

**University of Kentucky**  
**Human Research Accreditation Training #8**  
**For Association of the Accreditation for Human Research Protection Programs (AAHRPP)**  
**Site Visit January 17- 19, 2007**

**Case Study #8**

*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?

(Hint: See the Guidance for Enrolling University Students as Subjects [[PDF](#)], UK IRB Policy on Children in Research [[PDF](#)], and IRB Application "Form W" for Research Involving Children [[HTML](#)]. For regulatory requirements and UK IRB/ORI procedures, see the UK IRB/ORI Informed Consent SOP [[PDF](#)], and Protection of Vulnerable Subjects SOP [[PDF](#)].

**ANSWER:**

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.