Introduction to Course

Holly Taylor, PhD, MPH Department of Bioethics, NIH Clinical Center





Disclaimer

The views expressed in this talk are my own. They do not represent the position or policy of the NIH, DHHS, or US government





Course Objectives

- Utilize a systematic framework for evaluating the ethics of a clinical research protocol.
- Identify, define, and consider ethical issues in the conduct of human subject research
- Apply appropriate codes, regulations, and other documents governing the ethical conduct of human subject research to their own research.
- Describe the purpose, function, and challenges of IRBs





Course Objectives

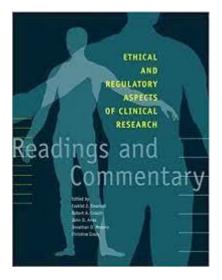
- Identify and apply relevant considerations for assessment of research risks and benefits
- Explore the ethical requirement of fair subject selection and its application
- Identify the critical elements of informed consent and strategies for implementing informed consent for clinical research.
- Appreciate ethical challenges with conducting international collaborative research in low- and middle-income countries.





Overview

Session	Date	Topics	Faculty	
1	9/21/22	Introduction/Framework/History/Institutional Review Boards	Taylor, Grady, Lederer	
2 9/28/22		Study Design/Risk-Benefit/Perspectives from the Field	Taylor, Wendler, <i>Ledgerwood</i> , Arlen	
3	10/12/22	Subject Selection/ Recruitment and Retention/Inclusion of Children	Taylor, Wendler, Shah	
4	10/19/22	Equity and Inclusion	Asada, Taylor, <i>Langford</i>	
5	10/26/22	Informed Consent/Decision Making/Capacity Assessment	Grady, Kim, Todman, Taylor	
6	11/2/22	Incidental Findings/Return of Results/Inclusion of Native Populations	Berkman, Jamal, Claw	
7	11/9/22	International/Standards of Care/Post-trial Obligations/Community Engagement	Rid, <i>Millum, Kamuya</i>	



Livestream 8:30-11:30 am Eastern





Administrative Details

- Self-Enrollment (link to Canvas)
 - Certificate or not
 - Access to all course materials
- Self-Registration (Canvas)
 - Required for Certificate, MNA, NIH Curriculum
- Session Quiz (Canvas)
 - Required for Certificate (at least 3): word-of-theday, two questions





Administrative Details

- Session Evaluation (link by email)
 - Sent to all who self-enroll
- Pre-Course/Post-Course Assessment (link by email)
 - Sent to all who self-enroll





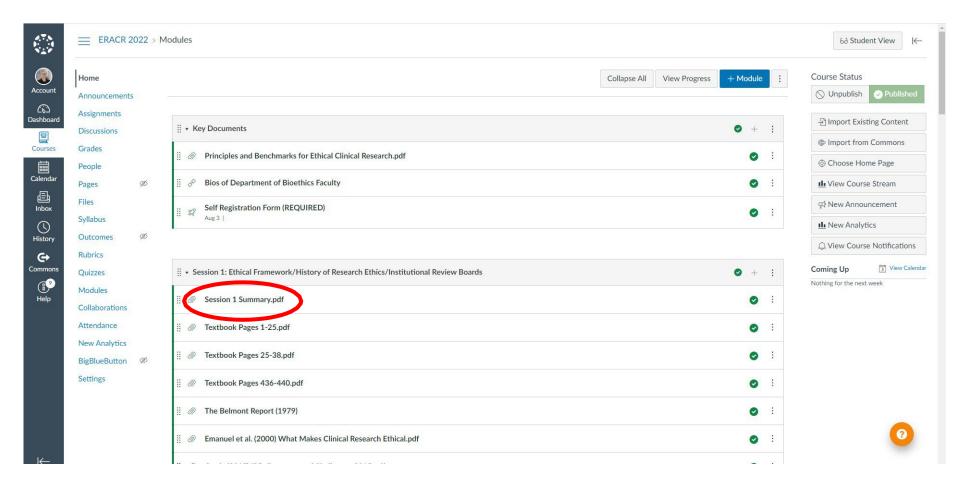
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Session Summaries

- Objectives
- Schedule
- Readings

Lecture PPTs posted at 8:00 am on day of class Session 1: Introduction/Framework/History/Institutional Review Boards September 21 Objectives:

- Identify and describe the ethical principles and historical basis that provide guidance for the
 ethical conduct of research.
- Describe important cases in the history of research and how cases shaped current ethical considerations, and regulations for clinical research.
- Describe ethical framework to be applied throughout course
- Understand the basis of the role and responsibilities of an Institutional Review Board

Time	Topic	Faculty			
8:30-8:45	Introduction to Course	Holly Taylor, PhD MPH NIH Clinical Center Department of Bioethics			
8:45-9:30	Framework for Ethical Conduct of Research	Christine Grady, RN PhD NIH Clinical Center Department of Bioethics			
9:30-9:40	Discussion				
9:40-10:25	History of Research Ethics	Susan E. Lederer, Ph.D. Robert Jurgil Professor of History of Medicine and Bioethics Chair, Department of Medical History and Bioethics University of Wisconsin School of Medicine and Public Health			
10:25-10:35	Discussion				
10:35-10:50	Break				
10:50-11:20	Institutional Review Boards	Holly Taylor, PhD MPH NIH Clinical Center Department of Bioethics			
11:20-11:30	Discussion				

Readings Assignment

Textbook

Part I: Scandals and Tragedies of Research with Human Participants: Nuremberg, the Jewish Chronic Disease Hospital, Beecher and Tuskegee (Overview and Chapters 1-4; pp. 1-25)

Part II: Ethical and Regulatory Guidance for Research with Humans (Overview and Chapters 5-7; pp. 25-38)

Part X: Challenges to the Institutional Review Board System (Chapter 85; pp-436-440)

Journal Articles

Emanuel E, Wendler D, & Grady C. What Makes Clinical Research Ethical JAMA 2000; 283 (20): 2701-2711.

Grady C. Institutional Review Boards: Purpose and Challenges. Chest. 2015; 148(5):1148-55.

US Federal Regulations

Common Rule, 45 CFR 46 (2018) https://www.hhs.gov/ohrp/regulations-andpolicy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

Optional

Jones DS, Grady C, Lederer S. "Ethics and Clinical Research" — The 50th Anniversary of Beecher's Bombshell. New England Journal of Medicine 2016; 374(24): 2393-2398.

Strauss DH, White SA, Bierer BE. Justice, Diversity, and Research Ethics Review. Science 2021;371(6535):1209-1211.





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Asking Questions

Send email to:

Bioethics-Inquiries@mail.nih.gov



National Institutes of Health



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Session 1

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8:30-8:45	Introduction to Course	Holly Taylor, PhD MPH	
		NIH Clinical Center Department of Bioethics	
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	of Research	NIH Clinical Center Department of Bioethics	
9:30-9:40	Discussion		
9:40-10:25	History of Research Ethics	Susan E. Lederer, Ph.D.	
		Robert Turell Professor of History of	
		Medicine and Bioethics	
		Chair, Department of Medical History and	
		Bioethics	
		University of Wisconsin School of Medicine	
		and Public Health	
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