ClinicalTrials.gov Pre-Registration Checklist

UF Clinical and Translational Science Institute
UNIVERSITY of FLORIDA

01 DID YOU INITIATE THE STUDY?

Yes

You are the sponsor-investigator for the study

No

You are not the sponsor. The sponsor is responsible for registering Applicable Clinical Trials and should provide you with the NCT number

If 'Yes' above, continue below...

02 IS THE STUDY AN APPLICABLE CLINICAL TRIAL ?

Yes

The study must be registered and report results on ClinicalTrials.gov through the Protocol Registration and Results System (PRS)

No

Registration is not required based on FDA regulations.Continue using the checklist to see if other regulations may apply

If 'Yes' above, continue below...

03 DOES THE STUDY HAVE NIH FUNDING?

Yes

NIH has their own requirements, definitions, and expectations for clinical trials that are conducted using NIH funding maybe mention review of NOA if CT 'yes' must register/post results

No

Check to see if federal regulations for ICMJE conditions apply

If 'Yes' above, continue below...

04 ICMJE JOURNAL PUBLICATION PLANNED?

Investigators should be award of their planned journals prior to beginning the study to assure they meet the necessary requirements.

Yes

ICMJE journals require all clinical trials wishing to publish in their journals to register on a database such as ClinicalTrials.gov before enrolling their first subject and to disclose whether Individual Patient Data (IPD) will be shared. This may apply to research that does not meet the FDA definition of an Applicable Clinical Trial or the NIH definition of a clinical trial, so check with your intended journal if you are unsure

No

If you are not planning to publish in an ICMJE journal and the above FDA regulations or NIH requirements do not apply, no action is required.

If you answered 'Yes' to 1 or more of the above, you will need to register on CT.gov

ClinicalTrials.gov Lifecycle Checklists

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USE THE CHECKLIST BELOW FOR REGISTRATION AND THROUGHOUT THE LIFE OF THE STUDY

Submit to the IRB	
Ancillary review by UFCT-gov: if registration required:	
• UFCT-gov will create a 'shell' record for the study in CT-gov for PI to finalize	
• Use the registration template to prepare for registration (Interventional) (Observational)	
• Required updates to active record in PRS	

SUBMIT

USE THE CHECKLISTS BELOW FOR PLANNING AND SUBMITTING RESULTS.

Use the checklists below for planning and submitting results. Results are due within 1 year of the final enrolled subject completing primary outcome procedures.

	Checklists	Templates
Participant Flow	Checklist	Template
Baseline Characteristics	Checklist	Age Sex/Gender Study Specific Measures
Outcome Measure and Statistical Analysis	Checklist	Template Examples
Adverse Events	Checklist	SAEs Other (non-serious) AEs