Clinical Research Management Training Program

Electronic Medical Records:

Access, Use and Compliance for Research

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Electronic Medical Records
Objectives

- Electronic Medical Records *(Clinical Access vs. Research Access)*
- HIPAA Regulations
- Pre-Planning and Study Feasibility
- Medical Record Content/Case Example
- IRB Medical Record Approvals including content review
- Clinical Trial Audits and Monitoring Visits

Electronic Medical Records: Clinical Access vs. Research Access

- Access/Limitations
  - All employees of CN have access to our EMRs who have a 'need to know' for business purposes such as Treatment, Payment and Operations (PTO)
  - All employees sign a Confidentiality Agreement upon employment and businesses who sign a Business Associate Agreement (BAA) if working for CN under contract.
  - All employees are bound by HIPAA Regulations for access and use
  - Limitations- *Not everyone can Print*

- What are the *systems* and access levels?
  - Depending of systems accessed
    - Cerner (*BearTracks)*
    - eCW *(e Clinical Works- primary/adolescent care)*
    - EPRS or HPF (*Electronic Patient Record System or McKesson's Horizon Patient Folder- specialty care)*

Electronic Medical Records: Clinical Access vs. Research Access

- Roles/Training Options
  - Job Roles/Responsibility: Clinician vs. Researcher
    - Providers documenting with EMR or specific forms vs. View Only
    - Some forms require the provider to co-sign while others do not
  - Cerner: Must take competency test via CHEX & pass for access. Even with pre-training, on-site researchers often need extra help from the HIM Audit Coordinator.
  - EPRS/HPF: Classroom setting through IT or CBT available but not mandatory. On-site researchers are given a small training class on how to navigate this system by the HIM Audit Coordinator.
  - eCW: WBT available but not mandatory. To date, HIM has not been asked for data coming from this system.

Electronic Medical Records: Clinical Access vs. Research Access

- Who and What is restricted?

- Researchers from inside of CN: Access based upon clinical role for *Treatment, Payment or Operations (TPO)* ***RESEARCH IS EXCLUDED FROM HOSPITAL OPERATIONS***. Need a separate authorization for research.
  - Researchers from outside of CN: Access specific work queues with pre-determined case lists. This location is generally within the Health Information Management Department (HIM) at an off-site location in Silver Spring, MD.
  - Researchers will have View Only access, no printing
    - Keep in mind, most protocols discuss abstraction of data during the review process, therefore, printing is highly discouraged and rarely endorsed for multiple reasons.

Electronic Medical Records
HIPAA Regulations

- What is HIPAA?
  - Health Insurance Portability and Accountability Act
  - A federal law that protects the privacy and security of identifiable health information- *Effective April 14, 2003*
  - Regulations apply unless state law provides more privacy protection for identifiable protected health information (PHI)
  - PHI: *paper, electronic or verbal*
  - Enforces standards for sharing and exchanging health information- *Providers, Payers and Clearinghouses*
  - Requires authorizations for disclosures and accounting of disclosures

Electronic Medical Records
HIPAA Regulations

- Patient Rights as defined by HIPAA
  - Patient can inspect their PHI and get copies
    - **Exceptions**:
      - Psychotherapy notes
      - On-going clinical trials (when the patient has been notified that access will be limited during the research specifically outlined in your Consent process)
  - Patient can request amendments to the medical record
  - Patient must be given full accounting of organization's disclosure of PHI
  - Patient can request restrictions on disclosures
  - Patient must receive Notice of Privacy Practices and Grievance procedure

Electronic Medical Records
HIPAA Regulations

Question:	Answer:
• I sometimes serve as the principal investigator on a clinical trial. **Can I still review my patient's records to determine which patients are good candidates for a clinical trial? Do I have to get an authorization first? Can I allow other researchers to review charts?**	• HIPAA permits you to use and disclose protected health information for preliminary research activities such as developing hypotheses and recruiting research participants. Two exceptions: **The researcher can only record de-identified information; and the researcher cannot remove PHI from the organization.**

