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Expectations of the IO

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

Quiz Results

You correctly answered **1 of 5** quiz questions.

Question 1

Question	For research that is governed by the FDA regulations, the institution must notify the appropriate FDA Center when:
Your Answer	An experimental drug/device fails to meet established end points
Result	**Incorrect**
Correct Answer	An unanticipated problem involving risk to subjects or others is encountered
Comment	: For research that is governed by the FDA regulations, the appropriate FDA Center must be notified when the IRB suspends study approval or an investigator is found to be in serious or continuing non-compliance or an “unanticipated problem

involving risk to subjects or others" is encountered. Reporting research results and financial conflicts of interest are a responsibility of sponsors, not the performance sites.

Question 2

Question	The major role of the IO is as
Your Answer	A researcher
Result	**Incorrect**
Correct Answer	An executive
Comment	The most important role of the IO is as an executive – the person who bears the ultimate responsibility for the institution's HRPP. The IO uses executive/management skills such as leadership, communication, and evaluation, to ensure that the HRPP operates effectively and meets all regulatory, legal, and institutional requirements. While some IOs may be researchers, that is not a job requirement. Hearing appeals is an optional duty that would be defined by institutional policy and is only a small part of the IO job. Although not prohibited, it would be an unusual case where the IO would also be the director of the IRB.

Question 3

Question	The purpose of an internal quality improvement (QI) program is to
Your Answer	Find problems and opportunities for improvement
Result	**Correct**
Comment	The purpose of an internal quality improvement (QI) program is intended to find opportunities for improvement and to prevent

situations that might place otherwise unrecognized risks on human subjects or lead to regulatory citations. The QI program should be structured and operated as fair and demonstrate concern about correcting problems and preventing recurrence. The QI activity should not report directly to the IRB to avoid the IRB being seen as the "police." Because of the pivotal role played by the researcher, the HRPP QI program should monitor research at the research site – preferably while recruitment and study activities are ongoing.

Question 4

Question	The institution must update its FWA within 90 days after changes occur in the legal name of the institution or which of the following?
Your Answer	The CEO/President or the IO changes
Result	**Incorrect**
Correct Answer	The Human Protections Administrator (HPA) or the IO changes
Comment	The institution must update its FWA within 90 days after changes occur in the legal name of the institution, the HPA changes, or the IO changes. Each of these is part of the FWA.

Question 5

Question	For research funded by the federal government, the institution must notify the funding agency and the office that issued the FWA whenever:
Your Answer	A researcher is found to be in continuing non-compliance with HIPAA regulations

Result	**Incorrect**
Correct Answer	The IRB suspends study approval
Comment	For research funded by the federal government, notice must be given to the funding agency and the office that issued the FWA whenever the IRB suspends approval, a researcher is found to be in serious or continuing non-compliance of the human subject protection regulations (not HIPAA), or an “unanticipated problem involving risk to participants or others” is encountered.

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