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Course Title:

ISO 14155:2019 - Ethical Considerations

Product ID: N175
Duration: 30 mins
SME: Danielle Giroud
First Released On: 06/06/2019

Course Description:
This course reviews ISO 14155 ethical considerations, including special circumstances where clinical investigations can be conducted in vulnerable populations. It also reviews specific requirements of the informed consent process, including obtaining informed consent when subjects cannot read or write or are incapable of giving consent due to a special clinical status.

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, learners will be able to:
- Know that the foundation of good clinical practice ethical considerations is the Declaration of Helsinki
- Use the information in ISO 14155 as a basis for ethical considerations in clinical documents and as part of the process for ethics committee submissions and ongoing communications
- Recognize that ISO 14155 can only provide general requirements and that national or local regulations may have more stringent requirements (if local or national rules are less stringent than ISO's, it is advisable to follow ISO whenever possible so as to guarantee worldwide acceptance of your data)
- Follow the ISO 14155 requirements for the informed consent process, special circumstances, or vulnerable populations
- Understand the essential elements of an informed consent and implement a compliant template.

Who Should Enroll:
Clinical research associates (monitors), clinical study coordinators, assistant senior clinical research associates, clinical project and data managers, data entry personnel, ethics committee and institutional review board members, regulators, and notified body personnel involved in auditing clinical evaluations are all welcome to participate in this course.

Related Resources: Yes

Prerequsite Knowledge
Familiarity with the Declaration of Helsinki and its contents, as well as an understanding of the need for ethics committees and informed consent during a clinical investigation is required.

Price:

Premium: €69.00.- **Basic:** €91.00.-

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.

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