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1. PURPOSE

To detail processes for RSPP Office and IRB review and subsequent reporting of 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

Continuing Noncompliance: Noncompliance (serious or non-serious) that continues to occur despite previous identification of the problem and subsequent corrective and preventive action, and which the reviewer or reviewing body, as applicable, has determined that, if allowed to continue, is likely to adversely affect the rights, welfare and/or safety of research subjects or adversely affect the scientific integrity of the study/data.

Investigator Noncompliance - Noncompliance by investigators or others engaged in or conducting the research.

IRB Noncompliance - Noncompliance by the IRB, IRB member or RSPP team member.


Serious Noncompliance: Noncompliance that in the judgement of the reviewer or reviewing body, as applicable, has been determined to:

- (a) result in hospitalization or an irreversible, long-term, life-threatening or fatal medical occurrence, or require medical or surgical intervention to prevent one of these outcomes;
- (b) Significantly increase the potential risk of harm to study subjects should the noncompliance recur;
- (c) Significantly compromise subject rights; or
- (d) Significantly impact the integrity of the study/data.

Severity: A Non-compliance designation of Serious, Continuing or Other Noncompliance

Significantly: In a way that is important enough to be worthy of attention or have an effect.

4. POLICY


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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


5.1 Self-reported Noncompliance

- a) RSPP team member (for Investigator Noncompliance) or Research Compliance Officer/designee (for IRB Noncompliance) reviews reported Noncompliance as soon as possible but in no case later than 5 working days of receipt.
- b) Reviewer obtains clarifying information as necessary and determines Severity or consults with RSPP Director, IRB Chair/Institutional Official or Chief Compliance Officer, as applicable, if unable to determine Severity.
- c) If severity of Investigator Noncompliance is initially determined to NOT meet the definition of serious or continuing:
 - i) Reviewer/designee determines whether additional action is necessary, documents action/decision on the RSPP *Noncompliance Reporting Form*, publishes form in IRBNet, and, as needed, provides written communication to the study team on any required additional action in IRBNet . Correspondence within IRBNet is available to all who are shared access to the study in the IRBNet system, including the reporter of the event, the Principal Investigator, and others as applicable.
 - ii) If Investigator Noncompliance and occurring on a study that has been ceded to an external IRB, RSPP Office will verify that the study team has reported the Noncompliance to the IRB of Record or direct them to do so as necessary. No local IRB review will occur. The completed *Noncompliance Reporting Form* will be published in the IRBNet system. The published form is available to all who are shared access to the study in the IRBNet system, including the reporter of the event, the Principal Investigator, and others as applicable. The RSPP Database will be updated with outcome.
- d) If severity of Investigator Noncompliance is initially determined to meet the definition of serious or continuing:
 - i) Reviewer/designee determines whether additional immediate action is necessary to alleviate apparent immediate risks to Subjects or Others or prevent immediate recurrence of the Noncompliance and documents action on the RSPP *Noncompliance Reporting Form*. If immediate action is needed, verbally communicates immediate action to PI and follows up

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in writing via IRBNet. Correspondence within IRBNet is available to all who are shared access to the study in the IRBNet system, including the reporter of the event, the Principal Investigator, and others as applicable.


- (a) RSPP team member schedules the item for further review at the next available convened IRB meeting following standard procedures for assignment of reviewer(s) and distribution of meeting material to IRB. (Additional information on IRB reviewer and roles in reviewing noncompliance and materials to be distributed may be found in *Meeting Materials* and *Convened IRB Meeting Administration* RSPP Guidance documents.);
 - (b) Convened IRB reviews Noncompliance Report, provides a final Severity determination and approves/issues a corrective and preventive action plan;
 - (c) RSPP office documents IRB's determination on the *Noncompliance Reporting Form*. The completed report is published in IRBNet, thereby communicating to the study team the outcome of the convened board review and any required additional corrective or preventive action. The published form is available to all who are shared access to the study in the IRBNet system, including the reporter of the event, the Principal Investigator, and others as applicable.
 - (d) RSPP will report any Serious and/or Continuing noncompliance as outlined in section 5.5 of this SOP/RSPP SOP #12.
 - (e) RSPP will update the RSPP Database with outcome.
- ii) If occurring on a study that has been ceded to an external IRB, RSPP Office will verify that the study team has reported the Noncompliance to the IRB of Record or direct them to do so as necessary. No local IRB review will occur. The completed *Noncompliance Reporting Form* will be published in the AAH IRBNet system. The published form is available to all who are shared access to the study in the IRBNet system, including the reporter of the event, the Principal Investigator, and others as applicable. The RSPP Database will be updated with outcome.
- (a) The IRB of Record will determine whether the reported noncompliance incident is serious and/or continuing per their policies.

