



Responding to The Audit Findings

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For CALGB Participants Only

Oh no! I've got to do what?



- Day of audit
 - Internal review of systems
 - Review audit report
 - Preparing your written 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!!!



Internal Review of Systems

- Research staff meeting: discuss areas for improvement
- Correct specific items identified
 - Communicate with audit team leader
- Develop action plan to address system problems

Final Audit Report

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

Rating System

- Each subcategory is rated
 - OK: No significant problems noted
 - Lesser deviation: minor, relevant problems noted
 - Major deviation: significant errors or omissions

Overall Category Assessment

- Acceptable
 - Acceptable, needs follow-up
 - Unacceptable
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Review Audit Report

- Acceptable rating: no written response required
 - Acceptable, needs follow-up: corrective action plan required within 30 days
 - Unacceptable: immediate corrective action plan required
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Preparing Your Written Response

- Review audit report
 - Address each deficient area
 - Submit corrected / missing data
 - Outline strategies to prevent future deficiencies
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Institutional Follow-up

- Implement plan of action
 - Contact available resources
 - Audit committee members
 - CRA committee members
 - Self audit
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Looking Forward

- Welcome change
 - Seek out new ideas
 - Celebrate successes
 - Goal: quality clinical research
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