Clinical Research Documentation in the Electronic Health Record: Bracing for the Impact of Patient Access

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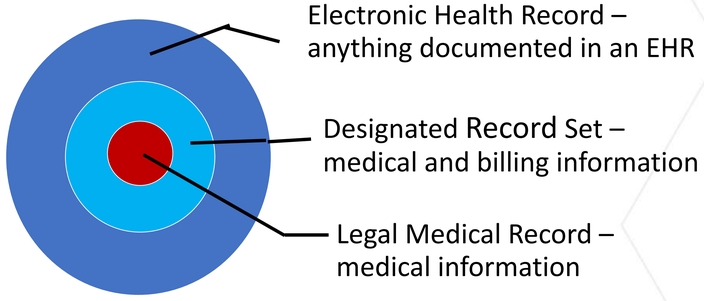
NURSING

Background and Significance

- Cures Act Final Rule prohibits information blocking
- Information blocking: anything that restricts access, exchange, or use of information from the electronic health record (EHR)
- Most organizations use a patient portal to share information with patients
- Designated record set (see figure below) must be shared with patients starting 10/6/22
- Participation in clinical research does not exempt information from being shared
- At UW Health, two Clinical Research Nurses provide guidance on research documentation in the EHR

Objectives:

- Define EHR data elements specific to research as legal medical record, designated record set, or neither; confirm with organizational leadership
- Document current information release from EHR to patient; determine if exceptions are needed for research
- Disseminate information to EHR research users



Implementation

Listed currently required EHR documentation elements for clinical research

Elicited research stakeholder feedback on what research documentation is required, optional, and prohibited in the EHR

Obtained operational/leadership decisions on what research documentation is part of legal medical record and/or designated record set

Decisions used to drive what research documentation is shared with patients via the EHR patient portal

Examples of research-specific documentation

Research Notes	Optional	Not LMR or DRS	Not shared to patient portal
Central Lab Results	Required if clinically significant	LMR and DRS	Shared to patient portal
Research Informed Consent Form	Required	Not LMR or DRS	Shared to patient portal

Special Considerations – No Impact on Sharing Information

- **Certificates of Confidentiality:** prohibit sharing protected health information without patient consent; patient portal only available to patients and those they consent to have access
- **Stigmatizing Studies:** documentation guidelines prevent stigmatizing research information from being documented in the EHR
- **Blinded Studies:** documentation guidelines advise excluding unblinding information from the EHR and special workflows to withhold it from the patient if it must be in the EHR

Dissemination

Education document was developed specifically for research users to share decisions about:

- Required, optional, and prohibited EHR documentation about clinical research
- Legal medical record and designated record set determinations for clinical research documentation

A monthly user group meeting was devoted to providing this education live and allowing for questions and answers.

Performance/Quality Improvement Outcomes and Implications for CRN Practice and for Future Research

- Outcomes
  - Defined/confirmed required, optional, and prohibited EHR documentation about clinical research participation
  - Defined clinical research documentation in EHR as legal medical record, designated record set, or neither
  - Technical restrictions put in place to withhold information that is not part of designated record set
- Implications for CRN Practice
  - Shows continued need for Clinical Research Nurse involvement integrating research into the EHR

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