HUMAN RESEARCH PROTECTION

HRPP Monitoring

Number 12 Version Date 30 AUG 2022
Resource type SOP - Administrative

Objective

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

Responsibilities

The Office for Education and Quality in Clinical Research (OEQCR) in collaboration with HRPO manages the procedures described below.

Procedures

1. Annually assess the quality, efficiency, and effectiveness in three areas of the HRPP.
   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:
   - Number of researchers
   - 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
   - Mean number of days from submission to review and final determination for new protocols reviewed in the last year by the expedited procedure
   - Mean number of days from protocol submission to exempt determination in the last year
   - Number of protocols disapproved by the IRB in the last year
   - Number of reported protocol deviations in the last year
   - Number of cases of alleged non-compliance investigated in the last year
   - Number of determinations of serious non-compliance in the last year
   - Number of determinations of continuing non-compliance in the last year
   - Number of unanticipated problems in the last year
   - 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:
   - The informed consent process
   - Documentation of research activities
   - Confidentiality procedures

- Protocol adherence and/or violations
- Completion of research team required training

4. Annual Investigator feedback via survey will be reviewed to understand investigator perspective about:
   - Interactions/communication between the study team and HRPO staff
   - Quality of information provided for researchers
   - Usability of online IRB system
   - Turnaround time for exempt/expedited review
   - Turnaround time for full committee review
   - Interaction/communication with OEQCR staff
   - Usability of required training
   - Any other feedback the researcher would like to provide

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 IRB Chair, and the HRPO Director.

7. Noted outliers or changes will be highlighted and plans to correct or make improvements 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.

References

None

Revision history

Version date	Summary of substantive revisions
30 AUG 2022	Update to reflect updated process for naming/numbering conventions, creation/revisions to resource documents and alignment with HRPO process changes; other minor revisions for clarity and formatting.
28 MAR 2022	Updates to reflect changes to investigator feedback survey questions.
09 DEC 2013	Origination