Breakout session 301

Optimizing Research Compliance with the Electronic Health Record System

Anna Taranova, MD, MS
Deidre Winnier, PhD
Tiffany Mince, MHIM,RHIA

Optimizing Research Compliance with the Electronic Health Record System

The speakers have no relevant financial and non-financial relationships to disclose.

The opinions presented are our individual opinions, based on our experience and do not represent those of anyone else, including the University Health System or their affiliates.

Optimizing Research Compliance with the Electronic Health Record System

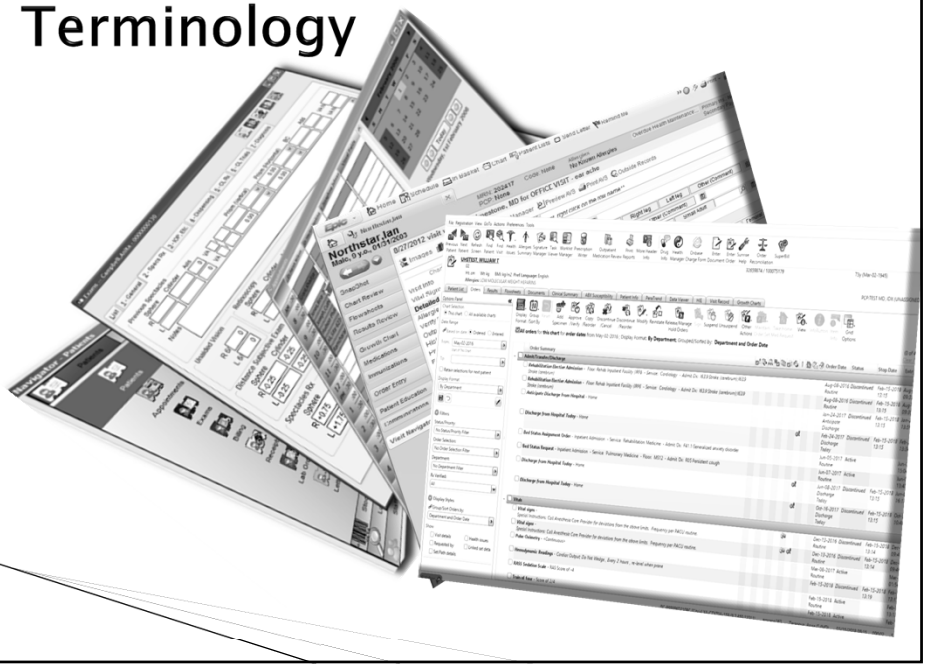
- Speakers:
  - Anna Taranova, MD, MS, CCRP, Executive Director, Research and Information Management, University Health System, San Antonio, Texas
  - Deidre Winnier, PhD, Director, Clinical Research, University Health System, San Antonio, Texas
  - Tiffany Mince, MHIM, RHIA, Assistant Director of Research Compliance, University Health System, San Antonio, Texas

Objectives

- Incorporating Research within the Electronic Medical Records System
  - Navigating rules, regulations and policies
  - FDA guidance on use of EHR clinical investigations
  - EHR conundrum: ethics and privacy
  - Data input and extraction
  - Benefits and challenges (data security, privacy, access, etc.)
- Standardization of documentation and billing processes
  - Standards for data entry
  - Implementation of a research protocol
  - Claims data vs medical records
  - Research orders
  - Integrated data capture
- Mining EHR for research:
  - Nature of the EHR
  - Access to reports
  - Records review and training
  - Use for research
  - Health Information Exchanges (HIE)
  - NHIN
  - Predictive Analytics

Incorporating Research within the Electronic Health Records System

Terminology



Electronic Medical Records

- CPRS- Computerized Patient Record System
- EMR-Electronic Medical Records
- EHR -Electronic Health Records
- EPR -Electronic Patient Record
- EDC -Electronic Data Capture
- HIE -Health Information Exchange
- NHIN -National Health Information Network Exchange
- PHI – Protected Health Information

Why in the EHR?

