



Research Ethics Committee (IRB) Course: Protocol Review, Informed Consent and Decision Letters



Research Ethics Committee (IRB) Course: Protocol Review, Informed Consent and Decision Letters

Introduction:

Research ethics committee IRB training for protocol review, informed consent and decision letters is a 5-day course for committee members, chairs, secretariat administrators and research governance staff that ends with an Ethics Committee Decision Letter for a case protocol. Universities and hospitals face stalled studies, inconsistent approvals and harm to participants when protocols are reviewed without clear criteria, a documented quorum or oversight after approval. Nominees already sit on or support review committees or submit protocols, and they work through case studies built on protocol, consent and safety report documents. CoreConcept Training Center delivers this research ethics committee course.

Course Objectives:

- Apply the Belmont principles, the Declaration of Helsinki and the CIOMS guidelines to judge whether a human-subject study is ethically acceptable
- Constitute an ethics committee with the membership mix, quorum, recusal rules and standard operating procedures that ICH GCP expects of an IRB or IEC
- Triage incoming protocols into exempt, expedited or full-board review and screen each submission for completeness
- Evaluate risk-benefit balance, consent documents and safeguards for vulnerable participants against stated review criteria
- Oversee approved studies through continuing review, amendments, deviations, safety reports, secondary data use requests and misconduct allegations
- Draft decision letters, minutes and records that state approval conditions, required modifications or grounds for deferral

Target Audience:

- Committee members and chairs who review human-subject protocols and vote on approval
 - Secretariat and research ethics office staff who screen submissions, schedule meetings and keep committee records
 - Research governance staff responsible for institutional oversight of studies involving people
 - Investigators and study coordinators who prepare protocols, consent forms and safety reports for committee review
 - Clinical research unit and quality staff who monitor approved studies in hospitals and universities
-

Course Outline:

Day 1: Human-Subject Research Ethics Foundations and the Review Landscape

- Belmont Principles of Respect, Beneficence and Justice Applied
- Declaration of Helsinki Requirements for Independent Prior Committee Approval
- CIOMS Guidelines for Health-Related Research Involving Humans
- Research Versus Audit and Service Evaluation Classification Test
- Institutional Research Ethics Review Gap Assessment Checklist

Day 2: Ethics Committee Constitution, Independence and Standard Operating Procedures

- ICH GCP Expectations for IRB and IEC Composition
- Membership Mix of Scientific, Lay and Independent Members
- Quorum Rules, Voting Procedure and Recusal of Conflicted Members
- Member Conflict of Interest Declarations and Institutional Pressure Safeguards
- Standard Operating Procedure Set for Committee Secretariat Workflows

Day 3: Protocol Review Criteria, Risk-Benefit Judgement and Informed Consent

- Protocol Submission Checklist and Secretariat Completeness Screening
- Exempt, Expedited and Full-Board Review Pathway Triage
- Risk-Benefit Assessment Grid and Minimal Risk Determination
- Consent Form Review for Information, Comprehension and Voluntariness
- Vulnerable Participant Safeguards and Surrogate Consent Arrangements

Day 4: Post-Approval Oversight, Data Protection and Research Misconduct

- Continuing Review Intervals Matched to Study Risk Level
- Amendment, Protocol Deviation and Serious Adverse Event Reporting
- Secondary Data Use, Anonymisation and Broad Consent Decisions
- Misconduct Allegations Covering Fabrication, Falsification and Plagiarism
- Committee Minutes, Records Retention and Quality Self-Assessment

Day 5: Case Study Mock Committee Meeting and Decision Letter

- Case Protocol Pre-Review by Primary and Secondary Reviewers
 - Case Consent Documents Assessed Against Vulnerability Findings
 - Mock Full-Board Meeting With Quorum Check and Deliberation
 - Approval Conditions, Required Modifications and Deferral Rationale Drafting
 - Ethics Committee Decision Letter Completed and Defended Before Peers
-

Skills You Will Gain:

- Ethical Principle Application
- Committee Constitution Design
- Review Pathway Triage
- Risk-Benefit Judgement
- Consent Document Appraisal
- Post-Approval Study Oversight
- Misconduct Allegation Handling
- Decision Letter Drafting

Why Attend This Course:

- Deliver an Ethics Committee Decision Letter for a case protocol to the committee chair and the institutional research governance lead
- Decide whether a submission qualifies for exempt, expedited or full-board review and which conditions an approval should carry
- Avoid stalled studies, invalid approvals and participant harm caused by a missing quorum, unmanaged conflicts or unreported safety events
- Share the submission checklist, risk-benefit grid and decision letter template with fellow members, secretariat staff and investigators

Conclusion:

Back at work, the participant gives the Ethics Committee Decision Letter, submission checklist and risk-benefit grid to the committee chair and the research governance lead. The committee uses them to standardise how protocols are triaged, how consent and vulnerability are judged and how approval conditions are worded at its next meetings. After the first full cycle of reviews, the secretariat should compare turnaround times, resubmission rates and investigator queries with earlier meetings, then revise the standard operating procedures and letter templates where decisions remain inconsistent.

Frequently Asked Questions FAQ:

What should participants know before the research ethics committee IRB course?

Participants should already sit on, support or submit to a research ethics committee, or manage studies involving people. Basic familiarity with study designs and consent forms helps. Bringing an anonymised protocol or committee standard operating procedure lets participants test the review tools on their own material.

How does a research ethics committee IRB course differ from a clinical ethics or research grant management course?

This course trains people who review and oversee research protocols involving human participants. Clinical ethics courses address bedside dilemmas and patient care decisions, while research grant management courses address proposals, budgets and funder reporting rather than ethical approval of studies.

When does a study need full-board review by a research ethics committee IRB?

A study generally needs full-board review when it carries more than minimal risk to participants. Lower-risk studies and minor amendments can often follow expedited review by the chair or designated members, and some categories qualify as exempt under institutional procedures.

What do participants take back from the research ethics committee IRB course?

Each participant takes back an Ethics Committee Decision Letter for a case protocol, plus a submission completeness checklist, review pathway triage guide, risk-benefit assessment grid and consent review template that can be adapted to the committee's own procedures.