SLUCare Physician Group

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Owner:	*Cherish Hoffman*
Document Area:	*Clinical Operations*
References:	

Epic Research Charting Policy

PURPOSE

The purpose of this policy is to outline the process of documenting study-related procedures or information in the Electronic Medical Record of patients receiving a medical or device treatment or procedure in a Clinical Research Study, at a SLU*Care* site.

POLICY

A. When a Clinical Research Study includes documentation of a Research Visit in the Electronic Medical Record, such documentation will be made by the Principal Investigator or the Research Staff in the patient's Electronic Medical Record using a research note SmartPhrase, an example of which is included as Appendix A. The research note can be accessed from within an encounter using the Research Note activity.

B. A research note should include the following information: study name, IRB#, study contact for more information, Principal Investigator, department, study visit number, and clinically relevant information, including study procedures, if any, obtained at the visit.

C. A research note **should NOT include** any of the following or any information relating to the following, unless already in the Electronic Medical Record for standard of care purposes:

- Psychiatric disorders, psychological well-being (including diagnoses and/or treatments)
- Substance use
- Sexual practices
- Illegal behaviors
- Infectious diseases
- Genetic Information obtained external to SLU*Care*
- Lab results obtained external to SLU*Care* (except for those key to the Clinical Research Study)
- Research with a Certificate of Confidentiality
- Questionnaires or surveys done for research only (including copies of such research tools)
- Case report forms (including scans of such documents)

D. If, during the course of a Research Visit, any non-study related procedures are necessary, the Principal Investigator or Research Staff will open a regular progress note to document such non-study related,

clinically relevant information.

DEFINITIONS

Clinical Research Study: For the purpose of this policy, a clinical research study uses consenting patients at Saint Louis University to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Electronic Health Record (EHR): The set of applications that provide the ability to maintain an Electronic Medical Record for SLU*Care* patients.

Electronic Medical Record: The portion of the medical record that was created electronically in the EHR or that originated on paper but was converted to an electronic format.

FYI Flags: Indicators about a patient's record statuses which are located in the Electronic Medical Record header. The FYI Flag includes additional detail regarding the FYI status. This flag is only applicable to the Saint Louis University Electronic Medical Record.

Medical Record: The collection of information concerning a patient and his or her health care that is created and maintained in the regular course of the University business in accordance with Saint Louis University policies, made by a person who has knowledge of the acts, events, opinions or diagnoses relating to the patient, and made at the time indicated in the document. The medical record may include records maintained in formats such as electronic, paper, or other media that integrate data from multiple sources, capture data at the point of care, and support caregiver decision making.

Principal Investigator (PI): Individual responsible for the overall conduct of the Clinical Research Study.

Research Staff (RS): Individuals working under the direction of a Principal Investigator to implement clinical research studies. Tasks may include: subject screening, recruitment, enrollment, complete and/or maintain source documents and case report forms, ensure site quality and protocol integrity, collaboration with sponsors or other outside agents.

Research Visit: (For purposes of this policy) an encounter with a patient for the purpose of monitoring or providing the patient with a medical or device treatment or procedure associated with a Clinical Research Study. A patient encounter is direct contact, communication, or visit between a patient, or the patient's designee, and a Principal Investigator or Research Staff in order to furnish services for diagnosis or treatment of the patient. Encounters will include face-to-face contact, tests, procedures, telephone and electronic contacts, and other forms of contact that include patient instruction.

ENFORCEMENT

Violation of this policy will result in disciplinary action, up to and including termination, and/or restrictions of privileges in accordance with SLU*Care* Policies.

At regular intervals, the SLU Clinical Trials Office will review customized reports generated within EPIC which will aggregate Research Note transactions and Research Flag activity. Variances which indicate a potential violation of this SLU*Care* Procedure will require further specific review and remediation.

APPROVAL AND AMENDMENTS

Changes to this policy may be necessary from time to time. At a minimum, the procedure will be reviewed and approved annually. All changes to this policy will be approved by the EHR Executive Steering Committee. This

policy, including a record of all changes (if applicable), will be maintained by the EHR Executive Steering Committee and available for inspection.

Attachments:

Appendix A: Research Documentation using a SmartPhrase

Approval Signatures

Step Description	Approver	Date
Executive Committee	Robert Wilmott	6/14/2017
Prep Executive Committee	Elizabeth Page	6/1/2017
Prep Executive Committee	Linda Whelan	6/1/2017
Clinical Operations	Peggy Fisher	5/9/2017
	Peggy Fisher	5/9/2017
	Cherish Hoffman	5/9/2017