

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Administrative
	SUBJECT	Standard Operating Procedures (SOPs)
	SOP #	1.1
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	January 29, 2020

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 Healthcare System campus.

APPLICABLE REGULATIONS AND GUIDELINES

None

REFERENCES TO RELATED SOPs

All SOPs are related to this SOP

ATTACHMENTS

None

- 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 Human Research Protection Program will collaborate in reviewing and ensuring all Office for Education and Quality in Clinical Research (OEQCR) SOPs are up to date and relevant to current regulatory and institutional requirements.

- 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:
 - 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 HHRI website and/or other platforms that provide information to researchers.

- 5) SOPs will be accessible on the HHRI website.
 - a) New SOPs, addendums, or revisions will be disseminated to research personnel.
 - b) All research personnel are responsible to review and enact SOPs.