Online Self-Learning Modules

These online modules will provide a basic overview of clinical research. All modules and the associated evaluations are designed to be completed during the first 6 weeks of employment. At the conclusion of a module, participants either complete an online evaluation or paper evaluation that will need to be faxed or emailed to Elizabeth (Liz) Ness at 301-496-9020 or nesse@mail.nih.gov.

1. Good Clinical Practice & Human Subjects Protection
2. Clinical Trial Design
3. Protocol Development
4. Informed Consent Process
5. Roles and Responsibilities of the Research Team
6. Clinical Data Management
7. Documentation in Clinical Research
8. Adverse Events and Unanticipated Problems
9. Regulatory Binder
10. RECIST: Applying the Rules (Optional): 1 slide per page or 6 slides per page
11. Monitoring and Auditing of Clinical Trials
12. Drug Development: Role of the FDA and Sponsor