

Subject: General Announcement: Human Research Accreditation Training Overview and Case Study #8 Answer

Important Dates: January 17 - 19, 2007 = The University of Kentucky's on-site review by the Association of the Accreditation for Human Research Protection Programs (AAHRPP).

Several of you have already been contacted directly by the Office of Research Integrity (ORI) regarding interviews AAHRPP has scheduled during that time span. However, it is known that while on-site, AAHRPP has on occasion requested unscheduled interviews. It is for this reason we are sending out weekly training "blurbs" through our listserv to help everyone get up-to-speed on the University of Kentucky's policies and procedures for human research protections, and to share information which should help you with an AAHRPP interview. If you know of someone that is not receiving these training bulletins who should, please have them contact our office at 257-8295 to sign-up. For future reference, all Human Research Accreditation Training blurbs will be archived on the ORI [Listserv Archives](http://www.research.uky.edu/ori/hotline/listserv_archives_2006.htm) web page [http://www.research.uky.edu/ori/hotline/listserv_archives_2006.htm].

Human Research Accreditation Listserv Training Overview:

Over the last several weeks through listserv messages, ORI has provided AAHRPP interview tips and case studies covering a range of topics. The topics covered to-date, and the links to the corresponding listserv message are as follows:

Interview Tips:

- Know your resources [[PDF](#)]
- Know your responsibilities [[PDF](#)]
- Know your study [[PDF](#)]
- Know the policies [[PDF](#)]
- When asked a question, answer only the question. Do not meander onto other topics. [[PDF](#)]
- Do not use your time in the interview to complain about the UK/IRB/ORI system. [[PDF](#)]
- If you do not immediately know an answer, or how to respond, know your options. [[PDF](#)]

Case Studies [http://www.research.uky.edu/ori/human/guidance.htm#Case_Studies]:

- #1 *Quality Improvement versus Research* [[PDF](#)]
- #2 *Changing study procedures* [[PDF](#)]
- #3 *Obtaining Informed Consent vs. Documenting Informed Consent* [[PDF](#)]
- #4 *Privacy vs. Confidentiality* [[PDF](#)]
- #5 *IRB Approval Lapses* [[PDF](#)]
- #6 *Human Participation in Research: Blood in the Lab* [[PDF](#)]
- #7 *Conflict of Interest* [[PDF](#)]
- #8 *Vulnerable Populations* [[PDF](#)]

Last Case Study #8 and ANSWER:

Vulnerable Populations

Professor Rhythm teaches music at a Community College for gifted individuals. He has been encouraged by his department chair to develop a study which would involve recruitment of the college attendees. Professor Rhythm has several of his own students he would like to include in the study because they are not even college-age yet, but have incredibly advanced musical talent.

Does Professor Rhythm need to describe any special provisions in his proposal for this subject population? If yes, what issues should he address?

Yes, Professor Rhythm needs to describe protections for students as research subjects, and because he may recruit students not of college-age yet (presumably under the age of 18), he should also describe provisions for protection of children (in Kentucky, a child refers to anyone less than 18 years of age unless the individual(s) is/are legally emancipated).

The Institutional Review Board (IRB) gives special consideration to protecting the welfare of vulnerable subjects such as children, prisoners, fetuses/neonates, pregnant women, and decisionally challenged/impaired persons. The IRB also recognizes that additional populations such as students may qualify as vulnerable populations and need safeguards in place for their protection during study participation.

For research involving students:

An underlying principle of the regulations governing use of human subjects in research is that the subject's participation is voluntary and based upon full and accurate information. The student-teacher relationship raises the issue of volunteer participation. Care should be taken to eliminate or reduce the risk that undue influence of faculty or coercion affects student participation in research. Guidelines to assist faculty who engage in research projects in which students will be asked to be research subjects can be found in the document "Guidance for Enrolling University Students as Subjects" [\[PDF\]](#).

If Professor Rhythm includes recruitment of the children in his research:

Parental permission must be obtained if the research involves children under the age of 18 unless the individuals are legally emancipated or the IRB waives the requirement. A written form must be reviewed by the IRB and used to document both parents' permission unless the requirement is waived by the IRB. Documentation of assent is required for subjects aged 12-17, unless the requirement is waived by the IRB. In most cases, a written assent form should be used to document assent. A copy of the assent form must be submitted to the IRB for review. Professor Rhythm would also need to include IRB Application "Form W" in his IRB submission.

Although this scenario does not specify the nature of the research, if it were to involve accessing students' educational records, the document Family Educational Rights and Privacy Act (FERPA) Guidance [\[PDF\]](#) would be of assistance to Dr. Rhythm.

A new case study will be sent in the New Year!

Happy Holidays!