



# 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
- Identify challenges and opportunities related to **genetics research** and research with stored samples
- Appreciate the perspective of individuals who have **participated** in research
- Appreciate ethical challenges with conducting **international collaborative research** in low- and middle-income countries

# Overview

Session	Date	Topics	Faculty
1	9/25/24	Introduction/Framework/History/Institutional Review Boards	Taylor, Grady, <i>Lederer</i>
2	10/2/24	Informed Consent/Decision Making/Capacity Assessment	Grady, Kim, Squires (NIMH), Taylor
3	10/9/24	Study Design/Risk-Benefit/Social Value/Inclusion of Children in Research	Taylor, Wendler, <i>Shah</i>
4	10/16/24	Equity/Subject Selection/Recruitment and Retention	Asada, Taylor, <i>Langford</i>
5	10/23/24	Genomic Sequencing, Return of Results from Field, Conducting Genetic Research with Indigenous Communities	Berkman, Sapp (NHGRI), <i>Claw</i>
6	10/30/24	Participant Experience	<i>Fisher</i> , Clinical Center Research Participants Panel
7	11/6/24	International/Standards of Care/Post-trial Obligations/Community Engagement	Steel, Millum, <i>Kamuya</i>

Guest Lecturers (unaffiliated with the NIH) noted in *Italics*

Livestream 8:30-11:30 am US Eastern  
Recordings available 48 hours later

# Administrative Details

- Self-Enrollment (link to Canvas)
  - Access to all course materials
  - If you want a Certificate of Completion, must self-register
- Self-Registration (on Canvas)
  - Required to receive Certificate of Completion
- Session Quiz (on Canvas)
  - Required for Certificate (must complete at least 3 quizzes, 6 or 7 for NIH Employees)

# Administrative Details

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

# Canvas Hub

Account

Dashboard

Courses

Calendar

Inbox

History

Help

ERACR 2024 > Modules

Home

Assignments

Discussions

Grades

People

Files

Syllabus

Quizzes

Modules

Collaborations

Lucid (Whiteboard)

Key Documents

Self Registration Form

Oct 16

Course Basics 2024.pdf

Continuing Education Slide 2024.pdf

Principles and Benchmarks for Ethical Clinical Research.pdf

Bios of Department of Bioethics Faculty

Syllabus 9 18 24 FINAL.pdf

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

Link to Live Video Cast

LEDERER Bio.pdf

Session 1 2024.pdf

Collapse All

View Course Stream

View Course Calendar

View Course Notifications

To Do

Self Registration Form

Ethical and Regulatory Aspects of Clinical Research 2024

Oct 16 at 11:59pm

You are currently logged into Student View

Resetting the test student will clear all history for this student, allowing you to view the course as a brand new student.

Reset Student

Leave Student View



# Canvas Hub

Canvas Hub interface showing the course page for "ERACR 2024" under the "Modules" section. The interface includes a sidebar with navigation options (Home, Assignments, Discussions, Grades, People, Files, Syllabus, Quizzes, Modules, Collaborations, Lucid (Whiteboard)) and a main content area displaying a list of documents under the "Key Documents" heading. A red circle highlights the "Self Registration Form" document in the list. Another red circle highlights the "Self Registration Form" notification in the "To Do" list on the right. The bottom of the interface shows a status bar indicating the user is logged into "Student View" and provides options to "Reset Student" or "Leave Student View".

Canvas Hub interface showing the course page for "ERACR 2024" under the "Modules" section. The interface includes a sidebar with navigation options (Home, Assignments, Discussions, Grades, People, Files, Syllabus, Quizzes, Modules, Collaborations, Lucid (Whiteboard)) and a main content area displaying a list of documents under the "Key Documents" heading. A red circle highlights the "Self Registration Form" document in the list. Another red circle highlights the "Self Registration Form" notification in the "To Do" list on the right. The bottom of the interface shows a status bar indicating the user is logged into "Student View" and provides options to "Reset Student" or "Leave Student View".

# Canvas Hub

The screenshot displays the Canvas LMS interface. The browser's address bar shows the URL <https://canvas.instructure.com/courses/10139756/quizzes/19163433>. The page title is "Self Registration Form : Ethical". The left sidebar contains navigation links: Home, Account, Dashboard, Courses, Calendar, Inbox, History, and Help. The main content area shows the "Self Registration Form" details. The form is titled "Self Registration Form" and includes the following information: Due Oct 16 at 11:59pm, Questions 5, Available Aug 23 at 12am - Oct 16 at 11:59pm, Time Limit None, and Allowed Attempts Unlimited. The instructions state: "You must complete this set of questions to be eligible for a Certificate of Completion." A blue button labeled "Take the Survey" is highlighted with a red circle. A "Next" button is visible at the bottom right of the form area.

