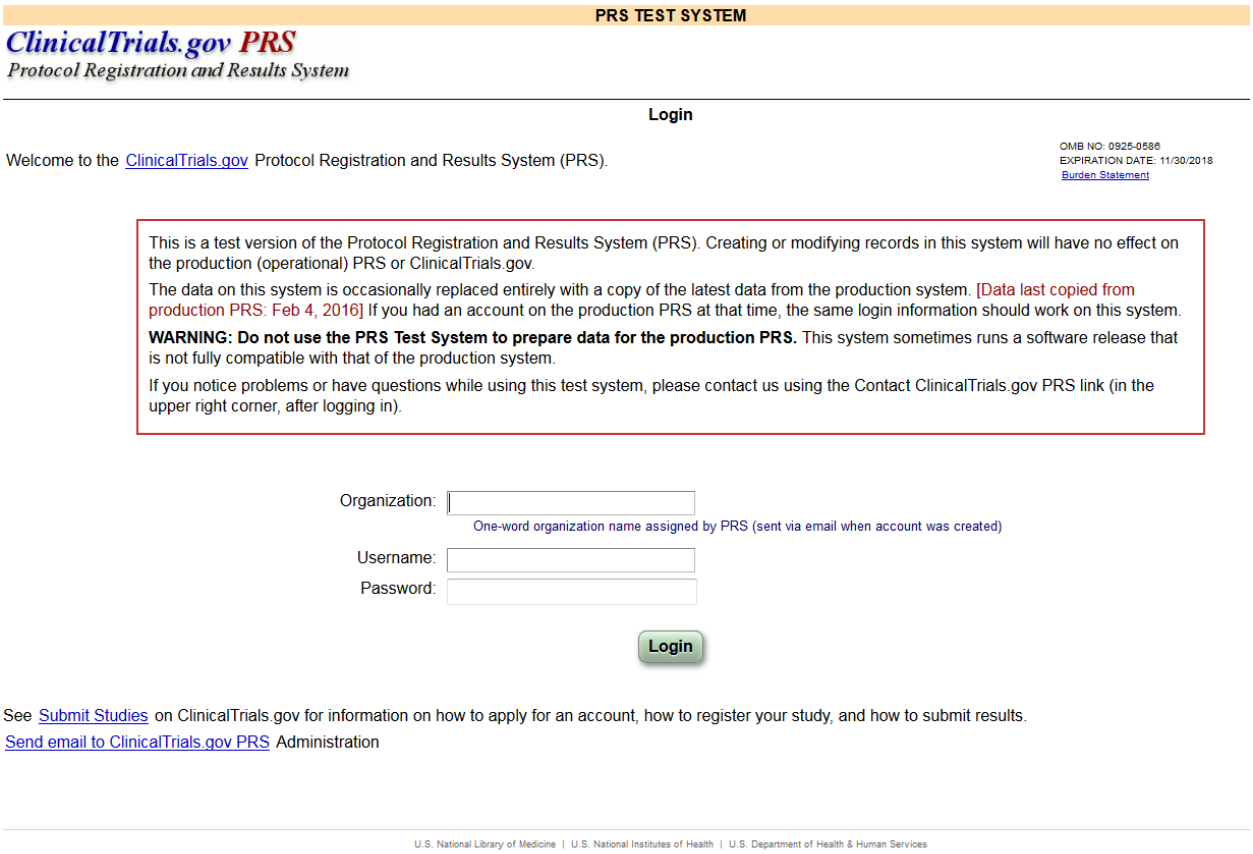
Attachment 5 - ClinicalTrials.gov Results Reporting Data Entry Screen Shots (DRAFT)



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

Edit Participant Flow

Help Definitions

Recruitment Details:	Edit
[*] Pre-assignment Details:	Edit

Arms/Groups (2) + Add Arm/Group

* Arm/Group Title:	Edit **Experimental Drug**	Edit **placebo**	Total (Not public)
* § Arm/Group Description:	Experimental Drug Description	Placebo Drug Description	
	× Delete Move ▶	× Delete ◀ Move	
[*] Type of Units Assigned:	+ Add Units Assigned (Optional) Use only if assigned units other than participants (e.g., eyes, lesions, implants).		

