Rule-of-Thumb #3 for an AAHRPP Interview:

Know your study!

AAHRPP interviewers may ask questions which will help them determine whether you are conducting research procedures according to your IRB approved protocol.

It is important that you not only know the research data, but that you have a firm grasp on all the aspects of the study: who is your research staff and what are they responsible for; what documents are filed, where and how; what informed consent process you are using; how information is collected from subjects.

Case Study #3:

Obtaining Informed Consent vs. Documenting Informed Consent

You have submitted a proposal for a minimal risk study. The IRB approves your proposal. In the Research Description you indicate the informed consent process will involve documenting subjects’ consent using the IRB approved consent form. You are in the field and are speaking to a subject eligible for enrollment in your study. You discover you do not have the consent documents with you. You have described all the study procedures to the subject and allowed ample time for the subject to consider whether to participate. The subject indicates he does not need anything in writing and agrees to participate. Is it ok to continue with the research activities with the subject?


ANSWER:

NO.

The IRB approved the protocol with the understanding that informed consent would be obtained and documented. Obtaining verbal consent does not satisfy this requirement. Changes in research procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the investigator without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. Any research procedures conducted that do not follow the IRB approved protocol are considered protocol violations and should be reported to the IRB upon discovery.


The IRB may waive the requirement to obtain a signed consent document for some or all of the subjects if certain conditions are met. In order for the IRB to consider approval for waiving this requirement, you must complete IRB Application “Form F” [http://www.research.uky.edu/ori/MedicalFullReviewApplication.htm#ICA] and submit it to the IRB for review.