

University of Kentucky
Human Research Accreditation Training #9
For Association of the Accreditation for Human Research Protection Programs (AAHRPP)
Site Visit January 17- 19, 2007

Quick Quiz:

1. Your IRB-approved protocol describes provisions for maintaining confidentiality of the study records (e.g., secure and locked location that is available to only authorized research staff as needed), but you have finished the study and closed it with a Final Review. How long do you need to maintain the research records now?

(Hint: Download the document "PI Guide to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" [PDF] under the topic *Investigator Responsibilities* on ORI's [Educational Materials, Regulations and Policy Guidance](#) web page.)

ANSWER: IRB policy requires investigators to maintain their research records (includes data collection form(s) including source documents and case report forms) for six years after completion of the study. For research which falls under authority of other agencies or statutes with longer research record retention requirements, the longer retention period applies. For more details on Investigator recordkeeping responsibilities, see the *Investigator Records and Documentation* section in "A Principal Investigator's Guide to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research". [PDF]

2. In order to receive federal funds for research, the University of Kentucky submits an agreement to follow all federal regulations; review all human research; monitor on-going studies; and report as appropriate, to the applicable agencies. To what federal agency does the University of Kentucky submit this agreement, and what is the name of the "agreement"?

(Hint: Visit ORI's [Educational Materials, Regulations and Policy Guidance](#) web page and click on the topic *Assurance Information* [<http://www.research.uky.edu/ori/human/guidance.htm#Assure>])

ANSWERS: To what federal agency does the University of Kentucky submit this agreement?: Office for Human Research Protections (OHRP). What is the name of the "agreement"?: Federalwide Assurance (FWA).

- 3a. What are the categories of vulnerable populations for which the Department of Health and Human Services (DHHS) regulations provide additional protections?

ANSWER: Pregnant Women, Human Fetuses and Neonates (Subpart B); prisoners (Subpart C); and children (Subpart D).

- b. For what vulnerable populations does the University of Kentucky have a policy and guidance to provide additional protections which are not provided in the HHS regulations?

ANSWER: Decisionally impaired/challenged, students as subjects.

(Hint: Download the UK IRB/ORI Standard Operating Procedure (SOP) for Protection of Vulnerable Subjects [PDF] from ORI's [Standard Operating Procedures](#) web page: http://www.research.uky.edu/ori/human/SOPs_&Policies.htm#3, and/or review [DHHS regulation 45 CFR 46](#).)

4. You have some research staff to assist you on a project you are preparing to submit to the IRB. Some of the research staff will be responsible for subject enrollment and data collection, and other research staff will conduct data analysis. Which of your staff needs to complete the University of Kentucky mandatory human research protections training?

(Hint: Download the document "What Constitutes Study Personnel on a Protocol Involving Human Subjects?" [PDF] under the topic *Study Personnel* on the [Educational Materials, Regulations and Policy Guidance](#) web page. Also, see the human research [Mandatory Education](#) [PDF] document from [ORI's web site](#).)

ANSWER: Any individual who will interact and/or intervene with human subjects or who handles personally identifiable data of a human subject is considered by the IRB as study personnel and should be listed on a study personnel list approved by the IRB. All study personnel are required to complete one of two options for human research protections training recognized by the University of Kentucky. Re-certification for human research protections training is required every three years. Study personnel who have not completed appropriate human research protections training will not be approved by the IRB to implement research activities.