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Support

Informed Consent - SBE

Georgia Institute of Technology - Group 2 Social / Behavioral Research
Investigators and Key Personnel

Quiz Results

You correctly answered **5 of 5** quiz questions.

Question 1

Question	A therapist at a free university clinic treats elementary school children with behavior problems who are referred by a social service agency. She is also a doctoral candidate who proposes using data she has and will collect about the children for a case-based research project. Which of the following statements about parental permission is correct?
Your Answer	The parents of the children might feel pressure to give permission to the therapist to use their children's data so that she will continue to provide services to their children.
Result	Correct
Comment	When a care provider becomes a researcher, both the child clients and their parents may not feel free to choose not to participate in the provider's study. A researcher who is also a care provider needs to be very clear that a decision not to participate in a study, or to allow records to be used, will not affect the care provided in the

future. The fact that the therapist has access to her clients' records as a clinician does not entitle her to use information in the records for research purposes without parental permission and child assent. A school authority's permission to conduct the research does not replace the need for permission or assent. Finally, the children's right to choose cannot be overridden in the pursuit of an indeterminate community interest.

Question 2

Question	A general requirement for informed consent is that no informed consent may include any exculpatory language. Exculpatory language is that which waives or appears to waive any of the subject's legal rights or releases or appears to release those conducting the research from liability for negligence. Which of the following statements in a consent form is an example of exculpatory language?
Your Answer	Taking part in the research is voluntary, but if you choose to take part, you waive the right to legal redress for any research-related injuries.
Result	Correct
Comment	A statement in a consent form that says that subjects who agree to take part in the research waive their legal rights constitutes exculpatory language. Statements about the voluntary nature of consent, about the possible need to remove subjects from a study in order to protect their welfare, and statements about providing referrals do not waive subjects' rights.

Question 3

Question	A criterion for waiving informed consent is that, when appropriate, subjects are provided additional pertinent information after the study. In which of the following studies would it NOT be appropriate to provide subjects with information about missing elements of consent:
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Your Answer A study in which subjects were assigned to study activities based on an undesirable or unflattering physical characteristic as assessed by members of the research team.

Result **Correct**

Comment If subjects were to learn that the research team assigned them to study conditions based on undesirable or unflattering physical characteristics, the knowledge that their appearance was judged negatively by the research team could be very distressing and, therefore, it would not be appropriate to inform subjects after the study about how they were assigned. Informing subjects about the actual research procedures in the other studies would be unlikely to cause them harm.

Question 4

Question A waiver of the requirement for documentation of informed consent may be granted when:

Your Answer The only record linking the subject and the research is the consent document and the principal risk is a breach of confidentiality.

Result **Correct**

Comment The requirement to document informed consent can be waived if the only record linking the subject and the research is the consent document and the principal risk is a breach of confidentiality. The requirement may also be waived if the study poses no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research context. With regard to non-English speakers, if documentation is required, investigators must provide informed consent materials in the subjects' language. If a researcher anticipates that subjects might be embarrassed by questions, this concern should be addressed in the consent process. Finally, identifying secure storage space for consent forms is an investigator's responsibility.

Question 5

Question	As part of the consent process, the federal regulations require researchers to:
Your Answer	Provide potential subjects with information at the appropriate reading comprehension level.
Result	Correct
Comment	Researchers must provide information to subjects in a manner that facilitates comprehension. Therefore, the material must be written at the appropriate reading comprehension level. Researchers may not impose penalties for non-participation because to do so would violate the ethical principle of respect for persons. In some circumstances it may be appropriate to ask subjects to discuss the research with their families before making a decision about whether to participate, but it is not a regulatory requirement. Finally, researchers are not required to provide a list of the IRB members who reviewed the research.

You scored 100% on the quiz.

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