HennepinHealthcare Research Institute

HUMAN RESEARCH PROTECTION

IRB Minutes Quality Improvement

Number 21 Version Date 21 JUL 2022
Resource type SOP - Compliance

OBJECTIVE

Describe the compliance activities conducted by the Office for Education & Quality in Clinical Research (OEQCR) to assure that the Institutional Review Board (IRB) documents discussions and decisions relevant to a research protocol in accordance with legal, regulatory, sponsor, and organizational requirements. These procedures apply to all human research reviewed by the Hennepin Healthcare convened IRB.

RELATED HRP RESOURCES

HRPO 108 GUIDANCE Regulatory and external guidance references

ATTACHMENTS

Attachment A: IRB Minutes Quality Improvement Assessment Tool
Attachment B: IRB Minutes Quality Improvement Follow-up Letter

PROCEDURES

1) IRB Minutes Quality Improvement:
    a. A minimum of two reviews will be done yearly. The OEQCR reserves the right to review minutes' content more frequently.

    b. The selection of minutes for scheduled reviews shall be a risk-based assessment. Selection criteria shall include but not be limited to: Investigator or research team new to clinical research; Investigator-initiated/sponsored protocols; type and complexity of the trial and decision making by the IRB members; level of risks to the trial subjects; and problems identified during not for cause or for cause audits.

    c. The reviewer(s) will have training in auditing processes and compliance as needed and possess the professional experience and expertise to understand and apply the applicable federal, state, and institutional regulations.

    d. Areas of the minutes that will be reviewed include, but are not limited to, the following:
        - Meeting attendance
        - Actions taken by the IRB
        - Vote on Actions
        - Required determinations and protocol-specific findings to justify a determination
        - Decisions about informed consent
        - Expedited Activities and Continuing Review

- Unanticipated problems, serious or continuing noncompliance, suspension or termination of IRB approval

2) Review process:
   a. IRB minutes to be reviewed will be identified from the IRB Cayuse database. Selected minutes will be chosen following a risk-based assessment.

   b. The reviewer will discuss minute review with the HRPO staff.

   c. The review will be conduct using the IRB Cayuse online system database. The reviewer will address questions with HRPO staff.

   e. A review questionnaire will be used as a tool to conduct the review (Attachment A). If needed, all minutes about a specific ongoing action are subject to review.

3) Post-review process:
   a. A post-review summary will be reviewed by/discussed with the OEQCR Director.

   b. The report will include the findings and outcome of the review or investigation as well as any recommendations or requirements.

   c. The report will outline follow-up procedures, if any are necessary.

   d. After review by the OEQCR, a follow-up letter (Attachment B) will be sent to HRPO@hhrinstitute.org. The letter will include the findings and outcome of the review as well as any recommendations or requirements.

   e. IRB minutes quality improvement reports and letters will not be shared with outside agencies.

   f. The HRPO will have two weeks to provide a written response to the post-review follow-up letter and planned corrective action as needed.

   g. If needed, the written response will be sent to OEQCR via EQ@hhrinstitute.org. The Director will review the response and decide if further review is required.

References

- OEQCR website: https://www.hhrinstitute.org/researcher-resources/office-for-education-quality-in-clinical-research/
- OEQCR network drive full path: N:\Resource Management\Active\ OEQCR 20-29 SOP Compliance

Revision history

Version date	Summary of substantive revisions

21 JUL 2022	Update process to focus on entire IRB minutes review versus selecting a specific protocol; 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.
22 DEC 2017	Origination

HennepinHealthcare Research Institute

Attachment A

IRB Minutes Quality Improvement Assessment Tool

Date of IRB meeting:	Person completing: Date of Assessment:

AREA OF REVIEW	MEASURE FOR COMPLIANCE	YES	NO	N/A	COMMENT
Attendance at the meeting	Is the date, time, and location of the meeting documented				
	Are the full name and representative capacity (scientist, nonscientist, unaffiliated) of each member present				
	Is at least one nonscientist member present				
	Are members participating by electronic means documented				
	Is the replacement of a primary member by an alternate member documented				
	Is the name of any consultants present at the meeting and their expertise documented				
	Are the names of non-members and guests that attended a meeting documented				
	Is a quorum present *(Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the roster, then 10/2 = 5 and the next whole number is 6. If there are 11 IRB members on the roster, then 11/2=5.5 and the next whole number is 6.)*				
	Are the name(s) of members who leave the meeting due to COI documented along with the fact that COI is the reason for the absence				
	Has a quorum been maintained for each vote				
Actions taken by the IRB	Are the actions taken by the IRB (approval, require modifications, defer, disapprove) documented				
	Are there separate deliberations for each action				
	Is there sufficient detail to justify IRB actions				
	Is there a summary of discussion of controverted issues and their resolution				
	Is there sufficient detail to show the basis for requiring changes in the study or disapproving research				
Vote on actions	Are votes for each protocol listed as numbers for, against, or abstaining documented				
	Is the approval period documented for initial and				

	continuing review				
	Has there been a vote to suspend or terminate approval of previously approved research				
	Is there documentation of the reasons to suspend or terminate approval of previously approved research				
	Has there been a vote to lift suspension of a study or to terminate a previously suspended study				
	Is there documentation of the reasons to lift suspension of a study or to terminate a previously suspended study				
	Are votes for presence of conflict of interest and recusals documented				
Are required determinations and protocol-specific findings to justify a determination documented	Waiver or alteration of the consent process				
	Research involving pregnant women, fetuses, and neonates (Subpart B)				
	Research involving prisoners (Subpart C)				
	Research involving children (Subpart D)				
	Research involving subjects with diminished capacity				
	Research involving children who are wards of the state or any other agency				
	Rationale for determining risk associated with using a medical device in a study deemed significant or non-significant				
	Research involving an exception from informed consent for emergency research				
Consent	Has the informed consent been reviewed and determined that it meets applicable regulatory requirements				
	Are required changes documented				
Expedited Activities and Continuing Review	Have expedited review activities been presented				
	Are continuing review assignments and requirements documented				
Compliance	Unanticipated problems, serious or continuing noncompliance, suspension or termination of IRB approval: If existing, have these been presented and reviewed				

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ATTACHMENT B

IRB MINUTES QUALITY IMPROVEMENT FOLLOW-UP LETTER

To: IRB Vice Chair
IRB Analyst

From: Reviewer Name/Title

Date: xx/xx/xxxx

Subject: IRB Minutes {add date of minutes}

Thank you for your cooperation in the review of the above named IRB minutes. Please review the enclosed observations and, if applicable, provide a written response by {DATE}. Your response should address all requests. If corrective action is warranted, please outline all actions to be implemented. {Sample wording can be adjusted as needed}

Please send a copy of your written response to:
EQ@hhrinstitute.org

The OEQCR Director will review your answers and corrective plan(s) as applicable and determine if further action is necessary.

Please feel free to contact me with any questions or concerns, {Email}.

Sincerely,

{PDF electronic Signature}

{Name and Title}