Rule-of-Thumb #6 for an AAHRPP Interview:

Do not use your time in the interview to complain about the UK/IRB/ORI system.

The University of Kentucky has a system in place for researchers, IRB members, and subjects to submit suggestions, concerns or complaints about the IRB/ORI Administrative Process or human research. Please relay constructive feedback to the AAHRPP site reviewers, and utilize the Office of Research Integrity’s Concerns/Suggestions Process for initiating communication about issues you feel need attention. For details, see the ORI web page: Concerns or Suggestions: IRB/ORI Administrative Process; Investigator Appeals; Subject Concerns [http://www.research.uky.edu/ori/concerns_suggestions.htm].

Case Study #6:

Human Participation in Research: Blood in the Lab*

A research lab was studying the biochemistry of white blood cells in certain disease states. Infected blood samples were acquired with informed consent, independently of the lab, and were received at the lab without identification. Most of the basic analysis was performed by fellows, occasional graduate students, medical school students on research rotations, technicians, and so forth. In the course of this work, samples of blood from unaffected individuals were needed as controls. It was common practice in this lab to draw blood from individuals working in the lab to use as controls, and everyone took a turn in donating. Blood was drawn by lab staff trained in venipuncture, using aseptic procedures. “JD”, a new graduate student in the lab, refused repeatedly to donate his blood, explaining that he was “anemic.” Other lab personnel felt that he was not being truthful and by refusing to donate was not a “team player.” In fact, this graduate student was HIV-positive. JD decided that he would rather be known as uncooperative than have his health status known throughout the lab.

Which of the following choices is most appropriate?

1. No further clarification is needed. This case does not involve human research issues.
2. JD has a responsibility to tell his colleagues and the Lab Director about his condition.
3. JD should donate and trust in the professionalism of his colleagues.
4. JD should discuss the request to provide blood samples with the Lab Director, UK ORI staff, or the IRB Chair.

[Hint: The ethical issues in this case relate to the collection of blood sample controls in the lab and participation under coercion. Materials of interest which address the ethical issues include (but are not limited to): the “PI Guide to Identification and Recruitment of Human Subjects for Research” (available in the IRB Survival Handbook under the topic Recruitment of Subjects, and on the ORI Educational Materials, Regulations and Policy Guidance web page); the IRB Application “Form B” [MS Word] (aka “Research Description”) #10 requesting details on “Safety Precautions” and #14 requesting details on “Confidentiality.” Also, ORI has a web page devoted to the process for submitting “Concerns or Suggestions” with a section on Subject Concerns or Suggestions.

CHOICES & ANSWER:

If you chose #1: As the infected blood samples were acquired with informed consent and not identified when they reached the lab, there is no human research issue for this acquisition, as long as participants consented to their tissue being used for research purposes. A copy of that protocol should be available for review. However, this case is not related to the infected blood samples – it is related to collection of blood sample controls in the lab and participation under coercion. Make another choice.

If you chose #2: Not appropriate: HIV infection status is a matter of privacy in these circumstances. JD is not participating in activities that put other people at risk for HIV infection and there is no ethical responsibility for him to disclose his status to anyone. If this research were being conducted ethically, procedures would be in place to protect participants' privacy rights and the confidentiality of data.

If you chose #3: Not appropriate: One of the many problems with what is going on in that lab is that there is no process for separating identity of donor from the control sample donated. No one in the lab should need to trust that others in the lab will keep their secrets.

If you chose #4: Good choice: There are a number of problems here relating to the use of human participants in research. The concern relates to those lab employees who become unwitting "volunteers." First, drawing blood to use as controls counts as "intervention" for purposes of research. A proposal must be completed by the PI, and reviewed by IRB, regarding the use of human participants. The IRB will want to know how the PI is protecting the privacy of those who provide blood for the control group and what safeguards the PI has put in place to ensure that giving blood is truly a voluntary act.