

ICMJE Clinical Trial Website Registration Requirements

DIRECTIONS:

1. Complete the form below.
2. If industry sponsored, obtain sponsor approval of this completed document.
3. After sponsor approval (if applicable), submit to HSC for approval.
4. E-mail the completed form along with the following:
 - a. HSC approval (hard copy can be delivered or mailed to RI/CRA, MSN 1039, 6 Wescoe)
 - b. If industry sponsored, e-mail of sponsor approval of the text in this form

E-mail to: cra@kumc.edu (checked weekly) or mgant@kumc.edu (checked daily)

Identifier	Instructions	To be Completed
1. Unique trial number	The unique trial number will be established by the primary registering entity (the registry).	DO NOT COMPLETE
2. Trial registration date	The date of registration will be established by the primary registering entity.	DO NOT COMPLETE
3. Secondary IDs	May be assigned by sponsors or other interested parties (there may be none).	DO NOT COMPLETE
4. Funding source(s)	Name of the organization(s) that provided funding for the study.	
5. Primary sponsor	The main entity responsible for performing the research.	
6. Secondary sponsor(s)	The secondary entities, if any, responsible for performing the research.	
7. Responsible contact person	Public contact person for the trial, for patients interested in participating.	
8. Research contact person	Person to contact for scientific inquiries about the trial.	
9. Title of the study	Brief title chosen by the research group (can be omitted if the researchers wish).	
10. Official scientific title of the study	This title must include the name of the intervention, the condition being studied,	

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	and the outcome (e.g., The International Study of Digoxin and Death from Congestive Heart Failure).	
11. Research ethics review	<p>1. Has the study at the time of registration received appropriate ethics committee approval (yes/no)?</p> <p>2. If yes, what date</p> <p>(It is assumed that all registered trials will be approved by an ethics board before commencing.)</p>	HSC approval status or submission date:
12. Condition	The medical condition being studied (e.g., asthma, myocardial infarction, depression).	
13. Intervention(s)	A description of the study and comparison/control intervention(s) (For a drug or other product registered for public sale anywhere in the world, this is the generic name; for an unregistered drug the generic name or company serial number is acceptable). The duration of the intervention(s) must be specified.	
14. Key inclusion and exclusion criteria	Key patient characteristics that determine eligibility for participation in the study.	
15. Study type	Database should provide drop-down lists for selection. This would include choices for randomized vs. non-randomized, type of masking (e.g., double-blind, single-blind), type of controls (e.g., placebo, active), and group assignment, (e.g., parallel, crossover, factorial).	
16. Anticipated trial start date	Estimated enrollment date of the first participant.	
17. Target sample size	The total number of subjects the investigators plan to enroll before closing	

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	the trial to new participants.	
18. Recruitment status	Is this information available (yes/no) (If yes, link to information).	
19. Primary outcome	The primary outcome that the study was designed to evaluate Description should include the time at which the outcome is measured (e.g., blood pressure at 12 months)	
20. Key secondary outcomes	The secondary outcomes specified in the protocol. Description should include time of measurement (e.g., creatinine clearance at 6 months).	

Is this study industry sponsored? Yes / No

If yes, attach documentation of the approval of this form (website text) from sponsor. This can be an e-mail or memo.