

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

March 5, 2014

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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



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Institutional Subscribers

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

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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

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Interactive Exercises



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Interactive Exercises



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Case Studies

Unit 7 Case Study

Click the Case Study image to read and print a summary of the Unit 7 Case Study.

When you are ready, click the Next button to answer questions about this case.



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Table of Contents

PRIM&R's Online Learning Center

Home » My courses » General » E-ROC

My courses

E-ROC: Ethical Research Oversight Course

All courses ...

Introduction

Course Overview

Course Units

Unit 1: Welcome to the Institutional Review Board

Unit 2: Minimizing Research Risks

Unit 3: Assessment of Risks and Burdens in Comparison with Benefits

Unit 4: Subject Selection and Recruitment

Unit 5: Informed Consent is Not Just a Document

Unit 6: Data and Safety Monitoring

Unit 7: Privacy and Confidentiality Protections

Unit 8: IRB Meeting Dynamics Shaping into A Group Process

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Unit 1: Welcome to the IRB

Unit 1: Welcome to the Institutional Review Board

Introduction

Unit 1 Learning Objectives

You will learn to:

- Explain the function, scope and authority of an IRB
- Describe some of the key historical events that have shaped today's research requirements and IRB practices
- Describe the roles and functions of members of an IRB
- Explain how each member of the IRB contributes to an ethical review process

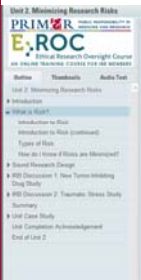
Estimated time to complete this unit: 35 to 45 minutes

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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
- PRIM&R

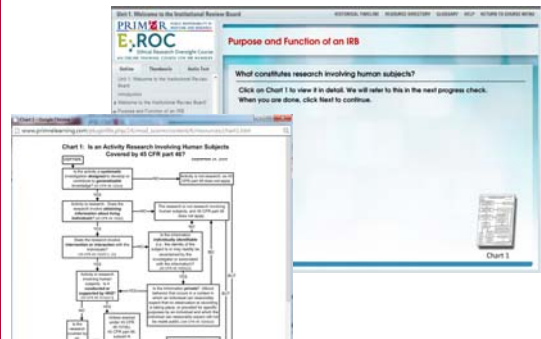
Left Screen Toolbar



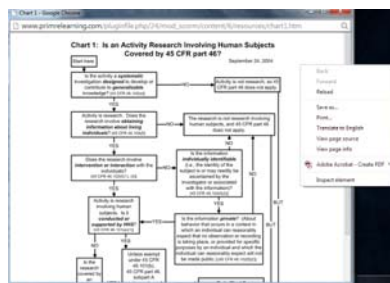
- The **Outline** screen acts as a table of contents for the unit.
- The **Thumbnails** screen previews each slide.
- The **Audio Text** screen transcribes what the narrator is saying.



Handouts



Printing Handouts

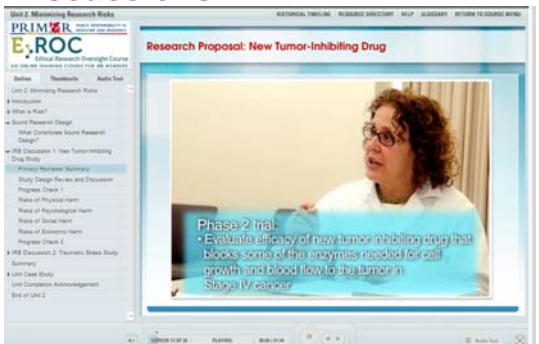


Unit 2 Summary

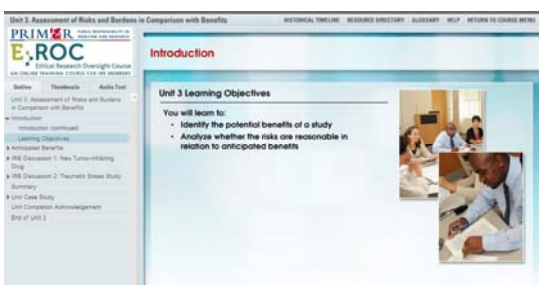
- Risk
- Minimal risk
- Types of risk
- Factors that minimize risk
- How to assess risk
- Sound research design
- Protocol considerations relevant to the minimization of risks