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- (b) The AAH RSPP will receive a copy of Noncompliance decisions per terms of reliance agreement executed between AAH and the external entity.
- e) If IRB/RSPP Noncompliance:
 - i) If Noncompliance is initially deemed to meet definition of Serious or Continuing Noncompliance,
 - (a) Research Compliance Officer (RCO)/designee schedules the item for further review by the Research Compliance Committee (RCC);
 - (b) RCO presents the Noncompliance issue to the RCC at a convened meeting, by phone or via email within three weeks of the initial determination whenever possible;
 - (c) RCC makes the final determination of Severity and approves proposed corrective and preventative action and/or requires additional action;
 - (d) RCO communicates RCC findings and any additional required action, via the completed *RSPP/IRB Noncompliance Reporting Form*, to the individual who reported the Noncompliance, the Institutional Official and IRB, IRB Chair(s) and/or RSPP team member(s) and RSPP leader, as applicable.
 - ii) If IRB Noncompliance is initially deemed to NOT meet definition of Serious or Continuing Noncompliance,
 - (a) RCO/designee documents and communicates outcome of review and any required additional corrective or preventive action via the completed *RSPP/IRB Noncompliance Reporting Form* to the individual who reported the Noncompliance, the Institutional Official and IRB, IRB Chair(s) and/or RSPP team member(s) and RSPP leader, as applicable.

5.2 Allegations of Noncompliance

- a) Determining Whether Alleged Noncompliance has a Basis in Fact.
 - i) Allegations will initially be reviewed by the RCO as soon as possible but in no case later than 5 working days of receipt.

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- ii) RCO will convene a panel of reviewers consisting of the Institutional Official /designee, RSPP Director/designee, and appropriate AARI Leader and may adjust membership to address potential conflicts of interest, needed expertise, etc.
 - iii) The RCO/designee will notify the investigator, or any caregiver(s) named in or otherwise involved in the Allegation before conducting the investigation.
 - iv) RCO/designee may gather or assign a panel member/designee responsibility for gathering information for the panel.
 - v) Panel will meet in person, via phone or email and will determine whether Allegation has a basis in fact and meets the definition of Noncompliance within 30 days from receipt of Allegation. An extension may be granted by the Chief Compliance Officer for purposes of additional fact gathering,
 - vi) The panel will respect the confidentiality of the individual reporting the Allegation as well as those named in or otherwise involved in the Allegation to the extent possible.
- b) Determined to be Based in Fact. If the panel determines Allegation has a basis in fact and meets the definition of Noncompliance, the RCO/designee will:
- i) document and communicate determination to the individual who reported the Allegation, Principal Investigator and any individual named in or otherwise involved in the Allegation;
 - ii) complete a *Noncompliance Reporting Form* or *RSPP/IRB Noncompliance Reporting Form* as soon as possible but in no case later than 10 working days from the date of panel determination;
 - iii) work with the Principal Investigator or any individual named in or otherwise involved in the Noncompliance to propose a corrective and preventive action plan.
- RSPP Office will conduct determination of Severity of Noncompliance and review of corrective and preventive action in accordance with section 5.1.
- c) Determined not to be Based in Fact. If the panel determines Allegation does not have a basis in fact or does not meet the definition of Noncompliance, the RCO/designee documents and communicates the determination to the individual who reported the Allegation, Principal Investigator and any individual named in or otherwise involved in the Allegation.

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- d) If Unable to Determine if Based in Fact. If the panel is unable to determine whether an Allegation has a basis in fact and/or meets the definition of Noncompliance or is otherwise unable to adequately investigate an Allegation, the RCO/designee will consult with and/or defer the matter to the Chief Compliance Officer or the Institutional Official. After a determination is made, the RCO/designee will take the steps noted in 5.2.b) or c), as applicable.

Note: If a Noncompliance report is received within a reasonable timeframe (even if past due) that correlates with an Allegation of Noncompliance, the originator of the Allegation will be notified, and the Allegation will be dismissed.

5.3 Dispute Resolution.

If there is disagreement about the initial determination of Noncompliance, the corrective or preventive action required, or if there is any other disagreement about the Noncompliance investigation or determination, the matter will be referred to the following individuals for resolution: (1) if the initial review was conducted by the RSPP (Director or team member), the issue will be referred to the IRB Chair or Institutional Official, and ultimately the IRB if needed; (2) If the initial review was conducted by the Research Compliance Officer, the issue will be referred to the Chief Compliance Officer, and ultimately the RCC if needed.

5.4 Additional Noncompliance Reviews


Periodic Prioritization of Research Monitoring and Education. As requested, RSPP will provide a summary of the various types of Noncompliance (e.g., dosing errors, data sharing/protection issues, informed consent errors, etc.) to the Council for Quality Assurance and Improvement in Research (CQAIR). CQAIR may use this data to determine monitoring and/or education priorities.

5.5 Reporting to regulatory agencies and institutional officials

Findings of serious or continuing noncompliance by the convened board will be reported via written communication to regulatory agencies and institutional officials, and others as applicable, in accordance with the RSPP SOP #12 – *External Reporting*.

Reporting of IRB determinations of Serious and/or Continuing Noncompliance in Research Ceded to an External IRB will be made per the terms of the executed reliance agreement.

5.6 RSPP Office will retain submitted materials and documentation of determinations in accordance with AAH record retention requirements as noted in AHC system policy – *AAH Record Retention, Storage and Destruction*.

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CROSS REFERENCES:

RSPP SOP #12 – *External Reporting*

RSPP Guidance – *Meeting Materials*

Convened IRB Meeting Administration

AHC system policy – *AAH Record Retention, Storage and Destruction*

Research Involving Humans or Their Identifiable Data or Biospecimens

OWNER:

Director, Research Subject Protection Program

REFERENCES:

21 CFR 56.108(b)

45 CFR 46.103(b)(5)

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)