Ethics and Compliance in Global Clinical Research Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

In the rapidly evolving landscape of medical science, maintaining patient trust and research integrity is paramount. Global clinical trials face unprecedented complexity, driven by diverse regulatory requirements, the proliferation of digital health technologies, and the ethical imperative for diversity and inclusion. Ethics and Compliance in Global Clinical Research Training Course is meticulously designed to transform clinical research professionals into compliance leaders capable of navigating this complex environment. We provide actionable, real-world strategies for risk-benefit analysis, proactive compliance monitoring, and fostering a culture of integrity across multi-regional studies, safeguarding human subject protection in a globally integrated ecosystem.

This program directly addresses the most pressing challenges of 2025: eConsent validity, AI oversight, and data transparency in a multi-regional regulatory context. Participants will master the foundational principles of biomedical ethics and their practical application in mitigating risks associated with data fabrication, protocol deviation, and the protection of vulnerable populations. By integrating trending keywords like Risk-Based Monitoring (RBM), GDPR/HIPAA compliance, and whistleblower protection, this course equips your team with the essential knowledge for regulatory readiness, ensuring your global trials are conducted with the highest standards of scientific credibility and ethical governance.

Programme Curriculum

Ethics and Compliance in Global Clinical Research Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the core principles of ICH-GCP (R3/R4) and ensure global regulatory harmonization across all study regions.
2. Develop and implement robust strategies for eConsent (electronic informed consent) in a digital health environment.
3. Design and execute a trial to meet patient diversity mandates and enhance inclusion in clinical trials.
4. Apply risk-based monitoring (RBM) techniques to proactively identify and mitigate protocol deviation and non-compliance.
5. Navigate the ethical and legal complexities of global data privacy (GDPR, HIPAA, PIPL) and cross-border data transfer.
6. Understand the regulatory landscape for the use of AI in clinical research and ensure responsible algorithmic bias mitigation.
7. Establish a strong framework for investigating and reporting research misconduct (FFP) and preventing data integrity fraud.
8. Implement effective safeguards for the protection of vulnerable subjects across varying international legal systems.
9. Develop a comprehensive whistleblower protection and non-retaliation policy for ethical reporting.
10. Conduct thorough ethics committee (IRB/IEC) submissions and manage complex multi-regional ethical approvals.
11. Perform a meticulous risk-benefit analysis that prioritizes the rights, safety, and well-being of trial participants.
12. Integrate Quality Management Systems (QMS) into the trial lifecycle for continuous compliance auditing and improvement.
13. Lead the adoption of a corporate culture of integrity and accountability within the clinical research organization.

Target Audience

1. Clinical Research Associates (CRAs) and Clinical Trial Managers (CTMs)
2. Investigators and Sub-Investigators (MDs, DOs, PhDs)
3. Regulatory Affairs/Submissions Staff
4. Quality Assurance (QA) and Compliance Auditors
5. Ethics Committee (IRB/IEC) Members and Administrators
6. Data Management and Biostatistics Staff
7. Sponsors and CRO Management
8. Bioethicists and Patient Advocates

Course Modules

Module 1: The Foundations of Global Research Ethics

- The Historical Context.
- Core Ethical Principles.
- The Role and Authority of the IRB/IEC in Initial and Continuing Review.
- Defining a Favorable Risk-Benefit Ratio for the Trial Subject and Society.
- Case Study: The legacy of the Tuskegee Study and the principle of Justice.

Module 2: ICH-GCP Harmonization and Compliance

- Detailed review of the 13 Core Principles of ICH-GCP.
- Sponsor, Investigator, and CRO Responsibilities under GCP.
- Trial Master File (TMF) and Investigator Site File (ISF).
- Understanding the differences between FDA, EMA, and other regional standards.
- Case Study: An international site is placed on hold due to missing or incomplete essential documents in the TMF.

Module 3: Informed Consent (IC) and Participant Autonomy

- Elements of Valid IC.
- Challenges of eConsent Implementation and digital comprehension checks.
- Re-consenting requirements for protocol amendments and emerging safety data.
- Documentation and cultural adaptation of the IC process in multi-regional trials.
- Case Study: Evaluating the validity of consent obtained via an app for a cognitively impaired subject.

Module 4: Protecting Vulnerable Populations

- Regulatory definitions of vulnerable subjects
- Assent and Parental/Legally Authorized Representative Consent.
- Ethical justification for including vulnerable groups in research.
- Addressing issues of coercion and undue influence in low-resource settings.
- Case Study: A protocol requires enrolling prisoners; justifying the inclusion and mitigating the risk of coercion.

Module 5: Data Integrity and Research Misconduct

- Defining and differentiating Fabrication, Falsification, and Plagiarism
- Implementing ALCOA-C principles for source data and documentation.
- Preventing and detecting data manipulation at the site and in the database.
- Consequences and regulatory actions for research fraud.
- Case Study: A whistleblower reports instances of manipulated lab reports at a high-enrolling trial site.

