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

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

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

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