

<b>OFFICE FOR EDUCATION &amp; QUALITY IN CLINICAL RESEARCH</b>	<b>CATEGORY</b>	<b>Clinical Research: HSRC</b>
	<b>SUBJECT</b>	<b>Intra-Study Communication</b>
	<b>SOP #</b>	<b>3.3</b>
	<b>EFFECTIVE DATE</b>	<b>August 6, 2008</b>
	<b>REVISION DATE</b>	<b>October 17, 2017</b>

#### **OBJECTIVE**

Outline the responsibilities of the research team for submitting new and/or revised study materials for previously approved trials to the Human Subjects Research Committee. 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 2.11  
SOP 2.12  
SOP 3.2

#### **ATTACHMENTS**

None

- 1) Fill out the HSRC request for study continuation in time to assure continuous HSRC study approval. Complete the Annual Re-approval form sent 2-3 months prior to the expiration date
  - a) It is the responsibility of the PI to be aware of renewal deadlines and initiate the re-approval process if it is not received from the HSRC.
  - b) Complete all required fields
  - c) Provide all required documents requested by the HSRC
  - d) Retain a copy of the submission and HSRC response in the regulatory binder.
  
- 2) Submit any changes to including, but not limited to, the protocol, informed consent, and modified advertising for HSRC evaluation.
  - a) Approval must be obtained before initiating any changes.
  - b) Retain copies of all correspondence to/from the HSRC.
  
- 3) Submit unanticipated problems involving risks to subjects or others, and protocol deviations per SOP# 3.2.
  
- 4) Submit all sponsor safety IND reports or new information concerning the study that is supplied by the sponsor per SOP# 3.2.
  
- 5) Notify the HSRC of any changes in study personnel.

6) Notify the HSRC when trial enrollment is closed and/or completed.