Research Documentation in the Legal Medical Record

MUSC
MEDICAL UNIVERSITY of SOUTH CAROLINA

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Responsible Office	Office of the Vice President for Research
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Summary

This policy describes under what circumstances research information should be documented in the portion of Epic (or other electronic health system) deemed a component of the legal medical record at the Medical University of South Carolina (MUSC) and how that information will be protected.

Policy

POLICY STATEMENT

The purpose of this policy is to:

a) define the types of research studies that should be documented in the legal medical record

b) define the circumstances under which obfuscation (de-identification) of research information is appropriate

RESPONSIBILITIES:

- The Principal Investigator (PI)/Sponsor determines which study data are part of the legal medical record using the following criteria:
    - Procedures/data are part of clinical care
    - Procedures/data will have immediate impact on clinical care
- The PI determines which information (whether in the legal medical or not) would be de-identified.
- The PI determines whether a Certificate of Confidentiality (CoC) has/will be obtained (per MUSC CoC policy), and is responsible for including appropriate research informed consent language describing limits of confidentiality.
- The PI is responsible for notifying participants via the informed consent document if research participation will be documented in the legal medical record.
- The Health Information Management Team is responsible for adhering to research flags which define which research documentation will be excluded from request fulfillment of the legal medical record.
- If de-identification is required, the PI (or designee) is responsible for consulting with the Epic Research Team to determine the appropriate process for de-identification and study designation in the SPARC Request system as well as the legal medical record.
    - De-identification is performed by the Health Information Management Team.

- The PI is responsible for keeping the key that identifies individual patients with de-identified legal medical records.

POLICY:

A. The legal medical record is not a repository for research documentation. The only research informed consents that should be included in the legal medical record are for those studies that provide clinical care and/or will have an immediate impact on clinical care.

B. Research studies where procedures are ordered or billed through Epic must be in Epic but are not necessarily part of the legal medical record.

1. All de-identification must occur in such a way that prevents other Epic users from knowing the protected information.
2. Research studies where procedures are part of clinical care or will be billed to insurance must be in the legal medical record under the participant's true name and medical record number and cannot be de-identified.

C. Research studies that do not include procedures that are ordered or billed through the hospital or physician billing systems and will not have immediate impact on clinical care are not required to be in Epic.

1. However, if an investigator *chooses* to document study participation in Epic, appropriate language should be included within the research informed consent document.

D. Any research project where research documentation will occur in Epic should include appropriate, relevant language in the research informed consent document.

PROCEDURES

1. Research studies where procedures are scheduled, ordered or billed within Epic must be in Epic. Studies are entered into Epic via the SPARC Request system, clearly identifying which procedures are billed to research versus billed clinically.

2. If research information will be in Epic, appropriate language to that effect should be incorporated into the informed consent document and reviewed and approved by the IRB.

3. If de-identification is deemed necessary, the PI or designee must consult with the Epic Research Team and document the need for de-identification through SPARC Request.

4. The de-identification process will proceed per the workflow determined by Health Information Management and the Epic Research team.

Contact Information

For information regarding the overall policy and related documents, please contact the SCTR SUCCESS center, (843-792-8300, success@musc.edu).

For questions related to Epic processes, please contact Epic Research Team at (843) 792-5363

For questions related to specific department roles/responsibilities, please contact the applicable department directly.

Related Information

Other Documents:

MUSC IRB Informed Consent Template
Use of Certificate of Confidentiality (CoC) in Research

Approved By	Information Contact	Effective On:
Kathleen T. Brady, M.D., Ph.D. Vice President for Research	South Carolina Clinical and Translational Research Center (SCTR) SUCCESS Center	August 18, 2016