



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

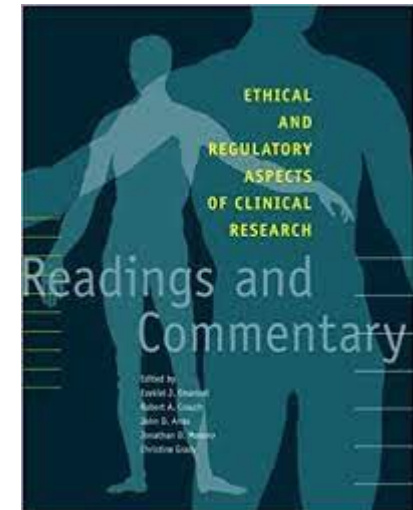
- Utilize a systematic framework for evaluating the ethics of a clinical research protocol.
- Identify, define, and consider ethical issues in the conduct of human subject research
- Apply appropriate codes, regulations, and other documents governing the ethical conduct of human subject research to their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

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
- Appreciate ethical challenges with conducting international collaborative research in low- and middle-income countries
- Apply knowledge gained in course to the inclusion of novel technology in the design and implementation of research

Overview

Session	Date	Topics	Faculty
1	9/20/23	Introduction/Framework/History/Institutional Review Boards	Taylor, Grady, Lederer
2	9/27/23	Informed Consent/Decision Making/Capacity Assessment	Grady, Kim, Brintnall, Taylor
3	10/4/2023	Study Design/Risk-Benefit/Social Value/Inclusion of Children in Research	Taylor, Wendler, Shah
4	10/11/23	Incidental Findings/Return of Results/Inclusion Indigenous Populations	Berkman, Jamal, Claw
5	10/18/23	Equity/Subject Selection/Recruitment and Retention	Asada, Taylor, Wendler
6	10/25/23	International/Standards of Care/Post-trial Obligations/Community Engagement	Rid, Millum, Kamuya
7	11/1/23	Wearables/Brain Implants/LLM	Gross, Hendriks, Rahimzadah



Livestream

8:30-11:30 am Eastern

Administrative Details

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

Administrative Details

- Session Evaluation (we will send link by email)
 - Sent to all who self-enroll
- Pre-Course/Post-Course Assessment (we already sent link by email)
 - Sent to all who self-enroll

Canvas Hub

ERACR 2023 > Modules

Home Collapse All

Account
Dashboard
Courses
Calendar
Inbox
History
Help

Announcements
Assignments
Discussions
Grades
People
Files
Syllabus
Quizzes
Modules
Collaborations

▼ Key Documents

- Self Registration Form
Oct 11
- Course Basics 2023.pdf
- DRAFT Syllabus 8 23 23.pdf
- Continuing Education Slide 2023.pdf
- Principles and Benchmarks for Ethical Clinical Research.pdf
- Bios of Department of Bioethics Faculty

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

- Session 1.docx
- Textbook Pages 1-25.pdf
- Textbook Pages 25-38.pdf

View Course Stream
View Course Calendar
View Course Notifications

To Do

- Self Registration Form
Ethical and Regulatory Aspects of Clinical Research 2023
Oct 11 at 11:59pm

Canvas Hub

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

- Session 1.docx
- Textbook Pages 1-25.pdf
- Textbook Pages 25-38.pdf

Canvas Hub

The screenshot shows the Canvas LMS interface for a quiz titled "Self Registration Form". The breadcrumb trail at the top left reads "ERACR 2023 > Quizzes > Self Registration Form". A left-hand navigation sidebar contains icons and labels for Account, Dashboard, Courses, Calendar, Inbox, History, and Help. The main content area features a title "Self Registration Form" followed by a metadata bar: "Due Oct 11 at 11:59pm", "Questions 5", "Available Aug 14 at 8am - Oct 11 at 11:59pm", "Time Limit None", and "Allowed Attempts Unlimited". Below this is a section titled "Instructions" with the text "You must complete this set of questions to be eligible for a Certificate of Completion". A prominent blue button labeled "Take the Survey" is circled in red. A "Next >" button is located at the bottom right of the instructions section.

Canvas Hub

ERACR 2023 > Modules

Home Collapse All

Announcements

Assignments

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

- Session 1.docx
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To Do

- Self Registration Form x
Ethical and Regulatory Aspects of Clinical Research 2023
Oct 11 at 11:59pm

View Course Stream

View Course Calendar

View Course Notifications

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 20

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. Ronald L. Numbers Professor 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.