Periods (1)

Protocol Enrollment: 200

* Period Title:	Overall Study		
	Experimental Drug	**placebo**	Total (Not public)
* Started: Add Comment	100 Add Comment	100 Add Comment	200
+ Add Milestone			
* Completed: Add Comment	95 Add Comment	100 Add Comment	195
Not Completed: (Started - Completed)	5	0	
Reason Not Completed			
[*] Lost to Follow-up × Delete	5	0	5
+ Add Reason Not Completed	Not Completed =5 Total from all reasons =5	Not Completed =0 Total from all reasons =0	

+ Add Period

Save Validate Cancel

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

[*] Pre-assignment Details

Definition: Description of significant events in the study (for example, wash out, run-in) that occur after participant enrollment, but prior to assignment of participants to an arm or group, if any. For example, an explanation of why enrolled participants were excluded from the study before assignment to groups.

Characters remaining: 350

OK Cancel

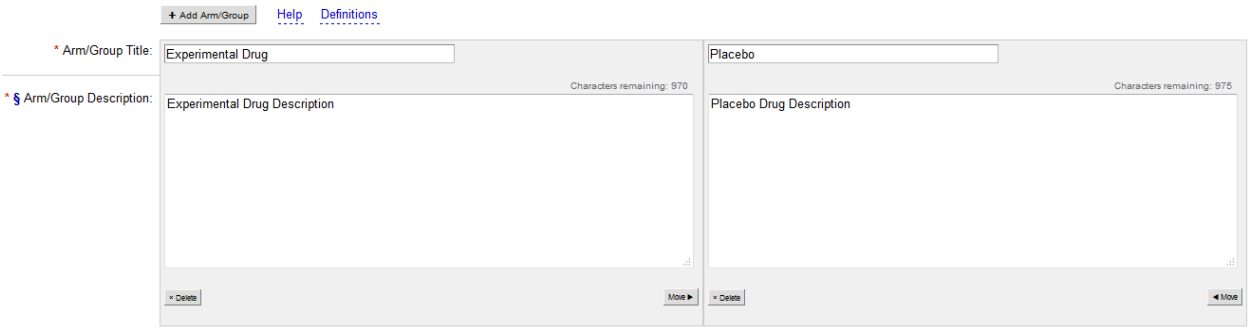
* Arm/Group Title:

Characters remaining: 999

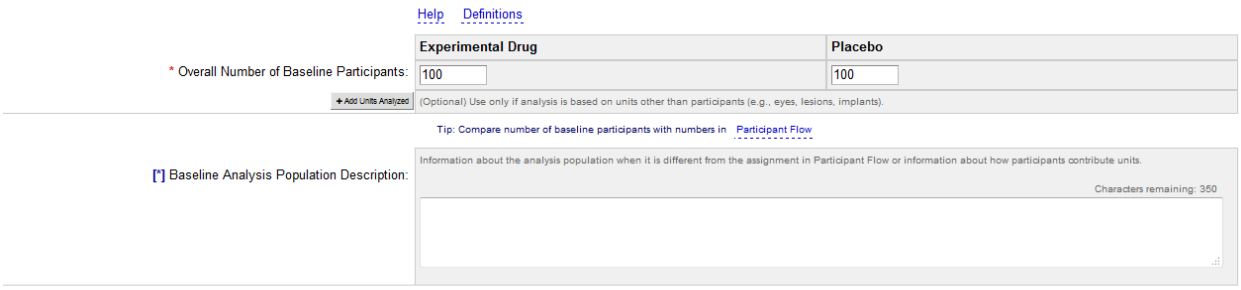
* § Arm/Group Description:

