Action Plans for Research

Background

Action plans are required to develop and document the response to noncompliance or unanticipated risk or harm that arises in the conduct of a research study or in an operational or administrative process that supports the conduct of research at KPNW. The purpose of an action plan is to assess the root cause of the event(s) or circumstances and implement a timely, effective, measurable response that corrects or mitigates the issue to the extent possible and prevents it from recurring.

KPNW Research Compliance is accountable for providing assistance to researchers and operational departments supporting research when an action plan is necessary, and for monitoring and documenting the implementation of these action plans.

Purpose

The purpose of this policy and procedure is to document the Kaiser Permanente Northwest (KPNW) process for receiving, reviewing, evaluating, and escalating action plans that result from non-compliance related to research, or new unanticipated risk or harm to research participants.

Scope

This policy and procedure applies to all research conducted by employees of KPNW or conducted within KPNW facilities.

Definitions

Action Plan: Also known as Corrective and Preventative Actions (CAPA) or Corrective Action Plans (CAP). The root cause analysis used to identify, implement, track, and evaluate effectiveness of actions taken as a result of a new incident of non-compliance, unanticipated risk or harm.

Action Plan Owner: The person responsible for producing and implementing an action plan to minimize or resolve a risk or issue of non-compliance.

Compliance: Adherence to applicable research-related policies and procedures, including state and federal laws and regulations.

Correction: The remedy of an incident of new non-compliance, unanticipated risk, or harm.

Corrective Action: An action taken to eliminate causes of an incident of non-compliance, risk, or harm.
Monitoring: The regular, ongoing observation, collection and recording of data or activities to validate adherence to applicable laws and standards.

Non-Compliance: Failure to follow applicable federal or state laws or regulations, KP policies, IRB determinations, or the IRB-approved research protocol.

Preventive Action: An action taken to eliminate causes of an incident or other undesirable situation in order to prevent a recurrence – usually longer term and may be broader in scope. Preventive actions are not dependent on the occurrence of non-compliance. They are initiated to eliminate potential causes of non-compliance, unanticipated harm, or risk.

Root Cause: Root cause is used to describe the depth in the causal chain where an intervention could reasonably be implemented to improve performance or prevent an undesirable outcome. Root cause analysis is a tool to help identify not only how an event occurred, but also why it happened.

Policy

1. The need for an action plan may be identified as the result of a specific incident of non-compliance, continuing non-compliance, or because of an unanticipated risk or harm to a research participant(s), the integrity of the study, or institutional risk. Examples include but are not limited to:
   a. Reportable New Information (RNI) as defined by HRPP policy (protocol violation, unanticipated problem, serious non-compliance, continuing non-compliance, etc.)
   b. participant complaint
   c. audit or internal monitoring
   d. breach of confidentiality

2. The need for an action plan will be evaluated by Research Compliance, the IRB, and/or Clinical Research Support Services (CRSS), as applicable, at the time of the incident’s discovery. An action plan may be required based on the impact to the protection of study participants, the integrity of the study, and regulatory requirements. Principal investigators are ultimately responsible for the conduct of the study and thus for any action plans related to their study. Some incidents may also require reporting to the IRB per KP-SOP-502.

3. The content of an action plan will be evaluated and approved by Research Compliance (including a delegate of the Research Compliance Manager or the Research Compliance Committee [RCC], per the RCC Charter), the IRB, and/or CRSS, as applicable. Action plans must contain:
   a. A root cause analysis of the incident;
   b. Corrective and preventive actions appropriate to the situation;
Action Plans for Research

4. Research Compliance will work with the IRB, CRSS, Center for Health Research leadership, Regional Compliance, and other departments and individuals as appropriate to evaluate, implement, track, and monitor compliance with research-related action plans in accordance with the procedures below.

**Procedures**

Researchers and operational departments supporting research are responsible for:

1. Recognizing when an issue exists that requires an action plan.

2. Reporting the issue to the appropriate entities: CRSS, Research Subjects Projects Office (RSPO)/IRB, Research Compliance, Regional Compliance, etc. per applicable policy and procedures. See SOP KP-502.