Self Registration Form : Ethical

https://canvas.instructure.com/courses/10139756/quizzes/19163433

ERACR 2024 > Quizzes > Self Registration Form

## Self Registration Form

Due Oct 16 at 11:59pm Questions 5 Available Aug 23 at 12am - Oct 16 at 11:59pm Time Limit None Allowed Attempts Unlimited

### Instructions

You must complete this set of questions to be eligible for a Certificate of Completion.

[Take the Survey](#)

Next >

# Canvas Hub

Canvas LMS interface showing the course page for "ERACR 2024" under the "Modules" section. The page displays a list of key documents and a session overview.

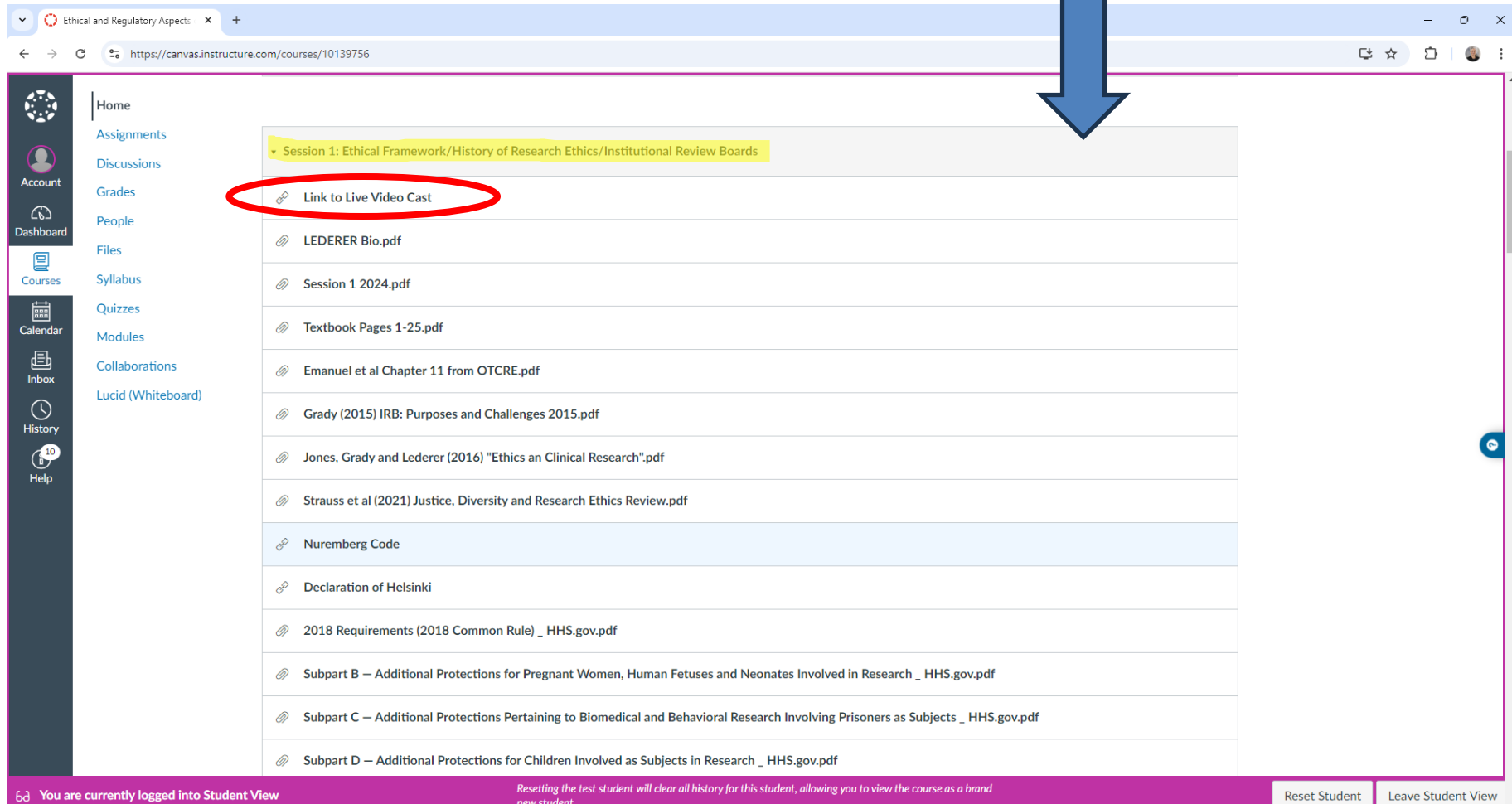
**Course Page Structure:**

- Header:** ERACR 2024 > Modules
- Left Sidebar (Navigation):**
  - Home
  - Assignments
  - Discussions
  - Grades
  - People
  - Files
  - Syllabus
  - Quizzes
  - Modules
  - Collaborations
  - Lucid (Whiteboard)
- Right Sidebar (Tools):**
  - View Course Stream
  - View Course Calendar
  - View Course Notifications
  - To Do
    - Self Registration Form (Ethical and Regulatory Aspects of Clinical Research 2024, Oct 16 at 11:59pm)
- Main Content Area:**
  - Key Documents:**
    - Self Registration Form (Oct 16)
    - Course Basics 2024.pdf
    - Continuing Education Slide 2024.pdf
    - Principles and Benchmarks for Ethical Clinical Research.pdf
    - Bios of Department of Bioethics Faculty
    - Syllabus 9 18 24 FINAL.pdf
  - Session 1: Ethical Framework/History of Research Ethics/Institutional Review Boards**
    - Link to Live Video Cast
    - LEDERER Bio.pdf
    - Session 1 2024.pdf

**Footer:**

- You are currently logged into Student View
- Resetting the test student will clear all history for this student, allowing you to view the course as a brand new student.
- Reset Student
- Leave Student View

# Canvas Hub



The screenshot displays the Canvas Hub interface for a course titled "Ethical and Regulatory Aspects". The URL in the browser is <https://canvas.instructure.com/courses/10139756>. The left sidebar shows navigation options: Home, Assignments, Discussions, Grades, People, Files, Syllabus, Quizzes, Modules, Collaborations, and Lucid (Whiteboard). The main content area lists resources for "Session 1: Ethical Framework/History of Research Ethics/Institutional Review Boards". A