Research Compliance Risks and HIPPA Privacy Pitfalls in a Healthcare Academic Setting

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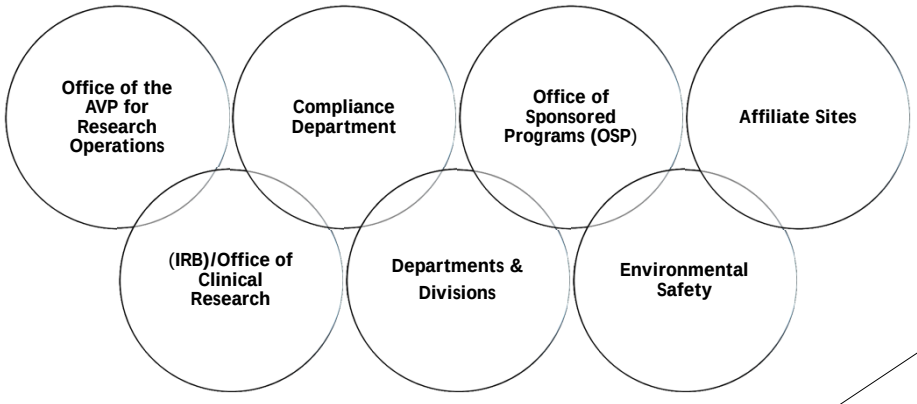
Overview

- Overview of research compliance in an academic healthcare setting
- Review research compliance risks in Investigator-Initiated reviews
- Explore HIPPA/Privacy Security Pitfalls
- Discuss the need for collaboration with IRB and other affiliated groups in the research process
- Offer suggestions for Research Improvement

Research Compliance in an Academic Healthcare Setting

- Protect the rights and welfare of the participants involved in human subject research
- Ensure excellent scientific research in compliance with institutional policies as well as local, state, and federal regulations
- Gain and establish trust of the university, affiliates, and the public
- Work with other departments and research affiliate groups to achieve compliance

Academic Healthcare University



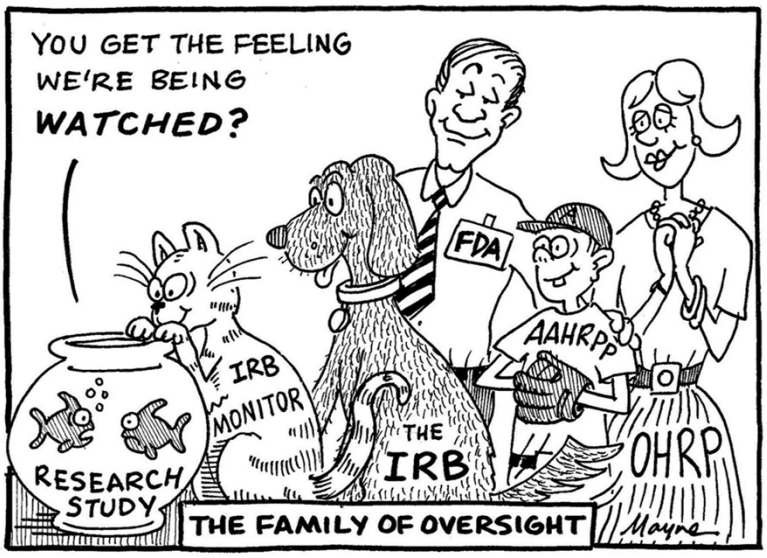
Additional Considerations

Affiliate Sites

- Policies and procedures
- Drug Accountability
- Additional safeguards
- Records retention/storage
- Electronic medical records
- Credentialing
- Billing/Participant Payment

National and International Regulations

- ICH-GCP E6
- Office of Research Integrity (ORI)
- National Institute of Health (NIH)
- Centers for Medicare and Medicaid Services (CMS)
- US Department of Health & Human Service (HHS)
- Office of Human Research Protections (OHRP)
- HIPPA



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Research Studies Conducted in an Academic Healthcare Setting

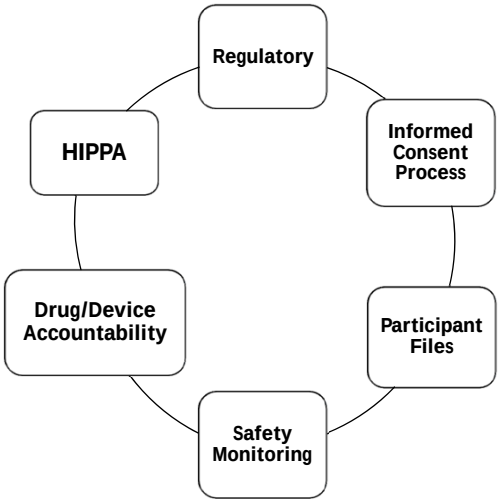
- Investigator-Initiated
- Company sponsored (ex. Pharma)
- Cooperative research
- Interventional
  - Treatment, preventative, diagnostic, supportive care,
- Observational
  - Prospective, retrospective, cross-sectional
- Repository
- Coordinating Centers
- Others

Investigator-Initiated Studies

- Observations of common findings in Investigator-Initiated studies reviewed at UT Health between fiscal year 2017-present
- 55 total studies reviewed
- 35 studies were Investigator-Initiated as indicated on the IRB submission forms
  - Local Investigator developed the study plan

