Investigator Standard Operating Procedures

SOP No.: 704  
Electronic Medical Record (EMR) Research Charting

Author: Office of Human Research

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Results of Review: Order of procedures changed, 'a' moved to 'd', content not revised, no new version issued

This SOP pertains to: All protocols used in human subject research within Memorial Healthcare System.

Responsibility for executing this Protocol: Investigator and Designated Research Personnel

Approved By (Sign & Date):

[Signature]
Senior Vice President & Chief Medical Officer, MHS

[Signature]
Chief Medical Research Officer, OHR

1  PURPOSE
This SOP serves as a guideline for all research-related charting within the Electronic Medical Record (EMR) for studies conducted within Memorial Healthcare System (MHS).

2  GENERAL PROCEDURES AND RESPONSIBILITIES
a) Each research subject should be linked to the appropriate study in the EMR.
b) Each research encounter should be tagged in the EMR.
c) For each research encounter, a research related secondary diagnosis code should be added by the physician or their designee.
d) Key research personnel are responsible for ensuring that excursions from the lab reference ranges for required laboratory values do not fall outside the parameters set by the protocol.
   • Most protocols require that the investigator review the labs and sign and date to document that they have seen the results and are aware of the patient's progress.
   • Where lab values exceed the reference ranges for the facility, the investigator may be asked to document whether the result is clinically significant (CS) or not clinically significant (NCS)

3  SPECIFIC PROCEDURES
Nurses and Investigators currently doing research at MHS will only chart by exemption on research related documents. Only labs that are clinically significant and which require medical intervention will be labeled (as required by the protocol).

4  REFERENCES TO OTHER APPLICABLE SOPS
None

5  ATTACHMENTS
None

6  APPLICABLE REGULATIONS AND GUIDELINES
None

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