AAH RSPP GUIDANCE
IRB meeting minutes

PURPOSE
The purpose of this document is to provide guidance on the creation of IRB meeting minutes and the content of those minutes.

Definitions of italicized words can be found in the AAH RSPP Glossary.

GUIDANCE
How are the IRB meeting minutes created?
Members of the RSPP Office will be in attendance at every convened IRB meeting. These individuals will take notes on the specific aspect of the meeting that is his/her responsibility.

Who is responsible for creating the minutes?
After the IRB meeting, the Research Compliance Analyst (RCA) or RSPP Director writes the minutes for each IRB activity for which he/she is responsible. The RSPP team member will place his/her meeting notes into the appropriate section of the RSPP Meeting Minutes template.

The IRB coordinator is responsible for gathering the respective minutes from the RSPP office staff and creating one master draft copy of the IRB meeting minutes;

What is included in the minutes?
As applicable, the minutes of the specific activity will include some or all of the following points depending on the study/action under review, and the IRB’s deliberation:

- Whether the PI or study team representative was present;
- The individual who served as the IRB reviewer/consultant;
- IRB discussion on the research action as it relates to the regulatory criteria for approval;
- NSR or SR decision for device research studies, and the rationale for that decision;
- Documentation of member discussion about study design and conduct, and discussion of whether the criteria for approval can be met in the study as submitted or with conditions of approval.
- Controverted issues (situations where IRB members had differences of opinion) and their resolution;
- If the IRB finds that substantive modifications to the study must be made in order for the criteria for approval to be met, the minutes will document the IRB’s discussion and include mention that the action will be tabled/deferred to a later meeting until changes are made by the PI.
- Whether a COI management plan was presented to the IRB for consideration, and their decision on acceptance of the proposed plan.
• Determinations and findings that require written documentation – for example, waiver or alteration of informed consent, inclusion of vulnerable populations including children, pregnant women, neonates, or cognitively impaired adults;
• HIPAA decisions made by the IRB/Privacy Board;
• Documentation of the approval period. If less than one year, the IRB’s rationale for making that decision will be documented.
• The IRB’s finding that the study meets the regulatory definition of no greater than minimal risk.
  o If the study is found to be no greater than minimal risk, the IRB will determine if future continuing review is required. The 2018 requirements of the DHHS regulations [46.109(f)(1)(i)] eliminate the continuing review requirement for research eligible for studies no greater than minimal risk unless an IRB determines otherwise. Documentation of whether continuing review is required, and the frequency if required, will be included in the minutes.
  o Per current FDA regulations, all FDA regulated research must undergo continuing review.
• Documentation of required changes noted as conditions of approval, and the name of the individual responsible for verifying that the conditions have been met.
  o If the action under review is a Change to previously approved research and conditions of approval were issued, the minutes will document the IRB’s determination of whether any conditions of approval need to be satisfied before an investigator can continue particular research activities related to those conditions (eg. enrollment of new subjects).
  o If the action under review is a continuing review, the minutes will document the following IRB determinations as applicable:
    ▪ that the conditions must be satisfied before study expiration. If the conditions of approval are not satisfied prior to a lapse of IRB approval, no research activities will be allowed to occur until the conditions are met, and approval issued.
    ▪ whether conditions of approval need to be satisfied before an investigator can continue particular research activities related to those conditions (eg. enrollment of new subjects).
• If the action under review is consideration of whether an incident meets the RSPP SOP definition of an Unanticipated Problem Involving Risk to Subject or Others (UPIRSO) or Serious and/or Continuing Noncompliance, the minutes will include the following:
  o A description of the event and any proposed corrective and preventative action;
  o Actions the institution has taken or plans to take to address the incident;
  o The IRB’s determination and a rationale for that decision;
  o Whether any action is required by the PI to address the incident. This may include: suspension of new subject enrollment; study termination; modification to the protocol or consent document, notification of previously-enrolled subject(s) of the incident; re-consent of previously enrolled subjects; researcher education.
If previously-enrolled subject notification is necessary, the minutes will document when/how such notification must occur, and how the notification will be recorded by the research team.