OK Cancel

Edit Baseline Arm/Groups



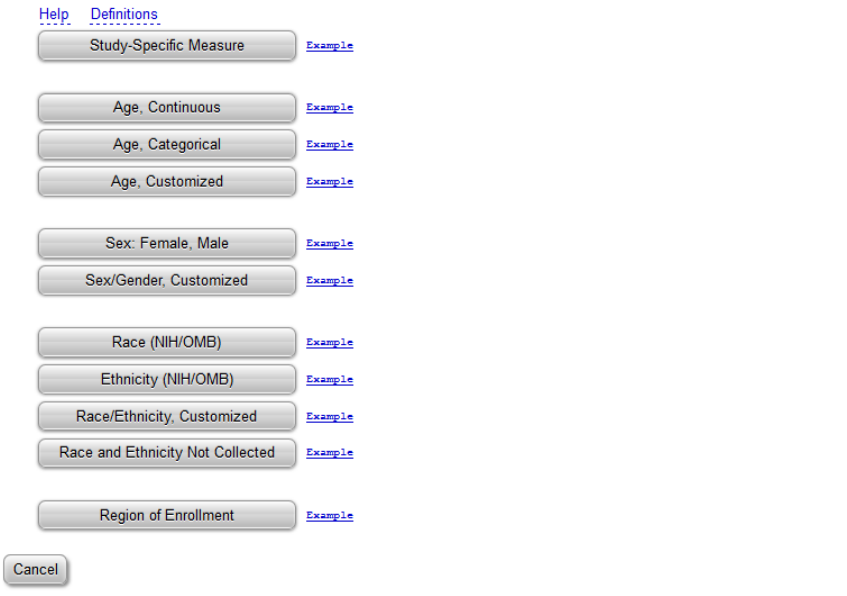
Edit Baseline Analysis Population



Save Validate Cancel

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

Add Baseline Measure



Edit Baseline Measure

Help Definitions

* Baseline Measure Title:	Race (NIH/OMB)
Baseline Measure Description:	Edit Additional information about the measure (e.g., description of scale)

	Experimental Drug	Placebo	Total
Overall Number of Baseline Participants:	100	100	200
Baseline Analysis Population Description:			

* Measure Type: Count of Participants — Hide calculated percentage

* Measure of Dispersion: Not Applicable

Number Analyzed: Participants	100 participants Edit	100 participants Edit	200
American Indian or Alaska Native	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
Asian	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
Native Hawaiian or Other Pacific Islander	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
Black or African American	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
White	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
More than one race	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%
Unknown or Not Reported	Count of Participants NA%	Count of Participants NA%	Count of Participants unknown NA%

+ Add Row

* Unit of Measure: participants

Save Validate Cancel

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

Outcome Measure Data

Help Definitions

* Outcome Measure Type: Primary

* Outcome Measure Title: Primary Outcome Measure Title 1 (Characters remaining: 224)

* § Outcome Measure Description: Primary Outcome Measure Description 1 (Characters remaining: 962)

* Outcome Measure Time Frame: Primary Outcome Measure Time Frame 1

Arms/Groups (2) + Add Arm/Group

* Arm/Group Title:	Edit **Experimental Drug**	Edit **Placebo**
* § Arm/Group Description:	Experimental Drug Description	Placebo Drug Description
	× Delete Move ►	× Delete ◄ Move
* Overall Number of Participants Analyzed:	100	100

+ Add Units Analyzed (Optional) Use only if analysis is based on units other than participants (e.g., eyes, lesions, implants).

[*] Analysis Population Description: (Characters remaining: 350)

Outcome Measure Data Table

* Measure Type: Count of Participants [Hide calculated percentage] [Convert Rows to Categories]

* Measure of Dispersion/Precision: Not Applicable

		Experimental Drug	Placebo
* Row Title: Row 1 [× Delete] [▼ Move]	Number Analyzed	100 participants [Edit]	100 participants [Edit]
	Count of Participants	50 50%	20 20%
[+ Add Category]			
* Row Title: Row 2 [× Delete] [▲ Move]	Number Analyzed	100 participants [Edit]	100 participants [Edit]
	Count of Participants	50 50%	80 80%

[+ Add Row]

* Unit of Measure: participants

[Save] [Validate] [Cancel]

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

Add Outcome Statistical Analysis

Primary Outcome	
Title:	Primary Outcome Measure Title 1
Time Frame:	Primary Outcome Measure Time Frame 1
Unit of Measure:	

Tip: Many of the data elements are optional and may be left blank. "Comparison Group Selection" and "Type of Statistical Test" are required. In addition, one of the following data elements are required with the associated information: "P-Value", "Estimation Parameter", or "Other Statistical Analysis."

