AAH RSPP GUIDANCE

Suspension or Termination of IRB Approval

PURPOSE
During the conduct of human subject research, it may become necessary to suspend or terminate some or all research activities associated with an IRB approved protocol. Suspensions or terminations may be investigator/sponsor initiated or IRB initiated. For research overseen by the Advocate Aurora Health (AAH) IRB, in order to resume research activities, regardless of who initiated the suspension of research activities, a Change form must be submitted for IRB review requesting re-initiation of the study.

The purpose of this document is to outline the AAH IRB’s authority to suspend or terminate approval of human subject research overseen by the AAH IRB.

In research ceded to an external IRB, should the IRB of record suspend or terminate IRB approval of the research study, the PI must notify the AAH RSPP immediately.

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

GUIDANCE
*When does the Advocate Aurora IRB have the authority to suspend or terminate already approved research under their oversight?*

The Advocate Aurora IRB has the authority, per federal regulation (45 CFR 46.113) and institutional policy (System Policy 2467), to suspend or terminate already-approved research under their oversight at any time it is thought that subjects – current or future – may be at increased risk of harm. Situations where a suspension or termination of research may be warranted include:

- Research is not being conducted in accordance with IRB requirements, AAH system policy, or federal regulations regarding the protection of human subjects;
- new information becomes available that could alter the original determination by the IRB to approve the study;
- the research is associated with unexpected serious harm to research participants or others; or
- there are immediate serious issues involving participant and/or others safety.

This action is most often determined by a convened board, however an IRB Chair or Institutional Official has the authority to suspend some or all research activities if exceptional human subject safety issues are identified. This authority is only exercised if an action is required prior to a convened meeting and it is not feasible to assemble an emergency meeting. When this authority if exercised, it will be reported at the next convened IRB meeting.
What is a suspension or termination of IRB approval?
A suspension of IRB approval is a directive of the convened IRB, IRB Chair or Institutional Official to stop temporarily some or all previously approved research activities of that study.

- Suspended research studies are not closed with the IRB, and therefore remain subject to continuing review, and requirements for reporting Noncompliance and Unanticipated Problems (RSPP SOPs #5-8).

A termination of IRB approval is a directive of the convened IRB, IRB Chair or Institutional Official to permanently stop all previously approved research activities of that study.

- Terminated research studies are closed with the IRB, and therefore no further continuing review or reporting is required (unless dictated by the IRB).

What is the process for IRB suspension or termination of approved research?
The IRB may determine, during review of:

- reports of unanticipated problems or serious or continuing noncompliance,
- unexpected findings during continuing review or proposed changes to the research; or
- problems identified during protocol monitoring or quality review

that suspension or termination of the research is necessary.

The convened board, an IRB Chair or Institutional Official has the authority to suspend or terminate previously approved research.

1. An IRB Chair or the Institutional Official may take immediate action when it is required for the urgent protection of the rights and welfare of participants and insufficient time exists for the convened IRB to review the event.

   - Should urgent action to suspend or terminate IRB approval be taken by one of these individuals, an immediate notice of action will be provided in writing to the PI.
   - The act to suspend or terminate the research is placed on the next available meeting agenda of the convened IRB.

   - The convened board will review the urgent action taken, and uphold, overturn or supplement the decision.

2. If there is sufficient time for the convened board to act, the incident will be placed on the next available meeting agenda of the convened IRB.

In either case, the IRB meeting minutes will record any action taken by the IRB.
Determinations to suspend or terminate IRB approval may necessitate further investigation and review under the RSPP’s Noncompliance SOPs (#5 and 6)

May the IRB impose additional steps to be taken by the PI as a result of the suspension or termination of IRB approval?
Yes, as part of their review, the IRB will determine if any additional steps are to be taken as a result of suspension or termination of the research. Steps may include:

- Written notification to currently enrolled subjects that the research has been terminated. The communication to the subjects must be approved by the IRB and should contain an explanation of the rationale for the action taken;
- A plan to withdraw any enrolled subjects, considering the rights and welfare of those individuals before such a step is taken;
- Informing subjects of any follow-up procedures permitted or required by the IRB for subject safety;
- Follow-up reporting to the IRB of any subject notifications or withdrawals;
- Submission of reports to the IRB and the sponsor of any unanticipated problems or outcomes that occurred during the period when suspension or termination occurred.

