

# How to Be a Principal Investigator: A Practical Training Program for Investigators

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## BACKGROUND

Clinical investigators complete rigorous medical training and are required to complete online, self-guided training in good clinical practice (GCP) and human subjects protection (HSP). These courses do not include the practical skills necessary to be a successful investigator. We formed a committee and created a practical investigator training seminar. After successful completion of the pilot seminar, we have offered the seminar regularly.

## METHOD

- The committee identified six competence domains (Figure 1).
- The pilot seminar included junior and senior faculty.
- The seminar is now mandatory for all investigators in the Department of Internal Medicine.
- The seminar is offered regularly on different days of the week and at different times to accommodate schedules.

### Figure 1. Core Competencies

1. Roles and responsibilities of the investigator
2. Federal and international regulations
3. Institutional processes and regulations
4. Informed consent, adverse event assessment, and source documentation
5. Roles and responsibilities of research staff
6. Resources available to investigators in clinical areas

### Figure 2. Qualitative Feedback Samples

“Very nicely done—thank you! I was afraid it would be painful; it wasn’t.”

**JW, Experienced PI**

“Stellar review overall.”

**WA, Experienced PI**

## RESULTS

- Self-assessed quantitative scores across the competence domains improved and persisted after three months.
- The average cumulative understanding score for investigators attending the seminar after the pilot was 25.95 of a possible 30.
- Qualitative feedback was generally positive (Figure 2).

## CONCLUSIONS

A seminar providing investigator training on practical applications of investigator responsibilities and best practices improved knowledge of investigators across the six competence domains.

## FUTURE PLANS

- The committee will explore updated format options such as an interactive online training.
- Based on a suggestion from an investigator, the committee will also explore a combined seminar including coordination staff.
- The committee will update content as needed.