RESEARCH COMPLIANCE CONFERENCE
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Corrective and Preventive Actions (CAPA) Plans

Guiding Clinical Research Professionals in Improving Weaknesses, Deficiencies, or in Rectifying Deviation Patterns and Areas of Noncompliance

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CONFLICT OF INTEREST

- David Staley, MA
  Research Compliance Officer
  Children's Hospital Colorado
- I do not have any conflicts to report.
- Lita Pereira, CHC
  Sr. Compliance Manager, Research
  Kaiser Permanente Colorado
- I do not have any conflicts to report.

OBJECTIVES

- Specify the elements that structure effective corrective and preventative action plans.
- Demonstrate writing and developing effective corrective and preventative action plans.
- Distinguish between a corrective action and preventative action.

Reference Handouts: Effective Corrective Action Template and Example;
Risk Response Action Plan Document

Effective Corrective and Preventative Action Plans

Quality Assurance Review Program

QUALITY ASSURANCE REVIEW

Purpose — And — Objectives

- Collaborate to uncover weaknesses, deficiencies, deviation patterns, or areas of noncompliance.
- Evince strengths in how research studies are conducted.

- Build trust: listen, respond, follow through.
- Educate on best practices.
- Foster a culture of mutual respect.

"We have the ability to create choice by altering our interpretations of the world."

—Sheena Iyengar, The Art of Choosing

Effective Corrective and Preventative Action Plans

Define

DEFINE

Ask a series of questions

Ask a series of questions to identify the root problem causing these weaknesses or deficiencies:

- What has occurred?
- How has it occurred?
- On what information have we based our findings?
- Is there a pattern in our findings that point to an underlying cause?
- How can we verify that we have pinpointed the underlying cause?
- Have we failed to consider other contributing factors before we attempt to decide on a course of action?

DEFINE

Ask a series of questions

Ask a series of questions to identify the root problem causing these weaknesses or deficiencies:

- What should be the proper course of action once we've identified the root cause of our weaknesses, deficiencies, deviation patterns, or areas of noncompliance?
- What are the questions we should ask to resolve our weaknesses, deficiencies, deviation patterns, or areas of noncompliance?
- What should be our corrective course of action? Has the Principal Investigator endorsed this course of action?

DEFINE

DEFINE THE PROBLEM

Clearly state the

- weaknesses,
- deficiencies,
- deviation patterns; or
- areas of noncompliance that have been observed.

DEFINE

DECIDE: CORRECTIVE OR PREVENTATIVE

Corrective Action — OR — Preventative Action

Actions designed to eliminate what causes deviations, noncompliance, or other undesirable mishaps to prevent recurrence.

Actions designed to prevent, detect, and respond appropriately to deviations, noncompliance, or other undesirable mishaps to prevent occurrence.

"The inclination to exaggerate our talents is amplified by our tendency to misperceive the causes of certain events. The typical pattern of such attribution errors, as psychologists call them, is for people to take credit for positive outcomes and to attribute negative outcomes to external factors, no matter what their true cause. "

Lovallo, D., & Kahneman, D. (2003). Delusions of success. How optimism undermines executives' decisions. Harvard Business Review, 81(7), 56-63, 117.

Effective Corrective Action Plans

Accountability

NAME THE RESPONSIBLE PARTIES

Name the persons who are going to take on the responsibility for carrying out the corrective course of action.

If relevant, do these people have the proper training and experience to fulfill with the expected duties?

- Who intends to be responsible for outcomes of the corrective action?
  - Should there be one person who's solely accountable?
  - Should a team share the responsibility?
  - Should the team separate out scope and responsibility?
  - What resources are needed to fulfill with this assignment?

DECIDE ON REPORTING ACCOUNTABILITY

Respond to the weaknesses, deficiencies, deviation patterns, or areas of noncompliance.

- How should we report progress, issues, or concerns?
  - How often should these matters be reported, deliberated, and sorted out?
  - To whom should we report these matters?

"People forget how fast you did a job—but they remember how well you did it."

—Howard W. Newton

Effective Corrective Action Plans

Course of Action

DECIDE ON A COURSE OF ACTION

Decide on a straightforward, measurable course of action to resolve the weaknesses, deficiencies, deviation patterns, or areas of noncompliance.

- Have we identified the corresponding regulatory requirements?
- What are the reviewing institutional review board (IRB) policies and requirements?
- Are there any institutional requirements that must be considered?
- Have we separated out the required corrective actions from the recommended corrective actions?

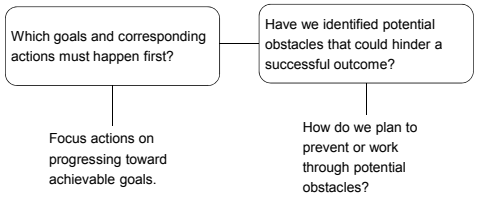
COURSE OF ACTION

DETERMINE WHAT'S REQUIRED

Required	Recommended
Study teams must respond to and address required corrective actions to comply with federal regulatory requirements, local (IRB) policies, and institutional research policies. Study teams should justify why they can't feasibly correct a required action.	Corrective actions that are recommendations should be thought of as being strongly encouraged. Consider how best to prioritize recommended corrective actions.

