Human Research Compliance Audits

Erica Ellington, CRA
Research Compliance Manager
University Compliance
Human Research Audits

A compliance audit is intended to be constructive, service oriented process conducted for several positive reasons....

- To **ensure full compliance** with the laws, policies and standards governing human subjects research
- To **identify potential problem areas** to be addressed
- To **educate** on standards and expectations of research practices and promote Good Clinical Practices
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Ultimate goal = to help improve the quality of human subjects research.

So….

Try to think of us as Partners not Adversaries
Human Research Audits

Scheduling

- Studies to be audited are selected several weeks in advance of the audit
- An e-mail is sent to the PI and study coordinator asking for preferable times within a specified week
- Included with the e-mail is a copy of an audit checklist for study team members to review prior to the audit
If my study is selected for a compliance audit, what exactly will be audited?

- At MUSC the audit process is guided by a checklist that lists the specific items that will be reviewed

**Resource: Policy**
http://academicdepartments.musc.edu/research/ori/irb/HRPP/HRPP%20Guide%20Section%2010

**Resource: Checklist**
http://academicdepartments.musc.edu/uco/documents/Site%20Audit%20Checklist.doc
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What is the audit checklist based on?

- Federal & State laws and regulations
- FDA Good Clinical Practices – Provides a unified standard for designing, conducting, recording and reporting & describes the essential documents that permit evaluation of the conduct of a study and the quality of the data produced
  

- IRB Human Research Protection Program
  
  [http://academicdepartments.musc.edu/research/ori/irb/policies.html](http://academicdepartments.musc.edu/research/ori/irb/policies.html)
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What are the Primary Audit Components?

- Review of all **Informed Consent Documents and HIPAA authorizations** to verify subjects have been properly consented

Resource:  (HRPP 6.1, 6.2, 6.3 and 4.13)
http://academicdepartments.musc.edu/research/ori/irb/policies.html
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What are the Primary Audit Components?

- Review of the **Regulatory Binder** for essential documents

Resource: Principal Investigator Responsibilities - Recordkeeping and Record Retention Requirements (HRPP 5.2)

http://academicdepartments.musc.edu/research/ori/irb/HRPP/HRPP%20Guide%20Section%205.2
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What are the Primary Audit Components?

- Review of **Individual Subject Data Records** for protocol adherence, safety and confidentiality

- Verification of **data storage and security**
  - Review of data storage to verify data is maintained as stated in protocol
  - Identifiable subject data is filed separately from study generated data and identifiers have not been included in coded subject files
  - Separate, lockable file compartments are used
  - Electronic data is password protected
  - Electronic data resides on MUSC servers

- Overall **site operations**

**Resource:** SCTR Toolkit

http://academicdepartments.musc.edu/sctr/tools_links/toolkit_design.html
What happens at the conclusion of a compliance audit?

- Auditor briefs PI and study coordinator on findings

- A written report is generated and sent to the University Compliance Officer to approve/disapprove, provide additional comments or make recommendations

- A copy is then sent to the PI who replies to the IRB specifying a corrective action plan

- The IRB reviews the corrective action plan making additional comments and recommendations as needed.
Contact Information

Erica Ellington, CRA
Phone: 792-9098
E-mail: ellingte@musc.edu