OBJECTIVE
Describe the process for written procedures to ensure compliance with federal, state, local, and institutional regulations and guidelines that govern 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

REFERENCES TO RELATED SOPs
All SOPs are related to this SOP

ATTACHMENTS
SOP Approval Form

1) SOP format
   a) HHRI name
   b) Category: Identifies a broad classing designation for pertinent SOPs
   c) Subject: Identifies the pertinent SOP
   d) SOP#: A uniquely assigned identification number. The first number identifies the category. The second number is the SOP identifier and is assigned numerically.
   e) Effective date: The date the SOP becomes official.
   f) Revision date: The date of the latest revision

2) SOP outline
   a) Objective: States the description of the SOP and to whom it applies.
   b) Applicable Regulations and Guidelines: Identifies pertinent regulations or guidelines that may be accessed for further information.
   c) References to Related SOPs: Direct reference(s) to related SOPs
   d) Attachments: Identifies attachments associated with the SOP.
   e) Procedures: Instruction for completing tasks contained in the SOP.

3) The SOP Approval Committee is responsible for approving SOPs with members reflecting their particular expertise.
   a) Members will have an administrative, clinical, and /or regulatory function within the HHRI.
   b) The SOP Approval Committee will consist at a minimum of the HHRI Vice President of Operations, HHRI Assistant Vice President of Operations, HHRI Office of Education and Quality in Clinical Research (OEQCR) Director, a HHRI Grants & Contracts Administrator, the HSRC Vice Chair, and one non-investigator HHRI staff member.
   c) The SOP Approval Committee will be convened as necessary. SOPs must be approved by unanimous vote. SOPs may be approved traditionally or electronically with the OEQCR Director documenting each member’s decision.
   i.) The SOP Approval Committee will review all new SOPs as well as applicable attachments.
ii.) Applicability to current practice, compliance with regulations, and accuracy of the content will be considered.

d) Completed SOP Approval Forms will be archived in the OEQCR.

4) SOP addendums and/or revisions will outline new or modified procedures based on federal, local, or institutional changes affecting the conduct of clinical research.
   a) The OEQCR will review SOPs:
      i.) Upon request
      ii.) When internal policies or procedures are devised or changed
      iii.) When external policies or procedures are devised or changed
   b) Notify the OEQCR to request a new SOP or a revision to an existent SOP.
      i.) Provide the rationale for a change.
      ii.) Provide pertinent references for a change.
   c) SOP addendums and/or revisions may be administratively approved by the OEQCR Director for minor changes that do not reflect an institutional, federal, state, or local change in clinical research practice.
   d) The OEQCR will:
      i.) Maintain a current copy of the SOPs
      ii.) Maintain a historical archive of obsolete SOPs
      iii.) Work with the appropriate personnel to maintain current SOPs on the MMRF web site

5) SOPs will be accessible on the HHRI web site.
   a) New SOPs, addendums, or revisions will be disseminated via the research personnel ListServ.
   b) All research personnel are responsible to review and enact SOPs.
# STANDARD OPERATING PROCEDURES
## APPROVAL FORM

<table>
<thead>
<tr>
<th>New SOP(s)</th>
<th>SOP#</th>
<th>SOP(s) Revision</th>
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**Rationale for Action:**

Approved by SOP approval committee?  Yes  No  Administrative

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<thead>
<tr>
<th>SOP committee member:</th>
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<tbody>
<tr>
<td>Mary Bergaas</td>
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<td></td>
<td>NO</td>
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<tr>
<td>Karen Heim-Duthoy</td>
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<tr>
<td>Carla Erickson</td>
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<tr>
<td>Kim Miller</td>
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<tr>
<td>Bonnie Crissman</td>
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<tr>
<td>Carey Nadeau</td>
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<tr>
<td>Barbara Wicklund</td>
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</table>

**Action taken?**

- New SOP(s)/Guidance added
- Current SOP(s)/Guidance revised
- SOP(s)/Guidance retired