

Getting Started with Research Audits



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WALES

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1 HOW TO START

Have a program that includes appropriate areas for audit such as:

- Research studies (prioritised by risk)
- Support Services (e.g. radiology, pathology and pharmacy)
- Process audits (e.g. consent, research passports)

2 PREPARE FOR AUDIT: BACKGROUND READING

- If auditing a research study, be familiar with the protocol, ethics application and any recent amendments.
- If auditing a support service or a process, be familiar with the applicable policies, Standard Operating Procedures (SOPs) or other guidelines.

3 PREPARE FOR AUDIT: PRACTICALITIES

- Use well designed audit tools to measure all applicable standards.
- Arrange a suitable date and time and request some desk space.

4 AUDIT DAY

- Make a record of those in attendance.
- Explain to your colleague what you are going to audit and how. This ensures there are no surprises!

5 DATA COLLECTION

- Review all available documents whether paper or electronic to complete the audit tool fully.
- Talk to the researcher or colleague! Seek clarifications to make sure data collection is accurate.

6 ANALYSE DATA

- As far as possible feedback the findings on the day. Your colleague will know what actions to expect and it gives the auditor further opportunity to clarify any queries.
- Don't forget to include positive findings!

7 THE REPORT

- Categorise each finding as appropriate according to local SOPs.
- Make clear factual statements of findings.

8 ACTION PLAN

- Specific corrective and preventative actions with a specific deadline. Think "What, Who and When"!
- Note common re-occurring themes....can such findings be addressed via other methods such as training? Newsletters? By clarifying an existing SOP?

9 FOLLOW UP ON THE ACTIONS

- Keep regular contact with the researcher or colleague to check progress against actions.
- Consider if any support can be offered to move actions along.

RE-AUDIT

This closes the audit cycle and ensures quality of research is sustained and informs if preventative measures are successful.