Module 6: Global Data Privacy and Security

- Comprehensive review of GDPR, HIPAA, and PIPL requirements.
- Legal basis for cross-border data transfer and anonymization techniques.
- Managing data breaches.
- Implementing security best practices.
- Case Study: A sponsor suffers a data breach involving personal health information (PHI) of EU and US participants; outlining the mandatory notification process.

Module 7: Compliance Monitoring and Risk-Based Quality

- Transitioning to Risk-Based Monitoring (RBM) strategies.
- Developing a risk management plan for the clinical trial protocol.
- Conducting targeted monitoring visits.
- Key Quality Tolerance Limits (QTLs) and metrics for compliance.
- Case Study: Utilizing centralized monitoring data to identify a site with a disproportionately high rate of eligibility violations, triggering a targeted on-site audit.

Module 8: Adverse Event Reporting and Pharmacovigilance

- Adverse Event, Serious AE, Suspected Unexpected Serious Adverse Reaction
- Global regulatory requirements for expedited reporting
- Role of the Investigator and Sponsor in safety signal detection.
- Ethical responsibilities to participants following an unexpected serious adverse event.
- Case Study: A blinded SAE occurs, and the investigator fails to report it within 24 hours to the sponsor; analyzing the cascading compliance failures.

Module 9: Protocol Adherence and Deviation Management

- Defining Protocol Deviation, Violation and Non-Compliance.
- Procedures for documenting, classifying, and reporting deviations to the IRB/IEC and Sponsor.
- The impact of unapproved deviations on data validity and regulatory acceptance.
- Strategies for root cause analysis and corrective and preventive actions
- Case Study: An investigator enrolls a patient who does not meet the BMI exclusion criteria and rationalizes it as "professional judgment."

Module 10: Ethics of AI and Digital Health

- Ethical implications of Machine Learning for trial participant selection and data analysis.
- Algorithmic bias mitigation to ensure fair and equitable research outcomes.
- Regulatory requirements for validating AI/ML software as a medical device
- Ethical oversight for data generated by wearables and remote patient monitoring tools.
- Case Study: An AI-driven recruitment tool systematically excludes an underrepresented demographic, requiring a review for embedded bias.

Module 11: Financial Compliance and Conflicts of Interest (COI)

- Regulations governing financial disclosure.
- Managing and disclosing potential and actual conflicts of interest for investigators and staff.
- Anti-bribery and anti-corruption regulations in global research settings
- Ethical compensation for participants and avoiding undue inducement.

- Case Study: An investigator holds significant stock in the sponsor company and fails to disclose it; detailing the severe regulatory consequences.

Module 12: Ethical Culture and Whistleblower Protection

- The importance of establishing a speak-up culture and corporate accountability.
- Developing confidential and non-retaliatory reporting mechanisms
- Management's responsibility in investigating ethical concerns and providing support.
- Training staff on ethical decision-making frameworks under pressure.
- Case Study: A research coordinator reports a pattern of research misconduct and faces immediate workplace isolation and retaliation.

Module 13: Audits, Inspections, and Regulatory Readiness

- Understanding the scope and focus of FDA, EMA, and WHO inspections.
- Preparation strategies for a successful regulatory inspection.
- Responding to Form 483s/Warning Letters and implementing effective CAPAs.
- The role of Quality Assurance in maintaining a state of inspection readiness.
- Case Study: A site fails a routine FDA inspection due to systemic IC process failures and poor drug accountability; developing the CAPA plan.

Module 14: Ensuring Patient Diversity and Inclusion

- Review of NIH and FDA patient diversity mandates and actionable strategies.
- Developing inclusive protocol design and eligibility criteria.
- Overcoming cultural, linguistic, and logistical barriers to participation.
- Community engagement and education strategies for diverse populations.
- Case Study: A trial for a disease with a high prevalence in a specific ethnic group is struggling to enroll non-white participants; designing a revised recruitment plan.

Module 15: Emerging Ethical Dilemmas and Future Trends

- The ethics of Adaptive Trial Designs and continuous data analysis.
- Legal and ethical issues in Genetic Research, Biobanking, and Genomic Data sharing.
- Public health ethics.
- The concept of Data Transparency and the ethical obligation to share results
- Case Study: Ethical considerations for returning individual research results from whole-genome sequencing to participants.

Training Methodology

The course employs a high-engagement, blended learning approach to ensure practical mastery and application.

- Interactive Lectures.
- Case Study Analysis.
- Role-Playing and Simulations.
- E-Learning Modules.
- Expert Guest Speakers.
- Compliance Toolkits.
- Final Certification Exam.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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