Maintenance of Essential Documents for the Conduct of a Clinical Trial

Procedure Overview
To describe requirements and define the standard procedures for maintaining the documents essential for clinical trials conducted within the NETT.

Responsible Individuals
Qualified NETT personnel including, but not limited to, Site Managers and Hub Study Staff; Contracted Clinical Research Associates

Procedure

1. Definitions
   a) Clinical investigator - An individual who actually conducts a clinical investigation, or people under whose immediate direction a drug, treatment, biologic, or medical device is administered or dispensed to a human subject in a clinical trial (21 CFR §§312.3, 812.3).
   b) Federal Wide Assurance (FWA)-An Institutional Review Board's assurance to the government to protect research participants and their rights.
   c) Hub complex - The NETT Hub institution and the spokes affiliated with the Hub.
   d) Institutional review board – The board within an institution providing oversight of research as described in 45 CFR Part 46.

2. Essential Documents
   a) Are to be present and up-to-date in the NETT WebDCU™ or the investigative site's regulatory file.
   b) The accuracy and completeness of document collection and maintenance will be verified by the NETT CCC project management staff.
   c) A description of NETT essential documents and maintenance are noted below:

Name of Document	Filing Location	Update Requirements	Retention Requirements	Comments
Protocol-Original, amendments and addenda	WebDCU™	With subsequent protocol amendments and addenda	Until study close out	First page of each protocol and/or amendments and/or addenda are signed by the hub and/or spoke principal investigator

Name of Document	Filing Location	Update Requirements	Retention Requirements	Comments
Signed Statement of Investigator (FDA Form 1572 for drugs or trial-specific document)	WebDCU™	With subsequent protocol or personnel changes	Until study close out	
CVs for all personnel on Statement of Investigator	WebDCU™	Every two (2) years	Until study close out	CVs should reflect current addresses, institutional and/or clinical affiliations, etc.
IRB approval and/ or acknowledgements letters	WebDCU™	With each subsequent protocol amendments and/or addenda	Until study close out	Includes letters for original approvals, amendments and addenda, informed consent documents, annual renewals, reports of SAEs and DSMB findings, study close-out, etc.
Documentation of FWA number	WebDCU™	Upon site-specific expiration date	Until study close out	
Copy of informed consent documents (ICD) approved by the IRB	WebDCU™	With each subsequent protocol amendments, addenda, and/or ICD change	Until study close out	Blank copy of approved documents
IRB applications submitted for approval to the IRB	WebDCU™	With subsequent protocol amendments, addenda, and/or changes to submitted documents	Until study close out	Includes original, amendments, and renewal applications. Include supplemental materials such as advertisements, scripts and patient education materials as applicable
Laboratory certifications	WebDCU™	Upon site-specific expiration date	Until study close out	
Test article accountability documentation, to include shipment and return documentation	WebDCU™	With each shipment of test article(s)	Until study close out	Documentation as applicable for study using investigational products

Name of Document	Filing Location	Update Requirements	Retention Requirements	Comments
Test article disclosure document	WebDCU™ and/or regulatory file at the site	As needed	Until study close out	Document maintenance is trial specific. Site may be defined as either the spoke or hub
Randomization code (if applicable)	WebDCU™	As needed	Until study close out	Documentation as applicable for study
Substantive site communications with sponsor and/or its agents	Regulatory file at the site	As needed	Until study close out	Including and not limited to reports, emails, letters, etc. Site may be defined as either the spoke or hub
IRB communications including documentation of notification of Serious Adverse Events to IRB	Regulatory binder at the site	Additions as applicable	Until study close out	Site may be defined as either the spoke or hub
Investigator Brochure	WebDCU™ or regulatory file at the site	As needed	Until study close out	Document maintenance is trial specific. Includes updated versions. Site may be defined as either the spoke or hub
Monitor visit reports	WebDCU™	Frequency as applicable for study	Until study close out	Documentation of findings entered after each visit. Includes pre-study, routine, study close-out visits
Master Subject Log	In a locked cabinet at the site	With each subject enrolled	For 15 years after the study has ended	Site may be defined as either the spoke or hub
Delegation of Authority Log	Regulatory binder at the site	Subsequent protocol amendments and/or addenda	Until study close out	Site may be defined as either the spoke or hub
Documentation of Study Discontinuance (notice to IRB)	WebDCU™	N/A	Until study close out	
CCC exemption approvals	WebDCU™	As needed	Until study close out	Description of reason for exemption to be included

3. Record retention
   a. The specifications for record maintenance and retention included above reflect the current guidelines for NETT trial documents. Documents and requirements listed are general and are subject to change based on the trial, if required by the applicable regulatory requirements or by an agreement with the NETT CCC or study sponsor.
   b. If documents need to be retained for a period longer than specified, it is the responsibility of the NETT CCC to inform the investigator/institution as to when these documents no longer need to be retained.
   c. Regulatory files for investigative sites within a hub may be maintained in a central hub location as permitted by the participating institutions.

4. Approval for Process Exemption
   a. The Director of Site Operations or designee must approve exemption from the processes outlined in this policy. The Director of Site Operations or designee must maintain documentation of the exemption approval.

Procedure Author
NETT Network Operations Committee, NETT CCC