## Attachment 2 – Registration Data Entry Forms

ClinicalTrials.gov PRS Protocol Registration and Results System		
	Login	
Welcome to the ClinicalTrials.gov Protocol Registr	ration and Results System (PRS).	OMB NO: 0925-0586 EXPIRATION DATE: 02/28/2023 Burden Statement
Organization: [	One-word organization name assigned by PRS (sent via email when account was created)	
Username:		
Password:	Forgot password	
	Login	
See <u>Submit Studies</u> on ClinicalTrials.gov for inform	nation on how to apply for a PRS account.	
Can DDC Cuided Tuterials for assistance with ante	wing registration and recults information in the DDC	

See PRS Guided Tutorials for assistance with entering registration and results information in the PRS.

Send email to ClinicalTrials.gov PRS Administration.

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.
- 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:	O Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
	O Observational participants not assigned to intervention(s) based on a protocol; typically in context of routine care
	O Expanded Access availability of an experimental drug or device outside of a clinical trial protocol
•	red red if Study Start Date is on or after January 18, 2017 tionally required (see Definitions)

Hein Definitions

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

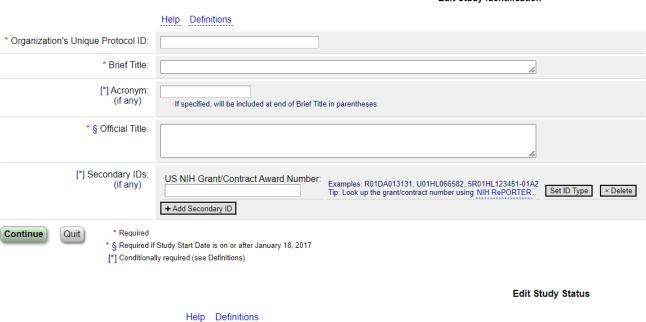
- · Study Identification
- Study Status
- · Sponsor/Collaborators
- Oversight
- Description
- Conditions
- · Study Design
- · Arms and Interventions
- · Outcome Measures
- Eligibility
- Contacts/Locations
- References

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.

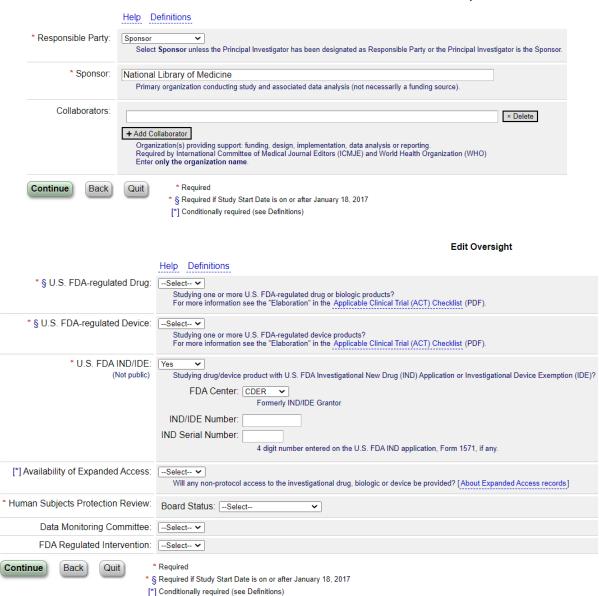
OK

### Edit Study Identification

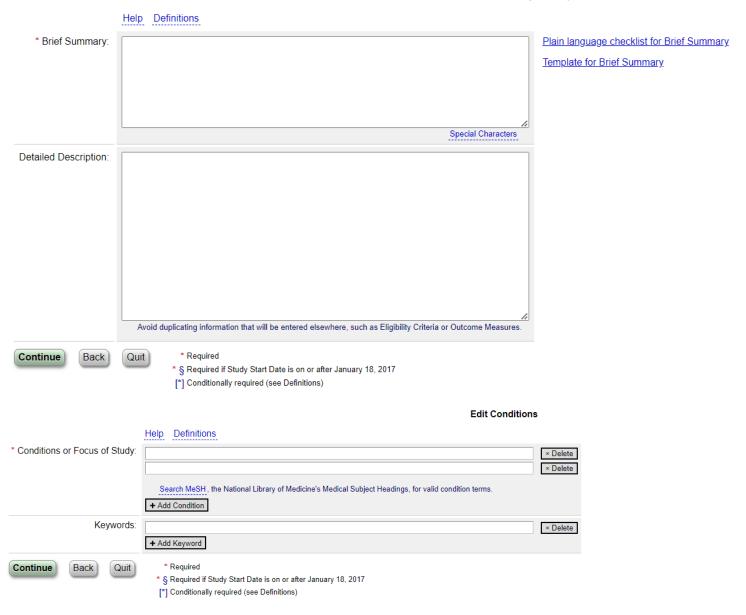


#### \* Record Verification Date: Month: October Vear: 2022 \* Overall Recruitment Status: --Select--Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition Tip: Day is not required for Anticipated dates. \* § Study Start Date: Month: --Select-- ➤ Day: Year: Type: --Select-- V Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual). \* Primary Completion Date: Month: --Select-- ➤ Day: Year: Type: --Select-- V Final data collection date for primary outcome measure. \* § Study Completion Date: Month: □--Select-- ➤ Day: Year: Type: --Select-- V Final data collection date for study. \* Required Continue Back Quit \* § Required if Study Start Date is on or after January 18, 2017 [\*] Conditionally required (see Definitions)