Statistical Analysis Overview

Help Definitions

* Comparison Group Selection: Select the Outcome Measure Arms/Groups involved in the statistical analysis.
☐ Experimental Drug ☐ Placebo

Comments: (Optional) Additional details about the statistical analysis, such as null hypothesis and description of power calculation.

Characters remaining: 500

* Type of Statistical Test: -- Please Select --

[*] Comments: If a non-inferiority or equivalence analysis, information on the definition of the non-inferiority or equivalence margin is required. Also describe any other key parameters and details of the power calculation (if not described elsewhere).

Characters remaining: 500

Statistical Test of Hypothesis

Help Definitions

[*] P-Value: (If applicable)

(e.g. <0.01)

Comments: (Optional) Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the *a priori* threshold for statistical significance.

Characters remaining: 250

[*] Method: (Required if a P-Value is entered)

-- Please Select -- If other, please specify:

Comments: (Optional) Any other relevant information, such as adjustments or degrees of freedom.

Characters remaining: 150

Method of Estimation

Help Definitions

[*] Estimation Parameter: (If applicable)

-- Please Select -- If other, please specify:

[*] Estimated Value: Provide the data for the Estimation Parameter.

Confidence Interval: (If applicable)

% Confidence Interval

Number of sides 2-Sided

Lower Limit:

Upper Limit:

Parameter Dispersion Type and Dispersion Value: (If applicable)

-- Please Select --

Estimation Comments: (Optional) Any other relevant estimation information, including the direction of the comparison (e.g., describe which arm or comparison group represents the numerator and denominator for relative risk).

Characters remaining: 250

Other Statistical Analysis

Help Definitions

If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results of the scientifically appropriate test of statistical significance.

Characters remaining: 999

Save Validate Cancel

* Required

* § Required if Primary Completion Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

Edit Adverse Event Table Defaults

Help Definitions

* § Time Frame: Provide a description of the specific period of time over which adverse event data were collected (e.g., 1 year, 6 months)

Characters remaining: 500

[*] Adverse Event Reporting Description: If the definition of adverse event and/or serious adverse event, used to collect adverse event information, differs from the clinicaltrials.gov Definitions, describe how the definitions differ.

Also, optionally provide additional relevant information about adverse event collection.

Characters remaining: 500

Source Vocabulary Name for Table Default: Please enter the name and version of the source vocabulary, if any, for adverse event terms. Source Vocabulary will be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified.
(e.g., SNOMED CT, MedDRA 10.0)

* § Collection Approach for Table Default: Assessment type will be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified.

If systematic, provide explanation of the method in Additional Description.

-- Please Select --

Save Cancel

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

Edit Adverse Event Arms/Groups

+ Add Arm/Group Help Definitions

* Arm/Group Title:	Experimental Drug	Placebo
* § Arm/Group Description:	Characters remaining: 970 Experimental Drug Description	Characters remaining: 975 Placebo Drug Description
	× Delete Move ▶	× Delete ◀ Move
Total for Serious Adverse Events:	0 Affected Participants out of 0 At Risk	0 Affected Participants out of 0 At Risk
Total for Other (Not Including Serious) Adverse Events:	0 Affected Participants out of 0 At Risk	0 Affected Participants out of 0 At Risk

Save Cancel

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

Edit All-Cause Mortality

Help Definitions

All-Cause Mortality	Experimental Drug	Placebo
* § Total Number Affected:	participants	participants
* § Total Number At Risk:	participants	participants

Save Validate Cancel

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

Edit Serious Adverse Event Total

Help Definitions

Serious Adverse Event(s)	Experimental Drug	Placebo
* Total Number Affected:	0 participants	0 participants
* Total Number At Risk:	0 participants	0 participants

Tip: The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow. Preview Participant Flow

