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CLINICALTRIALS.GOV REGISTRATION READY DEPARTMENTAL PROTOCOL REVIEW CHECKLIST

This checklist is intended for Investigator-Initiated Studies to ensure that all necessary elements required to be entered during clinicaltrials.gov registration are clearly defined in the study protocol prior to submission to the University of Miami IRB.

Study eProst ID:	
Name of Reviewer:	
Date of Review:	

Section	Description	Yes
Study Identification	For Spanish titles, the English title provided?	☐
Conditions	Condition being studied clearly defined and applicable Medical Subject Heading (MESH) term of condition being studied provided? • *For reference of applicable MESH terms - https://meshb.nlm.nih.gov/search*	☐
Study Design	Primary purpose of study defined? • *Treatment, Prevention, Diagnostic, Supportive Care, Screening, Health Services Research, Basic Science, Device Feasibility*	☐
	For Drug/Biologic study, study phase defined? • *Phase 1, Phase 1/2, Phase 2, Phase2/3, Phase 3, Phase 4*	☐
	For Device studies, study identified if primary purpose is feasibility? • *Device Feasibility studies are those whose device intervention is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.*	☐
	Interventional Study Model defined? • *Single Group, Parallel, Cross-Over, Factorial, Sequential*	☐
	Number of study arms clearly defined?	☐
	Masking/blinding defined? If study is blinded, blinded roles identified? • *Participant, Investigator, Care Provider, Outcomes Assessor*	☐
	Allocation (randomized/non-randomized) clearly defined?	☐
	Accrual target identified and justification for sample size explained? • *Statistical Power Analysis determining whether the study sample size is large enough to reject a null hypothesis.*	☐
	Per-Protocol vs. Intent-to-treat patients defined? • *Intent-to-treat patients constitute all participants that are randomized into the study whose data will be included in the analysis. Evaluable participants are those whose data will be included in the analysis under optimal conditions.*	☐

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Arms & Interventions	Study arms clearly defined? Identified number of study arms consistent throughout the protocol?	☐
	Intervention(s) provided for each arm identified? Intervention description provided? Identified Intervention consistent throughout the protocol? • *Intervention description includes intervention form, sequence of administration, dosage, frequency and duration.*	☐
Outcome Measures	Quantifiable Primary and secondary endpoint(s) clearly and specifically defined?	☐
	Metric to quantifiably achieve the study endpoint(s) clearly defined?	☐
	Time frame of when outcome(s) will be measured clearly defined?	☐
	Exploratory outcomes clearly distinguished from primary and secondary outcome(s)? • *Primary and Secondary Outcome Results are required to be reported in clinicaltrials.gov if the study falls under the criteria of being required to disclose results. Exploratory Outcome Results are not required to be reported.*	☐
	If questionnaires/rating scales will be used to assess outcomes, are the minimum and maximum ranges and interpretation/criteria provided?	☐
Eligibility	Age and gender requirements included in the eligibility criteria?	☐
	Comorbidities and concomitant medications that can exclude/include the participant included in the eligibility criteria?	☐
	Condition being studied included in the eligibility criteria?	☐
Adverse Events	Adverse Events/Serious Adverse Events definition, classification, time frame of collection and reporting process provided?	☐
	Adverse Events/Serious Adverse Events collection approach defined? • *Systematic Assessment or Non-Systematic Assessment*	☐
Documents	Statistical Analysis Plan/Data Management clearly provided?	☐