WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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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:
In this course we provide an overview of the basic requirements of the ethics committee (EC) and institutional review board(IRB) according to 21 CFR part 56, ISO 14155 and national laws throughout the world. This course provides a practical approach to the EC and IRB process and explains how to effectively manage the process as to prevent lengthy delays.

Learning Objectives:
Upon completion of this course, trainees will be able to successfully:
- Plan and Prepare EC/IRB submissions in compliance with the applicable rules and regulations.
- Work hand in hand with the investigation site personnel to ensure an efficient and smooth preparation and process.
- Meet deadlines for submissions and avoid delays in starting the clinical investigation.
- Ensure compliance in the documentation to and from the ethics committee or IRB.

Who Should Enroll:
Monitors, clinical project managers, investigators, study coordinators. Quality assurance, regulatory and marketing professionals wanting to learn the basics about EC or IRB submission processes.

Related Resources: Yes

Prerequsite Knowledge
Before taking this course it is recommended that learners fully understand the basis of Good Clinical Practice, contents and management of Clinical Investigation Plan document and comprehend the logistics in preparing, setup and conduct of the Informed Consent Process.

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.