



WORLD MEDICAL DEVICE ORGANIZATION

WMDO SA  
Route de Denges 28C  
1027 Lonay  
Switzerland  
Tel. +41 21 349 96 36  
Fax +41 21 349 96 37  
contact@wmdo.org

WMDO USA  
3565 IDS Center 80  
South 8th Street, Minneapolis  
MN 55402, USA

Online Training for Medical Device Professionals

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**Course Title:**

**Ethics Committee(EC) / Institutional Review Board Requirements**

Product ID: 46

Level: CMDA

Duration: 40 mins

SME: Danielle Giroud

First Released On: 09/30/2009

Course Updated On: 03/04/2013

**Course Description:**

This course provides an overview of the basic Ethics Committee (EC) and Institutional Review Board (IRB) requirements according to 21 CFR 56, ISO 14155, and international law. It offers a practical approach to the EC and IRB processes and explains how to effectively manage the processes to prevent delays.

**Watch the Course Trailer:**

**Learning Objectives:**

Upon successfully completing this course, learners will be able to:

- Plan and prepare EC and IRB submissions in compliance with applicable rules and regulations
- Work together with investigation site personnel to ensure smooth and efficient preparation and processes
- Meet deadlines for submissions and avoid delays in clinical investigations
- Ensure compliance in the documentation to and from the EC or IRB

**Who Should Enroll:**

Monitors, clinical project managers, investigators, study coordinators, and quality assurance, regulatory, and marketing professionals wanting to learn the basics of the EC or IRB submission processes are all welcome to enroll in this course.

**Related Resources:** Yes

**Prerequisite Knowledge**

An understanding of the following material is required:

- Basics of good clinical practice
- Content and management of clinical investigation plan documents
- Logistics in preparing, setting up, and conducting informed consent processes

**Price:**

**Premium:** €89.00.- **Basic:** €118.00.-

**Course Format:**

All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: <http://www.adobe.com/products/flashplayer>).

**Premium Account Holders:**

Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.