Objectives

• Discuss the recent merger of the School of Medicine Compliance Office with the Institutional Ethics and Compliance Program
• Detail how this office serves the Duke Medicine clinical research community
• Discuss new processes and endeavors of the Duke University Ethics and Compliance Office that affects the Duke clinical research community
• Identify trends that CTQA has noticed in clinical research audits and recent FDA inspections

What is Changing

• DECO – Duke Ethics & Compliance Office
• Combined responsibility for Institutional and Medical compliance
• Hiring an additional director for the office
DECO Goals

• Understand resources available at DECO
  – Compliance Review Service (CRS)
  – Clinical Trails Quality Assurance (CTQA)
  – University Compliance Monitoring
• Increase communication – both ways
• Ensure value-added process

Compliance Structure at Duke

DECO – Future Changes

• Evaluate monitoring and reporting process
  – Ensure efforts are consistent with risks
• Increase communication
  – Liaison meetings, newsletters
• Explore new tools for monitoring and reporting
• Website update
• Compliance training
New Initiatives

• Assisting CRUs with developing a standardized process for monitoring of studies in the CRUs and reporting to the QA committee.
• If we can improve monitoring CTQA may be able to reduce the number of routine reviews per year.
• Working with DOCR to create a monitoring group that could be available to study teams that need monitoring resources.
• Adverse events class development

Recent Trends

• Medical records access
• Uptick in FDA visits (3 since October)
• Informed Consent Process Issues
• HIPAA Violations
• Signature and Delegation Log Issues
• Missing Data on CRFs
• Protocol Not Being Followed

Accessing Medical Records

• We have seen an uptick in individuals reporting unauthorized medical records access.
  – Do not access medical records of employees or co-workers
  – Need authorization for family members
  – My Chart:
  – Maestro Care:
  – Unauthorized access can result in termination
FDA Visits
• Informed consent appropriately obtained
• 1572s in order
• Financial disclosures in order
• Subject meet eligibility criteria
• Test article accountability/ disposition adequately documented
• Protocol-specific blinding/randomization procedures were followed

FDA Visits (cont’d)
• Source documents and CRFs are consistent with the following data listings provided in the background materials:
  – Primary efficacy endpoint
  – Secondary efficacy endpoints related to disease progression
  – Adverse events, serious adverse events and deaths
  – Protocol deviations
  – Subject randomizations
  – Subject discontinuation
  – Concomitant medications
• Note that for Verification of the primary efficacy endpoint and adverse event reporting, review of all subject records is requested.

Informed Consent Process issues
• Use correct version of consent
• Reconsent subject as soon as possible after amendment requiring reconsent
• Initial don’t just put check mark for opt in/out selections if consent requires initials
• Consenters must be authorized (new IRB policy)
• All parties must sign, date and indicate time
• Phase in of time of consent for all signatures.
Informed Consent Process Issues (cont’d)

- No phone consent without IRB approval
- Consenter should NEVER sign for subject. If subject is unable to sign, there should be a line for LAR signature
- Short form or translated consent must be IRB approved for non-English speaking subjects
- No alteration of consent without IRB approval
- Subjects must be given a copy of the ICF as Duke’s HIPAA Authorization is contained in the ICF.

HIPAA Violations

- Storing research data, including Electronic Protected Health Information (ePHI), on non-Duke approved and/or non-HIPAA compliant servers.
- The use of non-encrypted personal computers, portable hard drives and USB thumb drives for storing research data, including ePHI.
- Creation and maintenance/adherence to Information Security Operations Plan (ISOPS) and Research Data Security Plans (RDSPs).
- Collection and use of PHI without proper Subject authorization and/or HIPAA Waiver of Authorization.

HIPAA Violations (cont’d)

- Notice of Privacy Practices (NPP) not provided to healthy Subjects per Duke policy and HIPAA regulations. (NPP Updated 9/2013)
- Failure to collect signed acknowledgement of receipt of the NPP or a procedure to identify subjects who have been given an NPP at first service delivery.
- Improper disposal and/or destruction of PHI.
- Contact Duke Medicine ISO before storing any VA data at Duke. VA data must be maintained in a FISMA compliant environment.
HIPAA Violations (cont’d)

- Disclosure of PHI without an executed Data Use Agreement (DUA) in place and/or without Subject authorization.
- Transmission of Sensitive Electronic Information (SEI) and/or PHI without proper electronic security encryption.
- Use of personal email (Gmail, Yahoo, etc.) for Duke business.
- Please report suspected HIPAA issues in a timely manner, Duke has only 60 days to complete a breach investigation and corrective action. The 60 days starts as soon as the first person at Duke knows of the breach, not when the Compliance Office is notified.

Signature and Delegation Log issues

- The investigator should maintain a list of appropriately qualified persons whom the investigator has delegated significant trial related duties. (GCP 4.1.5)
- Need to list all key personnel for the life of the study and list the duties they are authorized to perform on the study
- All personnel should sign – Important to obtain original signatures
- Collect all required CV’s and Licenses

Missing Data on CRFs

- All blanks need to be filled in or marked N/A
- Data should be consistent with source documentation – have a plan in place to look for transcription errors (data validation)
- Both paper and electronic CRFs data should agree
Protocol not being followed

- Do not make changes to a protocol without IRB approval unless imminent risk of safety to subjects then need to notify IRB immediately.
- Do not implement amendment changes until IRB approval is obtained.
- Make sure study visits in window (timeline in MC).
- Document monitoring if protocol requires monitoring.
- Be sure pregnancy tests are performed as needed for research.
- Make sure all study questionnaire being used are IRB approved.
- Make sure adverse events documented and reported as required.

Summary

- DECO is a resource for you.
- Share ideas and efforts.

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Questions?