UNIVERSITY of MARYLAND BALTIMORE

What to expect when you're expecting…OAC auditors

WHY DO WE AUDIT?

WRONG ANSWERS ONLY

WHY DO WE AUDIT?

RIGHT ANSWERS ONLY

WHY DO YOU DOCUMENT EVERYTHING RELATED TO HUMAN SUBJECTS RESEARCH?

WRONG ANSWERS ONLY

WHY DO YOU DOCUMENT EVERYTHING RELATED TO HUMAN SUBJECTS RESEARCH?

RIGHT ANSWERS ONLY

Protection of Human Subjects

- Protect the rights, welfare and safety of human subjects

Core Values

- Respect and Integrity
  - We value each other and hold ourselves accountable for acting ethically and transparently using compassion and empathy.
- Equity and Justice
  - We embrace and are committed to diversity, and we value inclusive and just communities. We oppose racism and oppression in all their forms.

Types of Audits

- For Cause
- Routine

What we review

- All documentation related to an IRB approved protocol
  - Regulatory Binder
  - Informed consent documentation
  - HIPAA
  - Study related labs
  - Surveys/measures
  - Biospecimen lab tracking
  - Storage of samples and drugs

IRB Approved Protocol

- If an activity is in the protocol, OAC auditors are looking for documentation that the activity took place
- If the activity did not take place, OAC auditors are looking for documentation as to why it did not

WHY MIGHT A STUDY ACTIVITY NOT TAKE PLACE?

What do OAC auditors reference

- ICH GCP (even if it is not a clinical trial)
- 45 CFR 46 (Common Rule)
- FDA regulations (if FDA regulated)
- Investigator Handbook

Regulatory Binder

- What is supposed to be in your regulatory binder?

Regulatory Binder

- Delegation log
- Training documentation of study team
- CVs & Medical Licenses
- Agreements
- Screening logs
- Enrollment logs
- Eligibility checklist
  - ICH GCP includes protocols, CRs, Mods, RNIs and informed consents but OAC checks CICERO
    - These may be required to be in the regulatory binder for your sponsor/monitor
    - Be sure to check requirements from your sponsor/monitor

Informed Consent Documentation

- Is having just the signed informed consent document sufficient?

Signed Informed Consent & Documentation Process

- OAC will be looking for documentation of the informed consent process
- Should detail what was covered, when, how long and by whom
  - Some study teams note questions participants ask

Study Documents

- What is a source document?

Source Documents

- The first place data are recorded
  - Could be EPIC for demographic information, labs, health information etc.
  - Could be the survey is in paper
    - It is the responsibility of the study team to provide or request access to all study related documentation including access to EPIC and RedCap

Process

- Email and CICERO notification
- Discuss scheduling first meeting
- CICERO notification confirming audit timeframe
- Audit takes place
- Exit meeting
- Submit response to report via RNI

Report Parts

- Participant Selection Criteria
- Reportable Events
- Protocol Adherence
- Application for Institutional Review
- Informed Consent
- Health Insurance Portability and Accountability Act (HIPAA)
- Data and Safety Monitoring
- Regulatory Documentation
- Training
- Drug Accountability
- Documentation
- Miscellaneous

Preparing for an Audit

- When should you prepare for an audit?

Preparing for an audit

- Study teams should prepare for an audit as they are designing & developing their IRB protocol

Preparing for an Audit

- Read the protocol
  - What activities are you telling the IRB you are going to do?
  - How are you going to document those activities?
- Training
  - Not just CITI & HIPAA
  - Study specific training
    - Usually PI led & ALWAYS document

Preparing for an Audit

- Resources
  - Do you have the resources to complete the activities (including personnel)?
- Other regulatory considerations
  - Are there other regulatory requirements (IBC, COI, Radiation Safety)

Preparing for an Audit

- Investigator Quality Improvement Assessment (HRP-430)

Common Findings

- Lack of documentation of the informed consent process
- Missing study activities (without note to file as to why)
- Missing or incomplete eligibility checklists
- Missing source documentation for eligibility checklists
- Study team members dating ICFs for participants
- Missing dates on ICFs & other documentation

Common Findings

- Missing CVs & training
- Missing or incomplete delegation of authority logs
- Study activities taking place out of study window

Closing Comments

- Document, document, document (if it is not documented it did not happen)
- If you have questions, ask (OAC is a resource)
- Keep Core Values in mind (Respect & Integrity, Equity & Justice)
- Human participant health, welfare, safety & rights is our #1 priority

OAC Auditing Team

- Edress P. Brunson, MS
- La'Tonya D. Brown, MJ
- Thomas O. Cole, MA

QUESTIONS?

Sarah N. Archibald, PhD, MSL, MS, MDE, MA, CCEP

Director, Auditing & Monitoring

Program Director, Research Administration Certificate Program

620 W. Lexington Street, 5th Floor

410-706-0149

sarchibald@umaryland.edu