red circle highlights the "Link to Live Video Cast" link. Below this, a list of PDF documents is provided, including "LEDERER Bio.pdf", "Session 1 2024.pdf", "Textbook Pages 1-25.pdf", "Emanuel et al Chapter 11 from OTCRE.pdf", "Grady (2015) IRB: Purposes and Challenges 2015.pdf", "Jones, Grady and Lederer (2016) 'Ethics an Clinical Research'.pdf", "Strauss et al (2021) Justice, Diversity and Research Ethics Review.pdf", "Nuremberg Code", "Declaration of Helsinki", "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", and "Subpart D – Additional Protections for Children Involved as Subjects in Research \_ HHS.gov.pdf". The bottom of the page features a purple banner with the text "You are currently logged into Student View" and a note: "Resetting the test student will clear all history for this student, allowing you to view the course as a brand new student." Buttons for "Reset Student" and "Leave Student View" are also present.

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

- Link to Live Video Cast
- LEDERER Bio.pdf
- Session 1 2024.pdf
- Textbook Pages 1-25.pdf
- Emanuel et al Chapter 11 from OTCRE.pdf
- Grady (2015) IRB: Purposes and Challenges 2015.pdf
- Jones, Grady and Lederer (2016) "Ethics an Clinical Research".pdf
- Strauss et al (2021) Justice, Diversity and Research Ethics Review.pdf
- Nuremberg Code
- Declaration of Helsinki
- 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

You are currently logged into Student View

Resetting the test student will clear all history for this student, allowing you to view the course as a brand new student.

Reset Student Leave Student View

# 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 25

### 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, PhD 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

#### 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)

#### Journal Articles

Emanuel L, Wendler D, & Grady C. An ethical framework for biomedical research. Chapter 11 in *The Oxford Textbook of Clinical Research Ethics*. (Edited by El Emanuel, C Grady, RA Crouch, RK Lie, PG Miller and D Wendler (Oxford University Press: New York): 123-135.

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

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(6555):1209-1211.

