Step 1: Clearly state the problem or weakness, including the root cause.

- Define the Problem:
  - What is happening?
  - What is the effect?
  - What should be happening?
  - How can it be fixed?

Step 2: List the individuals who will be accountable for the results of the corrective action

- Who should be responsible?
- How will they report issues/problems?
  - When should they report problems?

Step 3: Create simple, measurable solutions that address the root cause

- What are the regulatory requirements?
- What are the IRB requirements?
- What are the available resources allocated for the study?
- What can be reasonably accomplished?

Step 4: Each solution should have a person/s that is accountable for it.

- Who is accountable/ responsible?

Step 5: Set achievable deadlines

- What is a reasonable time frame to develop and address the proposed changes?

Step 6: Monitor the progress of your plan.

- When will supporting documentation be needed?
  - At the next periodic review?
  - On hand, in case of an audit?
  - If another problem occurs?
- What type of supporting documentation will be needed for:
  - The IRB?
  - FDA?
  - OHRP?
  - NIH?