Suraj Pratap
ID 9919506

Expectations of the IO

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	Shortly after an FDA inspection, the institution should develop a plan of correction for any deficiencies that were cited. A letter with the action plan should be:
Your Answer	Respectful in tone and factual in nature and sent to the FDA district office
Result	**Correct**
Comment	The letter should contain the institution's plan of correction for any deficiencies that were cited, be respectful in tone and factual in nature, and sent to the FDA field investigator's district office within a week of the inspection.

Question 2

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 Human Protections Administrator (HPA) or the IO changes
Result	**Correct**
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 3

Question	The major role of the IO is as
Your Answer	An executive
Result	**Correct**
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 4

Question	For research that is governed by the FDA regulations, the institution must notify the appropriate FDA Center when:
Your Answer	An unanticipated problem involving risk to subjects or others is encountered
Result	**Correct**
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 5

Question	An effective IO should build an organizational culture and monitoring system that:
Your Answer	Is operated by the legal/risk management office
Result	**Incorrect**
Correct Answer	Is fair and concerned with correcting problems and preventing recurrence
Comment	Researchers and employees are most likely to make self-reports when they believe they have an institutional/moral obligation to report problems and they see the institution as fair and concerned with correcting problems and preventing recurrence and not in punishing those who violate the rules. Whistleblowers may not speak up unless they believe they will be protected from retribution for having reported a problem; reasonable confidentiality precautions should be taken but anonymity cannot

be guaranteed. The intent of an institutional monitoring program is to discover opportunities for improvement; it is not intended to be punitive. As with any HRPP function, the organizational structure and responsibility depends upon the needs of the institution.

You scored 80% on the quiz.

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