1. PURPOSE

To define the various types of noncompliance related to human subject research and detail processes for reporting Noncompliance and Allegations of Noncompliance.

2. SCOPE

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

3. DEFINITIONS

Noncompliance: The failure (intentional or unintentional) of an Investigator, his/her designees, IRB members, Research Subject Protection Program (RSPP) staff members, or others involved in the conduct or review of research involving human subjects to adhere to:

a) federal, state or local human subject protection laws, regulations, or policies:

b) AAH system policy *Research Involving Humans or Their Identifiable Specimens*;

c) AAH RSPP standard operating procedures governing the review and conduct of human subject research;

d) IRB determination; and/or

e) IRB-approved protocols, excluding changes made to eliminate apparent immediate hazard to subjects (see RSPP SOP #9, *Changes to Previously Approved Human Subject Research*).

Noncompliance may be related to studies reviewed by AAH's IRB as well as studies ceded to an external IRB.

Note: Noncompliance does not include failure by the study subject to follow protocol or investigator/study team instructions.

Examples of Noncompliance include but are not limited to:

a) Failure to obtain IRB approval prior to <u>any</u> protocol change

b) Failure to follow protocol (e.g., out of window visits, dosing error, lab processing error, inclusion/exclusion criteria error, etc.) except for those caused by study subjects (e.g., subject refused follow-up appointment, subject failed to take prescribed drug despite instructions, etc.)

c) Failure to obtain or document informed consent or failure to use the IRB approved consent form or other material;

d) Failure to obtain IRB approval for human subject research;

e) Failure to follow AAH system policies on human subject research or RSPP/AAH IRB SOPs;

f) Failure to follow study-specific IRB directives;

g) Failure of the IRB or RSPP caregivers to follow applicable regulatory requirements (e.g., make required determinations);

h) Inappropriate use of expedited review by IRB Chair or others.

Allegation of Noncompliance: An assertion (made by a second party) of Noncompliance that must be proven or supported with evidence to either confirm or deny.

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research Misconduct does not include honest error or differences of opinion. See AAH system policy - *Research Misconduct* for definitions of fabrication, falsification and plagiarism.

Self-reported Noncompliance: Noncompliance reported by the individual or group responsible for the activity under which the Noncompliance occurred.

4. POLICY

This SOP implements requirements at sections IV,B.7., IV.B.8.a).(3) and IV.D.2.m) of AAH System Policy – *Research Involving Humans or Their Identifiable Data or Biospecimens*.

5. PROCEDURE

Follow steps outlined in section 5.1 for noncompliance that occurred on a study you or your team is responsible for. Follow steps outlined in section 5.2 if alleging noncompliance on the part of someone who is not a member of the study team. Allegations of Research Misconduct should be reported in accordance with AAH system policy *Research Misconduct*.

5.1 Self-reported Noncompliance

a) What to Report – Report anything meeting the definition of Noncompliance (see definitions above).

b) When to Report – Report as soon as possible but in no case later than 10 working days from the date of discovery.

c) How to Report

i) Noncompliance by investigators or others engaged in the research:
(1) report to the RSPP Office using the RSPP *Noncompliance Report Form* submitted via AAH IRBNet;
(2) if reported by other than the principal investigator, notify the PI prior to or at the time of *Noncompliance Report Form* submission.

ii) Noncompliance by the IRB, IRB member or RSPP team – Report via *RSPP/IRB Noncompliance Reporting Form* and submit to the Research Compliance Officer (RCO).

5.2 Allegations of Noncompliance

a) When to Report – Report Allegation of Noncompliance at any time.

b) How to Report. Allegations of Noncompliance should be reported to the Research Compliance Officer via email, or for those wishing to remain anonymous, via the Compliance Hotline.

5.3 Reporting

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

CROSS REFERENCES:	RSPP SOP 12 – *External Reporting* RSPP Guidance: *Deferral/Ceding Of IRB Oversight To An External IRB* AAH system policy - *Research Misconduct* *Research Involving Humans or Their Identifiable Data or Biospecimens*
OWNER:	Director, Research Subject Protection Program
REFERENCES:	21 CFR 56.108(b) 45 CFR 46.108(b)(4)(i) OHRP Guidance on Written IRB Procedures (July 1, 2011) AAHRPP Element I.5.D.
PRIOR REVIEW / REVISION DATES:	10/6/21 (effective 11/3/21); 1/3/22 (effective 1/24/22)