

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Compliance
	SUBJECT	Post-Approval Review
	SOP #	6.1
	EFFECTIVE DATE	January 8, 2018
	REVISION DATE	N/A

OBJECTIVE

Describe the compliance activities conducted by the OEQCR to protect the safety of study subjects, promote consistent research quality, and ensure compliance with federal, state, local, and institutional regulations and guidelines that govern clinical research. 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 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions
HHRI Conflict of Interest Policy

REFERENCES TO RELATED SOPS

All SOPs are applicable to this SOP

ATTACHMENTS

Attachment A: Post-Approval Review Notification Letter
Attachment B: Review Questionnaire/Report
Attachment C: Review Follow-up Letter

PROCEDURES

- 1) Post-Approval Reviews
 - a) A minimum of two reviews will be done yearly. The OEQCR reserves the right to review a protocol or investigator more frequently as needed if circumstances suggest increasing problems with protocol conduct. The OEQCR also reserves the right to interview or survey research subjects and/or to observe the consent process as needed to ensure compliance with federal, state, and institutional regulations.
 - b) The selection of protocols for scheduled reviews shall be a risk-based assessment. Assessment criteria shall include but not be limited to: Investigator or research team new to clinical research; Investigator-initiated/sponsored protocols; the number of enrolled and/or consented subjects, the type and complexity of the trial; the level of risks to the trial subjects; and any identified problems.
 - c) The reviewers shall perform their duties under the auspices of the Director of the Office for Education and Quality in Clinical Research (OEQCR), who will provide training in auditing processes and compliance as needed. Team members will possess the professional experience and expertise to understand and apply the applicable federal, state, and institutional regulations.

- d) The reviewers will not be involved in any past or current aspect of the protocol under review. In addition, reviewers will not be employed by the principal investigator in any research protocol.
- e) Areas of the research process that will be reviewed include, but are not limited to, the following:
 - i) Informed consent process
 - ii) Protocol adherence and/or violations
 - iii) Serious/unanticipated adverse events
 - iv) Documentation of research activities
 - v) Research team training
 - vi) Confidentiality procedures
- f) The review process will consist of the following:
 - i) Protocols will be identified from the Office for Human Subjects Research database. Selected protocols will be chosen following a risk-based assessment.
 - ii) The principal investigator and study coordinator will be notified in writing that his/her research protocol has been selected for review by the OEQCR (Attachment A).
 - iii) The review team will contact the principal investigator and study coordinator to schedule a date and time for an on-site review.
 - iv) The date and time of review should be scheduled as soon as possible after the written notification.
 - v) The principal investigator and research support personnel will be asked to provide a list of study subjects (initials or ID numbers only) of all consented subjects.
 - vi) The principal investigator and research support personnel will be asked to provide copies of any sponsor monitoring visit follow-up letters.
- g) The review procedure will include the following:
 - i) Prior to conducting the review, the reviewer(s) will review the study file, in the OHSR, for the following:
 - (1) Date of initial approval
 - (2) Dates and description of modification(s) to the approved protocol with dates of approval
 - (3) Serious and unanticipated adverse event reports
 - (4) Any lapse of approval
 - (5) Study personnel and updates
 - (6) Enrollment
 - ii) A review questionnaire will be used as a tool to conduct the review (Attachment B). All regulatory and study documents are subject to review.

- iii) A review of 5 consented subjects will be performed. Subjects will be selected at random. If deemed necessary, additional subjects will be reviewed.
- iv) If less than 5 subjects have been enrolled, all enrolled subjects will be reviewed.
- h) Post-review procedures will include the following:
 - i) The reviewers(s) will conduct an exit interview with appropriate research personnel, including the principal investigator if available. The interview will outline the review's preliminary observations and steps that could be/would need to be taken to improve the quality of the research process.
 - ii) A post-review summary will be reviewed/discussed with/by the Director of the OEQCR. (Attachment B and C).
 - (1) The report will include the findings and outcome of the review or investigation as well as any recommendations or requirements. If necessary, a requirement will be that research support personnel undergo further education to ensure they understand research regulations and procedures.
 - (2) The report will outline follow-up procedures, if any are necessary. This may include a follow-up review, at the next six month cycle or sooner, to reexamine deficits identified for corrective action.
 - iii) After review by the OEQCR a follow-up letter will be sent to the principal investigator and copied to the HSRC. The letter will include the findings and outcome of the review as well as any recommendations or requirements that must be met. (Attachment C)
 - iv) Post-review reports and letters will not be routinely shared with outside agencies unless the review findings result in the suspension or termination of research approval in which case the Institutional Official will notify the appropriate regulatory agencies.
 - v) The principal investigator will have two weeks to provide a written response to the post-review follow-up letter and planned corrective action as needed.
 - vi) The written response will be sent to the Office for Education and Quality in Clinical Research (OEQCR). The Director will review the response and decide if further review is required by the HSRC.
 - vii) A copy of the written response will be sent to the HSRC for inclusion in study records.
 - viii) Results of troublesome reviews will be discussed with the HSRC Chair or Vice Chair.