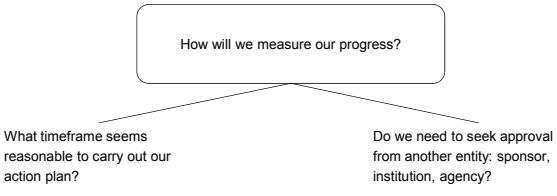
COURSE OF ACTION

ESTABLISH GOALS AND DEADLINES



COURSE OF ACTION

ESTABLISH GOALS AND DEADLINES



AVOID GROUPTHINK AND BIASES

Prevent skewing a course of action because of overconfidence and anchoring.

- Select an analogous comparison of action plans and preventative measures.
- Assess carefully how these past plans and measures were implemented: how successful were the outcomes?
- Predict intuitively various possible outcomes and their chances of succeeding. Ask: How does our proposed action plans measure up to previous implementation attempts?

AVOID GROUPTHINK AND BIASES

Prevent skewing a course of action because of overconfidence and anchoring.

- Compare and contrast objectively and mindfully how reliable and realistic possible outcomes are, based on predictions.
- Reconsider action plans and measures as a result of assessments, predications, and comparisons.

"Whenever you find yourself on the side of the majority, it is time to pause and reflect."

— Mark Twain

Effective Corrective Action Plans

Quality Assurance Process

DECIDE ON A PREVENTIVE COURSE OF ACTION

Decide on what the preventive course of action should be when implementing a corrective course of action.

- How often should we assess the completed actions in relation to their results?
  - Arrange periodic reviews and specify the type of supporting documentation needed to assess the plan's progress.

DETERMINE HOW TO MONITOR

Determine how to monitor and adjust accordingly a course of action.

- What results if unforeseen problems were to arise?
  - Get in the mindset that we're likely going to uncover problems that we hadn't anticipated.
  - Decide how to handle such discoveries and how to prioritize them.

ORGANIZE SUPPORTING DOCUMENTATION

Organize supporting documentation that we should have readily accessible.

- For whom should we have this supporting documentation?
  - IRB
  - FDA
  - OHRP
  - Research Compliance
  - Sponsor

"Our life is an apprenticeship to the truth that around every circle another can be drawn; that there is no end in nature, but every end is a beginning, and under every deep a lower deep opens."

—Ralph Waldo Emerson

Effective Corrective and Preventative Action Plans

Regulatory Cases: Practical Application

REGULATORY CASE

INFORMED CONSENT

A team of research professionals have uncovered irregularities in how they've obtained consent for a research study that involves collecting blood samples. These research professionals have uncovered that not only have they consented using outdated versions of the consent document, but they've, at times, also consented using the wrong study consent document entirely. After further review, the team has discovered inconsistent training and delegation records: some team members haven't been properly trained in obtaining consent, while others haven't been properly delegated the task of consenting research subjects.

REGULATORY CASE

UNAUTHORIZED DISCLOSURE OF PHI

When the research nurse hung up the phone, she knew she had an unanticipated problem—pun very much intended. Erroneously, two hundred tubes of blood-sample specimens with labels disclosing PHI arrived at WorldWide Expert Laboratories. Where these blood samples should've been deidentified before analysis—that's what research subjects consented to—the process for preparing and shipping them to WorldWide Expert Laboratories had somehow failed.

REGULATORY CASE

PROTOCOL DEVIATION

After careful review of REDCap documentation, a team of research professionals discovered errors in the data that had been collected. First, a REDCap questionnaire recorded research subjects' contact information, demographic information, and social security numbers (SSN). As it turned out, neither did an IRB approve SSNs to be recorded nor did the subjects authorize that they be collected as part of the research. To date, SSNs have been collected and recorded for thirteen subjects.

REGULATORY CASE

RESEARCH WITHOUT IRB REVIEW

Prestigious University got in contact to collaborate with a distinguished Physician Investigator, asking her to serve as a co-investigator on a retrospective case series. Seemed simple and straightforward, doesn't it? It's sad to say, but that distinguished Physician Investigator was unaware that her institution had an IRB. Where Prestigious University's IRB had determined the project to be exempt research under category 4, the distinguished Physician Investigator didn't submit her collaboration project for any kind of human subjects research determination. As a project collaborator, she provided collected patient data to Prestigious University. Because of an oversight, neither the local study site nor the Physician Investigator were named on the Prestigious University's multi-site IRB review materials.

REGULATORY CASE

INFORMED CONSENT

When a patient enrolled in a research study about vaccines, he was told that his vaccine wouldn't cost him anything. The immunization nurse, however, informed the patient that he would have to pay for his vaccine. He was concerned and brought his concern to the research coordinator's attention: his consent document stated he wouldn't have to pay for anything. The lead research coordinator discovered that the original, outdated consent document presented erroneous language about patient costs. What's more is that this outdated version was the only version available on the document management system, because the updated consent document with the accurate patient cost language hadn't ever been uploaded. Research coordinators had been downloading the outdated consent document version, according to their training, to consent subjects. As a result, A total of 62 subjects were consented using the wrong informed consent document.

REGULATORY CASE

RESEARCH WITHOUT IRB REVIEW

A student submitted a research poster to present at a local research symposium. There was one hiccup: She didn't submit an IRB approval for how she accessed and assessed patient data to substantiate her research conclusions. With permission to access a database, the student extracted patient data using a software reporting tool, selecting unique cases of data. Such access resulted in accessing PHI for research purposes without a valid authorization and conducting human subjects research without seeking proper IRB approval.

REGULATORY CASE

POOR DOCUMENTATION PRACTICES

During a recent quality assurance review, source documentation revealed that study team members have repeatedly used correction fluid to obscure errors on case report forms before revising them.

"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives, the cumulative experience of many masters of craftsmanship."

—Will A. Foster