#### Core Research Ethics Codes

Nuremberg Code (1948) as published in the *British Medical Journal* (1996) 313:1448  
<https://www.bmj.com/content/313/7070/1448.1>

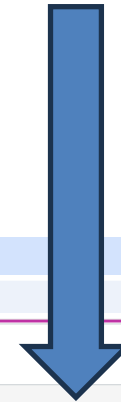
Declaration of Helsinki (also known as World Medical Association Declaration of Helsinki – ethical Principles for Medical Research Involving Human Subjects) (2013) <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research  
**Belmont Report** (also known as Ethical Principles and Guidelines for the Protection of Human Subjects of Research) (1979) <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>

#### US Federal Regulations

Common Rule (Protection of Human Subjects 45 CFR 46 (2018) <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html>

# Canvas Hub



Canvas Hub interface showing a course page for "Ethical and Regulatory Aspects". The page displays a list of resources under the heading "Session 1: Ethical Framework/History of Research Ethics/Institutional Review Boards". A red box highlights a section of the list, and the text "Links to Readings" is overlaid on the right side of the page.

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

- Link to Live Video Cast
- LEDERER Bio.pdf
- Session 1 2024.pdf
- Textbook Pages 1-25.pdf
- Emanuel et al Chapter 11 from OTCRE.pdf
- Grady (2015) IRB: Purposes and Challenges 2015.pdf
- Jones, Grady and Lederer (2016) "Ethics an Clinical Research".pdf
- Strauss et al (2021) Justice, Diversity and Research Ethics Review.pdf
- Nuremberg Code
- Declaration of Helsinki
- 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

