AAH RSPP GUIDANCE
Meeting Materials

PURPOSE
The purpose of this guidance is to outline the materials sent to the IRB members attending a convened IRB meeting.

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

GUIDANCE
What does a convened board meeting packet include?
An IRB meeting packet may include the following materials:
- Meeting agenda;
- Minutes from last convened board meeting of the IRB team;
- Educational materials;
- Resource materials pertinent to IRB review
  - Regulatory criteria of approval;
  - Appropriate IRB actions in the review of research;
- Materials for each activity that the convened board must review;
- Voting ballot.

What does the agenda include?
The agenda indicates:
- the meeting date, time and location/virtual meeting;
- educational topics for discussion;
- conflict of interest disclosure reminder;
- previous meeting minutes for review and approval;
- full board studies, full board modifications, and full board continuing reviews for review;
- Other business requiring full board review (possible UPIRSOs, possible serious and/or continuing noncompliance);
- previously approved exempt/expedited actions;
- notifications to the IRB.

What is included for each new research study to be reviewed by the convened board?
For each study to be initially reviewed by the convened IRB, all IRB members will receive, at a minimum, a copy of the following as applicable:
- Completed IRB application;
- Proposed informed consent document(s) and/or script as appropriate;
- The complete study protocol;
• Recruitment materials (Advertising) intended to be seen or heard by potential subjects, including flyers, media advertisements, e-mail solicitations, recruitment letters, and clinical trial web sites, if applicable;
• Sponsor’s sample informed consent, if applicable;
• Subject materials (questionnaires, surveys, diaries, etc.), if applicable;
• Any documentation from FDA related to a study with an IND or IDE (e.g. IDE letter or conditional approval letter);
• Delegation of Authority log.
• DSMB/DMC charter or prior reports.
• 502 form (prep to research or waiver of authorization), if applicable.

In addition to the above, the assigned primary reviewer or consultant to the IRB will receive the following as needed:
• Most recent Investigator Brochure or device manual (if applicable)
• Any adverse event reports submitted by the study sponsor with the protocol
• Primary Reviewer Checklist
• Case Report Forms/Data Collection Sheets (if applicable)
• Any other pertinent checklists
  o Drug/Device checklist
  o Vulnerable population checklists (e.g. research involving vulnerable populations (e.g. pregnant women or children), Department of Defense, Justice, et al. research, or research requesting use of a Legally Authorized Representative)

**What is included for each Change to Previously Approved Research to be reviewed by the convened board?**
For each study undergoing Change that must be reviewed by the convened IRB, all IRB members will receive, at a minimum, the following:
• The completed Change form, including a summary of the changes to the study;
• Correspondence from the sponsor, as needed
• Other modified documents (e.g. the annotated protocol, annotated consent document(s), application, recruitment tools, etc.) as applicable to the Change.

In addition to the above, the assigned primary reviewer or consultant to the IRB will receive the following as needed:
• Other revised documents (e.g. Investigator Brochure or Device Manual, etc.)
• Correspondence from sponsor
• Primary Reviewer checklist for convened IRB modifications.

**What is included for each Continuing Review to be reviewed by the convened board?**
For each study undergoing Continuing Review by the convened IRB, all IRB members will receive, at a minimum, the following:
• Completed Continuing Review application;
• A copy of the Continuing Review Checklist/Evaluation Form completed by the primary reviewer;
• Any submitted materials to address questions on the application;
• Current consent document(s) (when applicable).

In addition to the above, any consultant to the IRB for the Continuing Review will receive the following as needed:
• Complete protocol that includes any protocol modifications previously reviewed by the IRB;
• Any new information that could affect the risk level of the study or a subject’s willingness to participate/continue participation in the study;
• Any supplemental information pertinent to the study (UIRSO or Serious/Continuing Noncompliance Reports since the last review of the study; DMC or DMSB information; Sponsor’s annual report, etc;)
• Any information felt pertinent by the primary reviewer.

What is included for each Significant New Information (SNI), possible Unanticipated Problem Involving Subjects or Others (UIRSO) or Serious/Continuing Noncompliance to be reviewed by the convened board?
• Completed SNI form, Unanticipated Problem Reporting form or Noncompliance Reporting form;
• Any information provided by the PI to support the reported information;
• Any information provided by the Sponsor or others

In addition to the above, the assigned primary reviewer or consultant to the IRB will receive the following as needed:
• Latest version of IRB approved protocol;
• Latest version of IRB approved informed consent document(s);
• Any information felt pertinent to the event;
• Copy of RSPP UIRSO/NC review considerations.

Are convened board Primary Reviewer checklist(s) retained by the RSPP?
The Primary Reviewer shall use the appropriate checklist/review considerations to direct his/her presentation of the IRB action to the convened board. The minutes will document the discussion and controverted issues discussed by the IRB as well as document that the study meets/continues to meet the regulatory criteria for approval. Therefore, there is no need to retain the Primary Reviewer checklist for the study file.

REQUIREMENTS
• AAHRPP Accreditation Standards/Elements: I.5.D, II.2.G