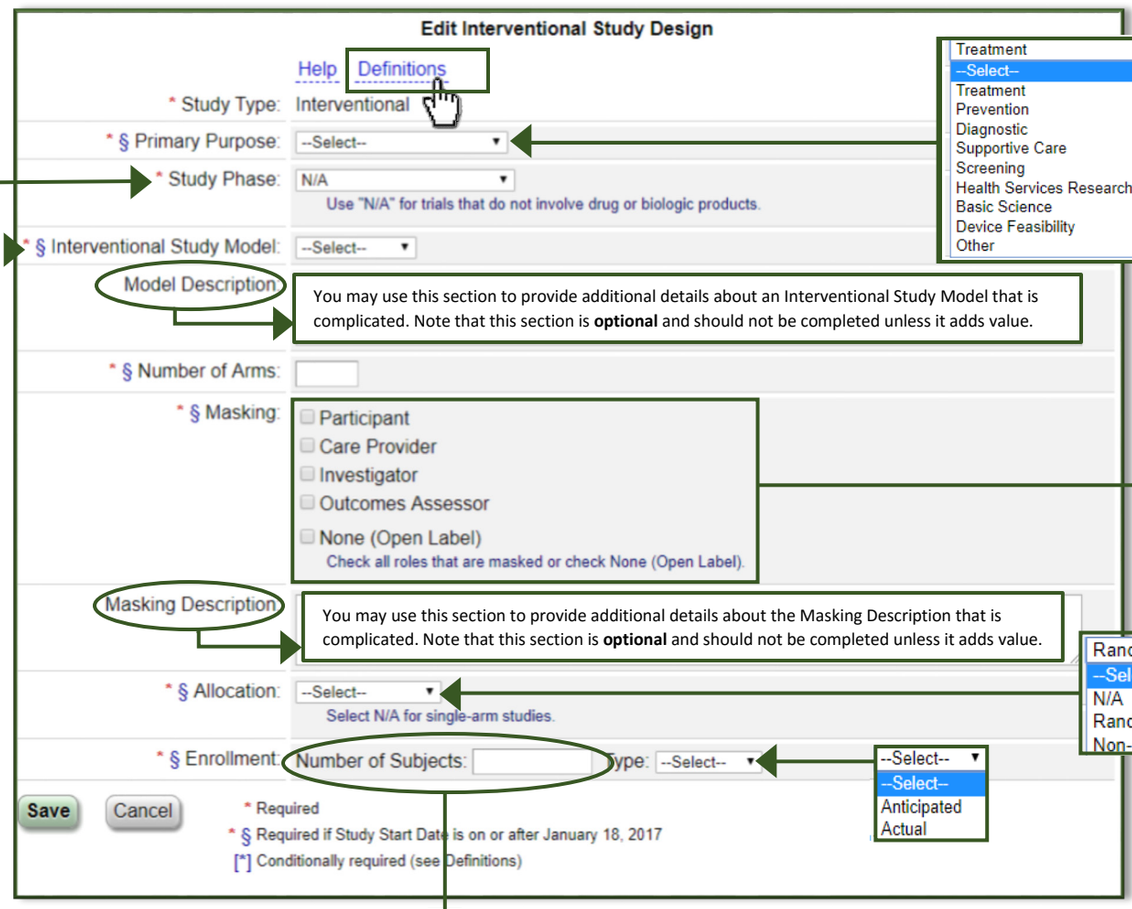
Study Design Cheat Sheet_ClinicalTrials.gov –Protocol Registration and Result Reporting System (PRS)



Select only one: This field is for studies that involve drugs and/or biological products **ONLY**. The definitions for each phase is consistent with the terminology in 21 CFR § 312.21 and 312.85.

Select the best option that fits your study. You may use the Definitions if you are unsure of the type of study design. If your study falls into multiple categories, select the primary model and then within the model description field, provide additional details.

Parallel
--Select--
Single Group
Parallel
Crossover
Factorial
Sequential

Treatment
--Select--
Treatment
Prevention
Diagnostic
Supportive Care
Screening
Health Services Research
Basic Science
Device Feasibility
Other

Select the primary purpose that is aligned with the main objective of the intervention(s) being evaluated by the clinical trial. You may use the Definitions option located at the top of the page if you are unsure of what you should select.

You may use this section to provide additional details about an Interventional Study Model that is complicated. Note that this section is **optional** and should not be completed unless it adds value.

Check all roles that are masked. Make sure that your selection is consistent with information recorded in related fields.

You may use this section to provide additional details about the Masking Description that is complicated. Note that this section is **optional** and should not be completed unless it adds value.

Randomized
--Select--
N/A
Randomized
Non-randomized

--Select--
--Select--
Anticipated
Actual

Enter the estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study. **Note**: *"Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for a study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.*

If you have any additional questions, you may contact the CTD group at 305-243-4538 or email us at ctgovum@miami.edu

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