AAH RSPP GUIDANCE
Convened IRB Meeting Administration

PURPOSE
The purpose of this guidance is to document the administration of convened board IRB meetings. Except when an expedited review process is used, the IRB will review proposed research at convened meetings.

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

GUIDANCE

When are convened board meetings held?
Convened board meetings are scheduled twice a month by the RSPP Office. The schedule is provided to researcher/research team members on the RSPP website. IRB Members scheduled to be in attendance at the meeting are sent Microsoft Outlook meeting invites.

Human subject research requiring full-board IRB review and approval will be assigned by the RSPP Office staff to the next scheduled full-board IRB meeting (i.e., subject to the availability of IRB committee members with appropriate expertise as determined by review of IRB Member Rosters).

If there are no actions requiring convened board review/consideration, the convened board meeting may be canceled by the RSPP Office.

Emergency convened board meetings may be called as needed and with 48 hours notice. Quorum for such a meeting will be constituted per regulation and as noted below.

How and when are meeting materials distributed?
IRB meeting materials [see RSPP Guidance: Meeting Materials] are provided electronically to scheduled attendees via encrypted email and/or as an attachment to the Outlook meeting invite.

Meeting materials will be distributed for routinely scheduled convened board meetings at a minimum of five working days prior to the meeting date. If the meeting is an emergency convened board meeting, the five working day minimum rule will not apply. In the case of an emergency meeting, scheduled attendees will be sent the meeting materials 48 hours in advance of the meeting date.

Where are convened board meetings held?
IRB meetings will be held at locations convenient to the majority of the committee members – either in-person meetings or remote meetings using teleconference/telepresence technology (Microsoft Teams or Zoom).
• In-person meetings will be held in the RSPP office conference area or other AAH conference area. If a member is not able to attend the in-person meeting, remote technology may be used to allow that member to participate in the meeting.

• Remote meetings using teleconference or telepresence technology will be held in such a manner that all members will be able to discuss the IRB actions.
  o To allow for appropriate discussion to take place, all members must be connected simultaneously. "Telephone polling" (where members are contacted individually) will not be accepted as a conference call.
  o Remote attendance does not require the member’s video presence.
  o Call-in telephone numbers/internet addresses will be provided to members in advance of the meeting.

In all cases, IRB members will receive all pertinent materials prior to the meeting, and all will be able and expected to actively and equally participate in the discussion of the IRB actions.

**What is the regulatory constitution of a ‘convened’ IRB??**

An IRB may conduct business, take action or vote on research actions, including proposed changes to previously approved research, at convened meetings at which a majority of the voting members of the IRB are present ("quorum"). Quorum must include at least one member whose primary concerns are in nonscientific areas (45 CFR 46.108(b) and 46.103(b)(4)).

- No member who is absent from a convened meeting, or a portion of the meeting where an IRB action is discussed, may vote on that study.

It is recommended, but not required by DDHS or FDA that a nonaffiliated member (a member not otherwise affiliated with the institution) and a member who represents the general perspective of research subjects be present at convened board meetings. These roles can be filled by the same person.

- While their presence at the meeting is not mandated, AAH strives to ensure the attendance of these members at every meeting. However, their presence is not required to constitute quorum.
- Frequent absences (> 10 of 12 meetings) of such member(s) are not acceptable.

Federal regulations require the presence of members who have the expertise to evaluate the research protocols and to ensure the protection of human subjects.

- While FDA regulations do not require the presence of a physician IRB member at a convened board meeting at which FDA regulated research is being reviewed, AAH strives to ensure the presence of a physician IRB member during the review of these studies. However, convened board meetings may be held without the presence of a physician member even when FDA regulated research is being reviewed.

It is the responsibility of the IRB Chair and RSPP Director to ensure the IRB is appropriately constituted with expertise in the area(s) of research being reviewed.

- When research involves the enrollment of subjects who are deemed ‘vulnerable’, every effort will be made to have at least one member who is knowledgeable about or has experience working with such a population present at the meeting.
The Advocate Aurora IRB is not constituted to review human subject research Involving Prisoners (45 CFR 56 subpart C).

**How is quorum calculated?**
Quorum is a majority of voting IRB members, or their designated alternates (see below), present at the IRB meeting.

