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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 **3 of 5** quiz questions.

Question 1

Question	In addition to the IO, who must be listed on the FWA?
Your Answer	The President/CEO
Result	**Incorrect**
Correct Answer	The Human Protection Administrator (HPA)
Comment	The HPA is correct. Both the IO who actually signs the FWA and the HRPP manager/director (HPA) are listed on the FWA. For most institutions, these are two different people. If one person plays both roles, however, that person would be listed both as the IO

and the HPA; this is the exception, not the rule.

Question 2

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 3

Question The federal regulations state that the IRB must conduct continuing review of research approved by a convened IRB (more than minimal risk research) at intervals appropriate to the degree of risk, but not less than once per year. Continuing review must be:

Your Answer Substantive and meaningful

Result **Correct**

Comment Federal guidance states that Continuing Review must be substantive and meaningful, which means that the IRB must collect sufficient information about the conduct and progress of the study and use the “111” criteria for re-approval. Continuing

Review may be conducted by the IRB through expedited procedures only if the study presents no more than minimal risk to subjects. Although on-site observation is permitted by the regulations, it is not required and no other institutional office or committee must ratify an IRB decision.

Question 4

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 5

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 are listed in descending order of importance
Result	**Incorrect**
Correct Answer	They carry equal moral weight and may sometimes conflict with each other
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.

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