Examples of answers to questions on Request for Exempt Status form

1. How are the subjects at no more than minimal risk?

EXAMPLES

a. The subjects will not be asked to perform any activity that involves more than what is ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

b. The information on the survey does not contain any information of a sensitive nature that might cause the subjects any psychological or emotional discomfort or harm.

c. The subjects will be exposed to activities that are part of their daily routines in the classroom and do not present any threat of harm or discomfort to them.

2. How will informed consent be obtained? (Include copy of informed consent form or implied consent letter for surveys)

EXAMPLES

a. The subjects will be given a copy of an informed consent to read and sign.

b. The subjects will be read the attached informed consent and asked to sign the form if they agree to participate in the study.

c. The subjects will be presented an informed consent letter. Their participation in the survey will imply consent.

3. How will assent be obtained when minors or other vulnerable populations are used?

EXAMPLES

a. The subjects’ participation the research activity is an educational requirement. They are expected to participate in the activity.

b. The subjects’ will be told all of the pertinent information about the study communicated in ways they will understand, i.e., in language consistent with their linguistic and cognitive abilities. Assent will be implied by their participation in the activity.

c. The subjects’ will be told all of the pertinent information about the study communicated in ways they will understand, i.e., in language consistent with their linguistic and cognitive abilities. The subjects will be asked to sign the attached assent letter or form.

d. The subjects are of an age that assent is not relevant or appropriate. Parental permission will be the only method used to for their participation in the study.
4. How will confidentiality be maintained?

EXAMPLES

a. Any identifying information about the subjects will be stored in a locked filing cabinet in the principal investigator’s office. Subject identities will not be disclosed to anyone verbally or in writing.

b. All information about the subjects is completely anonymous.

c. All videotapes used for collecting data will be stored in a locked filing cabinet in the principal investigator’s office. No one will have access to these video tapes except for the investigators in the study. The video tapes will be destroyed at the end of the study, or after ___ months, or after ___ years.