Corrective Action Plans (CAPs)

What is a Corrective Action Plan?
As it relates to research, a corrective action plan is a document describing exactly how a specific situation will be changed in order to achieve and maintain compliance with a research protocol, Good Clinical Practices (GCP), federal regulations and/or local IRB requirements.

How does the process work?
A corrective action plan is a response to a situation that is problematic.

For example, a research site may have found discrepancies in administering a valid informed consent document. In this situation, the problem identified that a subject's informed consent document was not valid because the most current version of the IRB-approved consent document was not used, and the corrective action plan will state how this situation will be corrected.

What should be included in a corrective action plan?

The plan should include the following information:

1. A clear statement defining the problem.
2. A statement of the desired outcome.
3. A listing of specific steps that need to be taken to in order to correct the issue.

Each step should list the individual responsible for completing the action, and an achievable deadline for completion.

Sample CAP Format
The attached Sample CAP Format and Example is intended to provide guidance as needed. It can be used in part or in whole. There is no particular format that is required for creating a CAP, as long as the CAP provides adequate information to identify the problem and defining the steps that will be implemented to address any further issues.

Note: If you have any questions about drafting a corrective action plan, you may consult the HCA-HealthONE Office of Research Compliance at 303-584-2202.

CORRECTIVE ACTION PLAN

I. ISSUE/PROBLEM DEFINITION (BE SPECIFIC—QUANTIFY IF POSSIBLE)

II. ROOT CAUSE EVALUATION

III. ACTION STEPS

IV. IMPROVEMENT BENCHMARK(S) AND TIMEFRAME

V. CERTIFICATION

The undersigned have read this Corrective Action Plan and agree to its terms.

_____ _____
Signature Date

_____ _____
Signature Date

CORRECTIVE ACTION PLAN EXAMPLE

I. ISSUE / PROBLEM DEFINITION

The most current version of the IRB-approved informed consent document is not used when administering consent to potential research subjects.

II. ROOT CAUSE EVALUATION

After reviewing the regulatory binder and the filing cabinet where informed consent documents are stored for use, it was determined that the most recent informed consent document approved by the IRB had not been retrieved from the IRBNet package and filed in the appropriate places:

- Consent administrators were not aware that the IRB had approved a more recent version of the informed consent document.
- Old versions of the consent document remain in the filing cabinet.
- The most current version of the IRB-approved informed consent document was not filed appropriately in the regulatory binder.

III. ACTION STEPS

Study Coordinator will:

1. Photocopy the most current IRB approved informed consent document as soon as it is approved by the IRB and published in IRBNet:
2. Notify consent administrators that the consent has been revised, highlighting the changes, and inform them where the most recently approved informed consent document can be found.
3. A copy will be placed in the regulatory binder, indexed appropriately in the section labeled informed consent document.
4. Outdated versions of the informed consent document will be removed from the file cabinet and destroyed.
5. Copies will be made of the updated version of the consent document and filed appropriately in the designated file cabinet.

Consent administrators will:

1. Retrieve copies of the informed consent document from the designated file cabinet and confirm that the most recently IRB approved version of the document is present.
2. Be familiar with the modifications made to the informed consent document.

IV. Improvement Benchmark(s) and Timeframe

The incidence of utilizing the wrong consent version must not occur for the remainder of the 2014 year and throughout the life of the study. The Study Coordinator will continue to monitor the version dates of the informed consent used by the Consent Administrators.

Failure to achieve this improvement benchmark could result in the IRB requesting additional corrective actions.

This Corrective Action Plan is effective 04/28/2014 through the close of the study.

V. Certification

The undersigned have read this Corrective Action Plan and agree to its terms.

John Doe	4/28/14
Principal Investigator	Date
Robin Hood	4/28/14
Study Coordinator	Date
Snow White	4/28/14
Sub-Investigator	Date
Peter Pan	4/28/14
Sub-Investigator	Date