
SOP Number ADM-006-01
SOP Name Documentation in the Medical Record of Research Patients SOP
Effective Date 01/MAR/2012

1.0 SCOPE

- 1.1 This procedure applies to all research that is conducted in a healthcare setting and which involves interaction or intervention with a registered patient.
- 1.2 Personnel responsible: Principal Investigator and, when delegated by the Research Principal Investigator, research team members.

2.0 PURPOSE

- 2.1 To describe standards for documenting research activities in a research participants' medical chart and to improve patient safety by ensuring transparency between the research activities and the medical treatment, while maintaining the confidentiality of the research data.

3.0 DEFINITIONS

- 3.1 None

4.0 PROCEDURES

- 4.1 When a research activity is associated with provision of healthcare, some documentation of the research activity may need to be included in the medical record to ensure the clinical care team is aware of any research activities that may impact medical care decisions. It is also to ensure all clinical and research regulatory requirements are met.
- 4.2 Unless otherwise specified by an Institutional Review Board, a copy of any informed consent document for any patient recruited into a clinical research study while registered as a patient in a hospital, or while attending a patient care visit, must be entered into the medical record.
- 4.3 The research team should ensure that the name of the study, responsible Principal Investigator, procedures performed, medications given, and relevant and clinically acceptable testing or evaluations are entered into the medical record. The research team should notify the clinical team when documentation is needed and provide the relevant content. Documentation should be readily accessible to the clinical care team if it is likely to impact care decisions.

5.0 LIST OF ATTACHED FORMS

- 5.1 None

6.0 REFERENCES

- 6.1 None

7.0 APPROVAL

Signature on file
VP of UC HEALTH RESEARCH OR DESIGNEE

14/FEB/2012
DATE