



**University of
Missouri-
Columbia School
of Medicine**

Subject:
Observation of the Informed Consent
Process

Function:
Clinical Trials

Office of Compliance & Quality

Procedure No:
C&Q 03

09/01/2008
Effective Date

Observation of the Informed Consent Process by the Research Participant Advocate

PURPOSE:

As part of the educational efforts of the Research Participant Advocate (RPA) for School of Medicine Office of Compliance and Quality, the RPA will observe the informed consent process of potential research participants to assure that the process is appropriately completed and documented, the participant has sufficient time to consider participation, that no coercion has been used by the administrator of the consent, and that the information presented accurately reflects the content of the consent document and is conveyed in understandable language.

SELECTION CRITERIA:

Protocols selected for observation may represent higher risk studies, those that involve complicated procedures or interventions, studies including potentially vulnerable populations, or those involving personnel with minimal experience in administering informed consent. Any protocol may be selected.

PROCEDURE:

1. The RPA will contact the study coordinator and/or the Principal Investigator (PI) to schedule an observation. Study staff will provide dates and times for the RPA to observe.
2. Prior to the observation, the RPA will introduce him/herself to the potential study participant and explain the reason for her/his presence. The RPA will obtain the potential subject's verbal permission to observe. The RPA will document his/her observations on the Consent Observation Checklist. The RPA may address questions or issues that arise during the process that the administrator of the consent is unable to answer if they fall within the expertise of the RPA.
3. The RPA will prepare a written report that will be conveyed electronically to the administrator of the consent as well as their supervisor. If either the administrator or the RPA wishes to discuss the findings, they will arrange a meeting. The RPA may request further observations if serious deficiencies are detected.
4. Informed consent observations are conducted for educational purposes and are not intended to be punitive. Should repeated serious deficiencies be noted by the RPA, they will be brought to the attention of the PI and the Institutional Review Board.