- Primary use: Patient care
- Longitudinal data collected during routine delivery of health care
- Consent documentation in EHR
- Patient Safety – ability to flag and follow up
- Adherence to the protocol
- Assists with Research Billing and Compliance
- Decrease recruitment challenges

Incentives for EHR Use

Government-led incentives for EHR adoption have raised increased awareness—as well as much influx in funding—towards leveraging large-scale computable EHR data for driving healthcare innovation, improving patient care, encouraging research:

- HITECH Act of 2009 and meaningful use
- President Obama's promotion of the Precision Medicine Initiative
- Cancer Moonshot Initiative
- Health Information Exchange Challenge Grant Program

Sources of Information

Data Sources	Advantages	Disadvantages
Electronic health record at a single institution	Easy management of rights and consents. Full clinical content, structured & unstructured data.	"Diluted" cases. No general purpose research tools
Disease registers at a regional or national level (often termed quality registers)	Larger sample size. Collect data from several institutions. Allow comparisons of results and Well-defined data variables	Limited data set. Updated rarely. Complicated rights and consent management. Extra work to record the data.
Special research database system for a specific project	Very well-controlled variables including functions to ensure project process support and reasonable compliance	Expensive to set up. Extra work because data cannot be retrieved from EHRs and may have manually entry
System of electronic health records (CPRS and others)	May allow very large case populations, especially if federation across national borders	Interoperability and consent are difficult to manage

P. Coorevits et al. J of Internal Medicine, 2013

Navigating the Legal Minefield

Navigating the Legal Minefield

- HIPAA privacy and security regulations;
- Joint Commission (JCAHO) accreditation requirements;
- Association for the Accreditation of Human Research Participation Programs (AAHRPP) accreditation requirements;
- Federal statutes in the Code of Federal Regulations (CFR);
- Food and Drug Administration (FDA) guidelines;
- Individual state regulations governing medical record confidentiality.
- Institutional policies
- Ethical considerations

Updated HIPAA Authorization

- As of September 23, 2013, newly enrolled participants who need to sign a HIPAA authorization must "opt-in" to allow the use of their PHI for optional sub-studies and future secondary use of personal health information (PHI).
- The HIPAA authorization to include a checkbox to indicate that the participant has agree to allow information to be disclosed for the additional optional research activities explained in the informed consent process.
- “Opt in” or “opt out” models?

Adhering to FDA’s Requirements

- In accordance with FDA regulations, good source documentation should be Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA).
- The FDA has issued guidelines for source documentation contained in electronic medical records in the Title 21 CFR Part 11 that addresses the need for controls, audit trails, electronic signatures, and software documentation for processing electronic data in the EHR.

FDA Guidance – May 2016

Provides recommendations on best practices"

- Deciding whether and how to use EHRs as a source of data in clinical investigations;
- Using EHRs that are interoperable with electronic systems supporting clinical investigations;
- Comply with inspection, recordkeeping and retention as well as privacy and security;
- Does not apply to recruitment and post-marketing studies

EHR Conundrum: Ethics and Privacy

- Secondary use of existing data – providers, patients and public are unaware of benefits and risks of secondary use
- Ownership and access: who owns health data and who has the right to access and for what purposes?
- Control: do patients have the right to audit or put other health constraints on the use of their data, even after anonymization?

Data Input and Extraction

Secondary use of EHR for research has barriers:

- Poor accuracy and completeness of EHR
- Legal and ethical consideration
- Information governance
- HITECH Act
- Manual data entry
- No interoperability

Benefits and Challenges

- Benefits
  - More access and control at lower cost
  - Easy data collection for databanks and registries
  - Vast data for large scale studies, trends, public health and outcomes
  - Safety measures
  - Patient Safety
  - Adherence to the protocol
  - Assists with Research Billing and Compliance
- Challenges:
  - Quality of data and access
  - Incomplete data capture
  - EHR vs Claims
  - Inadequate system knowledge
  - Systems heterogeneity in multisite research
  - Multiuser access, security and privacy

