OBJECTIVE
Provide the common steps for reviewing the preparations for study start-up when participating in clinical research trials. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES
45 CFR 46 Protection of Human Subjects
21 CFR 50 Protection of Human Subjects
21 CFR 56 Institutional Review Boards
21 CFR 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions

REFERENCES TO RELATED SOPs
SOP 2.1
SOP 2.2
SOP 2.5
SOP 3.1

ATTACHMENTS
Sample Delegation of Authority Form

1) The PI is responsible for, or may delegate study start up procedures. These include, but are not limited to:
   a) Ensure that all duties of the study have been delegated and that all individuals are knowledgeable about their responsibilities. Fill out a Delegation of Authority Form
   b) Verify that all personnel have completed required training
   c) Ensure that all pre-study activities required by other ancillary service providers have been completed
   d) Order any needed supplies not directly provided by the sponsor. Contact Supply Chain Management at 612-873-6598
   e) Ensure that reserved space for conducting trial visits, storage of study related materials, and equipment is prepared
   f) Develop (or utilize sponsor-generated) worksheets, checklists, and flow sheets to assist study personnel to conduct the study
   g) Confirm that the contract has been fully executed (talk with the appropriate Grant Administrator)
   h) Review study procedures with assigned study staff.
   i) Assure that any applicable HCMC employees are apprised and knowledgeable about the study. If an HCMC employee is working on the study independent of their standard duties ensure their names have been provided to the appropriate Grant Administrator. A service agreement between HCMC and HHRI may need to be completed for each HCMC employee. Notify manager/ supervisor of appropriate department(s). Items to discuss with manager/supervisor and involved staff include, but are not limited to:
      i) Name of the study
      ii) Rationale for the study
iii) Responsibilities to be performed by HCMC staff
iv) Prohibited medications or other interventions outlined by the protocol
v) Potential adverse events to monitor participant for
vi) Name and number of PI
vii) Name and number of research coordinator

2) Ensure that all regulatory documents are complete, up-to-date, and in the regulatory binder.

3) Evaluate the trial to assess the need to register it with clinicaltrials.gov according to guidelines of the International Committee of Medical Journal Editors (ICMJE). ICMJE member journals require, as a condition of consideration for publication, registration in a public trials registry. The ICMJE defines a clinical trial as:

“Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-or-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.”

4) Federal agencies including the FDA and NIH also have registration policies. See http://clinicaltrials.gov/ct2/manage-recs for further information.

5) Contact the Office of Education and Quality in Clinical Research (OEQCR) at 612-873-6341 if the trial qualifies to begin the registration process.
   a) PI or research staff is responsible for entering and updating information in the registry.
   b) Notify the OEQCR if the investigator is the holder of an IND.
   c) Sponsor/CROs usually have already registered their study. Check www.clinicaltrials.gov to assess if they are registered. Notify sponsor/CRO personnel if the study is not listed.
## SAMPLE DELEGATION OF AUTHORITY FORM

<table>
<thead>
<tr>
<th>Name (Print)</th>
<th>Signature</th>
<th>Initials</th>
<th>Role in Study (sub-investigator, coordinator, etc.)</th>
<th>Authorized Functions* (List all that apply)</th>
<th>Start Date</th>
<th>End Date</th>
<th>PI Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Principal Investigator</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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1. Screening  
2. Verify inclusion/exclusion criteria  
3. Obtain informed consent  
4. Randomization  
5. Physical exam and history  
6. Study drug/device dispensation  
7. Subject study instructions  
8. Follow-up visits  
9. Study drug/device accountability  
10. Assess AEs/SAEs  
11. Reporting SAEs  
12. HSRC communication  
13. Sponsor communication  
14. CRF completion  
15. Query resolution  
16. Regulatory documents maintenance  
17. Other (specify)  
18. Other (specify)