Save Validate Cancel

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

Results: Add Serious Adverse Event

Help Definitions

* Adverse Event Term:	
* Organ System:	-- Please Select --
Adverse Event Term Additional Description:	Characters remaining: 250
Source Vocabulary Name:	(table default)
* § Collection Approach:	-- Please Select -- (table default)

Save Cancel

* Required
* § Required if Primary Completion Date is on or after January 18, 2017

Edit Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events

Help Definitions

* Frequency Threshold for Reporting Other Adverse Events:	Enter a number between 0 (no threshold; all events reported) and 5 (only events occurring in greater than 5% of participants in any Arm/Group are reported). %

Save Cancel

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

Edit Other (Not Including Serious) Adverse Event Total

Help Definitions

Other Adverse Event(s)	Experimental Drug	Placebo
* Total Number Affected:	participants	participants
* Total Number At Risk:	participants	participants

Tip: The Total Number of Participants at Risk is typically equal to the Number of Participants who Started the first Period in the Participant Flow. Preview Participant Flow

Save Validate Cancel

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

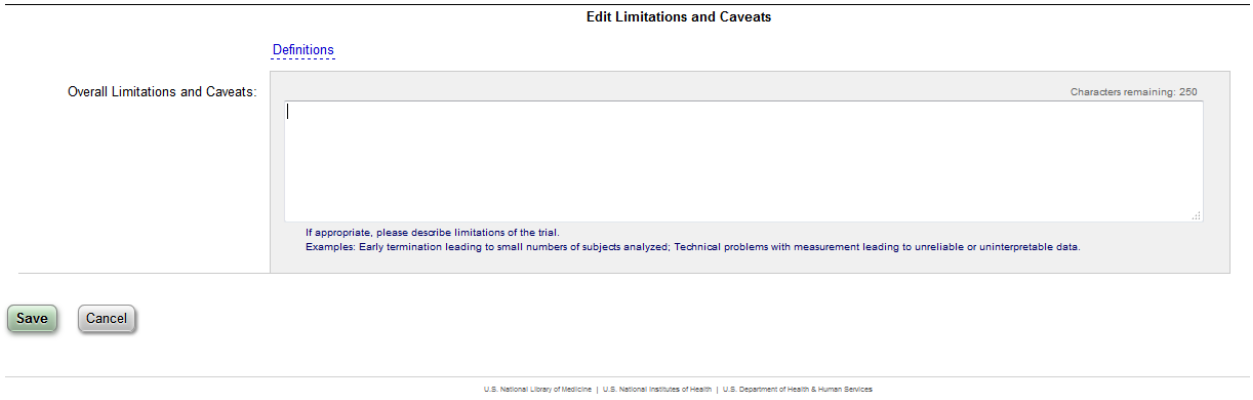
Results: Add Other (Not Including Serious) Adverse Event

Help Definitions

* Adverse Event Term:	
* Organ System:	-- Please Select --
Adverse Event Term Additional Description:	Characters remaining: 250
Source Vocabulary Name:	(table default)
* § Collection Approach:	-- Please Select -- (table default)