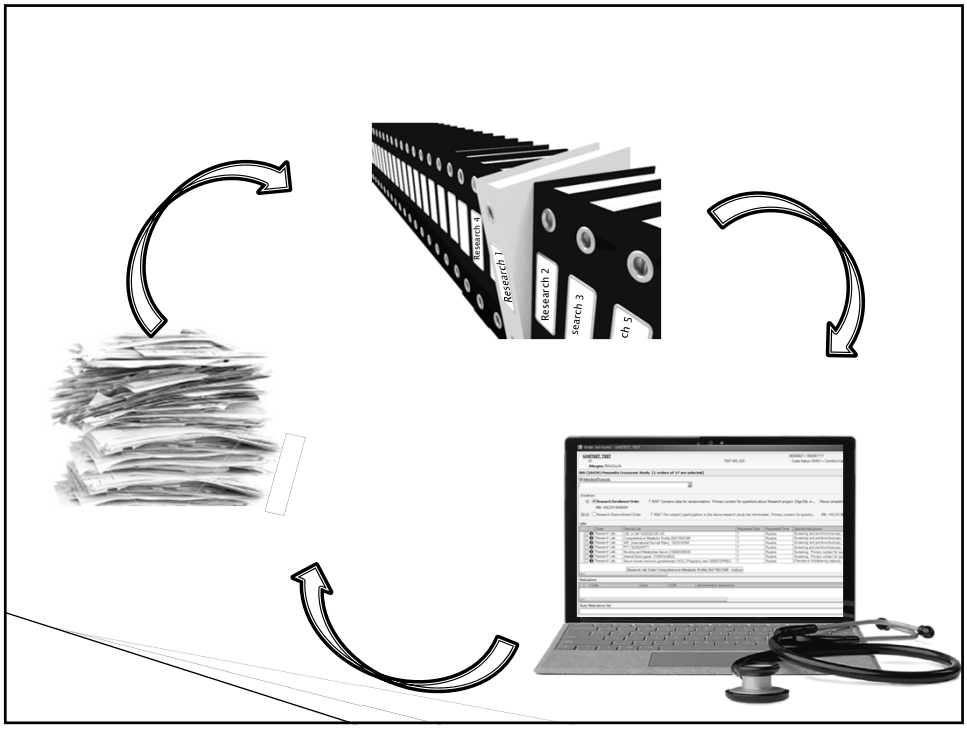
And More on Challenges

EHRs are designed to support health care provision, they are not structured in a way that facilitates the research process.

- Characteristics of the data in EHRs affect their use for research:
  1. providers decide where to put information (uniqueness of use);
  2. information may be entered in free-text form instead of being entered in defined fields or picked from a structured list of medical terms;
  3. providers use different terms for the same information (lack of standardization);
  4. information may not be stored in a way that is readily searchable and
  5. data that are not important to clinical care may be missing.

Potential Solutions

- Flagging research subjects in EHR
- Creating EHR Order sets for Research
- Including an Enrollment Note as well as a Disenrollment Note.
- Making available a copy of consent
- Following on AE/SAE
- Preventing “professional” subjects
- Accessing larger data
- Improving collaborations
- Training, training, training…



Standardization of Documentation and Billing Processes

Standards for Data Entry

- EHR template improvements
- Limited free-text option
- Standardization of data entry by registration staff
- Standardization of notes and data collection fields by medical staff
- Dedicated IT staff to extract EHR data

