



BANNER AUDIT READINESS

What You Need to Know to Be Successful

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Banner Research Compliance

- **Mission Statement:**

Committed to promoting a culture of compliance, research integrity and high-quality data to ensure human subject protection within Banner Research.

Banner Research Compliance

Sue Colvin

MHSA, BSN, CCRP, CHRC, CHPC

Research Regulatory Affairs Director

- Quality Management
 - Quality Assurance
 - Auditors
 - Education
- Regulatory Affairs
 - BAI, BSHRI, BMDACC
- Institutional Review Board
 - Phoenix Panel

Quality Management

Mary Rybka
Resrch Compliance Analyst

Steve Borwege
Resrch Compliance Analyst

Tracy McKay
Resrch Compliance Analyst

Pamela Kinder
Resrch Compliance Analyst

Cindy Soto
Resrch Regulatory Spec

Jeannie Farnsworth
Resrch Compliance Analyst

John Williams
Resrch Compliance Analyst

Justin Ford
Resrch Compliance Analyst

Why are we here auditing your study?

Special Provision No. 125 to Master Purchased Services Agreement

Research Support Staff at

Banner—University Medical Center Tucson Campus and

Banner—University Medical Center South Campus

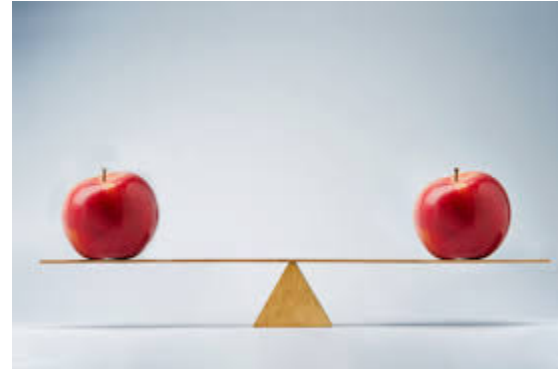
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B. Purchased Services.

3. Mutual Responsibilities of Both Parties. BH (through its Research compliance team) and the University (through its University Research and Compliance Program) will monitor and conduct random internal audits of the Research Studies subject to this Special Provision. Each party will notify the other party of its intent to audit to avoid multiple audits of the same investigators or programs in the same year, and will share its audit results with the other party.

Audit Work Plan

- Annual Plan set in Q1
 - Audit tool set for the year
- Types of Audits
 - Routine
 - For Cause
 - Focused
 - FDA Prep (Banner specific)



How do we identify a routine audit at BUMC-T

- UA Human Subjects Protection & Privacy Program provides quarterly list of Banner-AMC studies
 - 1500+ studies
 - Subject enrollment required
- Decision matrix
 - Higher risk, high enroller, phase I, new to research
 - Can be UA IRB or IRB oversight deferral
 - Generally not minimal risk studies

Banner Clinical Research Activities Process Interview

- Better understanding of the processes of a new BUMCT department entered in the audit rotation.
- Process interview objective is to help evaluate internal controls related to compliance with policies, the conduct of clinical research activities and promotion of operational efficiency.
- Prepare confidential report that is shared with University Research and Compliance Program

Audit Notification

- Ideally four weeks notification
 - Study identified
 - Scheduling of audit
 - Five days
 - Location/hours of operation
 - Advance notice of Pharmacy tour

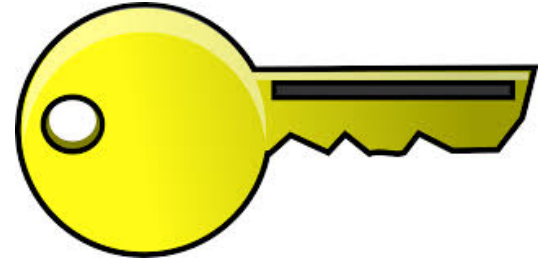


Pre-Audit Preparation

- In order to prepare for the audit we request:
 - Protocol
 - Screening and enrollment logs (encrypt)
 - All Auditors have Cerner access
 - ICFs
 - IRB letters
 - SOPs

Pre-Audit Preparation

- We want to ensure our time onsite is used efficiently to avoid creating an undue burden on your time.
- Communication is key
- Sticking point: EDC access



Audit Readiness

- Know you can ask questions about our process
- Request alternate dates and times
 - Subject and patient priority
- Internal department processes may dictate location due to security of data.

Audit-Day 1

- Meet with PI and research staff
- Review methodology
- Start with Regulatory Documents
- Check in at the end of the day *****
- Securing of study data

Scope of Audit Components for Project Evaluation

- Essential Documents
- IRB Documentation
- ICF/HIPAA Content
- Study Monitoring
- IP Accountability
- Equipment
- PI Oversight
- Clinical Trial Finance
 - (CTMS entry)



Scope of Audit Components for Subject Evaluation

- Informed Consent
- HIPAA
- Eligibility
- Study Assessment & Procedures
- Safety & Adverse Events
- Data Integrity (ALCOA-C)



Banner Research Compliance is ever evolving

- New for 2020
 - Audit team will visit once a quarter
 - Enhanced report aligned with recent FDA trends
 - Corrective and Preventive Action (CAPA) support
 - Offered optional close-out at the end of the onsite audit, now will need to have a meeting after draft report is issued.

What to expect following the audit

- Draft report within 10-15 business days
- We may have follow-up questions
- You are welcome to email us with questions while we are writing the report.
- We will schedule the CAPA review meeting

CAPA-Corrective and Preventive Action

- What is the difference?
 - Corrective: Fix the errors identified, if possible.
 - Preventive: Plan to prevent errors from recurring
 - Must be monitored and communicated to all staff
- Why is it important?
 - FDA inspectional objectives (device)
 - <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/corrective-and-preventive-actions-capa#page1>

But aren't audits punitive?

- That's not our goal.
 - For Cause audits can feel that way
- We are not the sponsor or a regulatory agency
 - Banner Research success is dependent on your success

Ultimately our goal is the same



Thank you

- Questions?
- Contact:

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