THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
105 Hardin Library for the Health Sciences
600 Newton Road
Iowa City, Iowa 52242-1098
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

ClinicalTrials.gov Checklist

Task	Yes	No
Did you initiate the study?	You are the Sponsor-investigator for the study.	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		
Is the study an Applicable Clinical Trial (ACT)?	The study must be registered and report results on ClinicalTrials.gov through the Protocol Registration and Results System (PRS).	Registration is not required based on FDA regulations. Continue using the checklist to see if other regulations may apply.
NIH Funding?	NIH has their own requirements, definitions, and expectations for clinical trials that are conducted using NIH funding.	Check to see if federal regulations or ICMJE conditions apply.
ICMJE journal publication planned? (Investigators should be aware of their planned journals prior to beginning the study to assure they meet the necessary requirements).	ICMJE journals require all clinical trials wishing to publish in their journals to register on ClinicalTrials.gov prior to enrolling the 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 Applicable Clinical Trial or the NIH definition of a clinical trial, so check with your intended journal if you are unsure.	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 ClinicalTrials.gov.

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ClinicalTrials.gov Checklist

Use the checklist below for registration and throughout the life of the study.

Submit to the IRB	
Create an account – contact ct-gov@uiowa.edu	
Start a new record	
Use the registration template to prepare for registration (here).	
Unique Protocol ID list the HawkIRB number	
Sponsor-investigator listed as 'Responsible Party Type' in Sponsor/Collaborators section	
IRB information filled out	
Contact information lists research team contacts	
Protocol and SAP (required for ACTs only) due at the time results are posted.	

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 Race, Ethnicity, Region Study Specific Measures
Outcome Measure and Statistical Analysis	Checklist	Template Examples
Adverse Events	Checklist	SAEs Other (non-serious) AEs