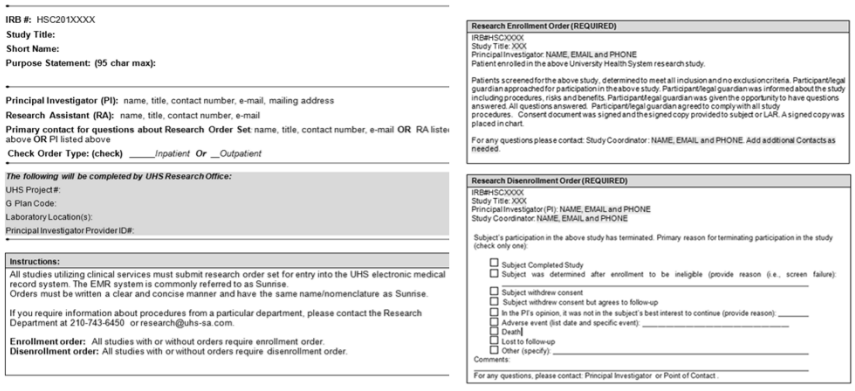
Research Protocol Implementation

- Best to have concurrent review of protocols between the IRB record and the affiliated institutions
- All faculty staff are required to submit their proposals for IRB determination. This is especially important for Quality Improvement Projects.
- A protocol should be reviewed for the impact- financial and patient care- to the affiliated institution.
- Oversight by a review committee and assistance with a medical director
- Issue institutional approval letters in addition to IRB approval

Claims Data vs Medical Records

- Claims data is extracted from the billing system and represents what services we are reimbursed for by patient or 3rd party insurer
- Medical records is the data that is collected in the EHR at the time of a visit

Research Order Set



IRB #: HSC201XXXX
Study Title:
Short Name:
Purpose Statement: (95 char max):

Principal Investigator (PI): name, title, contact number, e-mail, mailing address
Research Assistant (RA): name, title, contact number, e-mail
Primary contact for questions about Research Order Set: name, title, contact number, e-mail **OR** RA listed above **OR** PI listed above
Check Order Type: (check) _____*Inpatient* ***Or*** __*Outpatient*

The following will be completed by UHS Research Office:
UHS Project#:
G Plan Code:
Laboratory Location(s):
Principal Investigator Provider ID#:

Instructions:
All studies utilizing clinical services must submit research order set for entry into the UHS electronic medical record system. The EMR system is commonly referred to as Sunrise.
Orders must be written a clear and concise manner and have the same name/nomenclature as Sunrise.

If you require information about procedures from a particular department, please contact the Research Department at 210-743-6450 or research@uhs-sa.com.

Enrollment order: All studies with or without orders require enrollment order.
Disenrollment order: All studies with or without orders require disenrollment order.

Research Enrollment Order (REQUIRED)
IRB#HSCXXXX
Study Title: XXX
Principal Investigator: NAME, EMAIL and PHONE
Patient enrolled in the above University Health System research study.

Patients screened for the above study, determined to meet all inclusion and no exclusion criteria. Participant/legal guardian approached for participation in the above study. Participant/legal guardian was informed about the study including procedures, risks and benefits. Participant/legal guardian was given the opportunity to have questions answered. All questions answered. Participant/legal guardian agreed to comply with all study procedures. Consent document was signed and the signed copy provided to subject or LAR. A signed copy was placed in chart.

For any questions please contact: Study Coordinator: NAME, EMAIL and PHONE. Add additional Contacts as needed.

Research Disenrollment Order (REQUIRED)
IRB#HSCXXXX
Study Title: XXX
Principal Investigator (PI): NAME, EMAIL and PHONE
Study Coordinator: NAME, EMAIL and PHONE

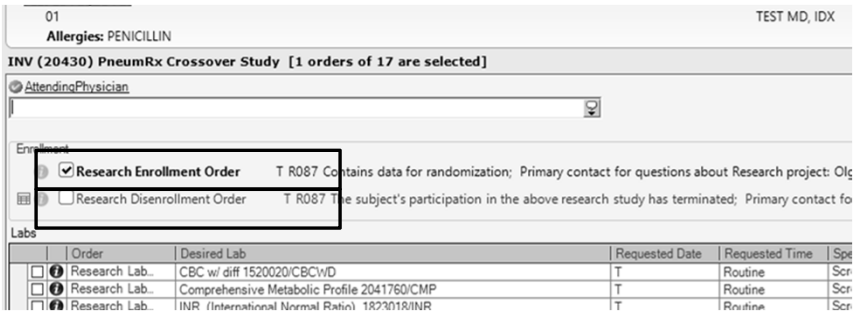
Subject's participation in the above study has terminated. Primary reason for terminating participation in the study (check only one):

- ☐ Subject Completed Study
- ☐ Subject was determined after enrollment to be ineligible (provide reason (i.e., screen failure): _____
- ☐ Subject withdrew consent
- ☐ Subject withdrew consent but agrees to follow-up
- ☐ In the PI's opinion, it was not in the subject's best interest to continue (provide reason): _____
- ☐ Adverse event (list date and specific event) _____
- ☐ Death
- ☐ Lost to follow-up
- ☐ Other (specify) _____

Comments:

For any questions, please contact: Principal Investigator or Point of Contact.

