A Review of Audit Case Studies

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Understand the how research compliance helps **facilitate research**.

- Reputation internally
- Reputation externally
Why for-cause audits?

• Who needs them?
• Why are they important?
For-cause audit flow

Requestor

Auditor: Finalize audit report and send to requestor

Investigator: Respond to audit recommendations

Exit Meeting: Discuss draft report with stakeholders

Auditor: Draft audit report

Auditor: Do the audit!

Auditor: Draft steps to measure requestor’s objectives

Entrance Meeting: Stakeholders meet to finalize audit program

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Auditor: Do the audit!
What’s SO GREAT ABOUT this?

Transparency
Case study #1

• Oncology: Consent
• AE reports
• Protocol adherence
Case 1

• **Scene:**
  – Out-patient/in-patient clinic with national referrals to the clinician (well-known oncologist)
  – 1000+ new patients referred annually, with 50-70% enrolled in 5+ research protocols
  – Protocols include intervention and 5-year adverse event follow-up
• Audit Prompt:
  – IRB continually concerned about the lack of adverse event reporting on annual reports
  – Results of internal compliance office cursory review of research consents
Case 1

• Audit Objectives:
  – Was legally effective informed consent documented for each participant?
  – Have all adverse events been reported appropriately?
  – Was the protocol followed for each participant?
For-cause audit flow

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Case 1

• Audit Findings:
  – Consent
  – Adverse events
  – Protocol followed
  – Record-keeping processes
Case 1

• **Conclusions:** YOU!
  – Compliance perspectives
  – Ethical perspectives
Case 1

• **Recommendations:** YOU!
  
  – Consent
  – Adverse events
  – Protocol adherence
  – Record-keeping
Case 1

• **Results:**
  
  – All studies were terminated
  – All study data were requisitioned by institution (consents, notes, databases, etc.)
  – Investigator required to redact all publications
  – Investigator lost research privileges at the institution for 2 years, with the option to begin again after completing robust training in conducting research with a single research project
• Lessons Learned:
  – Institution:
    • Heed **hunches** about problems while being **fair and objective**
    • Have **checks and balances** in place to measure if training is effective
  – Research team:
    • Understand your **responsibilities** and know the **consequences** for failure
    • Ensure you have enough **resources** to successfully manage your projects
Case study #2

• Genetics: Consent
• Release of rights
Case 2

• Scene:
  – Investigator is an internationally recognized expert in certain rare genetic diseases
  – IRB perspective = difficult investigator
  – Investigator perspective = inexpert IRB
Case 2

• **Audit Prompt:**
  – Research team requested to add existing specimens to an existing repository for rare genetic disorders
  – Patients want to provide specimens for research into the cause of the rare genetic diseases
  – IRB requires copy of research consent and release of specimen/rights to research results from the organization
  – Research team refused to provide these documents, and the IRB denied the request to add specimens to repository
  – Research team reported having obtained specimens in an annual report to the IRB
Audit Objectives:

– Does the research team understand their responsibilities to collect/maintain informed consent for each specimen, and to obtain documentation releasing the specimen/rights to research results?

– Is a consent form available for each specimen maintained in the repository?

– For the additional specimens in question, has the research team obtained consent forms and releases of specimens/rights to results?
For-cause audit flow

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Auditor: Draft audit report

Auditor: Do the audit!
• **Audit Findings:**
  
  – In identical individual interviews, all members of research team answered questions about receipt and storage of specimens and documentation accurately
  
  – The auditors completed the retrieval process for consents and specimens easily
  
  – Documents for the new specimens were present
Case 2

- **Conclusions:** YOU!
  - Compliance perspectives
  - Ethical perspectives
Case 2

- **Recommendations:** YOU!
Case 2

• Results:
  – Research team demonstrated accurate understanding of the research process
  – Research team asked to create and submit standard operating procedures for receiving specimens/documents and storage of both
  – The IRB approval for the project was reinstated
Case 2

• Lessons Learned:
  – Institution and Research Team:
    • Sometimes it *takes time to understand* one another
    • Don’t jump to conclusions
      – Find a way to *communicate*
      – Look for a *mediator*
Summary

• Good communication is hard. Transparency will take you far!
• Checks and balances are empowering:
  – Everyone knows their responsibilities.
  – They have the resources they need.
  – They can measure compliance on their own.
Questions