AUDIT RESPONSE/CAPA Plan

DATE OF AUDIT (MM/DD/YYYY):

LCH/NU STUDY NUMBER:

SITE NUMBER/NAME:

PRINCIPAL INVESTIGATOR:

INVOLVED PERSONNEL:

1. State the deficiency(ies) as cited in the audit report:
2. Response and Corrective and Preventative Action (CAPA) Plan:
3. Achievable Deadline:

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| Involved Personnel (Print) | Involved Personnel Signature | Date |

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| Direct Supervisor (Print) | Direct Supervisor Signature | Date |

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| Principal Investigator (Print) | Principal Investigator Signature | Date |

Preparing a CAPA Plan

The Principal Investigator or designee is responsible for submitting a written response no later than the date identified in the audit report. One CAPA plan/response document addressing any deficiencies for all audit components (regulatory, pharmacy, patient case review) is requested for each audit report received.

Provide a written response and/or CAPA plan with any requested or supporting documentation to:

Quality Assurance Department

676 N St. Clair Street, Suite 1200

Chicago, IL 60611

croqualityassurance@northwestern.edu

In preparing a CAPA Plan, there are several things to consider.

### 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? (No names, please, just list the position.) If applicable, how will they be trained to carry out their expected duties? How will they report issues or problems? To whom are issues reported? 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 who is accountable for it.

Should one person be solely accountable? Should two people share the responsibility? Should there be a segregation of duties?

### Step 5 – Set achievable deadlines.

How many people are dedicated to the effort of re-writing SOPs, consents, or protocols? Does an external entity need to sign off on the changes? What is a reasonable time frame to develop and train?

### Step 6 – Monitor the progress of your plan.

When will supporting documentation be needed? At the next periodic review (Continuing Review)? At the next audit? If another problem occurs? What type of supporting documentation will be needed for the following entities: IRB, FDA, OHRP, NIH, and Sponsor?