

Implementing the Revised Common Rule

Description:

Ending five and a half years of rulemaking and speculation, the US Department of Health and Human Services (HHS) and 15 other Federal Agencies released a final revision of the Federal Policy for the Protection of Human Subjects, or “Common Rule,” on January 19, 2017. These are the first revisions to the Common Rule since it was promulgated in 1991. What are the implications of these revised regulations for IRB program operations? What changes need to be made in administrative processes and procedures to promote compliance with the new Federal Policy? This interactive program will provide a practical, hands-on journey through the revised regulations, allowing participants to not only review the changes to the Rule but to discuss and identify best practices for implementation.

Audience:

This course is targeted for various audiences, including

- IRB administrators staff
- IRB Chairs, Vice Chairs administrators, and members
- Research administrators
- Research coordinators, scientists, and project managers
- Investigators, postdoctoral fellows, graduate students
- Academic, industry, or clinical research personnel

The content is appropriate for those new to the topic as well as those with knowledge or experience in implementing the Common Rule.

Learning Objectives:

- Compare the 2018 New Federal Policy regulations with the pre 2018 Common Rule
- Identify Areas in IRB Operation that Require Change
- Discuss Strategies for Implementing and Interpreting the Revised Common Rule Regulations

AGENDA

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| 7:30-8:30 AM | <i>On-Site Check-In (breakfast on your own)</i> |
| 8:30-10:15 AM | Welcome and introduction

Examine the changes in the revised common rule to determine the implications of these revised regulations for IRB program operations. Assess what changes need to be made in administrative processes and procedures to promote compliance with the new federal policy. |
| 10:15-10:30 AM | <i>Break</i> |
| 10:30 AM-12:30 PM | Examine the changes in the revised common rule to determine the implications of these revised regulations for IRB program operations. Assess what changes need to be made in administrative processes and procedures to promote compliance with the new federal policy. (continued) |
| 12:30-1:00 PM | Small group discussions
Questions & Answers |
| 1:00 PM | <i>Adjournment</i> |