AAH RSPP GUIDANCE

Significant New Information

PURPOSE
The purpose of this guidance is to instruct researcher/research team on what constitutes a Significant New information (SNI) and when/how it should be reported to the RSPP/IRB for studies overseen by the Advocate/Aurora IRB.

NOTE: The AAH RSPP separates reporting of Significant New information from the reporting of incidents that may or have caused harm to a subject or noncompliance.

- Information on any unexpected event in which harm or possible harm to the subject has or may occur (Unanticipated Problem- UP) must be reported as outlined in RSPP SOP #7 (UP Submission Requirements).
- Any event that deviates from the approved protocol or the human subject research (HSR) regulations or RSPP/ system policies, and has or may adversely affect the rights and welfare of human subjects or significantly compromise the quality of the research data (Noncompliance) is to be reported as outlined in RSPP SOPs 5 (Noncompliance Submission Requirements). Both SOPs can be found on the RSPP website.

Events reported as SNI may also be considered by the IRB as UPs or Noncompliance.

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

GUIDANCE

What is Significant New Information?
Significant New Information is information about a research study or the agent under study that may not necessarily indicate an immediate harm to a research subject, but may affect the conduct of the study or the subject and/or his/her willingness to continue participation in the research.

Examples of significant new information may include (not exhaustive list):

- Reports generated from a Data and Safety Monitoring Board (DSMB) or sponsors (annual reports) indicating problems in the conduct of the study;
- Reports of adverse events of the agent under investigation, or similar agents, from sources outside of the current research study (e.g. approved uses of the agent, reports from other research studies, etc.);
- Malfunctioning of equipment that did not cause harm to a research subject but could cause jeopardy to the research study, and necessitated the issuance of an Incident Report to the institution;
- Disruption of supply of investigational agent or other drug/device required for the study;
• Complaint of a subject that cannot be resolved by the research team but does not indicate that subjects or others may be at increased risk of harm or at risk of a new harm;
• Revised Investigator’s Brochures/Device Manuals noting a change in risk level or frequency of potential harm, or drug/device design or manufacturing. These changes may also require reporting as a Change to the approved study (RSPP SOP #9: Changes to Previously Approved Research-Submission Requirements) if the protocol or informed consent require revision;
• Publications/literature that may raise concern about efficacy or safety of the agent under investigation;
• audit reports by the sponsor, the FDA, or others indicating a serious or potentially serious issue in the conduct of the study;
• sponsor’s letter/memo indicating a temporary halt or sudden closure of the research study that may or may not be due to possible risk of harm (e.g. loss of funding).

Information other than that listed above may also rise to the level of reportable SNI. If there is a question of whether the new information should be reported as SNI, contact the RSPP for assistance. If not reportable as SNI, information may also be required to be submitted at the time of continuing review (e.g. latest DSMB or annual reports).

NOTE: Reports of subject incarceration or pregnancy of a research subject should not be reported to the IRB as a SNI. Rather this information should be reported as an UP (per RSPP SOP #7).

How should SNI be reported?
Reports of SNI should be submitted to the AAH RSPP using the form Significant New Information as outlined in RSPP SOP #3.

When should SNI be reported?
Significant New Information not reportable as UP or Noncompliance should be reported as soon as possible, but in no case, no later than 14 working days from the date of discovery or report to/from regulators.

How will the information be reviewed by the IRB?
• The initial SNI report will be reviewed by a Research Compliance Analyst (RCA) in the RSPP Office.
• The RCA may escalate the review of the report to the IRB Chair or designated reviewer as needed.
• The RCA or designated reviewer will consider whether the SNI describes information that requires further review and/or the information describes a reportable UP or incident of Noncompliance.
If the report indicates that convened board review is needed, the study will be placed on the next available IRB meeting. If convened board review is necessary, a Primary Reviewer will be assigned, and materials provided to the IRB as described in RSPP Guidance documents: Convened IRB Meeting Administration and Meeting Materials.

What actions may the IRB take in consideration of the SNI?
The IRB may decide that the SNI:

- requires action on the part of the PI or institution;
- meets the definition of an UPRISO or Noncompliance;
- has or will cause changes to the study design/conduct.

As in cases of UPIRSO or Noncompliance, the IRB may consider a range of options in addressing the SNI:

- Suspension or termination of the research;
- Notification of current subjects when such information may relate to subjects’ willingness to continue to take part in the research;
- Modification of the protocol and/or informed consent;
- Providing additional information to past subjects;
- Requiring current subjects to re-consent to participation;
- Modification of the continuing review schedule;
- Monitoring of the research by CQAIR or the IRB;
- Monitoring of the consent process;
- Other actions as determined by the IRB, e.g. suspension of Research Privileging of the investigator.

Deliberations and action taken by the IRB will be documented in the meeting minutes. Should the SNI be deemed an UPIRSO or serious/continuing Noncompliance, external reporting will be completed as outlined in RSPP SOP #12.

The PI/research team will receive written comments/instructions on next steps provided by the RSPP Office.

REQUIREMENTS

- AAHRPP Accreditation Standards/Elements: II.2.G
- RSPP SOPs: 3, 5, 7, 9, 12
- RSPP Guidance documents: Convened IRB Meeting Administration, Meeting Materials.