

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

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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



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.

Discussion: Potential Benefits

Benefits
 - Participants believe that they are engaged in a study that will help them learn about the progression of breast cancer.

Challenges
 - How do you measure the benefits to a study that is mostly social science? How do you measure the potential benefits and anticipated benefits?

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Progress Checks

Progress Check 1 - Question 1 of 1

Why do federal regulators require membership diversity on an IRB? Select all that apply.

- A. To provide the professional competence necessary to review specific research activities.
- B. To avoid lawsuits by the Anti-Defamation League (ADL).
- C. To bring awareness of sensitive community issues.
- D. To report suspicious board activity to the FDA.

Anticipated Benefits

Progress Check 1 - Question 1 of 2

Click the button to read the summary of the proposed study. Organize the risks/benefits and types of risks/benefits into 4 columns by dragging and dropping the labels that appear in the lower table to the appropriate places in the upper table. Click DONE when you have finished.

Risk	Type of Risk	Benefit	Type of Benefit
Injury to the world	?	Maintain blood flow to vital organs	?
?	?	Economic	?
?	Economic	?	?

Risk / Benefit

Blind fracture	Participant / researcher responsibility
Potential development of superior treatment	Prevent rupture and expansion of an aneurysm

Type of Risk / Benefit

Physical	Social
Psychological	Economic
Societal	Personal

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

Progress Checks

Anticipated Benefits

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Interactive Exercises



Interactive Exercises



Case Studies

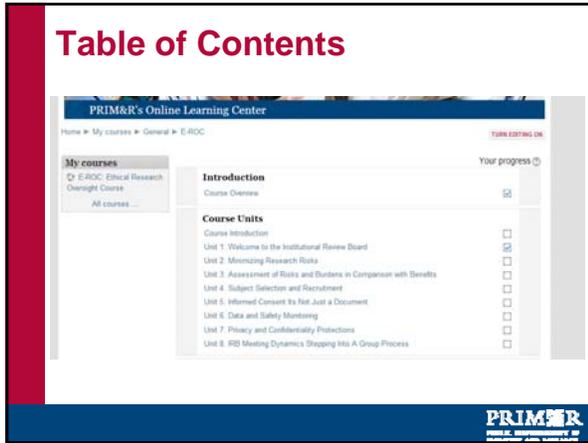
Unit 7 Case Study

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.



Table of Contents

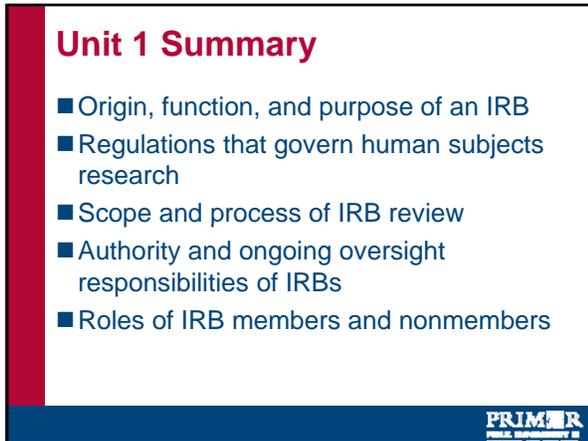


Unit 1: Welcome to the IRB



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



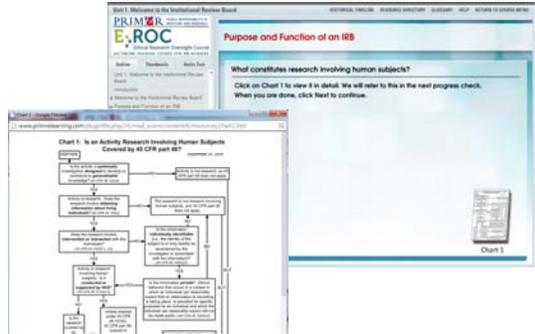
Left Screen Toolbar



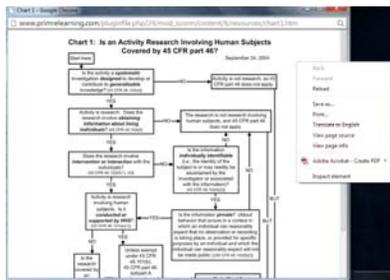
- The **Outline** screen acts as a table of contents for the unit.
- The **Thumbnails** screen previews each slide.
- The **Audio Text** screen transcribes what the narrator is saying.