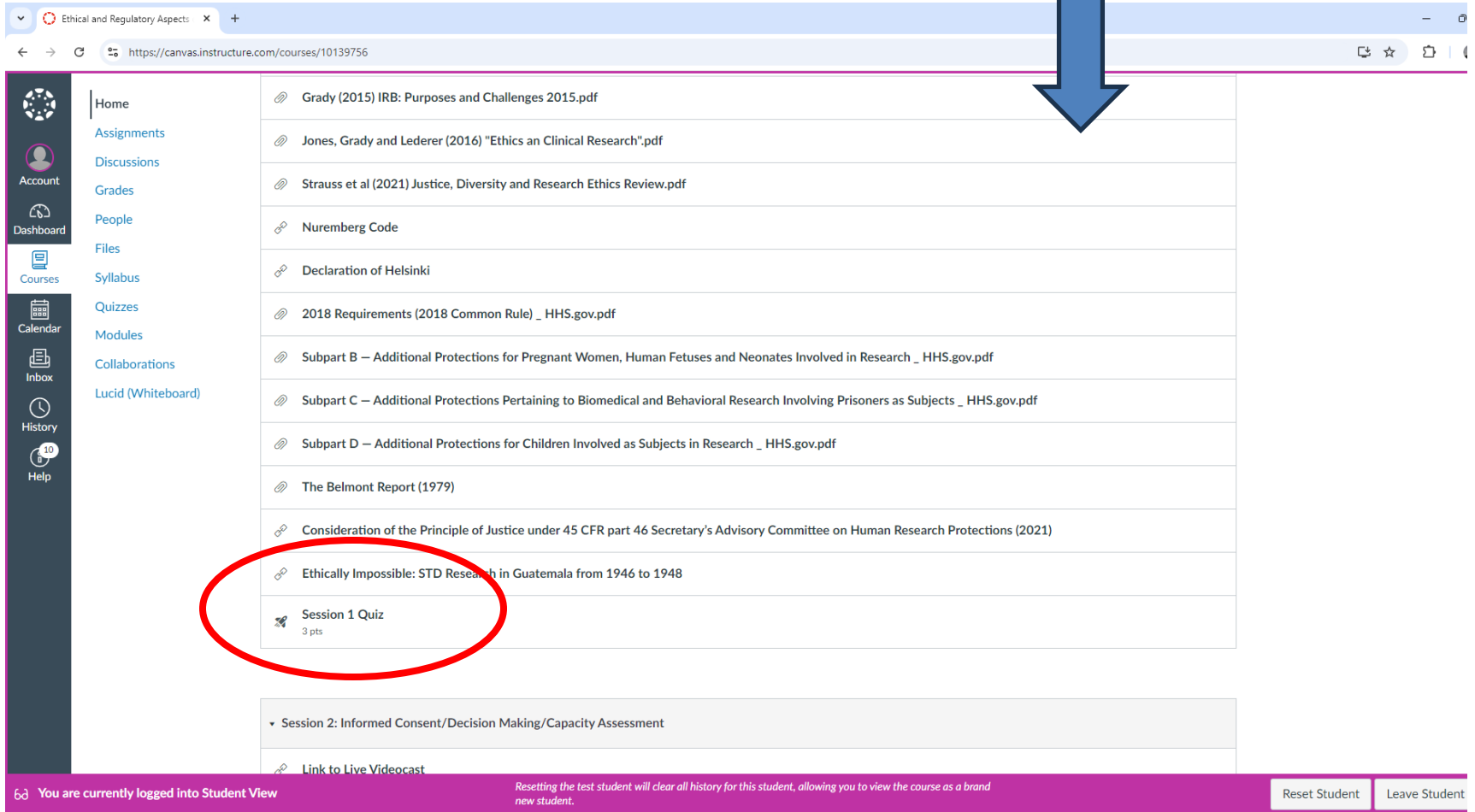
Links to Readings

You are currently logged into Student View

Resetting the test student will clear all history for this student, allowing you to view the course as a brand new student.

Reset Student | Leave Student View

# Canvas Hub



The screenshot displays the Canvas LMS interface for a course titled "Ethical and Regulatory Aspects". The browser address bar shows the URL <https://canvas.instructure.com/courses/10139756>. The left sidebar contains navigation links: Home, Assignments, Discussions, Grades, People, Files, Syllabus, Quizzes, Modules, Collaborations, and Lucid (Whiteboard). The main content area lists course items, including PDFs, codes, and a quiz. The "Session 1 Quiz" is highlighted with a red circle. The bottom status bar indicates the user is logged in as a student and provides options to reset or leave the student view.

Item
Grady (2015) IRB: Purposes and Challenges 2015.pdf
Jones, Grady and Lederer (2016) "Ethics an Clinical Research".pdf
Strauss et al (2021) Justice, Diversity and Research Ethics Review.pdf
Nuremberg Code
Declaration of Helsinki
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
The Belmont Report (1979)
Consideration of the Principle of Justice under 45 CFR part 46 Secretary's Advisory Committee on Human Research Protections (2021)
Ethically Impossible: STD Research in Guatemala from 1946 to 1948
<b>Session 1 Quiz</b> 3 pts
Session 2: Informed Consent/Decision Making/Capacity Assessment
Link to Live Videocast

63 You are currently logged into Student View

Resetting the test student will clear all history for this student, allowing you to view the course as a brand new student.

Reset Student Leave Student

# Asking Questions

The screenshot displays the Canvas LMS interface for the 'ERACR 2024' course. The left sidebar contains navigation links: Home, Assignments, Discussions, Grades, People, Files, Syllabus, Quizzes, Modules, Collaborations, and Lucid (Whiteboard). The 'Discussions' link is circled in red. The main content area shows the 'ERACR 2024 > Discussions' page. At the top, there is a search bar and a '+ Discussion' button. Below this, a discussion titled 'Session 1 Questions' is circled in red. The discussion is currently unavailable until September 25, 12:00 AM. Below the discussion, there is a section labeled 'Closed for Comments' which contains an illustration of two people with speech bubbles and the text 'You currently have no discussions with closed comments'.



# Asking Questions

If you are not in CANVAS  
Send email to:

[Bioethics-Inquiries@mail.nih.gov](mailto: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, you must take at least 6 of 7
- *Score does not matter*

# Session Quizzes

The screenshot shows the Canvas LMS interface for a course titled 'ERACR 2023' under the 'Modules' section. The left sidebar contains navigation links: Home, Announcements, Assignments, Discussions, Grades, People, Files, Quizzes (circled in red), Modules, and Collaborations. The main content area displays the 'ERACR 2024 > Quizzes' page. It includes a search bar, a '+ Quiz' button, and a list of quizzes under the 'Assignment Quizzes' section. Below this is a 'Surveys' section with a 'Self Registration Form'.

Quiz Name	Availability	Points	Questions	Status
Session 1 Quiz	Not available until Sep 25 at 11:30am	3 pts	3 Questions	Available
Session 2 Quiz	Not available until Oct 2 at 11:30am	3 pts	3 Questions	Available
Session 3 Quiz	Closed	3 pts	3 Questions	Completed
Session 4 Quiz	Closed	3 pts	3 Questions	Completed
Session 5 Quiz	Not available until Oct 23 at 11:30am	3 pts	3 Questions	Not Available
Session 6 Quiz	Not available until Oct 30 at 8:00am	3 pts	3 Questions	Available
Session 7 Quiz	Not available until Nov 6 at 11:30am	3 pts	3 Questions	Not Available
Self Registration Form	Available until Oct 16 at 11:59pm	Due Oct 16 at 11:59pm	5 Questions	Completed

# Session 1

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, PhD 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	