

Root Cause Analysis and the 5 Whys

1. Purpose

This document provides a step by step instructions for conducting a root cause analysis using the 5 Whys method. It is designed for clinical research settings (e.g. protocol deviations, data entry errors, informed consent issues) and helps ensure problems are investigated and corrected effectively.

2. What is a Root Cause Analysis

It is a structured process to help identify the underlying reason or reasons why a problem occurred. The goal is to find the true cause, so corrective and preventative actions(CAPA) address the right issue.

3. When to use a Root Cause Analysis

1. Significant protocol deviations
2. Repeated data entry or documentation errors
3. Safety concerns or adverse event reporting delays
4. Regulatory audit findings or inspection observations
5. Any issue that impacts subject safety, data integrity, or compliance

Please note the above list is not exhaustive.

4. Root Cause Analysis Process Steps

1. Describe the Problem Clearly
 - i. Write a short, factual statement about the issue
2. Collect Information
 - i. Review source documents, SOPs, monitoring reports
 - ii. Interview staff if needed
3. Apply a Root Cause Method
 - i. The 5 Whys is a simple and effective tool
4. Identify the Root Cause
 - i. Keep asking why? Until you reach a systematic issue (e.g. training gaps, unclear SOP)
5. Develop CAPA
 - i. Corrective Actions: Fix the immediate problem
 - ii. Preventive Actions: Change the process so it does not happen again

6. Check Effectiveness
 - i. Monitor after implementation

The 5 Whys Method

Instructions:

1. Write the problem statement at the top.
2. Ask “Why did this happen?” and record the answer.
3. For each answer ask “Why?” again.
4. Repeat until you have asked at least 5 times or have reached the root cause.
 - a. Avoid stopping at human error and look for other weaknesses.

Example:

Problem: Subject 5’s consent form is missing a signature.

Why 1: Why was the signature missing?

The subject left before signing

Why 2: Why did the subject leave before signing?

Coordinator did not notice missing field

Why 3: Why did the coordinator not notice?

Consent process checklist was not used

Why 4: Why was the checklist not used?

Coordinator was not trained on it

Why 5: Why was training not completed?

Site SOP did not include mandatory checklist training

Root Cause: Inadequate site training