Clinical trial audits… What is being checked?

Essential documents

- ☐ Protocol and amendment signature pages
- ☐ Licensure
- ☐ Form 1571/1572 Investigator Agreement (for device only)
- ☐ Sponsor financial disclosure forms
- ☐ Curricula vitae
- ☐ Lab documentation
- ☐ Study delegation log

IRB documentation

- ☐ Initial approval and start of research
- ☐ Approval of annual and continuing reviews
- ☐ Approval of protocol amendments
- ☐ IRB correspondence
- ☐ Protocol deviation notifications
- ☐ SAE notifications
- ☐ IRB roster
- ☐ Data safety reports
- ☐ Recruitment materials
- ☐ Investigator brochure / package insert/ device manual
- ☐ IRB approved **Informed Consent** document
- ☐ IRB approved **HIPAA** authorization document

Study Monitoring

- ☐ Study Monitoring logs
- ☐ Monitoring letters
- ☐ Documentation of completion of action items if applicable

Equipment

- ☐ Maintenance/calibration/validation records
- ☐ Monitoring logs including temp/alarms

Investigational product accountability

- ☐ Storage site
- ☐ Accountability log(s) Inventory
- ☐ Shipping receipts / packing slips
- ☐ Temperature (logs)
- ☐ Policies and procedures

Subject evaluation

- ☐ Signed informed consent & HIPAA authorization forms
- ☐ Inclusion / Exclusion documentation
- ☐ Medical records
- ☐ Physician orders
- ☐ Subject reimbursement documents or process
- ☐ Concomitant Medication log
- ☐ Subject Investigation product accountability log

Safety or Adverse events

- ☐ Documented in Medical records
- ☐ Severity and causality assigned and signed/dated by PI
- ☐ IRB correspondence
- ☐ Sponsor notification

Data integrity

- ☐ Source data
- ☐ Case report forms
- ☐ Research notes
- ☐ Good Documentation Practice

PI Oversight

- ☐ HSPP training for key personnel
- ☐ Subject Screening and Enrollment log
- ☐ Training documentation: Biohazard, Protocol specific, CITI

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