Quorum is calculated in the following manner: Divide the number of members present by two and select the next whole number. For example, if there are 8 voting members present then 8/2 = 4 and the next whole number is 5. If there 9 voting members present, then 9/2=4.5 and the next whole number is 5.

Members who attend remotely, such as by phone or video conference, may vote on research activities brought before the board, and are counted toward quorum. Members who leave the meeting or are absent for discussion and voting on an item due to a conflict of interest, or for any other reason, do not count toward quorum.

The IRB Coordinator is responsible for ensuring that quorum is maintained during the meeting and noting when members enter and leave the meeting. If at any time during the convened IRB meeting quorum is not maintained, proceedings will be suspended until the quorum is re-established. If quorum cannot be re-established, the meeting will be adjourned.

**May the IRB use alternate members?**
Yes. In order to ensure quorum and the presence of necessary membership, the IRB may appoint alternate voting IRB members for all positions including Chair. An alternate IRB member may be requested to participate in place of a scheduled IRB member.

IRB minutes will indicate if the member present at the meeting is an alternate. If an alternate is present, the minutes will reflect the name of the IRB member for whom the alternate is substituting.

- If for some reason, the regular member and his/her alternate attend the same convened board meeting, only one individual may vote, and the minutes will reflect which member was able to vote.

**May others attend IRB meetings?**
The IRB may allow observers/guests to attend IRB meetings. Such individuals may include: RSPP staff, an investigator whose study is being reviewed, research study staff, the Institutional Official, mentees, etc.

- These individuals may address comments/answer questions only when asked by the IRB Chair or an IRB member.

If not part of the RSPP Office, or the research team of a study under review, the guests/observers must obtain permission from the RSPP Director prior to attendance.

- These individuals must sign a confidentiality agreement in order to attend the meeting.
• Individuals who are part of the research team of a study under review will only be allowed to attend the portion of the IRB meeting where their study is being discussed. Research team members must absent the meeting prior to IRB deliberation of their study.

The IRB meeting minutes will record the name(s) of observers/guests.

**Does the Advocate Aurora IRB use a Primary Reviewer system?**

Yes, a Primary Reviewer system is used by the Advocate Aurora IRB for all IRB actions (new submissions, Unanticipated Problems, serious and/or continuing Noncompliance reviews, Significant New Information (SNI), and Changes to Approved Research) requiring convened board review.

Additional reviewers may also be asked to conduct reviews to supplement those provided by the Primary Reviewer, focusing on areas or issues not otherwise addressed.

The Primary Reviewer conducts a comprehensive review of all submitted materials for the assigned IRB action, presents a summary of the information to the IRB, provides an assessment of the criteria for approval (45 CFR 46.111; 21 CFR 46.111), and recommends specific actions to the IRB. In addition, assigned reviewers are expected to evaluate informed consent documents from the perspective of addressing the required and additional elements of informed consent addressed under 45 CFR 46.116, 21 CFR 50.20 (if applicable) and any other relevant ethical or compliance considerations. The primary reviewer leads the discussion of the assigned action.

Primary Reviewers are authorized and expected to contact investigators or other study personnel (if appropriate) to resolve questions or concerns whenever possible prior to the convened IRB meeting.

**How are Primary Reviewers assigned to IRB actions requiring convened board review?**

The RSPP Office, in consultation with the IRB Chair as needed, assigns an IRB member who has adequate expertise in the area(s) of the research to act as the Primary Reviewer.

For Changes to already approved research/Unanticipated Problems/Noncompliance/SNI, if the original Primary Reviewer remains an active member of the IRB, he/she is the first choice to act as the Primary Reviewer for this IRB action. If that individual is no longer part of the IRB or is not available, the RSPP Office, in consultation with the IRB Chair as needed, assigns an IRB member who has adequate expertise in the area(s) of the research to act as the Primary Reviewer.

Reviewers are provided with IRB Reviewer Checklists and/or Reviewer Evaluation forms as a guide to ensure inclusion of the regulatory criteria, informed consent requirements, as well as other considerations related to the IRB action. It is recommended that assigned reviewers use
these Reviewer Checklists to assist in organizing and documenting reviews for presentation to committee members.

For Continuing Reviews, a Research Compliance Analyst (RCA) in the RSPP Office, who is a voting member of the IRB, is assigned as Primary Reviewer. The RCA completes a Continuing Review checklist which is provided to the IRB along with the application.