Rollin F, Van Doren V, Alvarez J, Roussele R, Bussey-Jones J. Antiracist Structural Intervention at the Emory University Institutional Review Board. *Ethics and Human Research* 2023; <https://doi.org/10.1002/eahr.500174>

Canvas Hub

The screenshot shows the Canvas Hub interface. On the left is a dark sidebar with navigation icons for Home, Account, Dashboard, Courses, Calendar, Inbox, History, and Help. The main content area has a top navigation bar with Home, Announcements, Assignments, Discussions, Grades, People, Files, Syllabus, Quizzes, Modules, and Collaborations. Below this is a list of files. A red box highlights a section of files starting with 'Session 1: Ethical Framework/History of Research Ethics/Institutional Review Boards' and including 'Session 1.docx', 'Textbook Pages 1-25.pdf', 'Textbook Pages 25-38.pdf', 'Textbook Pages 436-440.pdf', 'Emanuel et al. (2000) What Makes Clinical Research Ethical.pdf', 'The Belmont Report (1979)', and 'Grady (2015) IRB: Purposes and Challenges 2015.pdf'. Other files listed include 'Principles and Benchmarks for Ethical Clinical Research.pdf', 'Bios of Department of Bioethics Faculty', '2018 Requirements (2018 Common Rule) _ HHS.gov.pdf', 'Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research _ HHS.gov.pdf', 'Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects _ HHS.gov.pdf', 'Subpart D - Additional Protections for Children Involved as Subjects in Research _ HHS.gov.pdf', and 'Consideration of the Principle of Justice under 45 CFR part 46 Secretary's Advisory Committee on Human Research Protections (2021)'. The text 'Links to Readings' is overlaid on the right side of the highlighted section.

Principles and Benchmarks for Ethical Clinical Research.pdf
Bios of Department of Bioethics Faculty
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Links to Readings

Asking Questions

The screenshot displays the Blackboard LMS interface. On the left, a dark sidebar contains navigation icons for Account, Dashboard, Courses, Calendar, Inbox, History, and Help. The main content area is titled 'ERACR 2023 > Modules'. Below this, a secondary sidebar lists navigation options: Home, Announcements, Discussions (highlighted with a red circle), Files, People, Syllabus, Quizzes, Modules, and Collaborations. The main content area shows the breadcrumb 'ERACR 2023 > Discussions > Post Questions for Session 1 Here'. At the top right of this area are buttons for 'Collapse All', 'View Course Stream', and 'View Course Calendar'. The central content area features a discussion post titled 'Post Questions for Session 1 Here' by Holly Taylor (She/Her) in 'All Sections'. Below the post title is a search bar for 'Search entries or author', an 'Unread' button, and a 'Subscribe' button. A 'Reply' button is visible at the bottom of the post area.

Asking Questions

Send email to:

Bioethics-Inquiries@mail.nih.gov

Session Quizzes

- If you don't want Certificate of Completion, don't need to take Session Quizzes
- If you want a Certificate of Completion, you must take at least 3 of 7
- If you are an NIH employee/contractor and want Core Curriculum credit or are a Nurse and want CEU, you must take at least 6 of 7
- *Score does not matter*

Session Quizzes

The screenshot displays a course management system interface. The top navigation bar shows 'ERACR 2023 > Modules'. The left sidebar contains a menu with 'Quizzes' highlighted in red. The main content area is titled 'ERACR 2023 > Quizzes' and features a search bar and a list of quizzes. The quizzes are categorized into 'Assignment Quizzes' and 'Surveys'. The 'Assignment Quizzes' section lists seven sessions, each with a status, availability date, and question count. The 'Surveys' section lists one item, 'Self Registration Form', with its availability and due dates and question count.

Quiz Name	Availability	Points	Questions
Session 1 Quiz	Not available until Sep 20 at 11:30am	3 pts	3 Questions
Session 2 Quiz	Not available until Sep 27 at 11:30am	3 pts	3 Questions
Session 3 Quiz	Not available until Oct 4 at 11:30am	3 pts	3 Questions
Session 4 Quiz	Not available until Oct 11 at 11:30am	3 pts	3 Questions
Session 5 Quiz	Not available until Oct 18 at 11:30am	3 pts	3 Questions
Session 6 Quiz	Not available until Oct 25 at 11:30am	3 pts	3 Questions
Session 7 Quiz	Not available until Nov 1 at 8:00am	3 pts	3 Questions
Self Registration Form	Available until Oct 11 at 11:59pm Due Oct 11 at 11:59pm	5 Questions	

Session 1

Session 1: Introduction/Framework/History/Institutional Review Boards September 20

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