Regulatory Binder

What should be in the binder?

- Table of Contents
- Protocols
- Investigator Credentials (CVs, CITI Training, Conflicts of Interest)
- Appendices (Questionnaires, Screening forms, Recruitment materials)
- Scientific Review
- Informed Consents/HIPAA Authorizations or Waivers
- IRB Submissions & Approvals
- Agreements (IAIRs, CRADAs, MOAs)
- Audit Documents

What should NOT be in the binder?

- Identifiable Data
- Signed Consent Forms
- Drafts and Unapproved Documents

BEST PRACTICES

- Use the AHRPO audit checklist to create your Table of Contents.
- Implement a version control process.
- Store your binder in an easily accessible location and update the binder in a timely manner.

AUDIT

- Regulatory Binders are auditable by AHRPO and USMA HRPP.
- The binder must be kept for 3 years after the study is closed.
- Can you use an electronic binder? Yes, but it must be as organized and accessible as a physical binder.

QUESTIONS?

A sample binder is available for check-out

For more information, please contact hrpp@westpoint.edu