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

		Login	
Velcome to the Cli	inicalTrials.gov Protocol Registration and Results S	System (PRS).	OMB NO: 0925-0586 EXPIRATION DATE: 11/30/20 Burden Statement
	This is a test version of the Protocol Registration a the production (operational) PRS or ClinicalTrials.	and Results System (PRS). Creating or modifying rec	ords in this system will have no effect on
		entirely with a copy of the latest data from the product ant on the production PRS at that time, the same login	
	WARNING: Do not use the PRS Test System to is not fully compatible with that of the production s	prepare data for the production PRS. This system ystem.	sometimes runs a software release that
	If you notice problems or have questions while usi upper right corner, after logging in).	ng this test system, please contact us using the Cont	act ClinicalTrials.gov PRS link (in the
L			
	Organization:		
		vord organization name assigned by PRS (sent via email when ac	count was created)
	Username:		
	Password:		
		Login	
		Login	
	s on ClinicalTrials.gov for information on how to ap	ply for an account, how to register your study, and ho	w to submit results.
	calTrials.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

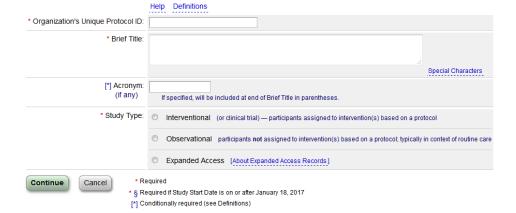
Public reporting burden for this collection of information is estimated to average 7.0 hours per response for initial registration, 2.0 hours for each of 8 updates to the registration information during the course of the trial, 25.0 hours per response for initial results submission, 8.0 hours for two 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.

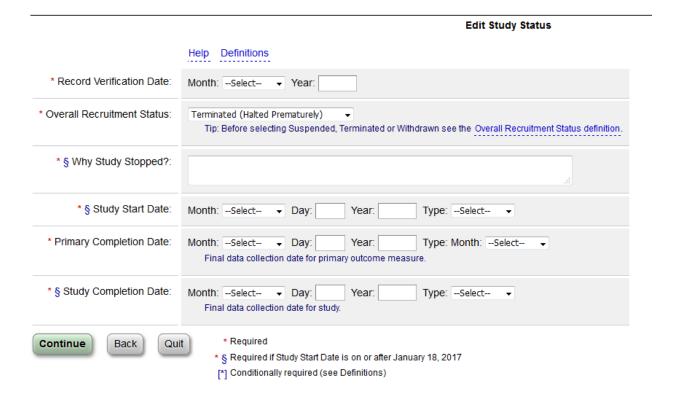
- When a study is subject to U.S. Food and Drug Administration regulations and conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE Holder is considered the Sponsor or Sponsor-Investigation.
- When a study is not conducted under an IND 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 submitfed.



* § 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:	.4				
[*] Acronym: (if any)	If specified, will be included at end of Brief Title in parentheses.				
* § Official Title:	.н.				
[*] 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				
Continue Quit * Requir	ed				



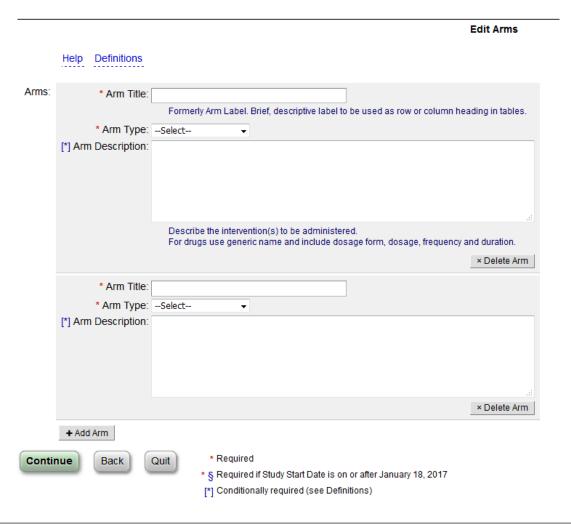
	Edit Sponsor/Collaborators					
	Help Definitions					
* Responsible Party:	Y: Principal Investigator ▼ Select Sponsor unless the Investigator has been designated as Responsible Party per FDAAA.					
	Investigator Information					
	Investigator Name [Username]:					
	The Investigator Name (i.e., the 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	Required * Required if Study Start Date is on or after January 18, 2017 [*] Conditionally required (see Definitions)					

	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: (Not public)	Yes 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/IDE Number: IND/IDE Strain Number: IND/IDE Strain Number: IND/IDE Num				
[*] 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 * § Required if Study Start Date is on or after January 18, 2017 [*] Conditionally required (see Definitions)				
	Edit Study Description				
	Haln Definitions				

	Edit Study	Description
	Help Definitions	
* Brief Summary:		
blief Sullillary.		
		Special Characters
Datailed Description		
Detailed Description:		
	Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria	
Continue Back	Quit * Required	
	* § Required if Study Start Date is on or after January 18, 2017	
	[*] Conditionally required (see Definitions)	

	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 Qu	* 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:	at
* § 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 ▼
v	Select N/A for single-arm studies.

