



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 **1 of 5** quiz questions.

### Question 1

<b>Question</b>	Which executive management skill plays the primary role in conflict resolution/management?
<b>Your Answer</b>	Leadership
<b>Result</b>	<b>Incorrect</b>
<b>Correct Answer</b>	Communication
<b>Comment</b>	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.

## Question 2

<b>Question</b>	Because the IO generally operates the HRPP through delegation, it is vital that the IO maintain:
<b>Your Answer</b>	Skills in ethics and philosophy
<b>Result</b>	<b>Incorrect</b>
<b>Correct Answer</b>	Effective communication and monitoring techniques
<b>Comment</b>	Effective communication and monitoring techniques are essential for gathering information and managing when using delegation. While skills in ethics and philosophy might be useful in some particular situations, management skills such as communication and monitoring are more broadly applicable when the IO delegates authorities. An “open door” policy is a way to demonstrate availability for input, but being available continuously is not required, nor sustainable. The IO need not be an active researcher to be an effective manager of the HRPP.

## Question 3

<b>Question</b>	Standard Operating Procedures (SOPs) are important to institutional compliance; therefore, the IO is typically involved with:
<b>Your Answer</b>	Establishing a policy appeals process
<b>Result</b>	<b>Incorrect</b>
<b>Correct Answer</b>	Setting the policy and approving the final SOP

**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 4

**Question** The federal regulations prohibit institutional officials from:

**Your Answer** Approving research if it has been disapproved by an IRB

**Result** **Correct**

**Comment** The federal regulations prohibit institutional officials from approving research if it has been disapproved or has not been approved by an IRB; however, research that has been approved by an IRB may be reviewed and approved or disapproved by officials of the institution. Institutional management styles and structures are not addressed in the federal regulations; therefore, the IO should feel free to attend IRB meetings and delegate the sign off on policy documents. In most organizations, the IO does not directly manage the IRB, but rather delegates those functions.

## Question 5

**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** Reading federal guidance and requiring immediate change to HRPP policy

**Result** **Incorrect**

**Correct Answer** Periodically reviewing institutional policy and reviewing federal regulatory agency determination/Warning Letters

**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.

You scored 20% 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](#)

