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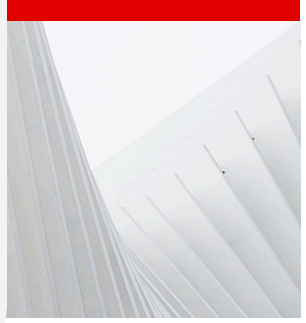
Are You Ready for a Successful Clinical Research Audit?

A BRANY Info Post:

Common Areas Where Our Auditors Find Significant Issues During Quality Assurance Reviews



To be audit prepared, make sure to review…

1: Delegation and PI Oversight

- **Key Aspects of a Delegation of Authority (DoA) Log:**
  - Ensure delegation of tasks are documented clearly (e.g. start and end dates, PI authorization via initials or signature)
  - Study personnel have appropriate qualifications prior to study start and are adequately trained throughout.
  - Periodic review to confirm accuracy and completeness, clarifying any discrepancies with start and end dates
  - Ensure appropriate delegation of tasks

- **Principal Investigator (PI) Overall Responsibility:**
  - Ultimately accountable for oversight and study conduct.
  - Maintains thorough knowledge of study protocol.
  - Ensures study team are informed of protocol changes.
  - Prompt assessment of any adverse events or deviations.
  - Confirms accurate and timely documentation of all trial-related activities.

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Some of our most noted findings involve…

#2: Documentation of the Informed Consent Process

- **Informed Consent:**
  - Must be signed prior to completing any study specific tasks.
  - Study personnel qualified and delegated are to obtain informed consent.
  - Provide comprehensive information about the study.
  - Must be IRB approved.

- **Essentials of Consenting Process:**
  - Documentation that elements of consent were captured, including interpreter information when applicable.
  - Obtained in a confidential setting.
  - Record of any questions asked by participants and the responses given.
  - Verification of participant’s comprehension and voluntary agreement to participate.

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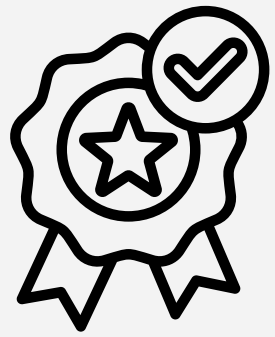
Top sites ensure all aspects of research adhere to...

#3: ALCOA & Good Clinical Practice (GCP)



The ALCOA principles are fundamental to Good Clinical Practice (GCP) and ensure the reliability and integrity of data collected in clinical trials. Data must be:

- **A: Attributable** – Data should be traceable to a specific individual or source.
- **L: Legible** – Data must be clear and readable.
- **C: Contemporaneous** – Data should be recorded at the time of the activity.
- **O: Original** – Data must be the first recorded instance.
- **A: Accurate** – Data should be correct and truthful.

This rigor is crucial for maintaining the credibility of the clinical trial results, ensuring regulatory compliance, and ultimately protecting patient safety.

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Want to learn more about the quality assurance function of auditing and how to ensure your site is performing at optimal compliance?

Please email your questions to QA@BRANY.com or visit BRANY's Research Auditing and Monitoring page for more information.