3. Developing thoughtful and complete action plans about which they may consult with Research Compliance, CRSS, or RSPO as needed. See appendices for resources and forms. Submitters are encouraged, but not required, to use the Action Plan Template in Appendix A.

4. Implementing the action plan as approved and maintaining documentation to demonstrate compliance.

Research Compliance or Clinical Research Support Services will:

1. Assist researchers and operational departments in creating action plans, as needed or requested.

2. Receive and evaluate action plans for completeness and effectiveness.

3. Track approval of action plans by the RCC (if delegated by Research Compliance Manager or designee), the IRB (if reportable as RNI), or Research Compliance. The Research Compliance team will work with internal audit, Regional Compliance, or other KP departments as needed.

4. Enter action plans into a tracking system to monitor and document follow-up and completion.
5. Update the Research Compliance Committee regularly about any on-going and completed action plans. The Regional Compliance Office (RCO), CHR Leadership, and KFRI will be included as needed.

6. Escalate action plans when warranted as follows:
   
a. **IRB:** If the incident is reportable and has not been submitted for IRB review, the PI or research staff must submit an RNI and include an action plan. See SOP KP-502 and RNI report in the eIRB. The IRB may also be required to escalate the report to any or all of the following entities in this list.

b. **OHRP:** Research Compliance must report to OHRP any unanticipated problems involving risk to subjects or others; any serious or continuing non-compliance; any suspension or termination of IRB approval. For details on what must be included in the report and how to report please see Guidance on Reporting Incidents to OHRP.

c. **FDA:** Research Compliance must report to the FDA when FDA oversight is required. Guidance varies based on whether the incident is related to a drug or device. See the FDA website for more information.

d. **RCO:** All events that involve a breach of confidentiality or require reporting to a federal agency must be reported to RCO and will be subject to Policy NW-RCO-002.

e. **KFRI:** Research Compliance will report serious or continuing non-compliance, UPs and suspensions and terminations to KFRI, per SOP KP-006.

7. Follow-up on open action plans with on-going monitoring as needed.

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**References and Supporting Policies**

**Federal**

- OHRP Guidance on Reporting Incidents to OHRP (2011)
- FDA Reporting Website

**KPNW Research Compliance/KFRI:**

- SOP KP-502, PI Reportable Events and Incident Requirements
- SOP KP-006, IRB Review and Reporting of Unanticipated Problems, Noncompliance, and Suspensions or Terminations

**KPNW Regional Compliance**

- NW-RCO-002 Corrective Action Plans following an Audit, Assessment, or Inquiry
Document Approval, Ownership, & History

This document will be reviewed every two years for accuracy, relevance, and completeness.

Document owner: Research Compliance Manager, KPNW

Document Approval Authority: Research Compliance Committee (RCC)

Approval Date: August 29, 2017

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Appendices

Appendix A: Action Plan Template
## Appendix A:

### Action Plan Form

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### I. Action Plan

#### A. Root Cause of the Event

Why did this happen? Root cause is used to describe the depth in the causal chain where an intervention could reasonably be implemented to improve performance or prevent an undesirable outcome.

#### B. Corrective Action

What steps have been or will be taken to deal with the incident?

#### C. Preventive Action

Explain preventive action plan to avoid recurrence of problem, e.g. training, new policy, or procedural changes. If applicable, include how new information will be communicated to staff. The chart below can be used when there are more than a few preventive action steps.

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#### D. Staff Responsible for Plan

List names and positions of staff responsible for implementation of Action Plan, if you don’t use the chart above.

#### E. Indicate the Timeframe and process for implementation, if not using the chart above:
II. Quality Assurance of plan – Provide a brief description of how you will ensure that the plan is being followed and how the plan’s effectiveness will be evaluated. How often will the QA be conducted? Include how you will document these ongoing QA assessments and compliance with the action plan.

III. Criteria for Resolution – When will you know that the action plan is ready for closure?