AAH RSPP GUIDANCE
Research Complaints

Purpose
The purpose of this document is to outline the process to receive and act on complaints regarding the conduct of human subject research at Advocate Aurora Health (AAH).

A complaint is the dissatisfaction or uncertainty voiced by an individual about some aspect of research conduct. Complaints do not involve non-compliance (allegations or fact) or research misconduct. [Noncompliance, allegation or fact, is addressed in RSPP SOP #5 and #6. Incidents of Research Misconduct are addressed in system policy 2490.]

Examples of complaints include:
1. A participant expresses dissatisfaction with the repeated late arrival of key research personnel for study visits, or
2. An employee, concerned about the appropriateness of a study protocol, seeks clarification from the IRB Chairperson, or
3. Subject issues with rectification of research billing.

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

Guidance
Where do research complaints originate?

AAH and the RSPP are committed to protecting the safety and welfare of human research participants, maintaining the scientific integrity of research conducted at our facilities, upholding the highest standards of ethical and professional conduct, and complying with application of Federal, State and local laws and regulations pertaining to human subject research. For this reason, research subjects are provided (in the informed consent document), with the phone number of the Research Subject Protection Program (RSPP) office, and an assurance the RSPP will address questions regarding their rights as research subjects, problems, concerns, complaints, requests for information or any input they wish to provide. Additionally, the RSPP website includes a section for the subject, or anyone else, to report concerns, or complaints about the conduct of human subject research conducted at AAH or by an AAH affiliated researcher. All complaints from any individual, including patients, research subjects or their family members, AAH research staff or other team members, and IRB members are taken seriously and are investigated.
The Principal Investigator/study team is responsible for ensuring the that all research informed consent document(s) contains accurate contact information for the PI/Study Team as well as the AAH Research Subject Protection Program (RSPP) office.

**How are complaints, concerns, or problems reported?**

Complaints may be submitted in any form (e.g., phone, written, e-mail), and may be anonymous. The complainant should be informed that if submitted as anonymous, no resolution/follow-up activity will be able to be shared.

If a concern, complaint or suggestion is made verbally (e.g., interpersonal conversation, phone call), every effort will be made to obtain the following information and record it in a written record of the verbal notification:

- Name of the individual making the complaint/suggestion [unless wishing to remain anonymous]
- Method of preferred contact for clarification or follow-up purposes
- Research study name or number (if applicable)
- The individual’s relationship to the study/situation (i.e. past or present subject, subject’s family member, study team member, etc.)
- Whether the reported has contacted any other person about the incident
- Specific information on issue/situation (including dates if possible)

The complainant will be encouraged to provide a written document outlining the issues from his/her perspective, but this is not required.

The complainant should also be informed that his/her identity will be protected to the extent possible. However, complete confidentiality cannot be guaranteed during the investigation.

Advocate Aurora Health will not tolerate any reprisal, retaliation, intimidation, coercion, or discrimination against the Complainant or those individuals participating in the review or investigation of any complaint.

**Who is responsible for acknowledging or addressing a complaint, concern or problem?**

Concerns, problems or complaints about the conduct of human subject research may be reported to numerous individuals, including but not limited to the research team/investigator, AAH Research Institute (AARI), Compliance/Privacy, IRB Chair, or the RSPP Office. It is the responsibility of the individual to whom the concern, problem, complaint is reported to take the matter seriously.

If the complaint is reported to the RSPP Office, the issue will be forwarded to the RSPP Director for handling. Others in their respective areas (AARI, research team, Compliance/Privacy) will need to establish who in that area is responsible for acting on the reported issue. In all instances, someone from the respective group (AARI, research team, Compliance, IRB, RSPP)
Office) must ensure an investigation of the issue is begun, at what point others in the organization should be involved, and an attempt to resolve the issue is made.

Following the investigation of the issue, the complainant should be contacted (if possible) to report action taken. In addition, a follow-up report should be made to the research team/investigator, AARI, IRB or others as necessary.

When/How are complaints, concerns or problems reported to the IRB?
- Routine complaints, problems, or concerns that are anticipated, and have been resolved by the research team or other individual(s) receiving the report (e.g. routine billing questions/issues, problems with the research team, etc.) do not need to be immediately reported to the IRB. These formally submitted complaints should be reported to the IRB on the next Continuing Review application.
- If no further continuing review is required of the study, and the issue is not unexpected and has been resolved, record of the issue and any action take should remain in the study file for future reference/use.
- Complaints not resolved by the individual(s) receiving the report, or those of a more serious nature, including those that are potential unanticipated problems involving risk to subjects or others (UPIRSO), should be promptly reported to the IRB.
  - Complaints that cannot be resolved by the receiver but that do NOT meet the definition of an unanticipated problem involving risk to subjects or others should be reported to the IRB on the Significant New Information form within 14 days of discovery. An IRB member will review the information and escalate the report to the convened IRB if necessary.
  - Complaints or problems that are unanticipated in nature and involve risks to subjects or others (UPIRSO) must be reported to the IRB no later than 5 working days from discovery on an Unanticipated Problem Reporting form as indicated in RSPP SOP #7. An IRB member will review the report and escalate it to the IRB as necessary per RSPP SOP# 8.

Is the complainant informed of the resolution of the complaint, concern or problem?
Yes, as long as the initial event was not reported anonymously, every effort will be made to report on the resolution of the event.

References:
- AAH RSPP SOPs: 7, 8
- OHRP Guidance on Continuing Review
- RSPP Guidance: Significant New Information