The PI will be informed of these additional requirements in writing. Any additional requirements taken by the IRB are noted in the meeting minutes.

How are IRB approval suspensions or terminations documented?
Suspension or termination of IRB approval shall be documented in a written notice to the PI. The notice will include:

- A statement of the reasons for the action;
- Any additional steps to be taken by the PI;
- A request a plan for ensuring that the rights and welfare of all currently enrolled or previously enrolled (if appropriate) subjects are protected;
- An opportunity for the PI to respond to the decision in writing within 10 working days.

Any PI response by the will be reviewed by an IRB Chair or convened IRB.

What reporting requirements are necessary?
Suspensions and terminations of IRB approval require reporting to OHRP, FDA and other agencies/entities (see RSPP SOP #12: External Reporting).

What is an ‘Administrative Hold’?
An Administrative Hold is a voluntary action taken by the Principal Investigator or sponsor (via the PI) to temporarily or permanently halt some or all research activities of an IRB approved protocol. This may also be referred to as “Investigator/Sponsor-Initiated Termination or Suspension of a Research Protocol”. Some examples of when this would be appropriate
include: reporting of unanticipated problems, investigator going on a sabbatical leave or leave of absence.

Although the investigator may discuss this action beforehand with the IRB chair, RSPP Director or Institutional Official, the hold must be initiated voluntarily by the investigator and must not be used to avoid IRB mandated suspension or termination or reporting requirements.

A voluntary hold of research activities is reported to the IRB and is not considered to be a reportable event (per federal regulations and RSPP SOP 12) unless the IRB, IRB Chair or institutional official independently determines that suspension or termination of research activities must occur (see above) A voluntary hold does not need to be externally reported per the federal regulations. (See more information on Administrative Holds in the RSPP Guidance: Changes to Already Approved Research and RSPP SOP #4).

During an voluntary suspension of research activities, the research study is not closed with the IRB. Therefore, the research study remains subject to continuing review and requirements for reporting of Noncompliance and Unanticipated Problems (per RSPP SOPs #4, 5-8).

**How is an Administrative Hold requested of the IRB?**
If a research project is being terminated or suspended by the principal investigator and/or the sponsor based on a change in the risk-to-benefit ratio of study participation, the unanticipated event should be reported using an Unanticipated Problem reporting form within 5 working days of discovery (see RSPP SOP # 7). The voluntary action should also be reported on a Change form submitted in IRB Net.

If the reason for the voluntary action is administrative in nature (loss of funding, departure of PI, etc.) a Change form should be submitted through IRB Net within 10 working days of discovery.

**What is the process for review of Administrative Holds? Can further action be taken by the IRB?**
All reports of voluntary holds to research activities are first reviewed by a Research Compliance Analyst or the RSPP Director in the RSPP office. The Change form and any other materials related to the request are provided to the IRB Chair/institutional official along with a Suspension/Termination guidance/checklist. The IRB Chair or institutional official determines if further/immediate action is necessary (up to and including IRB suspension or termination of the approved protocol) especially if it is determined that the research is not being conducted in accordance with the IRB policies and procedures, or the study has been associated with unexpected harm to participants or others.

The authority to suspend or terminate an IRB approved protocol is only exercised if an action is required prior to a convened meeting and it is not feasible to assemble an emergency meeting. When this authority is exercised, it will be reported at the next convened IRB meeting.
Written correspondence on the IRB’s suspension or termination is provided to the PI. The IRB is made aware of any IRB suspension/termination at the next convened IRB meeting. Further consideration of the action may be taken by the convened board at that meeting.

The RSPP Director will ensure that any IRB suspension or termination are reported to internal and external agencies/individuals as outlined in RSPP SOP #12.

REQUIREMENTS

- Common Rule Regulations 45 CFR 46.113
- FDA Regulations: 21 CFR 56.113
- AAH System Policy: 2467
- AAH RSPP SOPs: 3-8, 12