




The Day After: Preparing Plan B

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Oh no! I've got to do what? 

- Day of audit
 - After the audit: Day 1-30
 - Understanding the Final Audit Report
 - Preparing your response
 - Institutional follow-up
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Day of Audit

- Make notes of suggestions from auditors
 - Understand reviewers' comments
 - Exit Interview
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Exit Interview

- All members of research team invited to attend
 - Take note of specific problem areas
 - Clarify any issues that are not clear
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Celebrate!!!



After the audit: Day 1-30

- Research staff meeting: review deficiencies and discuss areas for improvement
 - Correct specific items identified
 - Communicate with audit team leader
 - Submit outstanding items (Unconfirmed Items List)
 - Amend and submit incorrect CRFs
 - Draft corrective action plan (CAP) to address known deficiencies
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After the audit: Day 1-30

- Unacceptable IRB/ICC rating
 - Exit Interview report
 - Review and discuss deficiencies
 - Prepare preliminary CAP
 - Submit CAP to the Audit Program Manager
(avoid possible suspension of patient accrual)
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Understanding the Final Audit Report

- Three primary review categories
 - IRB / Consent content
 - Pharmacy
 - Patient case review
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Rating System

- Each subcategory is rated
 - OK: No significant deficiencies noted
 - Lesser deviation: minor, relevant deficiencies noted
 - Major deviation: significant errors or omissions
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Overall Category Assessment

- Acceptable: no written response required
 - Acceptable, needs follow-up: corrective action plan required within 30 days
 - Unacceptable : immediate corrective action plan required for IRB/ICC
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Preparing Your Response

- Review audit report
 - Address each deficient area
 - Outline strategies to prevent future deficiencies
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Institutional Follow-up

- Implement plan of action
 - Contact available resources
 - Audit Program Staff
 - Audit committee members
 - CRA committee members
 - Self audit
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Going Forward

- Consider new processes/procedures
 - Celebrate successes
 - Goal: quality clinical research
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**Cancer and Leukemia Group B
Fall Group Meeting**

**2008 Tampa, FL
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