Discussions



Unit 3: Risks, Burdens, Benefits

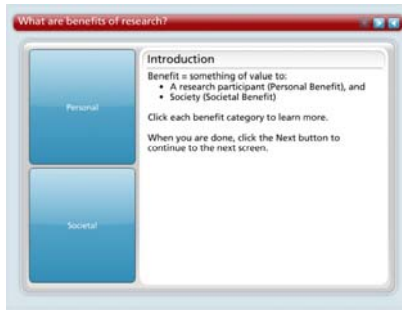


Unit 3 Summary

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

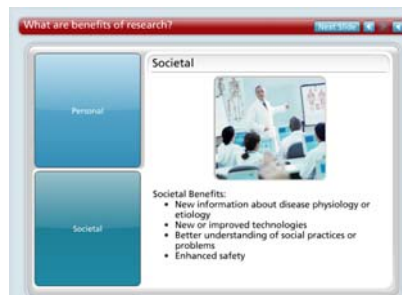
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Interactive Exercise



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Interactive Exercise



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Unit 4: Subject Selection & Recruitment



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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

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Timeline Integration



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Timeline Integration

Regulations and the Belmont Report

What do ethical principles and regulations require for subject selection?

45 CFR 46.111(a)(3)

Equitable Selection of Subjects

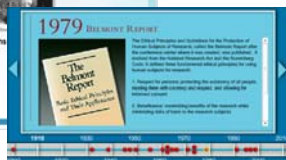
- Purpose of research
- Setting of the research
- Characteristics of study population

Vulnerable populations:

- Children
- Prisoners
- Pregnant women
- Mentally disabled persons
- Economically or educationally disadvantaged persons

Justice = the fair distribution of both the benefits and burdens of research

Tuskegee Syphilis Study – inequitable distribution of benefits and burdens



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Unit 5: Informed Consent

Unit 5: Informed Consent: It's Not Just a Document

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Ethical Research Oversight Course

and related resources created for the course

Before

Thumbnails

Audio Text

Unit 5: Informed Consent: It's Not Just a Document

Introduction

Introduction (continued)

4. Regulations and the Belmont Report

5. Informed Consent: Documentation

6. Review and Alterations

Informed Consent: Dealing with research

Start?

4. IRB: Overview 2: Traumatic Stress Study

Summary

Unit Case Study

Unit Completion Acknowledgment

End of Unit 5

Introduction

Unit 5 Learning Objectives

You will learn to:

- Describe the concept of informed consent as a process and not simply a document
- Review and critique an informed consent document for adherence to regulations and ethical principles
- Demonstrate that adequate measures are in place to maximize subjects' understanding of the information provided



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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

The screenshot shows the PRIMAR E-ROC interface. The main content area displays the 'Regulations and the Belmont Report' section, which includes text about federal regulations requiring researchers to obtain legally effective informed consent from study participants. A red arrow points to the 'Audio Text' feature in the left sidebar.

Audio Text Feature

The screenshot shows the PRIMAR E-ROC interface. The main content area displays the 'Informed Consent: Traumatic Stress Study' section, which includes a video of two men discussing the study. A red arrow points to the 'Audio Text' feature in the left sidebar.

Unit 6: Data & Safety Monitoring

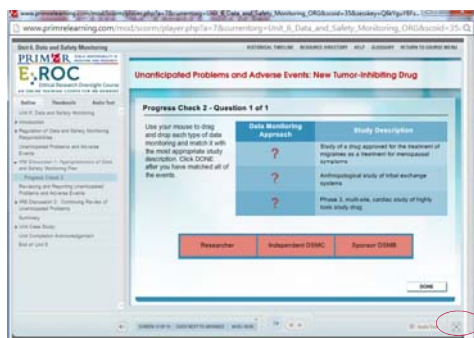
The screenshot shows the PRIMAR E-ROC interface. The main content area displays the 'Unit 6: Data & Safety Monitoring' section, which includes a video of two men discussing the study. A red arrow points to the 'Audio Text' feature in the left sidebar.

Unit 6 Summary

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

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Default Screen Mode



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Full Screen Mode



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Unit 7: Privacy & Confidentiality



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Unit 7 Summary

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

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Summary Screens



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Unit 8: IRB Meeting Dynamics



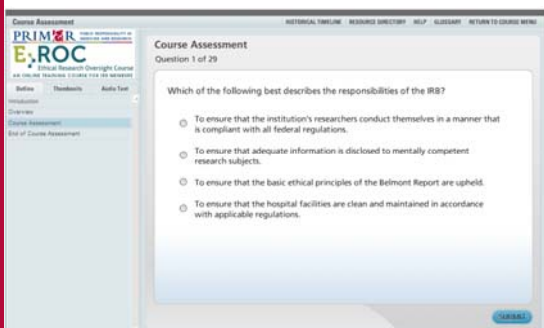
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Unit 8 Summary

- 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

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Course Assessment



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Historical Timeline



Resource Directory

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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



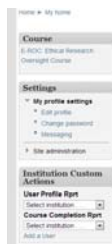
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Administrative Capabilities for Institutional Subscribers

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

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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.

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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)*TM



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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