# Requirements for Courses on Research Ethics and GCP
# Investigator Level

## Part 1: Introduction to Research Ethics

### Learning Objectives (•)

At the end of the course, the participants should be able to:

- Explain the importance of conducting research involving human participants for the advancement of biomedical sciences and in the interest of public health
- Explain the importance of protecting human participants in the design, conduct and follow-up of research projects involving human beings
- Describe the fundamental principles of human research participant protection including autonomy, beneficence, non-maleficence and justice
- Identify and describe the basic documents of reference in research ethics (from Declaration of Helsinki to ICH-GCP) including the applicable law and regulation in Switzerland
- Describe how conflicts of interest may impact the design, conduct and follow up of a research project and what are the main measures to limit them
- Explain the negative impact of fraud and science misconduct and name measures to act against them
- Identify the basic rules of research ethics applicable in given situations and apply them to solve simple cases, in particular:
  - Assuring a proper balance of the risks and the benefits in a given research project (defining and assessing the risks)
  - Obtaining a valid informed consent, including in situations where potential participants are legally incompetent (minors/incapacitated adults) or from a vulnerable group
  - Respecting the privacy of the participants as well as the data protection requirements in collecting, processing and storing data/human biological materials
  - Obtaining ethical clearance from the competent Research Ethics Committee (REC)
- Describe the responsibilities of investigators in the protection of human participants and how they have the capacity to face them

### List of content (○)

- Basic concepts:
  - What is research (different types of research)
  - What is research involving human participants
  - What is ethics
  - What is ethics review of research
- A brief history of research ethics
- The roles and responsibilities of all those involved in research (investigators, sponsors, REC members, competent authorities, participants)
- Conflicts of interests and commitments
- Ethics review by the competent REC
- Fundamental principles and normative framework:
  - Scientific accuracy
  - Risk-benefit analysis

  - Importance of equipoise
  - Autonomy/informed consent
  - Justice
  - Vulnerable populations
  - Confidentiality and privacy
  - Societal, religious and cultural factors
  - Local conditions
- Further requirements from REC after approval
- Applicable laws and regulation of research involving human participants in Switzerland (among others, Declaration of Helsinki, ICH-GCP, Data Protection Regulation)
- Participant information and informed consent
  - Definitions
  - Content and structure
  - Process of obtaining the consent
  - Rights of participants
  - Detailed requirements for content
  - Responsibilities and duties of research personnel
  - Impact of wording on understandability and recruitment
  - Document and change management
  - Re-consent
  - Issues in offering incentives
- Participant information and informed consent in special populations or situations
  - Clinical studies in emergency situations
  - Clinical studies with vulnerable populations

**Part 2: Good Clinical Practice**

**Learning Objectives (•) and List of content (○)**

At the end of the course, the participants should be able to:

- Describe the structure and content of the ICH-GCP E6 guideline
  - Aim and history of the International Conference on Harmonization
  - Overview on content of ICH-GCP E6
  - Discussion on ICH-GCP principles
  - Influence of ICH-GCP E6 on other regulations and laws
  - For medical devices: ISO 14155
  - Other ICH guidelines

- Explain the collaboration between the investigator and the ethics committee
  - Study registration according to Swiss law
  - Categorization of clinical studies and research projects according to Swiss law, including discussion of recognised standards according to guidelines prepared in accordance with internationally accepted quality criteria
  - Submission process and dossier structure for clinical studies and research projects
  - Reporting requirements
  - Role of the coordinating investigator in multicentre studies
  - Role of the lead ethics committee

- Handle, store and document study medication and investigational medical devices according to manufacturer's and legal requirements (GMP)
  - Importance of correct labelling, storage and handling
  - Drug/device accountability and shipment records

- Ensure transparency and reproducibility of study procedures and documentation
  - Essential Documents
  - Filing and archiving
  - Handling amendments
  - Reports to ethics committees and competent authorities
  - Aim and concept of Quality Control and Quality Assurance
  - SOPs
  - Audit and Inspections

- Ensure quality of research data
  - Quality Management System
  - Use and validation of Electronic Systems
  - Definition of Source Data
  - Good Documentation Practice
  - Case Report Forms
  - Audit Trail
  - Queries and query management
  - Anonymisation vs encoded/non-encoded
  - Data and sample protection regulations
  - Storage and archiving requirements of data and samples

- Classify, document and report Adverse Events according to protocol and regulatory requirements
  - Definitions
  - Requirements for documenting and reporting Adverse Events
  - Liability

- Prepare a study site adequately for monitoring visits
  - Aim of monitoring as part of Quality Control
  - Different monitoring visits: pre-study, initiation, routine, close-out visits
  - Source Data Verification
  - Monitoring plans and reports
  - Risk-based monitoring

- Critically assess a clinical study protocol and explain its significance
  - Structure and content of a study protocol according to ICH-GCP E6
  - Importance of consistency and comprehensibility of information
  - Protocol adherence
  - Good practice of handling protocol amendments

- Explain basic statistical concepts and principles
  - Different designs and objectives in research
  - Hypothesis testing
  - Parameters and distributions
  - Sample size calculations
  - Power
  - Confidence intervals
  - Measures to avoid bias and confounding
  - Blinding and randomisation