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IO Knowledge Requirements: Human Subject Protections

Harrisburg University of Science and Technology - Institutional/Signatory Official: Human Subject Research

Quiz Results

You correctly answered 4 of 5 quiz questions.

Question 1

Question The federal regulations require IRBs to use the "111 criteria" to

approve research. These standards require the IRB to ensure that:

Your Answer Study procedures are consistent with sound research design

Result Correct

Comment While researchers sometimes complain that the IRB is

inappropriately commenting on their study design, the IRB is specifically required to determine that "risks to subjects are

minimized by using procedures which are consistent with sound

research design and do not unnecessarily expose subjects to risks" (Protection of Human Subjects 2017). Although generally a good idea for both IRBs and researchers, the use of checklists is not required. Payment to subjects depends upon institutional policy and individual studies; it is not a requirement. One of the ethical dilemmas that concerns IRBs and researchers is the fact that often there is no direct benefit to subjects, thus the risks of research must be justified by benefits to science or society.

Question 2

Question The membership of the IRB committee has specific requirements

under the federal regulations. Therefore, the appointment

process for members and chairs:

Your Answer Must include an appointment letter from the organization's

President or CEO

Result Incorrect

Correct Answer Should be overseen by the IO

Comment The appointment process for IRB members and chairs should be

overseen by the IO. Typically, the IRB office or IRB chair will recommend suitable candidates to the IO, who then officially appoints the member or chair; however, there is no required process. The federal regulations require that an IRB be a mixed committee; not all men or women, nor only scientists – in fact, a non-scientist member must be present at every meeting for the IRB's actions to be valid. Most IRBs do use term limits for members, but again that is an institutional prerogative.

Question 3

Question Regarding the basic ethical principles described in the Belmont

Report for the conduct of human subject research, the *Belmont*

Report states that:

Your Answer They carry equal moral weight and may sometimes conflict with

each other

Result Correct

Comment The three basic ethical principles carry equal moral weight and

may sometimes conflict with each other. The *Belmont Report* specifically states that the order of appearance does not connote any hierarchy and that each must be considered as an equal obligation and that conflicts require careful consideration and

"balancing." The Belmont Principles are an ethical/moral

construct, not a legal requirement – although the regulations are

based on them.

Question 4

Question The size and scope of the HRPP varies depending on the size and

scope of the organization within which it operates. Even at a small research facility, the HRPP, with rare exception, includes the IRB

and which of the following?

Your Answer Researchers

Result Correct

Comment Researchers is correct. The core mission of the HRPP relates to

the basic ABCs of human subject protection. Therefore, Board review (IRB) and Consent, which is obtained by researchers, are

part of the HRPP in even the smallest research facilities.

Question 5

Question The IRB tends to be the center of an organization's HRPP because:

Your Answer The IRB has the best understanding of the human subject

protection regulations, guidelines and ethical norms

Result Correct

Comment The IRB has the best understanding and knowledge of the human

subject protection regulations, guidelines and ethical norms. Neither the federal regulations nor the FWA require any specific

organizational structure.

You scored 80% on the quiz.

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