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Version Control in Clinical Research

Section 8 of GCP E6 R2: These documents [essential documents] serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. Essential Documents also serve a number of other important purposes. Filing essential documents at the investigator/institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor, and monitor. These documents are also the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

Only the most current IRB approved informed consent should be used when a new participant is considered for a research study.

Tips and Best Practices:

- Study teams should ***not*** keep local copies of the current IRB approved protocol, informed consent documents, or any other documents submitted to the IRB.
    - There should be a central location (electronic or physical) where the most current IRB approved protocol, informed consent document, and other documents live. Study team members should take a copy from the central location when necessary.
    - Assign specific study team members to keep this central location up to date. Ideally, the person who receives the IRB approval should update the central location.
- The Regulatory Binder and participant source documents tell a story, and should navigate individuals through the lifecycle of the study. This is why it is still important to keep all versions of essential documents on file.
- All current and previous versions of following should be maintained in the Regulatory Binder:
    - Protocol
    - Informed Consent Form
    - Written information provided to participants
    - Advertisements for participant recruitment (if applicable)
    - Refer to the Clinical Research Regulatory Binder Index for a complete list
- Protocol Amendments
    - All study staff members should be trained on new protocol amendments and the training must be documented for each study staff member.
    - A study team member must be trained on the current protocol before approaching a participant to consent or re-consent.
    - Documentation for training on a new amendment can occur on the same day as consenting a participant on the new amendment.

Additional Resources:

- Clinical Research SOP: SS-301 - Maintenance of Research Regulatory Binders
- Clinical Research SOP: GA-105 - Investigator Responsibility for Study Team Training and Documentation
- GCP E6 R2: FDA Guidance on Good Clinical Practices