E-ROC: Introducing PRIM&R's Online Course

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PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

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40 YEARS

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PRIM&R

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Outline of Presentation

- Learn about **E-ROC's** learning objectives
- Explore the content covered in **E-ROC**
- Review **E-ROC's** special features
- Explain the administrative capabilities that **E-ROC** offers
- Subscription options
- Question and answer period

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History of E-ROC

- Developed in response to the need for high-quality distance education opportunities
- **E-ROC** launched in 2010 as the *Ethical Oversight of Human Subjects Research* online course
- Since its inception, over 1,500 users from eleven different countries have accessed **E-ROC**

Learning Objectives

- Define the function and purpose of IRBs
- Utilize the tools and strategies described in the course to build and strengthen an effective IRB
- Communicate effectively within IRB meetings and with investigators
- Describe the ethical principles and regulations that govern human subjects research
- Apply these rule and principles to both biomedical and social science case protocols

Flexibility

- The course takes approximately 4.5 hours for users to complete
- Users have the ability to start and stop the course whenever they want!
- Users are able to access the course from multiple computers
- Units take 15-45 minutes to complete

Core Audience

- HRPP/IRB staff members
- IRB members
- Regulatory and compliance staff
- Researchers
- Students

Institutional Subscribers

- Cancer centers
- Colleges and universities
- Community hospitals
- Government agencies
- Graduate degree programs
- Healthcare systems
- Independent IRBs
- Medical schools
- Pediatric hospitals

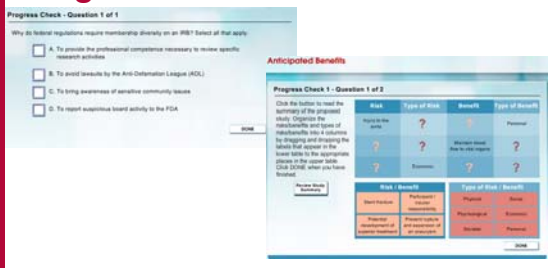
Structure

- The course is divided into eight units, and is professional narrated, with users having the option to read along
- Each unit includes:
  - ☐ IRB meeting discussions
  - ☐ 2-3 progress checks
  - ☐ 1-2 case studies

Simulated IRB Meeting

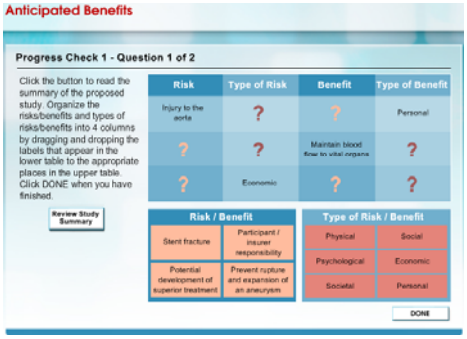
- Throughout the 8 units, the course follows an IRB meeting in which two protocols, one biomedical and the other social science, are discussed.

Progress Checks



Interactive progress checks, such as multiple choice questions and puzzles, reinforce the core concepts introduced in each lesson.

Progress Checks



Interactive Exercises

Interactive Exercises

Case Studies

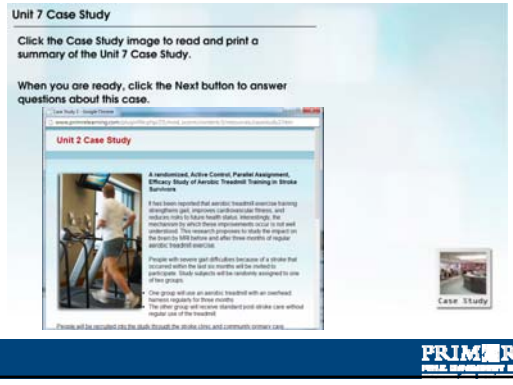
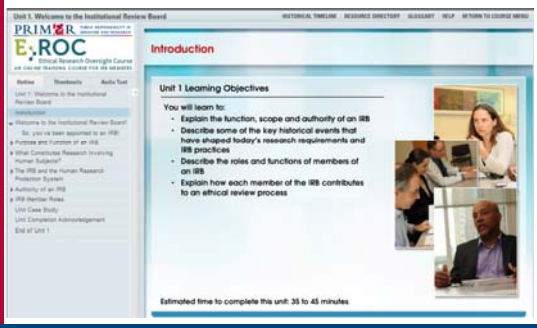


Table of Contents

Unit 1: Welcome to the IRB



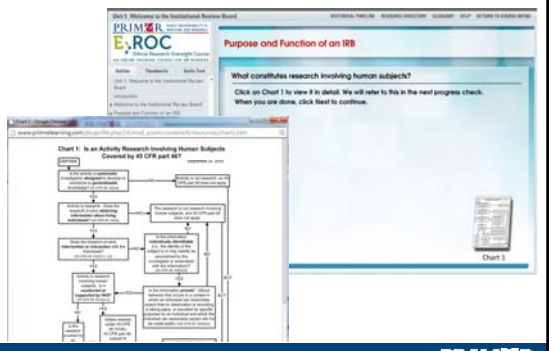
Unit 1 Summary

- Origin, function, and purpose of an IRB
- Regulations that govern human subjects research
- Scope and process of IRB review
- Authority and ongoing oversight responsibilities of IRBs
- Roles of IRB members and nonmembers

