CPN Electronic Regulatory Binders

Because the original copies of all signed documents are forwarded to DCP's regulatory contractor, CCS Associates, it is acceptable to keep regulatory files in an electronic format if all of the following issues are addressed:

- Electronic regulatory files must be kept in a secure system that is backed up regularly.
- There must be a procedure in place for providing access to the electronic regulatory files at the time of a visit by a monitor or auditor. If documents are copied to a CD or DVD for a monitor's visit, test the CD or DVD to make sure the documents were copied successfully and completely.
- PDF format is recommended but not required.
- Electronic regulatory documents and files must be labeled in such a way that the contents of each file and document are apparent when viewing the labels. The following labels are examples. When there is an expiration date, an "x" is added to the label for easy review. Any appropriate and easily understandable labeling convention is fine.
    - ☐ Limburg_medlic_x21Jan2010
    - ☐ Limburg_CV_02Feb2009
    - ☐ Limburg_HSP_x10Jul2010
    - ☐ MAY04-4-01_ss1572_02Feb2009
    - ☐ MAY04-4-01_CCF_DOR_revised_02Feb2009
    - ☐ MAY04-4-01_CCF_IRBapproval_V7A5_21Jan2009
    - ☐ MAY04-4-01_MCR_IRBcontinuingapproval+consent_x16Jun2009
    - ☐ MCR_CAP_x15May2011

Checklist

Note: This represents this list required by DCP's Regulatory Contractor. There may be additional documents required by the local institution.

Protocol and protocol-related documents

- ☐ Current/active version of the protocol
- ☐ Current/active version of informed consent document(s)
- ☐ Current/active version of pre-registration eligibility checklist
- ☐ Current/active version of eligibility checklist
- ☐ Current/active version of case report forms
- ☐ Copy of every version of the protocol and consent since initial IRB approval

DCP and IRB/REB approvals

- ☐ Documentation of Drug Shipment Authorization for specific site and study. Note: This represents confirmation that all applicable regulatory documents were on file with CCS Associates at the time of site activation to a given study.
- ☐ Documentation of current and ongoing Federal Wide Assurance (FWA)
- ☐ Documentation of initial IRB approval plus IRB-approved informed consent
- ☐ Documentation of annual/continuing IRB approval plus approved consent form for each year after initial approval
- ☐ Documentation of IRB approval of current study team members
- ☐ Documentation of IRB approval of any participant recruitment materials being utilized
- ☐ Documentation of submission of any applicable adverse events, deviations, safety letters, and data safety and monitoring board reports, per local institutional policies

- ☐ Documentation of IRB approval of each amendment to the protocol and/or consent since initial IRB approval
- ☐ Copy of actual IRB submission of each amendment to the protocol and/or consent since initial IRB approval

Note: The IRB/REB approval must specify the version and/or version date of each document that they approve. A revised approval letter or excerpt from meeting minutes must be requested if this information is not included.

Lab

- ☐ Current CAP and CLIA certificates, or note to file if not available, for all labs listed on the study-specific 1572 form
- ☐ Any other state/provincial laboratory certifications, as applicable
- ☐ Listing of laboratory normal values or reference ranges for all labs listed on study-specific 1572, no more than one year old.

Study-specific

- ☐ Study-specific 1572 (PI at the top, all co- and sub-investigators, and study coordinators in field #6; anyone who has contact with data and/or participants)
- ☐ DCP Delegation of Tasks (DOT) form
- ☐ Site/study Signature Log (Not needed if actual signatures are on the DOT form)
- ☐ CPN Site Application form
- ☐ CPN Receipt of Study Agents form
- ☐ Recruitment and Retention plan
- ☐ Study Agent Investigator Brochure (IB) or package insert, if applicable
- ☐ Acknowledgement of receipt of IB, signed and dated by site PI, if applicable
- ☐ Fully executed subcontract
- ☐ All monitoring reports
- ☐ Site responses to monitoring reports and action items
- ☐ Any submitted drug accountability or drug return forms
- ☐ Screening logs documenting contact and activities for all participants contacted for possible study participation.

Personnel

For PI and all study team members (cross reference list on study-specific 1572):

- ☐ DCP Financial Disclosure Form
- ☐ CV, signed and dated within the past two years
- ☐ Current medical license
- ☐ Documentation of current Human Subjects Protections training

For all other study personnel (cross reference list on Delegation of Tasks form):

- ☐ Documentation of current Human Subjects Protections training

Correspondence (recommended)

- ☐ Notes from teleconferences
- ☐ Study Coordinator memos
- ☐ Other correspondence to and from local IRB

Correspondence (required)

- ☐ All safety alert letters received since initial study activation
- ☐ All Data Safety and Monitoring Board reports received since initial study activation
- ☐ All correspondence from CLO regarding study activities, study implementation, or policies