Electronic Medical Records…
Pre-Planning and Study Feasibility

- Developing Hypotheses
  - Feasibility- report requests
  - Where to begin- data abstraction
    - Health Information Management (Medical Records) codes:
      - Diagnoses and procedures
      - Inpatients, Same Day Surgery and ED cases
      - ICD-9-CM codes and CPT codes (STAR)
      - Exception: Physician selection of SNOMED codes from May 2008- inpatients (Cerner)
      - Date limitations- availability of data
  - Health information-1997 and prior- microfilm/fiche

Electronic Medical Records…
Legal Medical Record Content

- EPRS/HPF
  - Dates: 1998 - current
  - Scanned documentation from Inpatients, ER, Specialty Clinics, including data feeds from Lab, Pathology and Radiology reports. Same day surgery, Observation and ASC cases as well.
  - Dates: 1998-current
- Cerner
  - Dates: May 18, 2008- current
  - Inpatient visits
  - ER visits *(both UMC and Main Campus)*
  - OPO, XOB *(observation*)
- eCW
  - Dates: August 2009- current
  - Primary care and Adolescent care visits from all sites. Backscanning of old documents are within eCW for the main campus for 2 years prior to go-live

Electronic Medical Records…
Legal Medical Record Content

- Clinical Trials vs. other Types of Records
  - Registration
    - Patient's in Clinical Trials are registered in McKesson's STAR system by Service type CTU and location is Main
  - Clinical Trial Records
    - Rule: NOT scanned into eCW or EPRS/HPF.
    - Exception: Clinical Trial Informed Consents can be found within EPRS/HPF if sent to Health Information Management (HIM) and Oncology patient records.
  - Informed Consent and Assents (barcoding/risk)
    - ARE scanned into EPRS/HPF *if sent to HIM*
  - Outside Labs
    - ARE scanned into EPRS/HPF under Outside Documents *if sent to HIM*
  - Privacy concerns (HIV status, paternity)
    - Part of the general medical record if part of TPO
    - Special Screening for Behavioral Health and Child Protection (special laws protect disclosure)
  - Discoverability (court)
    - Accountability

Electronic Medical Records
Case Example

Amy's medical record:

- Visit History
  - Medical Service
  - SDS
  - Oncology
  - Labs
  - Pathology
  - Radiology
  - Psychiatry
  - ER
  - Child Protection Services
  - Consents

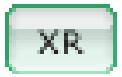
Amy's research record:

- Consents
- Assents
- Labs- paternity
- Study Progress Notes

- ***Discoverability and Risks of Leakage***

Electronic Medical Records…
IRB Medical Record Approvals

- IRBear
  - Protocol submission in designated application format with various reviews and pre-determined approvals.
- Approvals from Medical Records
- Issue Ancillary Approval



- Medical Record Content Review:
  - Section 5- Methods and Procedures: Data collection
  - Section 8- Informed Consent
  - Section 9: Data Privacy and Confidentiality
- Helpful Tips:
  - De-identification of data, storage either paper or electronic and physical security of each whether locked cabinet or password protection with limited access, data abstraction methods
  - Confidentiality including Consents and *Assents (pre-established format that meets JCH criteria)*

Electronic Medical Records… Clinical Trail Audits and Visits

- Clinical Trial Audit Process and Visits
  - Communication
    - Clinical Researchers email Director, HIM to check on status for approval in IRBear
    - Content review *(either approved via IRBear or email back for pending concerns)*
    - CNMC Clinical Research Coordinators contact HIM's Audit Coordinator to set up date availability
  - Pre-Education and additional assistance *(collaboration*)
    - HIM's Audit Coordinator reserves audit booths for researchers and populates an electronic work queue for each auditor based upon the case list
    - HIM coordinator obtains a Confidentiality Statement from each researcher
  - On-site Audits and Common misconceptions
    - No Copies of records for auditors while on-site
    - All PCs are unable to print
    - Access is limited to the scheduled audit time lines

Electronic Medical Records…
Access, Use and Compliance

- Questions
- Thank you