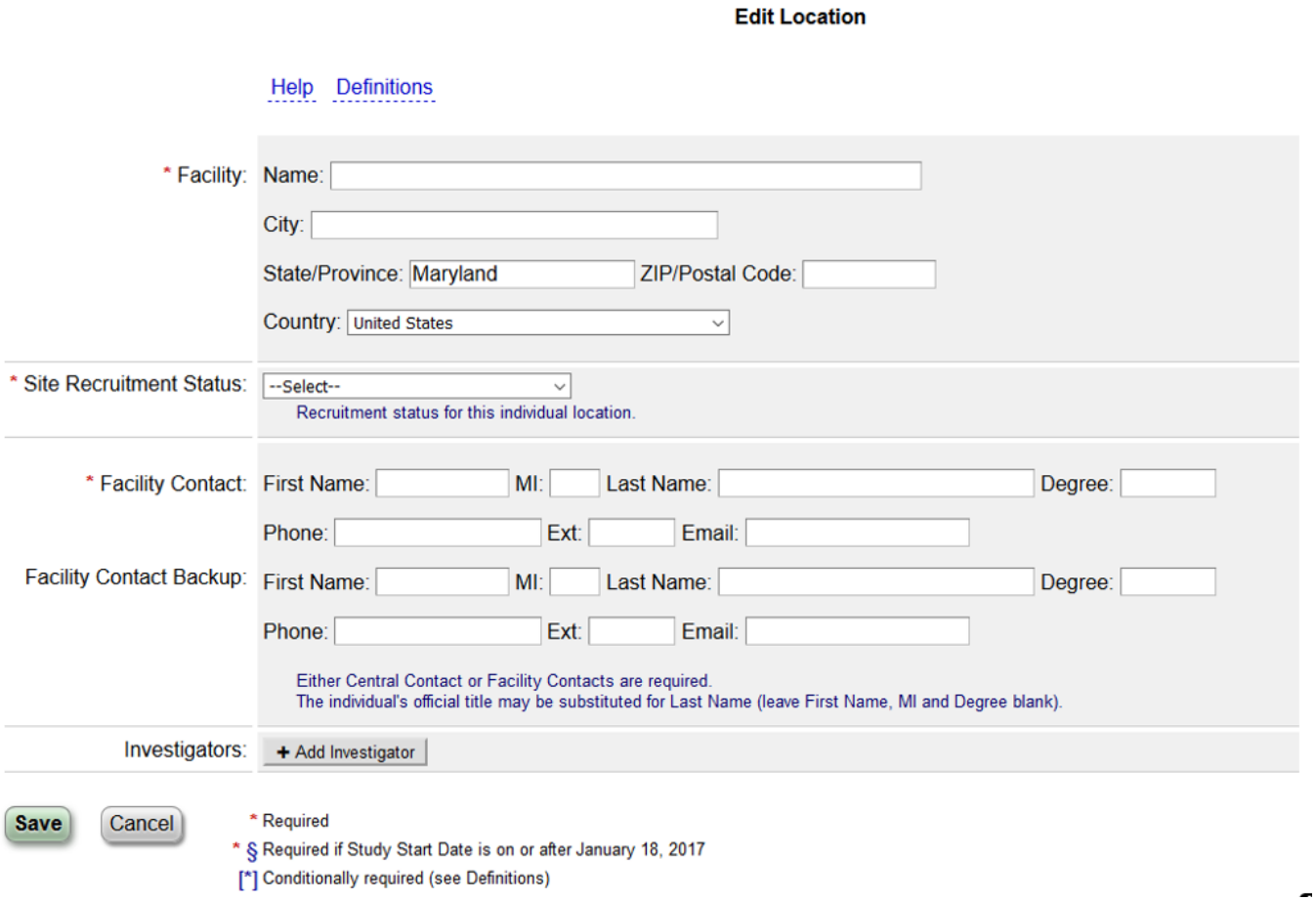


Edit Location

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://

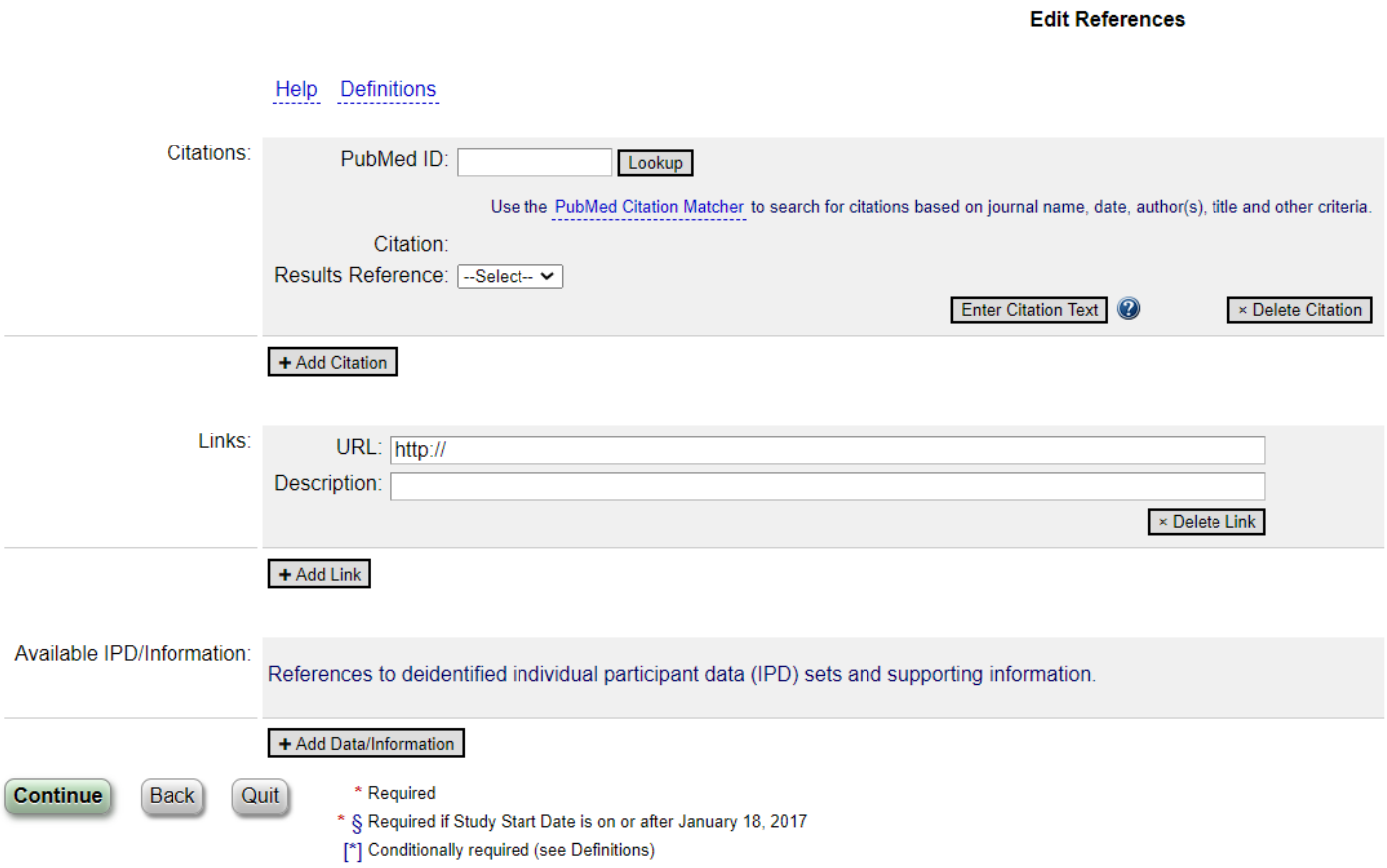
Web address (if any) with additional information about the plan to share IPD.

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.
+ Add Data/Information
Continue
Back
Quit
* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)