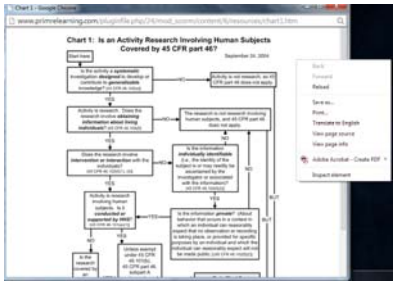
Left Screen Toolbar

- The Outline screen acts as a table of contents for the unit.
- The Thumbnails screen previews each slide.
- The Audio Text screen transcribes what the narrator is saying.

Handouts

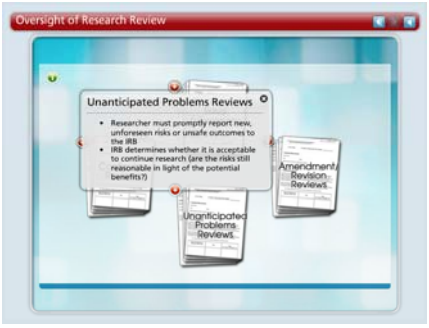


Printing Handouts



Interactive Exercise

Interactive Exercise

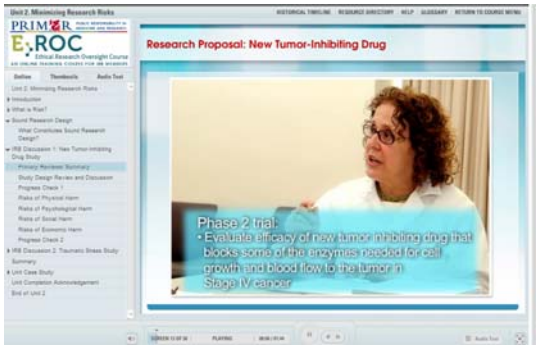


Unit 2: Minimizing Research Risks

Unit 2 Summary

- Risk
- Minimal risk
- Types of risk
- Factors that minimize risk
- How to assess risk
- Sound research design
- Protocol considerations relevant to the minimization of risks

Discussions

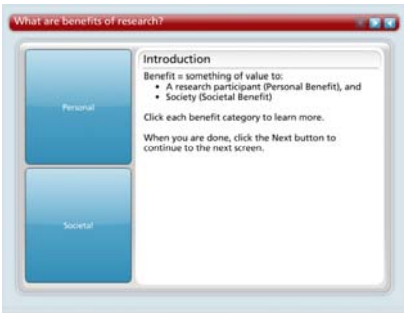


Unit 3: Risks, Burdens, Benefits

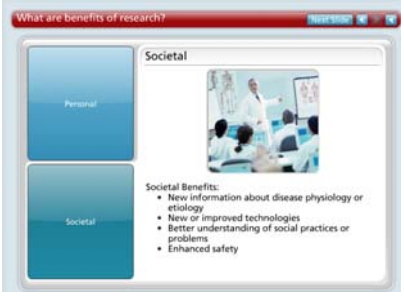
Unit 3 Summary

- Identifying anticipated benefits of research
- Personal benefits
- Societal benefits
- Quantifying harms and benefits
- Risks reasonable in relation to the anticipated benefits of the research

Interactive Exercise



Interactive Exercise



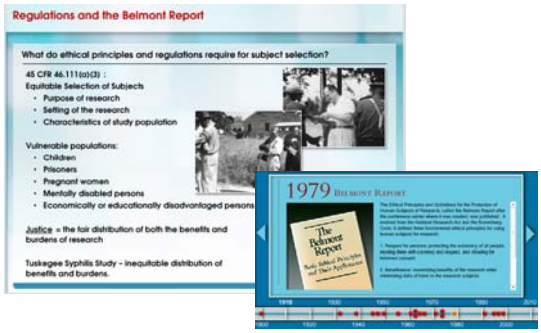
Unit 4: Subject Selection & Recruitment

Unit 4 Summary

- Fair distribution of benefits and risks
- Equitable selection of subjects
- Inclusion/exclusion criteria
- Recruitment of research subjects
- Advertisements
- Payments
- Informed consent
- Therapeutic misconception

Timeline Integration

Timeline Integration



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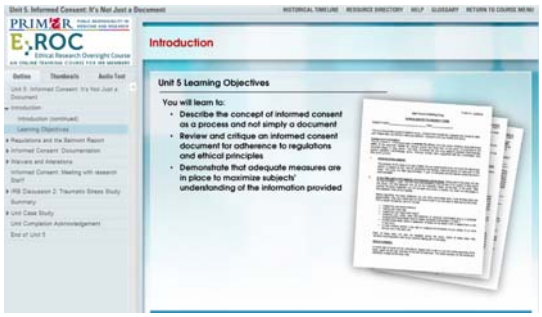
Unit 5: Informed Consent



