Rule-of-Thumb #5 for an AAHRPP Interview:

When asked a question, answer only the question. Do not meander onto other topics.

AAHRPP site-reviewers have a small block of time to conduct the interview. Only provide information relevant to the question, and try not to elaborate too much unless asked for more details.

Case Study #5:

IRB Approval Lapses

You received a Continuation Review Report Form from the Office of Research Integrity three months ago indicating your study is due for Continuation Review (CR). You missed the first deadline and received a second CR request a month later. You tried to get the CR materials in on time, but you had to be out-of-town for a lengthy professional conference, and now you are trying to catch up on all the work that piled up in your absence. You just came across a letter which must have been sitting in your mailbox for some time, because it indicates your approval has lapsed and all research activities for that protocol must stop. You have a lot more work to do before the research is over, and you gave the IRB an estimated project end date approximately five years from now. Under these circumstances, can the IRB end your study without conferring with you?

(Hint: Look at your Initial Review Approval letter (last sentence of the 1st paragraph), or, see the UK IRB/ORI Standard Operating Procedure “Continuation Review” [http://www.research.uky.edu/ori/human/SOPs_Policies.htm#2].

ANSWER:

YES.

Federal regulations dictate that previously approved research protocols must be re-reviewed by the IRB at intervals appropriate to the degree of risk, but not less than once per year. As a service to University of Kentucky researchers, the Office of Research Integrity (ORI) has a system in place to help remind Investigators when Continuation Review (CR) is due. If an Investigator has failed to provide sufficient materials to the IRB for Continuation Review, or the IRB has not reviewed and approved a research study by the approval end date specified by the IRB, all research activities for that study must cease - unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Neither enrollment of new subjects nor follow-up of currently enrolled subjects should occur after the expiration of IRB approval. If there are subjects whose best interests will be served by continuing to participate in the study, the IRB should be contacted immediately.

See the Office of Research Integrity IRB Review Types: Continuation Review web page for various regulatory documents [http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#CR].