**May consultants to the IRB be used when reviewing research?**
The RSPP and/or IRB Chair may assign a consultant when expertise is needed to review the research. A consultant may attend the meeting to participate in the review and discussion of a research study (see RSPP Guidance: IRB Composition for more information on who may serve as Consultant to the IRB).

The consultant attends only the part of the IRB meeting discussing the study under his/her review. Following his/her review, the consultant is excused from the meeting. Because the consultant is not typically a voting member of the IRB, s/he is not able to serve as the Primary Reviewer. An additional Primary Reviewer is assigned to the IRB action.

The consultant may not have a significant financial or non-financial interest in the research study under his/her review. A possible consultant must complete a Conflict Of Interest Disclosure Statement prior to his/her review assignment. Should the proposed consultant have a related significant financial or non-financial interest with the study, he/she will not be allowed to act in this capacity.

The consultant must sign a confidentiality agreement prior to being forwarded research study materials.

A consultant may not vote on the research nor count towards quorum.

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**MEETING PROCESS**

**Are IRB member conflicts of interest taken into consideration?**
Yes. All IRB members (regular or alternate) are required to annually report any conflicts of interest he/she may hold via the Significant Interest questionnaire submitted to AAH Compliance (see AAH policy 2302/RSPP Guidance: Significant Interest/Conflict of Interest).

IRB members are reminded of their responsibility and actions relative to potential conflicts of interest at the start of each convened board meeting. If any member (or his/her immediate family) has a potential related financial or non-financial conflict-of-interest (e.g. IRB member is part of the research team) with a study on the meeting agenda, he/she must absent him/herself from that portion of the meeting where IRB deliberation/decisions relating to that study are made. An exception would be to provide information specifically requested by the IRB.

- Members are polled at the start of the meeting about any potential conflicts of interest with any study on the agenda.
• The absence of any IRB member due to a possible financial or non-financial conflict of interest will be documented in the meeting minutes as well as the reason for his/her absence.

If the IRB Chair (or his/her immediate family member) holds a Significant Financial Interest or Significant Non-Financial Conflict of Interest related to a study, the IRB Chair must recuse him/herself from the meeting, and another IRB member will preside over the meeting during the Chair’s absence.

• Any issue related to whether a Significant Financial Interest or Significant Non-Financial Interest exists with respect to the IRB Chair shall be resolved by the Institutional Official.

No IRB member may vote on any study in which he/she holds a possible conflict of interest. He/she will not count towards quorum on that action.

**Are past meeting minutes reviewed?**
Yes. The final draft of the IRB meeting minutes will be included with the meeting materials sent to members at the next convened meeting of the IRB committee. [See RSPP Guidance: Meeting Minutes for discussion on the creation, management and voting on meeting minutes.]

**Is continuing education provided at the meeting?**
If any continuing education has been planned by the RSPP office, copies of applicable materials are provided in the meeting packet. The IRB Chair will encourage discussion of the materials/topic at the meeting.

**What is the review process for any IRB action?**
Each activity requiring convened board review/consideration (initial/new study, continuing review, protocol amendment, SNI, UPIRSO or Non-compliance) is addressed individually by the IRB.

In advance of the convened board meeting the IRB Chair, IRB members, Primary Reviewer are expected to conduct an in-depth review of all provided materials so that an in-depth discussion may ensue at the meeting.

The assigned Primary Reviewer leads the discussion of the IRB action.

The Primary Reviewer presents the following to the convened board as necessary to the action:

- a summary of the activity requiring IRB review/consideration;
- concerns related to the research or informed consent document(s);
- recommendation on risk level;
- consideration of whether the research meets/continues to meet the regulatory criteria of approval (45 CFR 46.111 or 21 CFR 56.111);
• consideration of other regulatory issues as applicable to the research (inclusion of vulnerable populations, waiver/alteration of consent or authorization, non-significant risk determinations, etc.);
• a recommendation on IRB action (approve as submitted, approve with conditions, tabling/deferral of the action, or disapproval).