Research Order Set Information



Integrated Data Capture

- EHR can capture research and flag patients
- Added package to capture and flag research patients
- CPRS, EPIC and others can flag a research patient and VELOS and additional software can allow for the scheduling of research visits
- These features aid in compliance

Mining EHR for Research

Nature of EHR

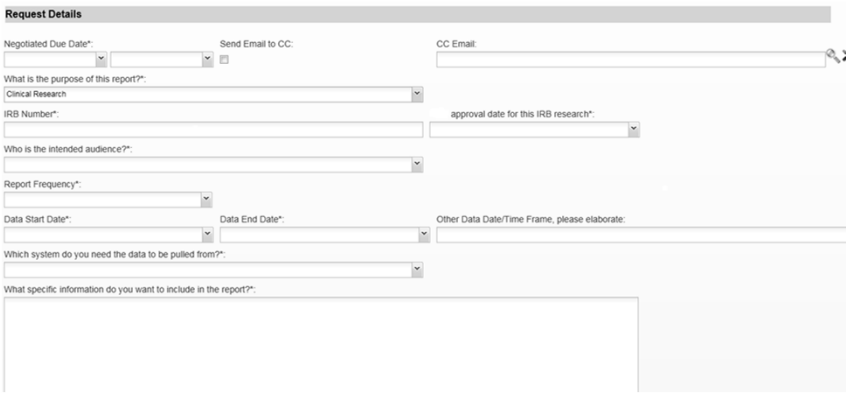
- Transforming Health Care: The President's Health Information Technology Plan
  - Within 10 years a plan for the United States be on Electronic Health Records- George Bush, 2004
  - EHRs will be designed to share information privately and securely.
- The Health Information Technology Plan
  - Addresses longstanding problems of preventable errors.
  - Uneven Quality
  - Rising Costs in the U.S. health care system.

"By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care."

--President George W. Bush, State of the Union Address, January 20, 2004

Access to Reports

- Data Request



Record Reviewing and Training

- Report Executed Dependent On:
  - Date Range
  - Age
  - Sex
  - International Classification of Diseases 10th Edition (ICD-10)

Use for Research

- Preparatory to Research
  45 CFR 164.512(i)(1)(ii)
  - Representations from the researcher, either in writing or orally, that the use or disclosure of the protected health information (PHI) is solely to prepare a research protocol or for similar purposes preparatory to research.
- Institutional Review Board (IRB) approval for waiver of research participants' authorization for use/disclosure of information about them for research purposes.
  45 CFR164.512(i)(1)(i)

EHR Applications in Research

- Epidemiologic studies
- Observational research
- Safety surveillance
- Feasibility and preparatory to research
- Prospective research
- Population health

What it the HIE and How is it Used?

- Health Information Exchange (HIE)
  - Data Content Standards
  - Data Exchange Standards
  - Meaningful Use (MU)
- Example of Organizational HIE
  - DB Motion
- Examples of Local and State HIEs
  - Health Access San Antonio (HASA)

"The HIE should be the highest priority for all healthcare stakeholders". (IOM, 2003)

National Health Information Network Exchange (NHIN)

- Goals of NHIN:
  - Effectiveness;
  - Efficiency;
  - Overall quality of healthcare within the United States
- Current Barriers
  - Insufficient Funding
  - Lack of ongoing economic incentives
  - Public concern of privacy

Predictive Analytics

- PeraHealth–The use of a real-time plotting of a patient's clinical condition over time.
  - The Rothman Index correlates with many measures of risk that include:
    - 24-Hour Mortality
    - Discharge Disposition
    - 30-Day Readmission
    - Intensive Care Unit (ICU) Mortality

Any Questions?

THANK YOU!