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The Federal Regulations - 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	In addition to pregnant women, fetuses, and neonates, another subpart of the HHS regulations provides additional protections for which of the following vulnerable populations?
Your Answer	Prisoners
Result	**Correct**
Comment	Prisoners are provided additional protections in the HHS regulations. The HHS regulations do not have specific additional protections for the elderly, for students, or for persons whose decision-making capabilities are impaired. Researchers may consider and the IRB may require additional safeguards for these populations.

Question 2

Question	Which of the following statements about the relationship between an institution and the institution's IRB(s) is correct?
Your Answer	Officials of the institution may overrule an IRB approval.
Result	**Correct**
Comment	If an IRB has disapproved a protocol, that disapproval may not be overturned by an institutional official or anyone at that institution, such as a department chair. However, an IRB-approved protocol may be subject to other reviews at the institution and may be disapproved (overruled).

Question 3

Question	According to the federal regulations, research is eligible for exemption, if:
Your Answer	The research falls into one of eight categories of research activity described in the regulations.
Result	**Correct**
Comment	Research is only eligible for exemption if all the activities associated with the research fall into one of eight categories of activities described in the federal regulations. The regulations do allow some research with children to be exempt (although institutional policy may not). The duration of the study and the experience of the researcher are not criteria for determining eligibility for exemption.

Question 4

Question	According to federal regulations, the expedited review process may be used when the study procedures pose:
Your Answer	No more than minimal risk and the research activities fall within regulatory categories identified as eligible.
Result	**Correct**

Comment	Research is eligible for expedited review when it poses no more than minimal risk to the participants and when all the activities fall within categories identified as eligible. Studies with more than minimal risk do not qualify for expedited review even if the subjects are adults, the sponsor is in a hurry, or the study replicates previously approved research.

Question 5

Question	Continuing review of an approved and ongoing study posing more than minimal risk that was initially approved by a convened IRB:
Your Answer	Must occur within 12 months of the approval date.
Result	**Correct**
Comment	Continuing review of an approved protocol must occur within 12 months of the approval date even if no additional risks have been identified. Review by a convened IRB is not always required (for example, if the study was complete and in data analysis only). Any unanticipated problems must be addressed during the continuing review process, but the review must include other information such as the number of subjects accrued, any relevant recent literature, and a copy of the current consent form.

You scored 100% on the quiz.

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