Policies for Research Data in the EMR

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Definitions

- Research data are data acquired through participation in research protocols that are either definitely clinical quality (ECG, lab tests, scans) or probably clinical quality (height, weight, BP, self reported health data)
- The clinical medical record is the same as the electronic medical record (EMR) for this exercise. Data in EMR cannot be removed.

Types of Research Data

- Research Informed Consent Form
- Labs and imaging (clinical quality)
- Patient reported outcomes
- Investigational drug orders
- Research visit notes
- ?Adverse reactions to research medications

Advantages for Including Research Data in the Clinical Medical Record

- Patient Safety
- Reduce need for duplicate tests
- Better documentation in clinical record or research protocol experience (chemotherapy)
- Prevent patients from getting bad care in the future (ex, adverse reaction to investigational medication)
- May increase research billing accuracy
- Most patients want their clinical providers to know about their research experience
- Clinicians more likely to refer patients to clinical protocols if they can follow their progress and check results

Advantages for Including Research Data in the Clinical Medical Record

- Electronic data can be moved more reliably than hand written data (lab notes)
- JCAHO standard that clinical teams need to be aware of all interventions on patients (clinical or research)

Disadvantages for Including Research Data in the Clinical Medical Record

- Research data (especially consent forms) indicate health condition of patient and difficult to protect
  - Are sensitive health conditions (ex, HIV, substance abuse) only seen in research data?
- Need some process for deciding what research data are clinical quality
- Need to be certain clarity on who reviews the test results
- Provides permanent record that someone participated in a study (not always bad)
- Some people may not participate in research because they are uncertain of protection of their data in the EMR

Certificate of Confidentiality (CoC)

- CoCs protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. NIH funded researchers are automatically issued a CoC through their award (new policy Sep 2017)

CoC Exemptions

- Disclosure is permitted only when:
- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

CoC

- For the purposes of this Policy, consistent with subsection 301(d) of the Public Health Service Act (42 U.S.C 241), the term “identifiable, sensitive information” means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:
- An individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

CoC

- All recipients of a Certificate shall not:
- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

CofC

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- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

CoC

- Suggested consent language:
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

What are the options?

- Include language in consent form that your research information will be included in the EMR
  - No option for any protocols
  - Difficult for researchers that enroll patients with substance abuse
- Carve out certain studies (substance abuse with no investigational treatment) where research data are not included in EMR
  - No options for patient/research participants to indicate they wanted the research data in the EMR

What are the options?

- Develop a system where a research participant can control when they want research data to be included in the EMR.
  - Options for type of data?
  - Options to change consent in middle of the study?