Following the Primary Reviewer presentation, the IRB Chair will lead the IRB committee members in an open and frank discussion of the study/IRB action. The members will discuss whether the regulatory criteria of approval are met/continue to be met, as well as any other pertinent regulatory issues (e.g. inclusion of vulnerable populations, non-significant risk determinations, etc.). Any controverted issues will be discussed, and if applicable, conditions of approval generated.

If the committee determines that the regulatory criteria cannot be met without substantive changes, the IRB Chair will hold a verbal vote on whether the research should be tabled/deferred. If tabled/deferred, this action will be noted in the meeting minutes along with a rationale for the decision.
• If tabled/deferred, the Research Compliance Analyst will provide the IRB’s recommendations to assist the Principal Investigator in making appropriate revisions.

If, based upon IRB discussion/deliberation, it seems apparent that the regulatory criteria cannot be met even with substantive changes, the IRB Chair will hold a verbal vote on whether the research should be disapproved. If disapproved, this action will be noted in the meeting minutes along with a rationale for the decision.

If the study has not been disapproved or tabled/deferred by verbal vote, the IRB Chair will ask the Research Compliance Analyst or other RSPP staff member in attendance to summarize any conditions of approval to be issued to the Principal Investigator. IRB members will be reminded that if conditions of approval are issued by the IRB, a vote to ‘approve’ the study/action requires that those conditions be met before the IRB approval letter is generated by the RSPP office.

The Chair will then instruct members to vote on the study/action. [More information on IRB actions can be found in RSPP guidance: IRB Decisions.] Voting at this time is accomplished via confidential ballot.

In all cases, pertinent comments and concerns of the IRB committee members will be recorded by the Research Compliance Analyst for inclusion in the meeting minutes.

**What happens if the Primary Reviewer is not able to attend the meeting?**
When the Primary Reviewer is not able to attend the meeting, written comments/completed reviewer checklist are requested to be provided. The IRB Chair will be informed of the Primary Reviewer’s absence as soon as possible. The IRB Chair will be responsible for presenting the Primary Reviewer comments and/or seeking consult/review from another IRB member or
consultant with adequate expertise in the area(s) of the research. The IRB Chair and/or convened board has the option of tabling/deferring the study/IRB action if adequate representation/expertise is not available at the meeting.

How is IRB member voting accomplished?
Voting occurs only after there has been a full, open discussion of the study/IRB action. Members are instructed to 'vote their conscience' by indicating their choice for study approval on the confidential voting ballot. Voting options on the ballot are For (Approve), Against (Disapprove), Abstain.

At the conclusion of the meeting, the ballots are collected by the IRB Coordinator or the ballot is sent to the IRB Coordinator via email. Members have 24 hours from the meeting to provide his/her ballot. The IRB Coordinator will make several attempts during this period to get the voting ballot from the member.

Following receipt of the ballots, the IRB Coordinator tabulates the votes and includes the voting tally in the meeting minutes.

- The ballot contains a place for the member to include his/her initials. This is done to ensure that no member with a known significant financial or non-financial conflict of interest votes on that study. There is no tracking of an individual member’s vote.
- Only those IRB members present for the entire discussion will have their vote counted.
- If a member does not provide a vote on an IRB action or his/her ballot was not returned within the 24-hour time period, but he/she was present at the meeting during deliberation, the member’s vote is documented as an abstention.
- The vote of the majority (> 50%) of the IRB members present at the meeting is required to determine the final approval status. For example, if 6 members are present, and this number constitutes quorum, 4 ‘For’ votes is required for approval of the study.
- If there is no majority of ‘For’ or ‘Against’ votes due to an elevated number of abstentions, the study will need to be returned to the convened board at a later meeting for further consideration of approval.
  - The IRB Coordinator will immediately notify the Research Compliance Analyst so that he/she may notify the PI of the need to table the study to the next convened board meeting.

If the tabulated vote is a majority of ‘Against’ votes (noting disapproval of the study), the IRB Coordinator will immediately notify the members who were in attendance and the Research Compliance Analyst of that decision.

Voting ballots are not retained after the votes are tabulated in the meeting minutes.

REQUIREMENTS
- Common Rule Regulations: 45 CFR 46 subpart C; 45 CFR 46.107, 111; 115, and 116
• FDA guidance – Institutional Review Boards Frequently Asked Questions
• RSPP Guidance: Meeting Materials, Significant Interest/Conflict of Interest, IRB Decisions