Save Cancel

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



Edit Limitations and Caveats

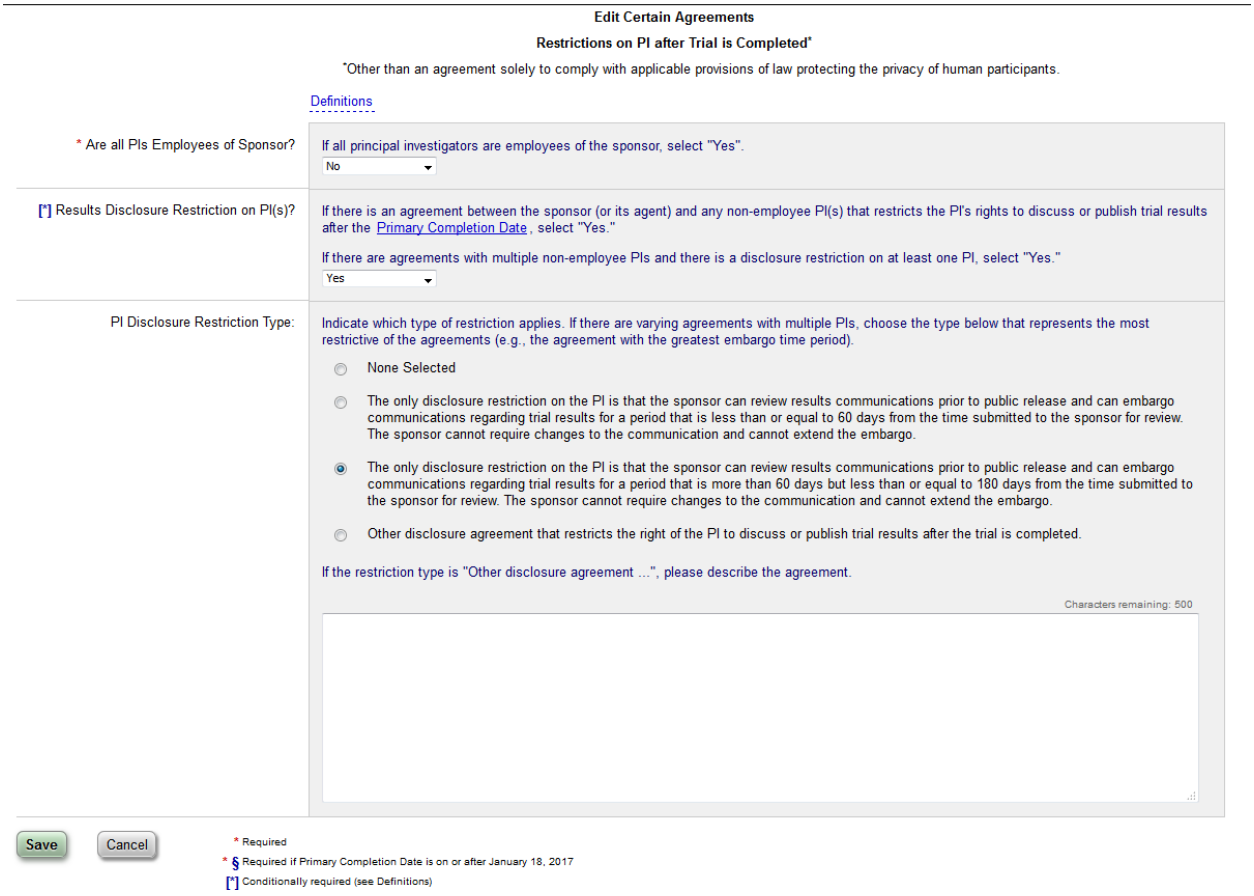
Definitions

Overall Limitations and Caveats:

Characters remaining: 250

If appropriate, please describe limitations of the trial.
Examples: Early termination leading to small numbers of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.

Save Cancel



Edit Certain Agreements

Restrictions on PI after Trial is Completed*

*Other than an agreement solely to comply with applicable provisions of law protecting the privacy of human participants.

Definitions

* Are all PIs Employees of Sponsor?

If all principal investigators are employees of the sponsor, select "Yes".

No

[*] Results Disclosure Restriction on PI(s)?

If there is an agreement between the sponsor (or its agent) and any non-employee PI(s) that restricts the PI's rights to discuss or publish trial results after the Primary Completion Date, select "Yes."

If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes."

Yes

PI Disclosure Restriction Type:

Indicate which type of restriction applies. If there are varying agreements with multiple PIs, choose the type below that represents the most restrictive of the agreements (e.g., the agreement with the greatest embargo time period).

- None Selected
- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is less than or equal to 60 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.
- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is more than 60 days but less than or equal to 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.
- Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

If the restriction type is "Other disclosure agreement ...", please describe the agreement.

Characters remaining: 500

Save Cancel

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

Edit Results Point of Contact

Definitions

* Name or Official Title: (of Investigator)	Enter the specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials).
* Organization Name:	
* § Phone:	Ext.
* § Email:	

Save Cancel

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