# Informed Consent

Our Informed Consent course provides a comprehensive introduction to the principles, processes, and practical considerations involved in obtaining valid informed consent in clinical research. Designed for professionals working in or aspiring to work in clinical trials, this course equips participants with the knowledge and skills needed to support ethical, compliant, and participant-centreed consent practices.

Developed by experienced clinical research professionals, the course blends theoretical knowledge with practical guidance. Participants will gain a thorough understanding of the regulatory and ethical foundations of informed consent, the critical steps involved in the process, and strategies to address common challenges. Topics include the informed consent form (ICF) and participant information sheet, re-consent, withdrawal, and the use of digital or decentralized consent methods.

Through engaging, self-paced online learning, learners will develop the confidence to take an active role in the informed consent process, ensuring participant understanding, safety, and compliance with Good Clinical Practice (GCP).

Course Learning Outcomes:

By the end of this course, participants will be able to:

- Explain the ethical, legal, and regulatory principles that underpin the informed consent process in clinical research.
- Apply the five key steps of the informed consent process to real-world clinical trial scenarios, ensuring participant understanding and compliance with GCP.
- Evaluate common challenges and barriers to obtaining valid consent, including those related to vulnerable populations, language, and decentralised or digital consent approaches.
- Demonstrate the ability to conduct, document, and manage informed consent procedures confidently and accurately within their professional role.

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## COURSE CONTENTS:

- Introduction: informed consent
- What is informed consent?
- The five steps of the informed consent process
- Digital and decentralised consent
- Informed consent form and information sheet
- Re-consent
- Withdrawal
- Challenges to the informed consent process
- Course exam

## SUITABLE FOR:

This course is designed for all clinical research professionals, including investigators, study coordinators, monitors, and sponsor/CRO staff who are involved in the informed consent process.

Duration: Approx. 2 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.