Reference Document for Protocol Summary

Protocol Summary of Brief Background and Rationale:
Answer the questions: why, what, where, how
Who: the population description
Total time involved (study duration)

Example:

Study Phase		See definitions from clinicaltrials.gov: https://prsinfo.clinicaltrials.gov/definitions.html Drug studies: • Early Phase 1 • Phase 1 • Phase 1/2 • Phase 2 • Phase 2/3 • Phase 3 • Phase 4 Devices/ non-drug/ radiation only • N/A
Brief Background/Rationale		This is a prospective, randomized, parallel arm, multicenter study. Up to 222 men with a pathologically confirmed diagnosis of clinical stage T1 or T2 prostate cancer indicated for IG-IMRT will be randomized.
Agent/Device		Name of Agent/Device
Disease Sites/Conditions		Use ICD terminology from the link: http://seer.cancer.gov/tools/casefinding/case2013long.html Leukemia Lymphoma Myelodysplastic Syndromes Myelodysplastic/Myeloproliferative Diseases
Objectives	**Primary**	To assess clinical response associated with Agent X treatment using the RECIST 1.1 assessment criteria
	Secondary	Overall Survival
	Secondary	Incidence of graft-versus-host Disease (GVHD) in study participants with disease X
	Exploratory	Evaluation of biomarkers (specific biomarkers must be listed separately)
Estimated Study Duration		Estimated date first subject enrolled: June 2014 Estimated date last subject completed: July 2016
Duration of Participation		Subject participation is expected to average 12 to 18 months.
Sample Size		100 participants (state # per arm, if applicable)

Interventions - Experimental	Patients receive Agent X 3.0gm/M² IV over 1 hour twice daily on days -9 to -7 and Agent Y 45mg/kg IV over 2 hours on days -6 and -5. Patients also undergo total body irradiation (TBI), 165 cGY, twice daily on days -4 to -1 for a total of 1320 cGY.
Intervention - Control	Patients receive total body irradiation (TBI) on days T -6, -5 and -4 for a total of 1320 cGy , then Agent Z (60mg/kg/dose) on day -3.

Protocol Summary of Objectives and Endpoints:

- Below is a list of examples.
- Assess the main purpose of a study when picking your objectives and endpoints. Remember, ClinicalTrials.gov requires results to be reported on ALL primary and secondary endpoints. Other interesting data collected which are collected but are not the main purpose of the study should be listed as exploratory endpoints.
- Remember, for endpoints there must be specifics as to what is measured, description of the metric that will be used and at what time point. Objectives describe what you want to learn by analyzing these endpoint
- Recommended to have only **one** primary objective.

EXAMPLE: Objectives and endpoints. Note that each time point includes the timeframe for when it will be analyzed	
Primary Objective: to assess clinical response associated with Agent X treatment using the RECIST 1.1 assessment criteria	**Primary Endpoint:** Clinical benefit rate as defined by the number of patients that have a CR, PR or SD after 16 weeks of treatment
Primary Objective: progression free survival among patients with disease X	**Primary Endpoint:** Progression free survival according to RECIST 1.1 criteria. Defined as the average time (in months) from first day of treatment received to the earlier documented disease progression or death from any cause, assessed up to 1 year
Secondary Objective: Overall Survival among patients with disease X	**Secondary Endpoint:** Overall survival measured in months and summarized using the Kaplan-Meier method. This will be calculated from the date of registration on-study to the dates of documented evidence of progression or death, up to 3 years.
Secondary Objective: incidence of graft-versus-host Disease (GVHD) in study participants with disease X	**Secondary Endpoint:** Number of patients that develop acute graft-versus-host disease by grades 0-4 within the first 100 days post-transplant. Grade 0 is no development of GVHD. Grade 1-4 is increase severity of skin,

	liver and gut involvement with 1 being least severe and 4 being most severe.
Exploratory Objective: Average change in CD4+ count	**Exploratory Endpoint:** Average change in CD4+ from baseline to end of study, measured up to six months after first treatment.
Exploratory Objective: To determine the pharmacokinetics (PK) of Agent X	**Exploratory Endpoint:** Plasma PK of concentrations of unchanged Agent X after 3 cycles of treatment