**Guidelines**

**National Institute of Neurological Disorders and Stroke**

**Quality Control/Quality Assurance Checklist**

| 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 may be reviewed during a site visit. Definitions of underlined terms are available in the NINDS Glossary. |
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|  |  | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- | --- |
| **Overview - Study Administration and Procedures** | | | | |
|  | Are all study documents, including [**protocol**](http://www.ninds.nih.gov/research/clinical_research/toolkit/protocoltemplate.htm), [**manual of procedures (MOP)**](http://www.ninds.nih.gov/research/clinical_research/toolkit/things_nowfunded.htm#manual)*,* data collection forms, [**statistical analysis plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) (SAP), etc. consistent with data management procedures? |  |  |  |
|  | Is the MOP, protocol, data collection forms, [**informed consent**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm), etc., easily accessible, in a centrally located binder, to assist study investigators? |  |  |  |
|  | Are there accessible participant files that contain [**source documentation**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)of clinical observations such as lab results, medical record, progress notes, etc.? |  |  |  |
|  | Is there a [**study regulatory binder**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)\* that contains key study documents such as [**Institutional Review Board (IRB) approval**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm), protocol versions, [**informed consent form**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm), C.V.s, forms, [**financial disclosures**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm#informedconsent), [**site** **monitoring reports**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)? |  |  |  |
|  | Does the [**training plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) describe how and when procedures for [**quality assurance (QA)**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) are implemented? |  |  |  |
|  | Does the training plan include procedures on how to train new staff? |  |  |  |
|  | Does the [**Drug / Device Distribution Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) specify procedures for the storage of, preparation of, dispensing of and handling unused intervention as well as procedures for completing [**treatment** **accountability**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) logs? |  |  |  |
|  | Are there written plans for obtaining, handling, storing, and sending participant samples/materials? |  |  |  |
|  | Are there written procedures for obtaining and transmitting laboratory data? |  |  |  |
|  | Are there procedures in place for following participants from screening and enrollment through completion of the study? |  |  |  |
|  | Is there documentation of [**pre-screening and screening procedures**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)so that data on eligible and ineligible individuals are captured in an appropriate format? |  |  |  |
|  | Does the informed consent include statements about the use of the data and specimen sharing for future research? |  |  |  |
|  | 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? |  |  |  |
|  | Has the [**manual of procedures (MOP)**](http://www.ninds.nih.gov/research/clinical_research/toolkit/things_nowfunded.htm#manual), which includes the protocol, CRFs, informed consent, study staff roster, screening log, and [**standard operating procedures**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) (SOPs), been distributed to all clinical sites and updated as needed? |  |  |  |
|  | *Have the following study operation procedures or plans been created for the MOP:* |  |  |  |
|  | 1. [**Organizational Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. [**Safety Monitoring Plan**](http://www.ninds.nih.gov/research/clinical_research/policies/data_safety_monitoring.htm) |  |  |  |
|  | 1. [**Training Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. [**Study Communications Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. Maintaining MOP |  |  |  |
|  | 1. Site Signature Log/Description of Responsibility |  |  |  |
|  | 1. [**Recruitment Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. Screening and Informed Consent |  |  |  |
|  | 1. Enrollment and [**Randomization**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. [**Retention Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. Study Timelines/Study Visits |  |  |  |
|  | 1. [**Drug/Device Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. Laboratory Specimen Plan |  |  |  |
|  | 1. [**Blinding**/**Unblinding**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. Concomitant Medications |  |  |  |
|  | 1. Data Management |  |  |  |
|  | 1. [**Source Documentation**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) |  |  |  |
|  | 1. [**Case Report Form**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) completion |  |  |  |
|  | 1. AEs/SAEs |  |  |  |
|  | 1. Participant withdrawals from study and lost to follow-ups |  |  |  |
|  | 1. [**Protocol Deviations**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) and violations |  |  |  |
|  | 1. [**Quality Assurance (QA)/Quality Control (QC)**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) procedures |  |  |  |
|  | 1. [**Monitoring Plan**](http://www.ninds.nih.gov/research/clinical_research/toolkit/things_nowfunded.htm#monitoring) |  |  |  |
|  | 1. Study Completion |  |  |  |
|  | 1. Website (if applicable) |  |  |  |
| **Randomization** | | | | |
|  | Are there written procedures to assure that participants are randomized according to the [**randomization plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)? |  |  |  |
|  | Are there written procedures for maintaining the confidentiality of the [**randomization code**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)? |  |  |  |
|  | Is there a procedure that verifies the correct randomization number was assigned? |  |  |  |
|  | Are there written procedures to ensure that the randomization assignment stays with the participant through the entire data collection process? |  |  |  |
|  | Are [**masking/blinding**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) and [**unmasking/unblinding**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) procedures in place? |  |  |  |
| **Data Collection (Data system)** | | | | |
|  | Is there a schedule of participant contacts (i.e. study visits)? |  |  |  |
|  | Are there written procedures that guide data collection at each participant contact? |  |  |  |
|  | Is there a complete description and definition of how each data item is to be collected on each study form for each participant contact? |  |  |  |
|  | Do the forms and data collected at each participant contact correspond to and reflect the [**statistical analysis plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)? |  |  |  |
|  | Are there [**adverse event (AE) forms**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) and do they include the necessary data to generate safety reports? |  |  |  |
|  | Are there automated range and logic checks built into the system? |  |  |  |
| **Data Management** | | | | |
|  | Is there a detailed description of how forms are sent or transmitted to the data coordinating center? |  |  |  |
|  | Is there a [**Data Management Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) or do written procedures document data handling from collection through analysis? |  |  |  |
|  | Are there tracking procedures that document and confirm participant enrollment, data collected, forms completed, and forms received at the data collection/coordinating center? |  |  |  |
|  | 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? |  |  |  |
|  | Are there procedures for correcting data so that changes can be identified for accuracy and completeness in a systematic way? |  |  |  |
|  | Are there procedures in place that identify and track the status of each participant throughout the study? |  |  |  |
|  | Are there procedures in place for data cleaning? |  |  |  |
|  | Are there automated range and logic checks? |  |  |  |
| **Safety Plan** | | | | |
|  | Is a [**Safety Monitoring Plan**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) in place that outlines independent oversight in the form of a [**DSMB / Safety Monitoring Body (SMB) /Medical Safety Monitor**](http://www.ninds.nih.gov/research/clinical_research/policies/data_safety_monitoring.htm#requirements) ? |  |  |  |
|  | 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** | | | | |
|  | Are screening, recruitment, enrollment, and retention reports reviewed regularly and action plans documented? |  |  |  |
|  | Are [**protocol deviation reports**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) reviewed regularly and violations documented systematically? |  |  |  |
|  | Are there data quality reports that describe missing or erroneous data reviewed regularly to detect and correct problems? |  |  |  |
|  | Are [**site monitoring reports**](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm) generated to provide feedback regarding problems and issues discovered during site visits and to report on the quality of data reviewed? |  |  |  |
| **Quality Standards** | | | | |
|  | Have quality standards been established for enrollment and accrual deviations, drop-outs, and data entry and analysis? |  |  |  |
|  | Are procedures in place for correcting inaccurate data and documenting the changes systematically? |  |  |  |
|  | Are procedures in place for amending the protocol and the MOP and documenting the changes? |  |  |  |
|  | Are procedures in place to modify quality control reports, if necessary, to capture correct data? |  |  |  |
|  | 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)*