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Unit 5 Summary

- Elements of informed consent
- Informed consent documents
- IRB's role in informed consent
- Waivers and alterations to the
  - ☐ Informed consent process
  - ☐ Informed consent documentation
- Overprotection
- Informed consent and decisional impairment

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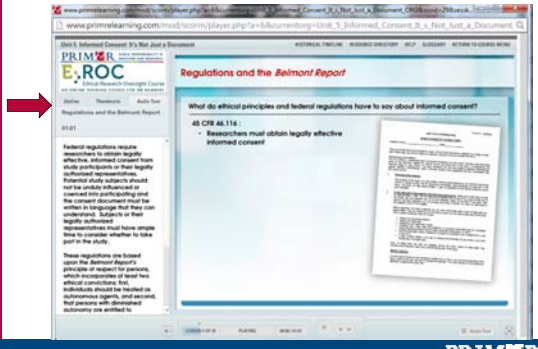
Audio Text Feature



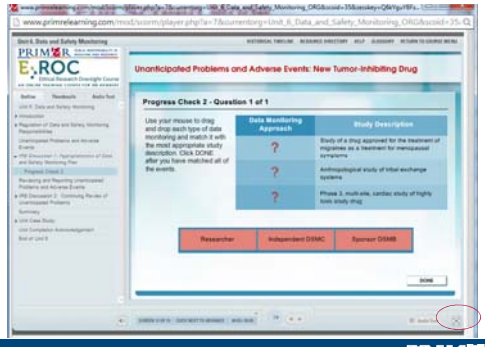
Audio Text Feature

Unit 6: Data & Safety Monitoring

Unit 6 Summary

- Data and safety monitoring plans
- Data and safety monitoring boards
- Unanticipated problems
- Adverse events
- Reporting mechanisms
- Action plans

Default Screen Mode



Full Screen Mode

Unit 7: Privacy & Confidentiality

Unit 7 Summary

- Privacy
- Confidentiality
- HIPAA
- Procedures to ensure that privacy and confidentiality concerns are appropriately addressed

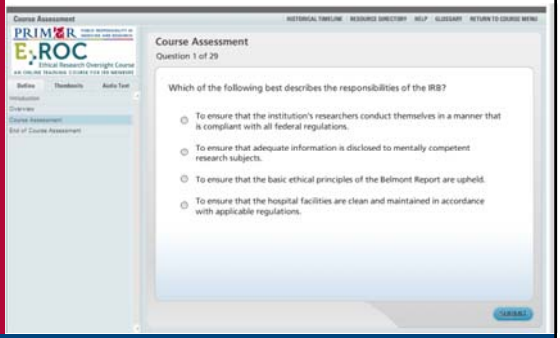
Summary Screens

Unit 8: IRB Meeting Dynamics

Unit 8 Summary

- Composition of an IRB
  - ☐ Diversity of perspectives
  - ☐ Non-scientific member
  - ☐ Unaffiliated member
- Conflict between members
- Overprotection, institutional pressures, orienting newcomers
- Running an IRB meeting
- Robert's Rules of Order

Course Assessment



Course Features

Links to the Historical Timeline, Resource Directory, Help Menu, and Glossary appear at the top of each screen.

Historical Timeline

The **historical timeline** details important events in the history of research ethics, dating back to 1900. Users can navigate using the arrows on the side of each slide, or you can click on the red dots that appear at the bottom of the screen.

Resource Directory

The **Resource Directory** links to documents and web pages referenced throughout the course.

Help Menu

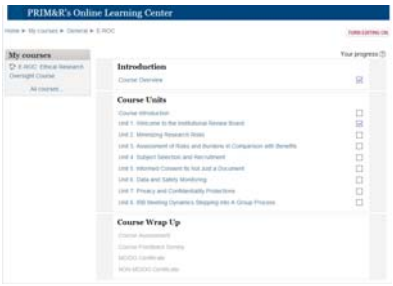
The **Help** screen offers an overview of how the course works. To explore a feature, just click or hover over the red dot.

Glossary

The **Glossary** defines key terms and acronyms referenced in the course.

Bookmarking Features

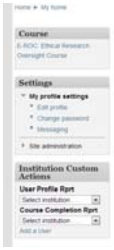
Bookmarking Features



Administrative Capabilities for Institutional Subscribers

- Creating user accounts
- Running roster reports
- Running course completion reports

Site Manager Permissions



Site managers are able to access special administrative features that allow them to create accounts, and to run reports that track those users' progress and successful completion of the course.

CME Credits and Certificates

- All users who achieve 80% or higher on the final Course Assessment receive a Certificate of Completion
- Boston University School of Medicine designates **E-ROC** as enduring material for a maximum of 4.5 *AMA PRA Category 1 Credit(s)™*

Institutional Annual Subscriptions:

- $1,850 per year
- Allows for an unlimited number of users
- Designated site managers are able to create accounts for colleagues, track their progress with the course, and verify their completion

Individual Annual Subscriptions

- $200 for PRIM&R members
- $250 for nonmembers
- $365 for those who wish to bundle a **PRIM&R** membership and **E-ROC** subscription

Questions and comments

To submit a question,
simply click on the Q & A menu
at the top of the screen.

info@primr.org

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Thank you!

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