Source Documentation Tips

CARDINAL RULE IN GCP COMPLIANCE

- ☐ Case report forms and the source documents/medical records must match, data point to data point.

EXAMPLES OF SOURCE DATA

- ☐ Medical History information
- ☐ Medical Examination results
- ☐ All lab results
- ☐ DOB, gender, weight
- ☐ Patient ID number
- ☐ Study number
- ☐ Drug dispensing information
- ☐ Informed consent
- ☐ IRB approval
- ☐ Visit dates
- ☐ Concomitant medicines
- ☐ Intercurrent illnesses

DELEGATION OF AUTHORITY

- ☐ Used to clearly outline the name of each individual to whom the PI has delegated authority to perform certain clinical study related tasks.
- ☐ Individuals name/title must correspond to one or more specific tasks.
- ☐ Should describe delegated tasks, identify the training, dates of involvement on study
- ☐ PI should sign DOA within a reasonable time prior to staff performing duties
- ☐ If there is a lapse of time for the PI to sign DOA, then there should be a Note to File explaining the delay and that this was communicated to the IRB and Sponsor

NOTES TO FILE

- ☐ A note to file is an entry, normally in the form of a document, in the regulatory binder that makes a correction to another entry or document or explains something.
- ☐ Can be written by any study team member to provide additional information or clarification. NTF should be reviewed and signed by PI.
- ☐ Can be used to explain how information was obtained and who obtained the information, discrepancies, missing and/or incomplete data, actions taken and or measurements assigned.
- ☐ Can be patient or non-patient related.
  May be used when other documentation is not adequate or not complete elsewhere
- ☐ *NTF are not necessary* when actions, clarifications, plans or discrepancies are addressed fully in other study documentation
- ☐ Caution! Significant number of NTF observed during an inspection may be an indicator or poor oversight, inadequate training of study coordinators, overly taxing work load, sloppy record keeping.

For more information contact the Quality Assurance Dept at 520-621-5196 bpernic@email.arizona.edu