



University of
Missouri-
Columbia School
of Medicine

Subject:

Identification of Research Participants
in the Medical Record

Function:

Clinical Trials

Office of Compliance & Quality

Procedure No:

C&Q 04

12-01-2009

Effective Date

Participants in clinical trials should, in some cases, be identified in the medical record.

PURPOSE:

The purpose of this procedure is to provide for the safety of research participants by informing health care providers that the patient is a human subject in a clinical trial.

PROCEDURE:

1. The Institutional Review Board office (IRB) will identify which studies will be included in the medical record. The IRB will communicate inclusion to the investigator.
2. A statement that the informed consent document will become a part of the medical record and will therefore be available to anyone with access to the record will be added to the informed consent document.
3. The study coordinator or the investigator is responsible for assuring the signed document is provided to the Medical Record Department. Amended consent documents will follow the same process. The signed consent document will be scanned, indexed, and validated by the Medical Record staff and placed in the document section, Research Consents/Legal Documentation."
4. Study participation will be noted on the individual problem list in Powerchart by the study coordinator or the investigator. The specific problem to be entered is V70.7. Information to be included in the comments section will be:
 - the IRB number
 - a study title that is meaningful to the investigator
 - the investigator's name and after-hours contact information
 - the telephone number for the investigational pharmacy if there is a study drug
 - absolute contraindications (i.e. anticoagulants or classes of drugs)

- a statement that the informed consent document may be found in the clinical notes under "research consents/legal documentation."
5. Once the study is completed, the coordinator or investigator will inactivate the problem on the list.
 6. The process will be periodically monitored by the Office of Compliance and Quality to include assuring the accuracy of posting and inactivation.