

University of Kentucky
Human Research Accreditation Training #10
For Association of the Accreditation for Human Research Protection Programs (AAHRPP)
Site Visit January 17- 19, 2007

Quick Quiz:

1. Studies involving a level of risk no greater than that encountered in the daily lives of those in the general population (i.e. healthy subjects) should be considered minimal risk.

True or False?

ANSWER: True. "Minimal risk" means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102].

2. On "Form Z" (Signature Assurance Sheet) of the IRB application, the Principal Investigator (PI) documents his/her agreement to use only IRB-approved advertisements for recruitment of subjects.

True or False?

ANSWER: True, although not directly. When the PI signs "Form Z" (Signature Assurance Sheet) [\[WORD\]](#), (s)he is agreeing to comply with all IRB policies, decisions, conditions, and requirements. It is an IRB requirement that direct recruitment materials, intended to be seen or heard by prospective subjects to solicit their participation in a research study, receive IRB review and approval (because direct advertising for study subjects is the start of the informed consent and subject selection process). Guidance on recruitment can be found in the "PI Guide to Identification and Recruitment of Human Subjects for Research" [\[PDF\]](#).

3. The informed consent template ("Form C" of the IRB Application which must be used as a guide when developing your informed consent document), includes the ORI Research Compliance Officer's toll-free phone number (1-866-400-9428) for subjects to call in case of an emergency.

True or False?

ANSWER: False. Each IRB approved informed consent document should include the ORI Research Compliance Officer's toll-free phone number (1-866-400-9428) to serve as a subject's primary contact point for *submitting concerns or suggestions*.

It is IRB policy that a safe confidential, and reliable channel for current, prospective, or past research participants, their representatives or others, is provided that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol. For standard operating procedures regarding how the Research Compliance Officer handles concerns or complaints from research subjects, download the UK IRB/ORI Standard Operating Procedure (SOP) "Subject Concerns or Complaints" [\[PDF\]](#).

4. A waiver of the requirement for obtaining documentation of informed consent means you do not need to tell a subject (s)he is participating in a research study.

True or False?

ANSWER: False. Waiver of the requirement for obtaining *documentation* of informed consent means the subject does not put in writing/document his/her agreement to participate in the study. The subject is still informed about the study and given the opportunity to decide whether to participate (e.g., mail survey, telephone survey).

Waiver of the requirement for obtaining informed consent means the subject is not informed about his/her participation in the research (e.g., deception research, medical record review).