# IRB Audit

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# Objectives

- Describe what is included in an IRB audit
- Discuss common deficiencies identified during IRB audits

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# What Will be Audited

Regulatory documents

- For all protocols on the patient case list scheduled for audit, including CTSU cases and the unannounced case
- Unannounced IRB cases

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# Regulatory Documents

- The “Paper Trail”

  Every correspondence with the IRB

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# IRB Binder for Each Protocol

- Initial IRB approvals
- Approval of all Amendment/Addendums/ Updates
- Annual renewals
- Current version of protocol
- Current approved consent
- CIRB approvals

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# What are auditors looking for?

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# IRB - What Are Auditors Looking For?

- Original approvals completed before patient registered
- Updates approved within 90 days of distribution (expedited and full board)
- Local SAEs reported to NCI via AdEERS as well as notification to local IRB

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# IRB - What Are Auditors Looking For?

- Broadcast SAEs submitted to IRB within 90 days of distribution or copy of IRB policy for auditor
- Adherence to Corrective & Preventative Action plan since prior audit
- Renewals within 365 days every year

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# IRB - Major Deficiencies

- Protocol never approved
- Protocol approved via expedited approval
- Annual renewal delayed > 30 days but < 1 year
- Missing or expired annual renewal
- Local SAEs not reported to IRB

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# Informed Consent - What Will be Audited

- A minimum of 3  consent forms per audit
- Consent content is reviewed for regulatory compliance
- Compared to the model consent

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# Major Deficiencies for Informed Consent

- One or more risk(s) omitted
- Failure to revise consent in response to updates or NCI Action Letters
- Omission of one or more required element(s)
- Omission of content from Model Consent
- Accumulation of multiple minor problems

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# CIRB

- All consent changes MUST have written approval by the CIRB prior to use (keep in regulatory binders)

- NCI CIRB SOPs found at www.ncicirb.org

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# What if……?

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# What happens if I submitted the annual renewal to the IRB *before* the expiration date but the IRB reviewed and approved it *after* it had expired?

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# The Answer Is…

- You will still receive a deficiency since the renewal was not done within 365 days.
- Have the IRB develop a policy to prevent this from happening in the future – consider 11 month renewals
- Develop a system check to verify that you receive IRB approvals on all IRB submissions

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# What if my IRB wishes to discontinue the practice of reviewing external SAEs?

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# The Answer Is…

- Have your IRB develop a written policy or SOP to address their procedure

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# What if my IRB wants to change the risks from the Alliance model consent, either adding or removing risks?

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# The Answer Is…

- Changes to risks must be submitted to the Alliance Central Office for approval
- Approval documentation must be available during the audit
- The best procedure is to “mirror” the Alliance consent risks since NCI has approved it

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# Questions?

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