Clinical Research and The Medical Record

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Agenda

- Introduction
- What are the Regulations that Govern the Medical Record?
- The Research Record and the Medical Record
  - Exploring the Challenges to handling the record
- Questions and Answers

What are the Regulations Governing the Records?

- HIPAA: Privacy and Security and the intersection with Research
- Accreditation:
  - JCAHO – Health Providers
  - AAHRPP – IRB
- Code of Federal Regulations (CFR)
- FDA Guidelines
- State Regulations regarding the Medical Record and Confidentiality

What is the Record?

- The Legal Medical Record Contains:
  - Clinical Data both Inpatient and Outpatient
  - Consents and Terms and Conditions

- The Research Record
  - Documentation as prepared by the PI
  - Study notes
  - Informed Consent Form and the HIPAA Authorization
  - Offsite Lab Results and other outside records

Who Decides What Goes Into the Medical Record?

- Possible decision makers:
  - IRB
    - Criteria for IRB Approval for Research "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintaining the confidentiality of the data" 45 CFR 46.111(a) (7)
  - Health System Governing Body
    - JCAHO Standards

What Records Are Needed?

- Every Human Subject needs:
  - A research record
  - A medical record
  - A billing record to the grant or payer
  - For every time and every visit

How To Communicate The Rules to the PI and the Team?

- Include the record keeping requirements in Hospital/Health System Policy
- Contained within the IRB Approval letter for the study are the specifications of what must be included (e.g., Informed Consent Form, HIPAA Authorization)
- Alternative, if the IRB letter does not state to exclude records relating to the patient, then all records are included in the medical record

Why should certain research documents exist in the Medical Record?

- The advantages for combining the information:
  - Patient Safety
  - Facilitate Billing Compliance
  - Accurately account for the cost allocations associated with Research Activities at your institution
  - HIPAA Regulatory Considerations

Why should certain research documents exist in the Medical Record? (cont.)

- Consider Lab and Radiology Procedures
  - May be very relevant to the total patient care provided by other providers outside of the research team
  - Provide the best health for the patient and provide patient safety
  - Improve communication and help to "tell the story" about the patient

General Rule for the Record

- Always include in both the research record and the medical record the following:
  - Informed Consent
  - HIPAA Authorization
  - Test results that are relevant to the care of the patient, even if part of the research protocol and paid by the grant

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General Rule for the Record (cont.)

- Consider the confidentiality of the patient
  - Are there certain tests or procedures that should be excluded from the record because of the nature of the test?
  - Are there certain tests or procedures that should be excluded from the record because of the nature of the study?

What Tests Could Be Excluded?

- Tests resulted by a central lab designed for the study as defined by the sponsor

- Results of tests performed by facilities not authorized to provide clinical services, (e.g., a research lab which is not licensed or credentialed)

What Studies Would Give Rise to Confidentiality of the Information?

- Sensitive Studies –
  - For example, evaluating the use of alcohol, drug or other illicit products, or mental health, genetic testing, or other sensitive issues
  - Studies under Certificate of Confidentiality
  - Drug study, blinded and patient require alias as basis of participation

Informing the Subject of the Record

- The Informed Consent should state:
  - Define the patient safety considerations for including and excluding information in the chart
  - The documentation expected to be found in the medical record
  - Records excluded from the medical record and found only in the research record

Other Patient Safety Concerns

- Study relates to Sensitive Matter
  - In the patient locator or other prominent portion of the record list the following:\
    - Patient enrolled in Clinical Trial
    - In the event of an emergency or question pertaining to care, contact Dr. PI
  - Study to be performed only on the GCRC help ensure confidentiality and safety

Why Maintain Duplicate Records?

- Record Retention Processes
  - Protocol will define length of time to maintain the research records
  - Time under the protocol may exceed the time required to maintain records under the institutional Record Retention Policy
  - Responsibility of the PI

What is the Future of Managing Research Records?

- Does the Electronic Health Record (EHR) foster the following:
  - Creating a separate complete Research Medical Record while allowing other members of the treatment team to be informed?
  - Managing access keeping in mind access control and minimum necessary standards understanding HIPAA and research falling outside of treatment?
  - Supporting the record retention requirements of the protocol?

Questions and Answers