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|  Advocate Aurora Health Research Subject Protection Program SOP | NO: | 7 |
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| | EFFECTIVE DATE: | 6/10/22 |
| | LAST REVISION DATE: | 4/14/22 |
| | LAST REVIEW DATE: | 6/8/22 |

1. PURPOSE

To define the various types of unanticipated problems related to human subject research and outline submission requirements.

2. SCOPE

This SOP applies to all human subject research reviewed by Advocate Aurora Health's (AAH's) IRB and conducted by researchers on staff at or affiliated with AAH, conducted at any AAH facility, or utilizing individually identifiable data of AAH patients.

Note: If research is Ceded to an External IRB, the external IRB's policy on reporting of unanticipated problems must be followed. However, there is also an obligation for study teams to report to the AAH RSPP Office any unanticipated problems that occur at local/AAH sites. These incidents should be reported to the AAH RSPP at the time that they are reported to the external IRB. See RSPP SOP #3 and the AAH RSPP guidance: *Deferral/Ceding of IRB Oversight to an External IRB* for more information on AAH UP reporting requirements in Ceded Research.

3. DEFINITIONS

External Unanticipated Problem is an Unanticipated Problems that occurs on a multi-center study that AAH is engaged in but does not occur at an AAH facility (i.e., the Unanticipated Problem occurs at another center). [External Unanticipated Problems are not Unanticipated Problems that occur in studies ceded to non-AAH IRB.]


Local Unanticipated Problem is an Unanticipated Problem that occurs at a site for which AAH IRB has oversight.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Others may include but is not limited to research subjects' family members, health care providers and research staff.

Significant New Information is any information not previously reported to the IRB about the research that may relate to subject's willingness to continue participation. Significant new information may be revealed in publications, data safety monitoring reports, interim study results, revised package inserts, or other material.

Subject is a living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

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Unanticipated Problem (UP) is any incident, experience or outcome that is:

- a) unexpected in terms of its nature, severity or frequency given the research and the characteristics of the Subject population being studied;
- b) regarded as unwelcome or harmful and something that may need to be dealt with or overcome; and
- c) is related or possibly related to the research.

UPs might include but are not limited to:

- (1) Complaints from Subjects or Others
- (2) Breaches of privacy or confidentiality
- (3) A series of adverse events and rarely a single adverse event (see [FDA](#) and [OHRP guidance](#) for a description of on those adverse events FDA and OHRP consider Unanticipated Problems Involving Risks to Subjects or Others requiring reporting to the IRB)
- (4) Events determined by a sponsor or multi-center lead PI to be meet the definition of a UPIRSO
- (5) Changes made to research without prior approval in order to eliminate apparent immediate harm
- (6) An unintentional change in the study plan for an individual Subject or series of Subjects
- (7) Subject noncompliance (e.g., missed dosing, refused appointment)
- (8) Significant New Findings
- (9) Other incidents, experiences or outcomes that are unexpected, related to the research, and unwelcome or harmful and something that may need to be dealt with or overcome.

Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO) is an Unanticipated Problem that the IRB Chair/designee determines involves a new or increased risk to Subjects or Others (including physical, psychological, economic or social) that either might affect Subjects' willingness to continue participation or requires some action (e.g., modification of the consent process, informing participants, modifying the study protocol or procedures, etc.).


4. POLICY

This SOP implements requirements at sections IV.B.7.a) & b), IV.B.8.a) and IV.B.10) of AAH System Policy– *Research Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURE

5.1 What to Report

- a) Local UPs that, in the judgement of the PI or study sponsor, are determined to more likely than not meet the definition of an Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO).
- b) External UPs that the sponsor or lead PI of a multi-center trial has determined meets the definition of a UPIRSO.

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5.2 When to Report

- a) Report within 5 working days of discovery.
- b) Report regardless of whether the UP occurred during the study, after study completion, or after participant withdrawal or completion.

5.3 How to Report

- a) Report UPs using the RSPP *Unanticipated Problem Reporting* form. Submit the report to AAH IRBNet.
- b) If there are also changes to previously approved research as a result of a UP, report those in accordance with RSPP SOP 9 - *Changes to Previously Approved Research--Submission & Implementation Requirements*.

5.4 Reporting

See RSPP SOP 12 – *External Reporting* for reporting procedures.

CROSS REFERENCES:

RSPP SOP 3 – Post-Approval Responsibilities & Submissions

12 – External Reporting

RSPP Guidance – *Deferral/Ceding of IRB Oversight to an External IRB*

AAH System Policy– *Research Involving Humans or Their Identifiable Data or Biospecimens*

OWNER:

Director, Research Subject Protection Program

REFERENCES:


45 CFR 46.103(b)(5)

21 CFR 56.108(b)

AAHRPP Element II.2.G. & II.2.I.

PRIOR REVIEW / REVISION DATES:

1/3/22 (effective 1/24/22)

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