Handouts



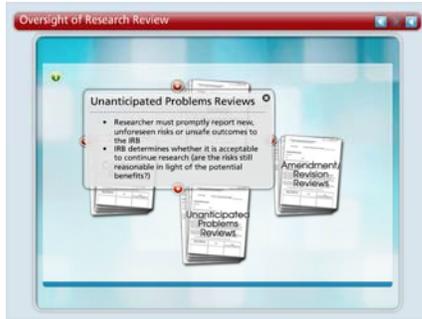
Printing Handouts



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

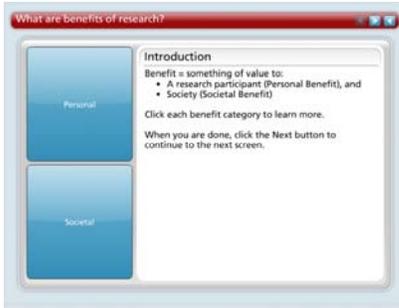


Unit 3 Summary

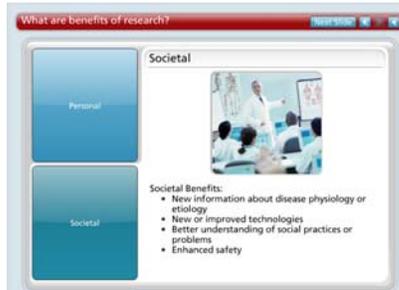
- Identifying anticipated benefits of research
- Personal benefits
- Societal benefits
- Quantifying harms and benefits
- Risks reasonable in relation to the anticipated benefits of the research



Interactive Exercise



Interactive Exercise



Unit 4: Subject Selection & Recruitment

Unit 4 Learning Objectives

You will learn to:

- Apply the principles of equitable selection of research subjects
- Identify potentially vulnerable subjects
- Identify ethical recruitment practices



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

Regulations and the Belmont Report

What do ethical principles and regulations require for subject selection?

45 CFR 46.111(a)(2):
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



Timeline Integration

Regulations and the Belmont Report

What do ethical principles and regulations require for subject selection?

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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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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

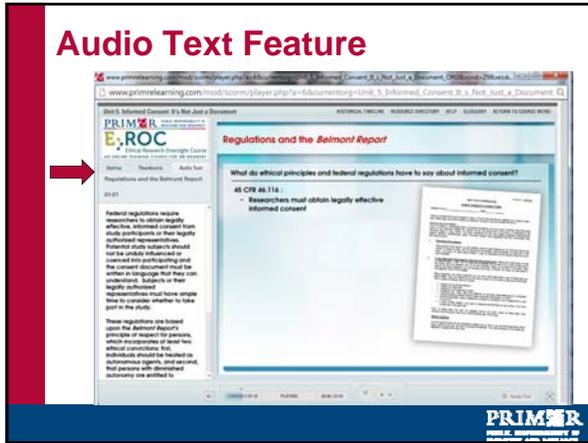
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Unit 5 Summary

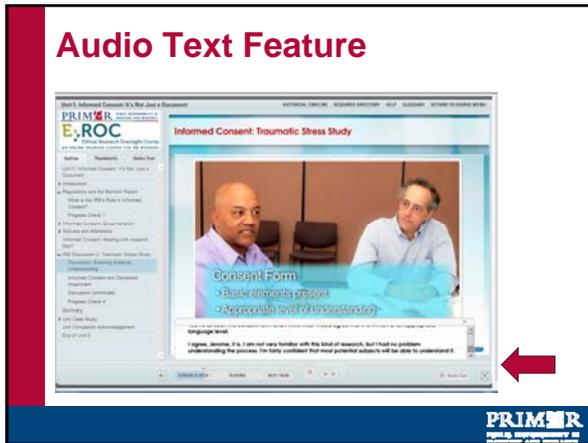
- Elements of informed consent
- Informed consent documents
- IRB's role in informed consent
- Waivers and alterations to the
 - Informed consent process
 - Informed consent documentation
- Overprotection
- Informed consent and decisional impairment

