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
Overview - Study Administration and Procedures				
1.	Are all study documents, including **protocol**, manual of procedures (MOP), data collection forms, **statistical analysis plan** (SAP), etc. consistent with data management procedures?	☐	☐	☐
2.	Are the **MOP**, protocol, data collection forms, **informed consent**, etc., easily accessible, in a centrally located binder (electronic or paper), to assist study investigators?	☐	☐	☐
3.	Are there accessible participant files that contain **source documentation** of clinical observations such as lab results, medical record, progress notes, etc.?	☐	☐	☐
4.	Is there a **study regulatory binder*** that contains key study documents such as **Institutional Review Board (IRB) approval**, protocol versions, **informed consent form**, C.V.s, forms, **financial disclosures**, **site monitoring reports**?	☐	☐	☐
5.	Does the **training plan** describe how and when procedures for **quality assurance (QA)** are implemented?	☐	☐	☐
6.	Does the **training plan** include procedures on how to train new staff?	☐	☐	☐
7.	Does the **Drug / Device Distribution Plan** specify procedures for the storage of, preparation of, dispensing of and handling unused intervention as well as procedures for completing **treatment accountability** logs?	☐	☐	☐
8.	Are there written plans for obtaining, handling, storing, and sending participant samples/materials?	☐	☐	☐
9.	Are there written procedures for obtaining and transmitting laboratory data?	☐	☐	☐
10.	Are there procedures in place for following participants from screening and enrollment through completion of the study?	☐	☐	☐
11.	Is there documentation of **pre-screening and screening procedures** so that data on eligible and ineligible individuals are captured in an appropriate format? Is a **screening log** provided?	☐	☐	☐

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

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

		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?	☐	☐	☐
32.	Are there procedures in place that identify and track the status of each participant throughout the study?	☐	☐	☐
33.	Are there procedures in place for data cleaning?			
34.	Are there automated range and logic checks?			
Safety Plan				
35.	Is a **Safety Monitoring Plan** in place that outlines independent oversight in the form of a **DSMB / Safety Monitoring Body (SMB) /Medical Safety Monitor** ?	☐	☐	☐
36.	Are there procedures in place for documenting and reporting **AEs, serious AEs** and **unexpected AEs**, according to NIH Guidelines (http://grants.nih.gov/grants/guide/notice-files/not99-107.html)? See also OHRP Guidelines and NIH Policy regarding unanticipated problems involving research subjects or others (UPIRTSOs). OHRP: http://www.hhs.gov/ohrp/policy/advevntguid.html NIH: http://grants.nih.gov/grants/policy/hs/data_safety.htm	☐	☐	☐
Compliance and Monitoring				
37.	Are screening, recruitment, enrollment, and retention reports reviewed regularly and action plans documented?	☐	☐	☐
38.	Are **protocol deviation reports** reviewed regularly and violations documented systematically?	☐	☐	☐
39.	Are there data quality reports that describe missing or erroneous data reviewed regularly to detect and correct problems?	☐	☐	☐
40.	Are **site-monitoring reports** generated to provide feedback regarding problems and issues discovered during site visits and to report on the quality of data reviewed?	☐	☐	☐
Quality Standards				
41.	Have quality standards been established for enrollment and accrual deviations, drop-outs, and data entry and analysis?	☐	☐	☐
42.	Are procedures in place for correcting inaccurate data and documenting the changes systematically?	☐	☐	☐
43.	Are procedures in place for amending the **protocol** and the **MOP** and documenting the changes?	☐	☐	☐

		YES	NO	N/A
44.	Are procedures in place to modify quality control reports, if necessary, to capture correct data?	☐	☐	☐
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?	☐	☐	☐

**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.)*