

Investigator Orientation: an Educational Psychology Approach

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1. Background

A survey conducted amongst principal investigators and sub-investigators (n=92) at the Stanford Cancer Institute revealed that while 68 percent received peer-to-peer training, only 38 percent received training from non-peer groups. General feedback cited a lack of a standardized orientation, knowledge of resources, and quality of content as factors in the lack of participation in non-peer education courses. To address these concerns, it was determined that an in-person workshop focused on clinical operations and policy would be created.

2. Goals

The primary goal of the workshop is to increase investigator confidence in clinical operations material in the following categories: Informed Consent, Good Documentation Practices, Participant Eligibility, and Adverse Events and Safety Reporting. These key clinical research topics are essential in the proper conduct of a clinical trial. Confidence and proficiency in the policy and procedures in these topic areas may decrease findings on monitoring and audit reports, and increase the reliability of data and the safety of participants.

Secondary goals include creating standardized language and knowledge of resources to aid in the communication between investigators, clinical operations teams, and regulatory oversight bodies.

3. Solutions and Methods

An in-person workshop informed by basic pedagogical practices¹ was developed to address the educational needs of investigators from a range of expertise or experience. The workshop was then peer-reviewed by quality assurance, clinical operations leaders, clinical operations managers, and principal investigators to ensure accuracy of information and presentation effectiveness. In September 2025, a process of presenting the workshop to investigators, collecting feedback, and improving the material began. In February 2026, the finalized workshop was presented with the following structure:

Part 1: Regulatory and Institutional Structures and Policies

Diagrams and visual representations of policies are used to educate attendees on what policies affect clinical trials, why the policies are in place, and how to navigate resources to find answers to everyday questions. The purpose of this section is to review material already known to the attendee through prior knowledge and onboarding material (such as GCP training) and show the relevance to everyday tasks and problem-solving in a new visual format. Information across several resources is consolidated to simplify learning.

Part 2: Topics and Breakout Sessions

Clinical operations material is presented with corresponding standard operating procedures and regulatory policy. After learning the policy and procedures, attendees form small peer groups with a clinical operations proctor who is pre-chosen for proficiency in the material, and work through real-world scenarios and examples by applying the information that was just presented. Then, data from our institution's Data and Safety Monitoring Committee is presented to show the most common findings from recent inspections and audits. Relevance to the attendees is highlighted using inspection findings to increase retention of policy.

Data is collected in the form of a pre- and post-survey utilizing a Likert scale to assess confidence levels in the four topic groups.

1. Merrill, M. D. (2002). First principles of instruction. *Educational Technology Research and Development*, 50(3), 43-59. ([Click for copy from Dr. Merrill's personal website](#)) [Archived](#) 2012-03-25 at the [Wayback Machine](#)

4. Outcomes

Preliminary trial runs of the workshop successfully enrolled 39 participants within the institution. Initial data collection of the finalized workshop shows that all attendees (n= seven) increased one or two points in confidence in three or more areas. Areas that did not show an increase in confidence were already rated as four or five on the five-point scale, indicating high confidence.

5. Lessons Learned and Future Directions

Standardized education utilizing common pedagogical practices is essential in supporting the growth of clinical research within an institution. Investigators seek out reliable education and report back a growth in confidence after participating in an in-person workshop.

We will continue running this workshop and collecting data, and plan to expand the program to specialized workshops for Principal Investigators and incoming fellows.