



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, Ledgerwood, 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, Langford
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, Millum, Kamuya



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-the-day*, 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

Canvas Hub

ERACR 2022 > Modules Student View

Home Collapse All View Progress + Module

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Key Documents

- Principles and Benchmarks for Ethical Clinical Research.pdf
- Bios of Department of Bioethics Faculty
- Self Registration Form (REQUIRED)
Aug 3 |

Session 1: Ethical Framework/History of Research Ethics/Institutional Review Boards

- Session 1 Summary.pdf
- Textbook Pages 1-25.pdf
- Textbook Pages 25-38.pdf
- Textbook Pages 436-440.pdf
- The Belmont Report (1979)
- Emanuel et al. (2000) What Makes Clinical Research Ethical.pdf

Course Status
Unpublish Published

- Import Existing Content
- Import from Commons
- Choose Home Page
- View Course Stream
- New Announcement
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Coming Up View Calendar
Nothing for the next week

?

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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 Juggli, 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-and-policy/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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Links to Readings

Asking Questions

The screenshot displays the Blackboard LMS interface. On the left, a dark navigation sidebar contains icons for Account, Dashboard, Courses, Calendar, Inbox, History, Commons, and Help. A secondary menu lists various course components: Home, Announcements, Assignments, Discussions (highlighted with a red circle), Grades, People, Pages, Files, Syllabus, Outcomes, Rubrics, Quizzes, Modules, Collaborations, Attendance, New Analytics, BigBlueButton, and Settings. The main content area shows the breadcrumb path 'ERACR 2022 > Modules' and a 'Student View' button. Below this, there are buttons for 'Collapse All', 'View Progress', and '+ Module'. The 'Course Status' is shown as 'Published'. The main content area is titled 'ERACR 2022 > Discussions > Discussion Board for Session 1' and includes a 'Student View' button. The discussion board itself shows a post by 'Holly Taylor (She/Her)' titled 'Discussion Board for Session 1' with 'All Sections'. It features a search bar, 'Unread' status, and a 'Subscribed' button. A 'Reply' button is visible at the bottom of the post area.

Asking Questions

Send email to:

Bioethics-Inquiries@mail.nih.gov

Quizzes

The screenshot displays a course management interface for 'ERACR 2022'. The left sidebar contains navigation options: Home, Announcements, Assignments, Discussions, Grades, People, Pages, Files, Syllabus, Outcomes, Rubrics, **Quizzes** (circled in red), Modules, Collaborations, Attendance, New Analytics, BigBlueButton, and Settings. The main content area is titled 'ERACR 2022 > Quizzes' and features a search bar and a '+ Quiz' button. Below this, there are two sections: 'Assignment Quizzes' and 'Surveys'. The 'Assignment Quizzes' section lists seven sessions, each with a status of 'Closed', '3 pts', and '3 Questions'. The 'Surveys' section lists one survey: 'Self Registration Form (REQUIRED)', which is also circled in red. This survey is available until Oct 12 at 11:59pm and due Aug 3 at 11:59pm, with 5 questions.

Quiz Name	Status	Points	Questions	Actions
Session 1 Quiz	Closed	3 pts	3 Questions	✓ ⋮
Session 2 Quiz	Closed	3 pts	3 Questions	✓ ⋮
Session 3 Quiz	Closed	3 pts	3 Questions	✓ ⋮
Session 4 Quiz	Closed	3 pts	3 Questions	✓ ⋮
Session 5 Quiz	Closed	3 pts	3 Questions	✓ ⋮
Session 6 Quiz	Closed	3 pts	3 Questions	✓ ⋮
Session 7 Quiz	Closed	3 pts	3 Questions	✓ ⋮
Unnamed Quiz				⊘ ⋮

Survey Name	Availability	Due Date	Questions	Actions
Self Registration Form (REQUIRED)	Available until Oct 12 at 11:59pm	Due Aug 3 at 11:59pm	5 Questions	ⓘ ?

Session 1

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