

# **Guidelines**

## **National Institute of Neurological Disorders and Stroke**

### **Clinical Study Quality Control / Quality Assurance Checklist**

PROCESS CHECKLIST FOR NINDS CLINICAL STUDIES  
(AND PREPARING FOR A SITE VISIT)

**This checklist outlines a review of study organization and processes, with a focus on data management.**

Note: NINDS has established these guidelines as a resource for items that NINDS or its contractor may review during a site visit. Definitions of **underlined terms** are available in the NINDS [Glossary](#).

		YES	NO	N/A
<b>Overview - Study Administration and Procedures</b>				
1.	Are all study documents, including <b>protocol</b> , <b>manual of procedures (MOP)</b> , data collection forms, <b>statistical analysis plan (SAP)</b> , etc. consistent with data management procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Are the <b>MOP</b> , protocol, data collection forms, <b>informed consent</b> , etc., easily accessible, in a centrally located binder (electronic or paper), to assist study investigators?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	Are there accessible participant files that contain <b>source documentation</b> of clinical observations such as lab results, medical record, progress notes, etc.?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	Is there a <b>study regulatory binder*</b> that contains key study documents such as <b>Institutional Review Board (IRB) approval</b> , protocol versions, <b>informed consent form</b> , C.V.s, forms, <b>financial disclosures</b> , <b>site monitoring reports</b> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	Does the <b>training plan</b> describe how and when procedures for <b>quality assurance (QA)</b> are implemented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	Does the <b>training plan</b> include procedures on how to train new staff?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	Does the <b>Drug / Device Distribution Plan</b> specify procedures for the storage of, preparation of, dispensing of and handling unused intervention as well as procedures for completing <b>treatment accountability</b> logs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Are there written plans for obtaining, handling, storing, and sending participant samples/materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Are there written procedures for obtaining and transmitting laboratory data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Are there procedures in place for following participants from screening and enrollment through completion of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Is there documentation of <b>pre-screening and screening procedures</b> so that data on eligible and ineligible individuals are captured in an appropriate format? Is a <b>screening log</b> provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		YES	NO	N/A
12.	Does the <b>informed consent</b> include statements about the use of the <b>data and specimen sharing</b> for future research?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
13.	Is there a written procedure to insure that the current copy of the IRB approved informed consent form is signed before each participant is enrolled?			
14.	Has the <b>manual of procedures (MOP)</b> , which includes the protocol, CRFs, informed consent, study staff roster, screening log, and <b>standard operating procedures (SOPs)</b> , been distributed to all clinical sites and updated as needed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15.	<i>Have the following study operation procedures or plans been created for the MOP:</i>			
	a. <b>Organizational Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	b. <b>Safety Monitoring Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	c. <b>Training Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	d. <b>Study Communications Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	e. Maintaining MOP	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	f. <b>Site Signature Log/Delegation of Authority (Description of Responsibility)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	g. <b>Recruitment Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	h. Screening and Informed Consent	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	i. Enrollment and <b>Randomization</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	j. <b>Retention Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	k. Study Timelines/Study Visits	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	l. <b>Drug/Device Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	m. Laboratory Specimen Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	n. <b>Blinding/Unblinding</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	o. Concomitant Medications	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	p. Data Management	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	q. <b>Source Documentation</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	r. <b>Case Report Form</b> completion	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	s. <b>Adverse Events (AEs)/Serious Adverse Events (SAEs)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	t. Participant <b>Withdrawals</b> from study and <b>Lost-to-Follow-ups</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	u. <b>Protocol Deviations</b> and violations	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	v. <b>Quality Assurance (QA)/Quality Control (QC)</b> procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	w. <b>Monitoring Plan</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	x. Study Completion	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

		YES	NO	N/A
	y. Website (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Randomization</b>				
16.	Are there written procedures to assure that participants are randomized according to the <b>randomization plan</b> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	Are there written procedures for maintaining the confidentiality of the <b>randomization code</b> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	Is there a procedure that verifies the correct randomization number was assigned?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19.	Are there written procedures to ensure that the randomization assignment stays with the participant through the entire data collection process?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20.	Are <b>masking/blinding</b> and <b>unmasking/unblinding</b> procedures in place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Data Collection (Data system)</b>				
21.	Is there a schedule of participant contacts (i.e. study visits)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22.	Are there written procedures that guide data collection at each participant contact?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23.	Is there a complete description and definition of how each data item is to be collected on each study form for each participant contact?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24.	Do the forms and data collected at each participant contact correspond to and reflect the <b>statistical analysis plan</b> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25.	Are there <b>adverse event (AE) forms</b> and do they include the necessary data to generate safety reports?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26.	Are there automated range and logic checks built into the system?			
<b>Data Management</b>				
27.	Is there a detailed description of how forms are sent or transmitted to the data-coordinating center?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28.	Is there a <b>Data Management Plan</b> or do written procedures document data handling from collection through analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29.	Are there tracking procedures that document and confirm participant enrollment, data collected, forms completed, and forms received at the data collection/coordinating center?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30.	Are there written procedures that describe how data are transformed from paper into a computer system, edited, and transferred to an analysis data base, as relevant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		YES	NO	N/A
31.	Are there procedures for correcting data so that changes can be identified for accuracy and completeness in a systematic way?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
32.	Are there procedures in place that identify and track the status of each participant throughout the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
33.	Are there procedures in place for data cleaning?			
34.	Are there automated range and logic checks?			
<b>Safety Plan</b>				
35.	Is a <a href="#">Safety Monitoring Plan</a> in place that outlines independent oversight in the form of a <a href="#">DSMB / Safety Monitoring Body (SMB) /Medical Safety Monitor</a> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
36.	Are there procedures in place for documenting and reporting <b>AEs, serious AEs</b> and <b>unexpected AEs</b> , according to NIH Guidelines ( <a href="http://grants.nih.gov/grants/guide/notice-files/not99-107.html">http://grants.nih.gov/grants/guide/notice-files/not99-107.html</a> )? See also <a href="#">OHRP Guidelines</a> and <a href="#">NIH Policy</a> regarding unanticipated problems involving research subjects or others (UPIRTSOs). OHRP: <a href="http://www.hhs.gov/ohrp/policy/advevntguid.html">http://www.hhs.gov/ohrp/policy/advevntguid.html</a> NIH: <a href="http://grants.nih.gov/grants/policy/hs/data_safety.htm">http://grants.nih.gov/grants/policy/hs/data_safety.htm</a>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Compliance and Monitoring</b>				
37.	Are screening, recruitment, enrollment, and retention reports reviewed regularly and action plans documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
38.	Are <b>protocol deviation reports</b> reviewed regularly and violations documented systematically?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
39.	Are there data quality reports that describe missing or erroneous data reviewed regularly to detect and correct problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
40.	Are <b>site-monitoring reports</b> generated to provide feedback regarding problems and issues discovered during site visits and to report on the quality of data reviewed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Quality Standards</b>				
41.	Have quality standards been established for enrollment and accrual deviations, drop-outs, and data entry and analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
42.	Are procedures in place for correcting inaccurate data and documenting the changes systematically?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
43.	Are procedures in place for amending the <b>protocol</b> and the <b>MOP</b> and documenting the changes?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

		YES	NO	N/A
44.	Are procedures in place to modify quality control reports, if necessary, to capture correct data?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
45.	Are procedures in place to modify training, if necessary, so clinical study site personnel accurately collect data according to the procedures specified in the protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

*\*Even if the study is not under IND, the expectation is that there is a binder that holds all study related documents (IRB submissions and approvals, CVs for key study staff, etc. Study binders may be electronic and/or paper.)*