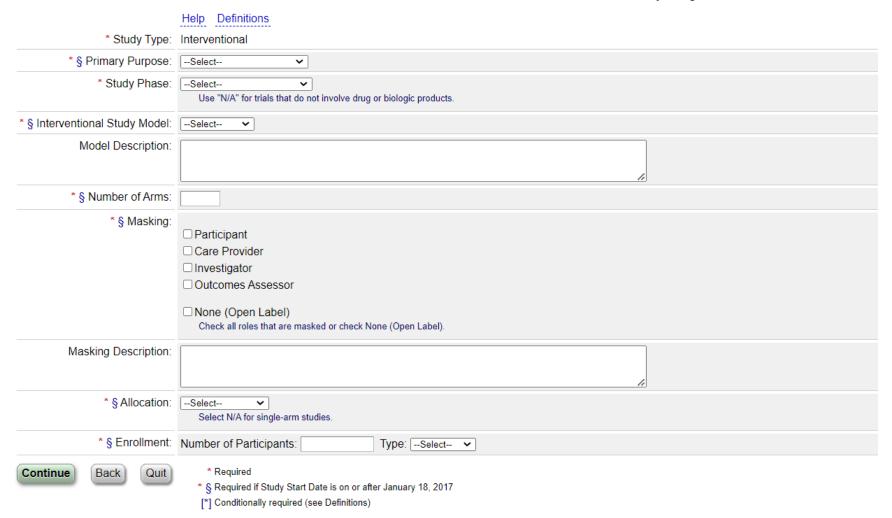
#### Edit Sponsor/Collaborators



### **Edit Study Description**

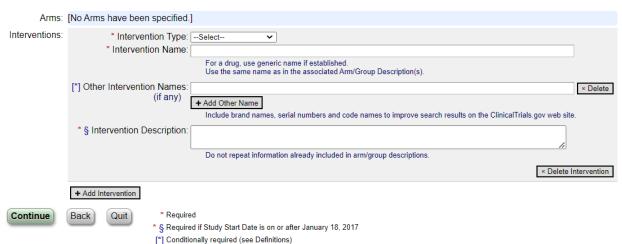


## Edit Interventional Study Design



#### **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 \* Required Continue Back Quit \* § Required if Study Start Date is on or after January 18, 2017 [\*] Conditionally required (see Definitions) **Edit Interventions** Help Definitions



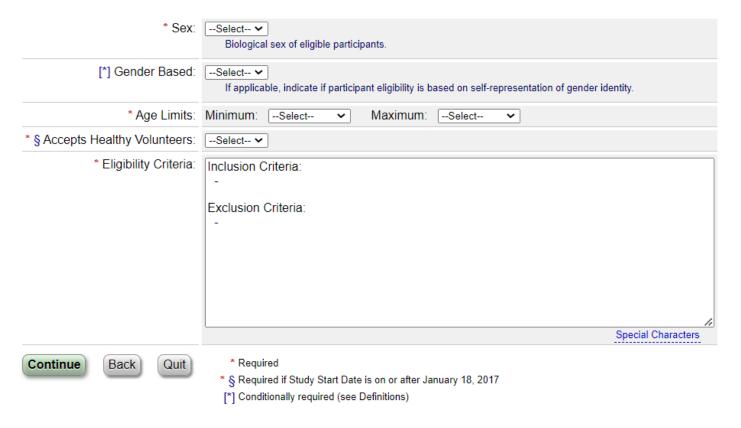
#### Edit Arm/Intervention Cross-Reference

### Help Definitions \* Cross-Reference: Interventions Arms 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: Outcome 2 (if any) Title: Description: Time Frame: Change Type + Copy Outcome × Delete Outcome + Add Secondary Outcome Other Pre-specified Outcomes: + Add Other Outcome \* Required Continue Quit Back \* § Required if Study Start Date is on or after January 18, 2017

[\*] Conditionally required (see Definitions)

# **Edit Eligibility**

# Help Definitions



## **Edit Overall Contacts**

	Help Definitions		
* Central Contact Person:	First Name: Degree: 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: Degree: Degree:		
	Phone: Ext: Email:		
Overall Study Officials:			
	First Name: Degree:		
	Organizational Affiliation:		
	Official's Role: ☐Select ▼  × Delete		
	+ Add Study Official		
Save Cancel	* Required		
Curicor)	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:
Facility Contact Backup:	First Name:
Investigators:	+ Add Investigator
* 5	Required Required if Study Start Date is on or after January 18, 2017 Conditionally required (see Definitions)

# **Edit IPD Sharing Statement**

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### **Edit References**

