

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Administrative
	SUBJECT	Human Research Protection Program Monitoring
	SOP #	1.3
	EFFECTIVE DATE	December 9, 2013
	REVISION DATE	January 29, 2020

OBJECTIVE

Describe the process by which information is collected and monitored to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin Healthcare System.

APPLICABLE REGULATIONS AND GUIDELINES

None

REFERENCES TO RELATED SOPs

None

ATTACHMENTS

None

- 1) The Office of Education and Quality in Clinical Research (OEQCR) will annually assess three areas of the quality, efficiency, and effectiveness of the Human Research Protection Program.
 - a) IRB metrics
 - b) Audits concerning the research process
 - c) Investigator feedback

- 2) IRB metrics to be collected annually will include but not be limited to:
 - a) Number of researchers.
 - b) Mean number of days from submission to review at meeting and final determination for new protocols reviewed in the last year by the convened IRB.
 - c) Mean number of days from submission to review and final determination for new protocols reviewed in the last year by the expedited procedure.
 - d) Mean number of days from protocol submission to exempt determination in the last year.
 - e) Number of protocols disapproved by the IRB in the last year.
 - f) Number of reported protocol deviations in the last year.
 - g) Number of cases of alleged non-compliance investigated in the last year.
 - h) Number of determinations of serious non-compliance in the last year.
 - i) Number of determinations of continuing non-compliance in the last year.
 - j) Number of unanticipated problems in the last year.
 - k) Number of unanticipated problems involving risks to participants or others in the last year.

- 3) Audit findings concerning the research process will include, but not be limited to:

- a) The informed consent process.
 - b) Documentation of research activities.
 - c) Confidentiality procedures.
 - d) Protocol adherence and/or violations.
 - e) Completion of research team required training.
- 4) Investigator feedback which is collected annually via survey by the HCMC Vice President of Medical Affairs will be examined to ascertain:
- a) Helpfulness and knowledge of the OHSR staff.
 - b) Helpfulness and knowledge of the Primary Reviewers.
 - c) Helpfulness and knowledge of the Chair.
 - d) Helpfulness and knowledge of the Vice Chair.
 - e) Relevant information about the submission process and how to write an informed consent document is readily available.
 - f) The primary review process is handled effectively by the HSRC.
 - g) The continuing review process is handled effectively by the CRC.
 - h) The OHSR provides timely service.
 - i) The OHSR minimizes logistical hurdles where possible.
 - j) The OHSR does an effective job of protecting human subjects.
- 5) The OEQCR will annually compile results. Results will be compared to published metrics from AAHRPP. In addition changes noted over the past year will be highlighted.
- 6) Findings will be shared with the Institutional Official, the Chair, and the Vice Chair of the OHSR.
- 7) Noted outliers or changes will be highlighted and plans to correct or improve metrics will be discussed and instituted as needed.
- 8) Results of improvement plans will be discussed with the next annual assessment or earlier if deemed necessary.