    OR
  - A collaborating investigator developed the study plan

Research Compliance Areas of Risks



Billing and Participant Payments

Regulatory

- Engaged research personnel not added/updated on the IRB Institutional form
- Protocol training not documented or updated
- Essential Documents not updated and/or missing
- Research personnel completing study procedures beyond their scope of practice
- Changes to the protocol were not submitted to IRB
- Conflict of Interest not updated

Informed Consent Process

Not consenting the participant with the most current IRB approved ICF
*Missing required signatures
Correction errors made to the signature lines of the ICF
*Failure to provide study information in the language that is understandable to the subject
Documentation of the consent process does not provide enough detail
Person obtaining consent is not IRB approved to obtain consent
Reconsenting not done or not completed in a timely manner

* affiliate sites may require additional signatures and/or translation services

Participant Files

Participant Files CRFs Source Documents	Incomplete/Disorganized Source Documents
	Missing study test results
	Correction error technique not used (strike-through, initial, and date)
	Data being collected prior to consent
	Eligibility checklist doesn't exist or doesn't state who reviewed inclusion/exclusion
	Protocol deviations not reported or recorded
	Enrollment log not maintained
	Limited documentation on study visit notes
	Extensive Notes to File

Safety Monitoring

Research Space	Adequate space to conduct study procedures
Accountability	
Reporting	Adverse event reporting limited -no additional documentation AEs are being asked
	Lack of documentation for Concomitant Medications taken
	Clinical significance not being documented on labs and other study procedures
	No sponsor monitoring (sponsor, data, medical)
	Data Safety Monitoring Reports not submitted to IRB

Drug Accountability

Drug Device	Logs not maintained
	Room/Refrigerator/Freezer temperature not recorded
	Shipment receipts not maintained
	Drug diaries/device diaries(if applicable) not kept
	No indication of additional monitoring questions asked
	If applicable-no drug return bottles or reporting by the participant
	Location and storage of drug not reviewed and approved by institution

HIPAA Compliance

- **Federal Regulations-Enforced by Office of Civil Rights**
- **State Regulations**
- **Institutional Policies-IRB Policies**
- **Affiliates Policies**

What is PHI?

Individually identifiable health information:

- **Pertaining to past, present, or future**
  - **Diagnosis and/or treatment of health condition**
  - **Payment for healthcare**
- **Maintained in electronic, paper or oral format**
- **Created, used (accessed) or disclosed (released to) by a covered entity.**

18 Identifiers

- Name
- Street address, zip code
- All elements of dates--DOB, DOS, Discharge date
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- SSN
- MRN
- Health plan beneficiary number
- Account number
- Certificate/license numbers
- Vehicle license plate
- Device identifier
- URL
- Internet Protocol (IP) Numbers
- Biometric identifiers
- Full face photo images
- Any other unique identifying number, characteristic, or code

Important Point

Personal Identifier

+ = PHI

Health Information

Ways To Obtain & Use PHI For Research

- HIPAA Authorization by Research Participant
- Waiver or Alteration of HIPAA Authorization by IRB/Privacy Board
- De-Identification of Data
- Limited Data Set & Data Use Agreement

Limited Data Sets May Include Identifiable Data

- Admission, discharge, and service dates
- Date of birth
- Date of death
- Age (includes ages 90 or over)
- Five digit zip code or any other geographic subdivision, such as state, county, city, precinct

De-identification Methods

There are two methods :

- **Expert Determination-statistical or scientific principles**
- **Safe Harbor**
  - **Removal of 18 types of identifiers**
  - **No actual knowledge residual information can identify individual**
- **Once de-identified the data no longer falls under the Privacy Rule**

Database Security

- **All databases, including data containing PHI from research studies will need the following:**
  - **A designated administrator**
  - **Security measures taken for data security-encryption for storage/transmission**
  - **Policies on research databases to define location and when other approvals needed.**
  - **Use of RedCap or other secure software**

Business Associates and Their Subcontractors

- Person or entity that carries out, assists with the performance of, or performs a function, service or activity for a covered entity using that entity's PHI
- Contractual agreement
- Subject to compliance with HIPAA privacy and security rules
- Examples

HIPAA Breach/Incident

- Report incidents immediately to supervisor, Privacy Officer, and IRB
- Privacy Officer will notify patients if information is breached
- Reporting requirements to Office of Civil Rights and possibly media. There is an annual reporting requirement.
- Institutional disciplinary guidelines are followed
- Enforcement with penalties by Office of Civil Rights

Other HIPAA Issues With Research

- Encryption of emails to external email domains
- Mobile device management
- Use of USBs, CDs, etc
- Access to electronic health records
- Use of personal clouds or DropBox
- Others?

Collaboration with IRB and Research Affiliates

- Relationship building
- Oversight
- Improved access to data
- Recruitment
- Delegate regulation and policy to the affiliate site
- Improves Multidisciplinary research
- Community engagement
- Centralizing access (training, education)

Improve your Research Compliance

- Your best resource is your institution
- Don't trust your memory
- Establish a relationship with the department contacts
- Attend additional training and conferences
- Keep ongoing communication with affiliate sites
- Have bi-weekly/monthly meetings to address compliance issues and invite other departments or affiliates to speak

What is your Responsibility?

Document! Document! Document!

Provide education/training to departments

Know your institutional requirements as well as local, state, and federal regulations

Build and foster trust with affiliate sites