



Suraj Pratap
ID 9919506

Courses

Records

CE/CMEs

Support

Challenges of Being an IO: 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	Communication is most effective when
Your Answer	All messages and responses regarding research are documented in writing
Result	Incorrect
Correct Answer	Messages are sent in a timely fashion to the appropriate people
Comment	Effective communication ensures that messages are sent in a timely fashion to the appropriate people. Establishing effective lines of communication should ensure that every employee feels

that they are/can be heard, but that is only partly a measure of effectiveness. Written documentation may be required in certain circumstances, but not for all messages.

Question 2

Question	Two techniques that allow the IO to play a useful advisory role even without direct experience in human subject protection areas are:
Your Answer	Periodically reviewing institutional policy and reviewing federal regulatory agency determination/Warning Letters
Result	Correct
Comment	Many IOs find that is helpful to review federal guidance, OHRP determination letters, FDA Warning Letters, and periodically review institutional policy. Guidance documents are intended to clarify federal policy and provide examples of acceptable methods for compliance; because guidance is “non-binding” and written for a nationwide audience, changes in institutional policy may not be needed. Email and memos are written communication techniques. While the IO should delegate duties to qualified and skilled professionals, to be effective, the IO should probe and ask appropriate questions to ensure an adequate evaluation and identify opportunities for improvement.

Question 3

Question	Using a “chain of command” reporting structure allows for messages to be sent to the leadership of the organization:
Your Answer	And ensures that leadership is responsive

Result**Incorrect**

Correct Answer And allows for appropriate filtering and resolution at intermediate levels

Comment

A “chain of command” reporting structure allows for appropriate filtering and response/resolution at intermediate levels (for example, the immediate supervisor, department head, dean/manager, etc.), which also permits quick response/feedback to the originator. Leadership response times are set by institutional culture and expectations as well as individual commitment, not by the reporting structure. While chain-of-command works well in hierarchical structures such as the military, any organization can effectively implement this reporting structure.

Question 4

Question

Standard Operating Procedures (SOPs) are important to institutional compliance; therefore, the IO is typically involved with:

Your Answer

Setting the policy and approving the final SOP

Result**Correct****Comment**

Both the Common Rule and the FDA regulations require written procedures for certain human subject protection operations. Because human subject protection SOPs are important for maintaining consistency and compliance, the IO should be involved in policy development, typically by determining policy needs and reviewing the draft SOP and/or approving the final SOP. Monitoring of compliance, especially on a day-to-day basis, is a role for the QI program. Even if the IO has a legal background, legal interpretations of policy are in the domain of the legal office.

Policies are not appealed; however, there should be a process for updating and revising policies when needed.

Question 5

Question	Which executive management skill plays the primary role in conflict resolution/management?
Your Answer	Communication
Result	Correct
Comment	Communication plays the key role in conflict resolution/management. Of the other three IO tasks/roles, leadership may be needed to foster communication. Program evaluation and resource allocation may help prevent conflicts from occurring, but are not typically useful in conflict resolution.

You scored 60% on the quiz.

[Return to Gradebook](#)

- [Review Module / Retake Quiz](#)
- [Leave feedback for this Module](#)

- [View Courses](#)

SUPPORT

888.529.5929

8:30 a.m. – 7:30 p.m. ET

Monday – Friday

[Contact Us](#)

LEGAL

[Accessibility](#)

[Copyright](#)

[Privacy and Cookie Policy](#)

[Statement of Security Practices](#)

[Terms of Service](#)