The IRB Coordinator adds the following general information to the minutes:

- The meeting start/end time;
- The names of all members (regular and if alternates, the name of the regular member who he/she is replacing) in attendance and the time of arrival of any member if after the meeting is convened;
- The departure of members,
- Tracking/recording the number of IRB members required for quorum;
- That all members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions.
- Any observers/guests present at the meeting;
- The count of votes (number of votes in favor, opposed, and abstained) for each action requiring a vote.
  - Should an IRB member not return a voting ballot, his/her vote on all IRB actions will be documented as an abstention. This individual will count towards quorum.
- If any member recuses due to a conflict of interest, this individual will be named in the minutes, and noted that he/she did not vote on the action, nor count toward quorum.
- If an initial or continuing review, the period for which the study is approved is noted.
- Include other notes as indicated in the template.

Should any IRB action necessitate changes to a research study consent document(s) due to a condition of approval, the consent document noting the changes required as a condition of approval will be appended to the draft IRB meeting minutes.

**When are IRB meeting minutes created?**
The draft meeting minutes will be created as soon as possible after the meeting but no later than 4 weeks from the date of the IRB meeting.

**Who reviews the draft IRB meeting minutes?**
Once created, the draft minutes will be sent to the RSPP Director and the Chair of the IRB meeting. These individuals will have one week to make necessary changes to the draft minutes for clarity/accuracy.

Upon review by the RSPP Director and IRB Chair, the draft meeting minutes will be sent to the same IRB team in their next meeting materials packet.
How is approval of the IRB meeting minutes documented?
The minutes will be discussed at a subsequent meeting of the same IRB team. The IRB Chair will ask members whether changes to the draft minutes are necessary or if the minutes may be considered approved as submitted.

If no changes to the draft minutes are required by the IRB, the minutes will be considered ‘approved as submitted’.
- The status of the meeting minutes will change from ‘draft’ to ‘final’.

If changes are required, the changes will be categorized as minor, ie. specific changes that do not alter the meaning; or substantive, ie. changes that alter the meaning.
- The current meeting minutes will document the substantive changes that are necessary to be made.
- Minor changes will be collected by the IRB Coordinator.
- All revisions will be made outside of the meeting.
- The draft minutes will be labeled as ‘revised’ and include the date of meeting as the ‘revised’ date.

Minutes with minor revisions:
- will be sent to the IRB members via email. No response from the members is necessary – action is taken only for member notification.
- will be considered ‘approved with minor revisions’;
- the status will change from ‘draft’ to ‘final’.

Minutes with substantive changes:
- will be brought back to a subsequent meeting of the same IRB team. At that meeting, the IRB will again consider whether the minutes may be approved as submitted or with revisions.
  - If no changes to the draft revised minutes are required by the IRB, the minutes will be considered ‘approved as submitted’.
  - The status of the meeting minutes will change from ‘draft’ to ‘final’.
- If changes are required, the changes will be categorized as minor or substantive, and the above actions will ensue.

If changes affect the correspondence that was forwarded to the principal investigator, a correction will be issued.

Once finalized, a PDF of the ‘final’ meeting minutes will be created and stored electronically on a secure AAH drive. Access to this drive is limited to members of the RSPP office. Final meeting minutes are retained for the period required by regulation [see RSPP Guidance: IRB Record Retention].
Documentation of approval of the draft meeting minutes will be included in the current meeting’s minutes.

**May the minutes be shared with others not part of the IRB?**

It is not the practice of the Advocate Aurora IRB to make available the minutes of convened board meetings to individuals outside of IRB members and meeting observers/guests (who sign a confidentiality agreement).

Exceptions to this practice may include:

- OHRP/FDA auditors/inspectors;
- AAHRPP site visitors;
- others within the institution, including site administrators where research is to be conducted or Advocate Aurora Research Institute leadership.

Individuals may make a request of the RSPP Director for a copy of the IRB meeting minutes. The request will be considered in consultation with the Institutional Official, but access is not guaranteed.

If it is decided that meeting minutes may be shared with a study sponsor, only the minutes of the applicable study will be provided.

**REQUIREMENTS**

- Common Rule Regulations: 45 CFR 46 110(d); 115(a)(2); applicable Subparts
- FDA Regulations 21 CFR 56.110(d); 115(a)(2); applicable Subparts
- Joint Guidance (OHRP/FDA): Minutes of Institutional Review Board (IRB) Meetings
- AAHRPP Accreditation Standards/Elements: II.1.D; II.2.D; II.5.B
- AAH RSPP Guidance: IRB Record Retention, Convened IRB Meeting Administration, Meeting Materials
- AAH RSPP SOPs 2, 4, 8, 10