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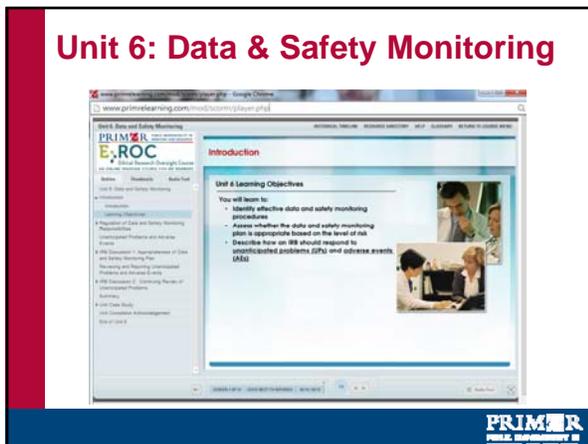
Audio Text Feature



Audio Text Feature



Unit 6: Data & Safety Monitoring

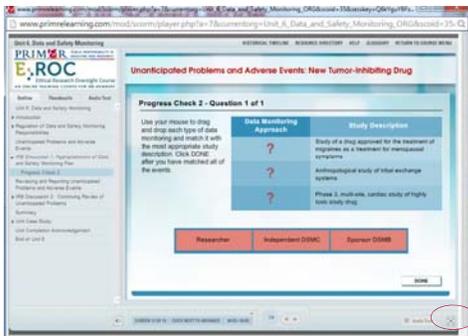


Unit 6 Summary

- 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 8: IRB Meeting Dynamics

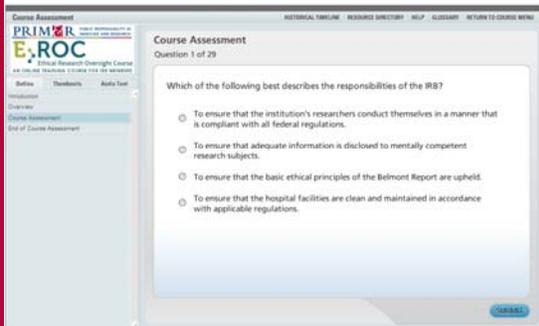


Unit 8 Summary

- 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



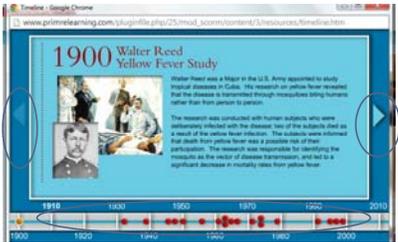
Course Features

HISTORICAL TIMELINE RESOURCE DIRECTORY HELP GLOSSARY RETURN TO COURSE MENU

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

Resource Directory

The following are links to documents that are referenced within the course:

Reference Document or Link	Total Page Count
Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp/	1
Basic HHS Policy for Protection of Human Research Subjects (Includes the Common Rule) http://www.hhs.gov/ohrp/policy/ohrp-02-001-01.pdf	1
FDA Regulations on the Protection of Human Subjects http://www.fda.gov/oc/ohrt/ohrtreg/ohrtreg.html	1
Office for Human Research Protections (OHRP) Decision Charts http://www.hhs.gov/ohrp/policy/ohrp-02-001-01.pdf	1
U.S. Food and Drug Administration http://www.fda.gov/	1
Comparison of FDA and Common Rule Provisions Table http://www.fda.gov/oc/ohrt/ohrtreg/ohrtreg.html#table	1
Federalwide Assurance (FWA) for the Protection of Human Subjects http://www.hhs.gov/ohrp/policy/ohrp-02-001-01.pdf	1
Common Rule: OHRP Compliance Through Adherence Determinations of Noncompliance http://www.hhs.gov/ohrp/policy/ohrp-02-001-01.pdf	1

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)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



Thank you!