



# Responding to Your Audit Report

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## Responding to Your Audit Report

- Day of audit
  - Internal review of systems
  - Review audit report
  - Written response to audit report
  - Institutional follow-up
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## Day of Audit

- Make notes of suggestions from auditors
  - Understand reviewers' comments
  - Goal: quality clinical research
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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!!!

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## 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
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## 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 problems noted
    - Lesser deviation: minor, relevant problems noted
    - Major deviation: significant errors or omissions
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## Overall Category Assessment

- Acceptable
  - Acceptable, needs follow-up
  - Unacceptable
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## Written Response to 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 Written Report

- 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
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## Contact Information

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