

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 subject's 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

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L Reisser



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