

NCC Standard Operating Procedure Site Self Reliance Visit and Action Plan - March 13, 2009 Revision

Date of Revision:

13 March 2009

Scope:

This SOP applies to all SEAICRN staff conducting and participating in site visits, development of action plans, and the implementation of action plans in collaboration with SEAICRN research sites.

Glossary and Acronyms:

NCC: Network Coordinating Center

NCC CO: Network Coordinating Center Country Office

CTSS: Clinical Trials Support Specialist

PI: Principal Investigator

Co-PI: Co-principal investigator; assists the PI in site operations

SC: Study Coordinator

Preparing the Site:

1. ***Contact the site.*** The NCC CO team leader or designee will contact the site PI and SC to explain what is needed for the site visit and answer any questions. The CTSS will be involved in this contact if possible.

A full explanation of the site assessment process and the roles of the NCC assessment team will be provided to the PI; the site staff needed for the visit will be clarified by the NCC CO team leader (Attachment 1).

2. ***Schedule the visit.*** The NCC CO team leader will coordinate a visit schedule in collaboration with the site SC or designee prior to the site visit. Ideally the site visit will last three days divided as follows:

- An opening session with entire assessment team and all involved site staff (Day One)
- Conduct of the assessment activities (Day One and Day Two)
- A final summary session with findings discussed and action plan developed (Day Three)

To schedule the visit as efficiently as possible, the NCC CO team leader will ask the designated site staff to complete a blank schedule form indicating when the requested site staff can be available during the three days of the visit (Attachment 2).

3. ***Prepare for the visit.*** The NCC CO team leader will assign a lead person for the site visit. This person will lead the opening discussions, assist the site staff in leading the closing session, and be responsible for writing the final report.

Conducting the site visit:

4. ***Opening session:*** As scheduled with the site, meet with the entire group of participating site staff and the NCC site assessment team.
 - Review the purpose of the visit and the schedule.
 - Review the Proficiency Skills table upon which the assessment standards are based.
5. ***Evaluate the site according to the schedule.*** As agreed to in the visit schedule, break into teams if necessary and work with the assigned site staff for each of the assessment areas. Ideally this will be completed by the end of the second day.
6. ***Compile the visit findings collaboratively:*** The combined NCC and designated site staff assessment team will meet together in the morning of the third day of the visit and discuss the findings from each of the sections that were evaluated. The lead NCC team member and the SC or designee will compile the findings into a presentation for the closing session; a rough draft of an Action Plan will be discussed and outlined.
7. ***Present the findings and draft the Action Plan:*** In the afternoon of the third day the combined assessment team (NCC and site staff) will meet with the site PI and all key site staff who participated in the assessment. Ideally the SC or site staff designee will lead the discussion and present the findings and the draft of the Action Plan. If the SC or site staff are not able to do this, the lead NCC team member will co-lead the discussion with a designated site staff member. All members of the assessment team will contribute to the discussion.

During the meeting the rough draft of the Action Plan customized to the site will be presented. The lead NCC team member or designee will take notes on the decisions regarding the Action Plan and will draft a proposed plan with a timeline.

After the Visit:

8. ***Review of draft Plan by NCC.*** The assessment team leader will present the draft Action Plan to the NCC COO or designee. Decision on whether to approve each of the requested actions will be given (considering budget and program limitations), and a decision made about how to proceed with the Plan. If changes are needed the lead team member will notify the site PI and staff, and communicate recommended changes to the Plan. A revised and final plan will be generated for discussion with the site staff.
9. ***Implement the Action Plan.*** The Plan will be a flexible document that can be continually updated as the needs of the site change.
10. ***Follow up and Tracking.*** The NCC Project Manager and/or Clinical Research Manager along with the SC or designee at the site will collaboratively track the progress of the plan, and issue a progress report according to the timeline established in the Plan.

Related Documents to be shared with all assessment team members:

- Site Management and Support Roles
- CTSS Support for Site Self Reliance
- Proficiency Skills Table
- Site Assessment Checklist/Worksheet

Attachment 1. Roles of NCC Assessment Team and Participating Site Staff

*Note: Designated substitutes may be assigned for any staff member as needed

<i>Staff*</i>	<i>Role in assessment</i>
CTSS/SC	<ul style="list-style-type: none"> • Review Regulatory procedures and files • Review existing site procedures for ICF, site management and data management and quality systems • Review site procedures for staffing and team management
NCC Clinical Research Manager/SC	Same evaluations as CTSS
NCC CO Team Leader / SC or designee	<ul style="list-style-type: none"> • Review site procedures for team management and Network participation
NCC Laboratory representative / Clinical lab director or designee	<ul style="list-style-type: none"> • Review the procedures and quality systems for the clinical laboratory
NCC Pharmacist or designee / site pharmacist	<ul style="list-style-type: none"> • Review the procedures and quality systems for the research pharmacy
NCC Finance manager / site finance manager	<ul style="list-style-type: none"> • Review the systems in place and training history of the finance unit for research
Site PI	<ul style="list-style-type: none"> • Oversee the participation of the site staff, give approval for each area to be evaluated, determine how the site will participate in an Action Plan
Site co-PIs	<ul style="list-style-type: none"> • As needed meet with the NCC assessment team on specified topics

Attachment 2. Template visit schedule

<i>Staff</i>	<i>Topic/area</i>	<i>Scheduled time: Date and hour</i>	<i>Location</i>
<ul style="list-style-type: none"> • CTSS • SC • NCC Clinical Research Manager 	Review Regulatory procedures and files		
<ul style="list-style-type: none"> • CTSS • SC • NCC Clinical Research Manage 	Review existing site SOPs and quality systems (ICF, site management and data management)		
<ul style="list-style-type: none"> • CTSS • SC • NCC Clinical Research Manage 	Review site procedures for staffing and team management		
<ul style="list-style-type: none"> • NCC CO Team Leader • SC or designee 	Review site procedures for team management and Network participation		
<ul style="list-style-type: none"> • NCC Laboratory representative • Clinical lab director or designee 	Review the procedures and quality systems for the clinical laboratory		
<ul style="list-style-type: none"> • NCC Pharmacist or designee • site pharmacist 	Review the procedures and quality systems for the research pharmacy		
<ul style="list-style-type: none"> • NCC CO Finance manage • site finance manager 	Review the systems in place and training history of the finance unit for research		
Site co-PIs	As needed meet with the NCC assessment team on specified topics		
<ul style="list-style-type: none"> • All NCC team members • Designated site staff 	Review of initial findings and drafting of Action Plan on Day 3 morning		
<ul style="list-style-type: none"> • All participating staff 	Closing session on Day 3 afternoon		

Note: Schedule may be modified as needed to fit the needs of the site