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.
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
### Question:

- 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?**

### Answer:

- 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

<table>
<thead>
<tr>
<th>Amy’s medical record:</th>
<th>Amy’s research record:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visit History</strong></td>
<td><strong>Consents</strong></td>
</tr>
<tr>
<td>– Medical Service</td>
<td><strong>Assents</strong></td>
</tr>
<tr>
<td>– SDS</td>
<td><strong>Labs- paternity</strong></td>
</tr>
<tr>
<td>– Oncology</td>
<td><strong>Study Progress Notes</strong></td>
</tr>
<tr>
<td>– Labs</td>
<td></td>
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<tr>
<td>– Pathology</td>
<td></td>
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<tr>
<td>– Radiology</td>
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<tr>
<td>– Psychiatry</td>
<td></td>
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<tr>
<td>– ER</td>
<td></td>
</tr>
<tr>
<td>– Child Protection Services</td>
<td></td>
</tr>
<tr>
<td>– Consents</td>
<td></td>
</tr>
</tbody>
</table>

- **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