Rule-of-Thumb #2 for an AAHRPP Interview:

Know your responsibilities!

AAHRPP interviewers will want you to demonstrate that you understand your role as a researcher, and if your own research practices and understanding of the research process corresponds with UK IRB/ORI policies and procedures.


Case Study #2:

Changing study procedures

Your clinical trial is going well. Enrollment is going smoothly and data is being collected and submitted on time. This study involves a series of blood tests that are to be collected for 6 consecutive weeks after the first dose of study drug. A new study subject, ABC, has decided to enroll. However, ABC has requested that his study blood be collected at his local doctor's office rather than driving into the city. You decide that these are only blood draws and you can supply ABC with the study tubes, plus the local doctor can answer questions about side effects that ABC may experience as a result of the blood draw. You are satisfied that this is the best thing to do for ABC.

Any reason to double check with the IRB office?

(Hint: See the Office of Research Integrity's (ORI) web page: Modification of a Currently Approved Protocol [http://www.research.uky.edu/ori/human/modification.htm]. Also, you may be interested to know there is a UK IRB/ORI Standard Operation Procedure on "Modification, Deviations, and Exceptions - IRB Review of Changes" [http://www.research.uky.edu/ori/human/SOPs & Policies.htm#2] and one on "Off-site Research" [http://www.research.uky.edu/ori/human/SOPs & Policies.htm#1].)

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ANSWER:

YES.

At a minimum, the change in location for the subject's blood draw is considered a change in protocol and should be submitted to the IRB as a modification request (if for a single instance, it could be a requested deviation from the protocol). See the IRB Modification Request Form [http://www.research.uky.edu/ori/Med_forms_IRB.htm#Mod]. In addition, situations such as these may
require that the local doctor have IRB approval. If the local doctor is collecting data and sharing it with you, the local doctor may be engaged in research. Better call the IRB office at 859-257-9428 for assistance in making a determination.

Also, please note, the University of Kentucky has additional requirements for off-site research. For details on the requirements for conducting off-site research, see the ORI's Off-site Research Guidance document [http://www.research.uky.edu/ori/human/guidance.htm#offsite], the UK IRB/ORI Standard Operation Procedure on "Off-site Research," [http://www.research.uky.edu/ori/human/SOPs_&_Policies.htm#1], the IRB Application for more information on off-site research, and the IRB Application "Form N" [http://www.research.uky.edu/ori/MedicalFullReviewApplication.htm#Add].