[*] Conditionally required (see Definitions)



Edit Interventions

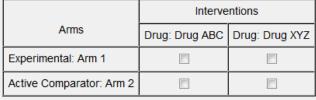
Help Definitions



Edit Arm/Intervention Cross-Reference

Help Definitions

* Cross-Reference:



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

	Co	nti	n	ue	
ч					

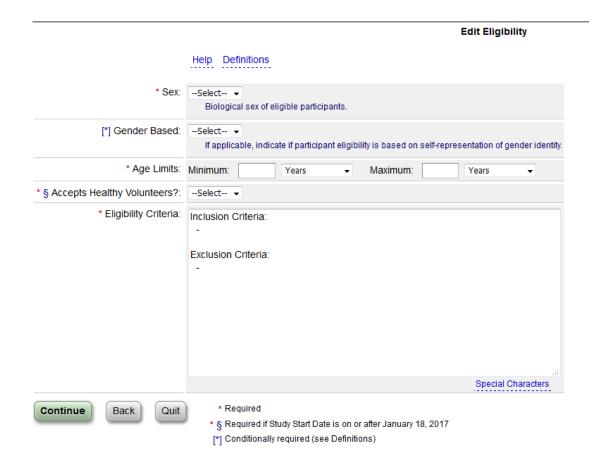




- * Required
- * § Required if Study Start Date is on or after January 18, 2017
- [*] Conditionally required (see Definitions)

		Edit	Outcome Measure	es
	Help Definiti	ons		
* Primary Outcome Measure:	Outcome 1			
	Title:			
	Description:			.ii.
	Time Frame:			
	Timo Tramo.			× Delete Outcome
	+ Add Primary	Outcome		
[*] Secondary Outcome Measures: (if any)	Outcome 2 Title:			
				al
	Description:			
	Time Frame:			
			+ Copy Outcome	× Delete Outcome
	+ Add Second	ary Outcome		
Other Pre-specified Outcomes:				
	+ Add Other O	utcome		
Continue Back Quit	* 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: Degree: Degree: 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).
Overall Study Officials:	First Name: Degree: Organizational Affiliation: Official's Role:Select Add Study Official Degree: × Delete
Save Cancel	* Required * § Required if Study Start Date is on or after January 18, 2017 [*] Conditionally required (see Definitions)

						Edit Location	
	Help Defini	tions					
* Facility						7	
* Facility:	Traine.						
	City:						
	State/Province		ZIP	Postal Code	e:		
	Country: Unit	ed States		▼			
* Site Recruitment Status:	Select Recruitmen	nt status for this ind	ividual location.				
* Facility Contact:	First Name:	MI:	Last Na	ime:		Degree:	
	Phone:		Ext:	Email:			
Facility Contact Backup:	First Name:	MI:	Last Na	ime:		Degree:	
	Phone:		Ext:	Email:			
		ral Contact or Facil ual's official title ma			e (leave First	Name, MI and Degree blank	;).
Investigators:	First Name	MI	Last Name	9	Degree	Role	
						Select	▼ × Delete
	+ Add Investig	gator					
Save Cancel	* Required						
	•	tudy Start Date is o		ry 18, 2017			
	["] Conditionally	required (see Defi	minoris)				
				Edit R	eferences		
	Help Definit	ions					
Citations	Pub/	led ID:	Lookup Citation Ma	stables to exercise	for citations has	and an incurred name, data, author	r(a) title and other criteria
	C	itation:	-ubilied Citation in	icher to search	ioi citations bas	ed on journal name, date, author	(s), title and other criteria.
		rence?Select •					
						Enter Citation Text	× Delete Citation
	+ Add Citation						
Links	URL:	http://					
	Description:						
						× Delete Link	
	+ Add Link						
Available Study Data/Documents	.,,,,,,		▼				
	URL: h	•	dy data or docume	nt can be access	ed, downloade	d or requested, if applicable.	
	Identifier:						
	_	Unique ID used by	a data repository, if	applicable.			
	Comments:						
						× Delete Data/Document	
						Selete Data/Document	
	+ Add Data/Do						
Continue Back Quit		d d if Study Start Date is	on or after January	18 2017			
	•	nally required (see De		.5, 2011			