

Human Subjects Protections Course Modules

- **Required Modules (learner must complete all)**
 - Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)
 - History and Ethical Principles - SBE (ID: 490)
 - Defining Research with Human Subjects - SBE (ID: 491)
 - Assessing Risk - SBE (ID: 503)
 - Informed Consent - SBE (ID: 504)
 - Investigator Responsibilities - EDSBS (ID: 16391)
 - UW-Madison Human Subjects Research Infrastructure (ID: 16392)
 - University of Wisconsin - Madison (ID: 12133)
- **Elective Modules (learner must complete at least 2)**
 - Research with Children - SBE (ID: 507)
 - Research in Public Elementary and Secondary Schools - SBE (ID: 508)
 - Consent and Subject Recruitment Challenges: Therapeutic Misconception (ID: 17259)
 - Consent with Subjects Who Do Not Speak English (ID: 17260)
 - Research with Decisionally Impaired Subjects (ID: 16610)

Good Clinical Practice Modules by Course

Good Clinical Practice for Drug/Device Researchers:

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)
- Overview of New Drug Development (ID: 1351)
- Overview of ICH GCP (ID: 1352)
- ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)
- Investigator Obligations in FDA-Regulated Research (ID: 1356)
- Managing Investigational Agents According to GCP Requirements (ID: 1357)
- Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)
- Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)
- Detecting and Evaluating Adverse Events (ID: 1360)
- Reporting Serious Adverse Events (ID: 1361)
- Audits and Inspections of Clinical Trials (ID: 1363)
- Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)
- Completing the CITI GCP Course (ID: 1364)

GCP – Social and Behavioral Research Best Practices for Clinical Research:

- Introduction (ID: 17531)
- Research Protocol (ID: 17532)
- Recruitment and Retention (ID: 17533)
- Informed Consent Communication (ID: 17534)
- Privacy and Confidentiality (ID: 17535)
- Participant Safety and Adverse Event Reporting (ID: 17536)
- Quality Control and Assurance (ID: 17537)
- Research Misconduct (ID: 17538)
- Conclusion (ID: 17539)