PROCESS CHECKLIST FOR NINDS CLINICAL STUDIES
(AND PREPARE 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 KAI 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**, etc. consistent with data management procedures?	☐	☐	☐
2.	Is the MOP, which can include the protocol, data collection forms, **informed consent**, etc., easily accessible, in a centrally located binder, to assist study investigators?	☐	☐	☐
3.	Are there accessible patient files that contain **source documentation** of clinical observations such as lab results, medical record, progress notes, etc.?	☐	☐	☐
4.	Is there a **study 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.	Are **Federal and local "Conflict of Interest" policies** followed?	☐	☐	☐
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 patient 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.	Are **masking/blinding** and **unmasking/unblinding** procedures in place to limit unmasking/unblinding?	☐	☐	☐
	Pre-Screening/Screening, Enrollment			
12.	Is there documentation of **pre-screening and screening procedures** so that data on eligible and ineligible individuals are captured in an appropriate format?	☐	☐	☐

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		YES	**NO**	**N/A**
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**, 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 Plan**	☐	☐	☐
	c. **Training Plan**	☐	☐	☐
	d. **Study Communications Plan**	☐	☐	☐
	e. Maintaining MOP	☐	☐	☐
	f. Site Signature Log/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**	☐	☐	☐

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		YES	NO	N/A
	r. **Case Report Form** completion	☐	☐	☐
	s. AEs/SAEs	☐	☐	☐
	t. Participant withdrawals from study and lost to follow-ups	☐	☐	☐
	u. **Protocol deviations** and violations	☐	☐	☐
	v. **Quality Assurance (QA)/Quality Control (QC)** procedures	☐	☐	☐
	w. **Monitoring Plan**	☐	☐	☐
	x. Study Completion	☐	☐	☐
	y. Website	☐	☐	☐
	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?	☐	☐	☐
	Data Collection			
20.	Is there a schedule of participant contacts (i.e. study visits)?	☐	☐	☐
21.	Are there written procedures that guide data collection at each participant contact?	☐	☐	☐
22.	Is there a complete description and definition of how each data item is to be collected on each study form for each participant contact?	☐	☐	☐
23.	Do the forms and data collected at each participant contact correspond to and reflect the **statistical analysis plan**?	☐	☐	☐
24.	Are there **adverse event (AE) forms** and do they include the necessary data to generate safety reports?	☐	☐	☐
	Data Management			

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		YES	**NO**	**N/A**
25.	Is there a detailed description of how forms are sent or transmitted to the data coordinating center?	☐	☐	☐
26.	Is there a **Data Management Plan** or do written procedures document data handling from collection through analysis?	☐	☐	☐
27.	Are there tracking procedures that document and confirm participant enrollment, data collected, forms completed, and forms received at the data collection/coordinating center?	☐	☐	☐
28.	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?	☐	☐	☐
29.	Are there procedures for correcting data so that changes can be identified for accuracy and completeness in a systematic way?	☐	☐	☐
30.	Are there procedures in place that identify and track the status of each participant throughout the study?	☐	☐	☐
	Safety Plan			
31.	Is a **Safety Monitoring Plan** in place that outlines independent oversight in the form of a **DSMB / Safety Monitoring Body (SMB) /Medical Safety Monitor?**	☐	☐	☐
32.	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)?	☐	☐	☐
	Compliance and Monitoring			
33.	Are screening, recruitment, enrollment, and retention reports reviewed regularly and action plans documented?	☐	☐	☐
34.	Are **protocol deviation reports** reviewed regularly and violations documented systematically?	☐	☐	☐
35.	Are reports that describe missing or erroneous data reviewed regularly to detect and correct problems?	☐	☐	☐
36.	Are **site monitoring reports** generated to provide feed back regarding problems and issues discovered during site visits and to report on the quality of data reviewed?	☐	☐	☐
	Quality Standards			
37.	Have quality standards been established for enrollment and accrual deviations, drop-outs, and data entry and analysis?	☐	☐	☐

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		YES	NO	N/A
38.	Are procedures in place for correcting inaccurate data and documenting the changes systematically?	☐	☐	☐
39.	Are procedures in place for amending the protocol and the MOP and documenting the changes?	☐	☐	☐
40.	Are procedures in place to modify quality control reports, if necessary, to capture correct data?	☐	☐	☐
41.	Are procedures in place to modify training, if necessary, so clinical center personnel accurately collect data according to the procedures specified in the protocol?	☐	☐	☐