Ethical and Regulatory Aspects of Clinical Research

Introduction

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NIH BIOETHICS

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.

Welcome

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.

Welcome

Course Objectives (cont'):

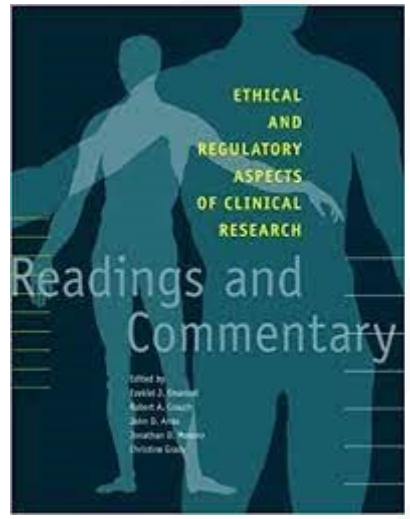
- Identify the critical elements of informed consent and strategies for implementing informed consent for clinical research.
- Describe the purpose, function, and challenges of IRBs.
- Discuss controversial issues relating to human subject research, including, randomization, enrollment of pregnant women in research, COVID related vaccine research, and research conducted in low and middle income countries.

Format

Session	Date	Topics	Faculty
1	9/22/21	Ethical Framework/ Physician-Investigator Role/History of Research Ethics	Taylor, Grady, *Joffe*
2	9/29/21	Randomized Clinical Trials/ Risk-Benefit/Institutional Review Boards	Wendler, *Truog,* Taylor
3	10/6/21	Subject Selection/Inclusion of Pregnant Women/Recruitment and Retention	Wendler, *Lyerly,* Taylor
4	10/13/21	Informed Consent/Decision Making/Capacity Assessment	Grady, Kim, Todman, Taylor
5	10/20/21	Returning Results/Incidental Findings/ Collaborating with Indigenous Communities	Berkman, Jamal, Hull, *Claw* and Taylor
6	10/27/21	Vaccines	Grady, Rid, *Langford*
7	11/3/21	International Research/Standard of Care/Post-trial Obligations	Millum, Rid, *Kamuya*

Livestream

8:30-11:30 am Eastern



Administrative Details

Registration Quiz (Canvas)

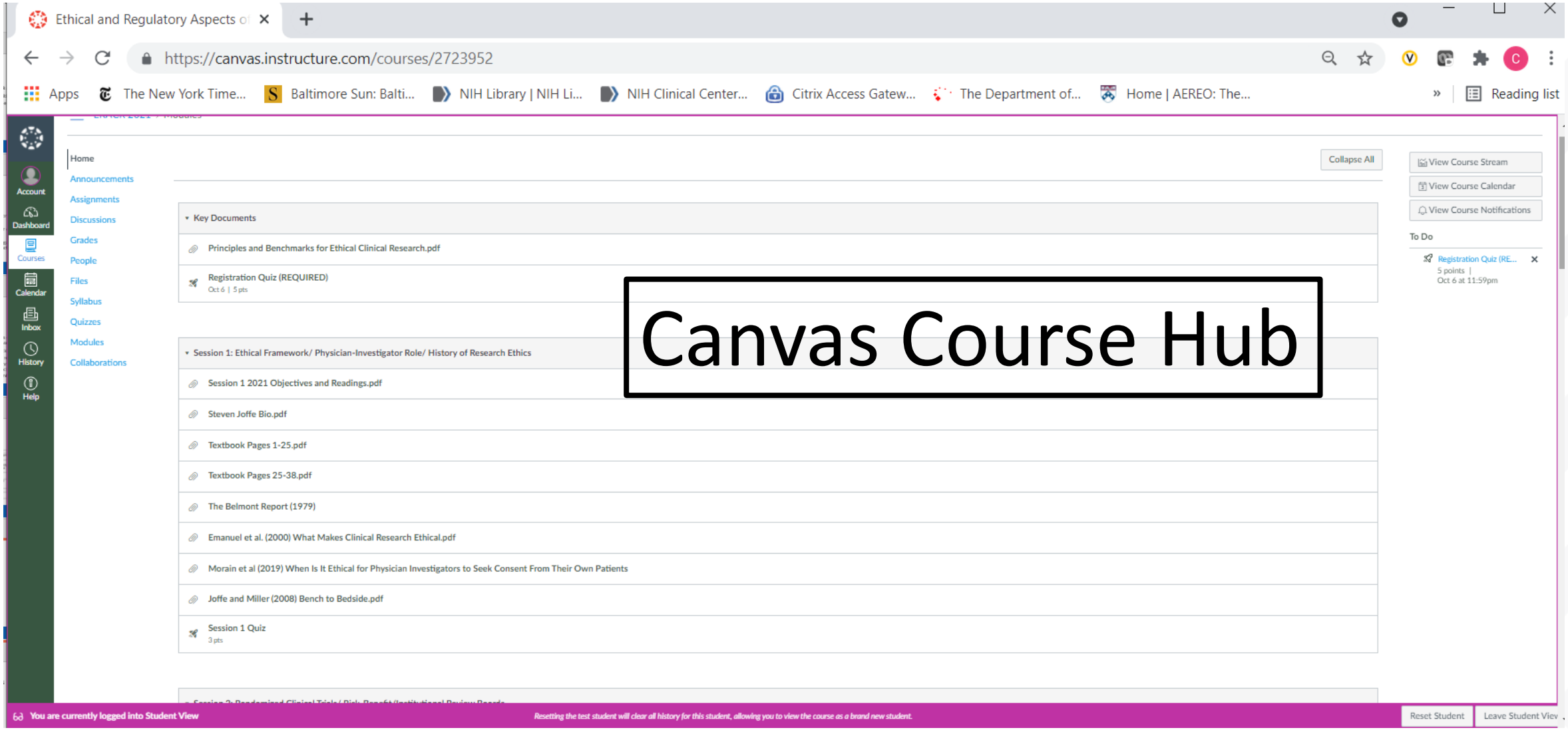
- Certificate or not

Session Quiz (Canvas)

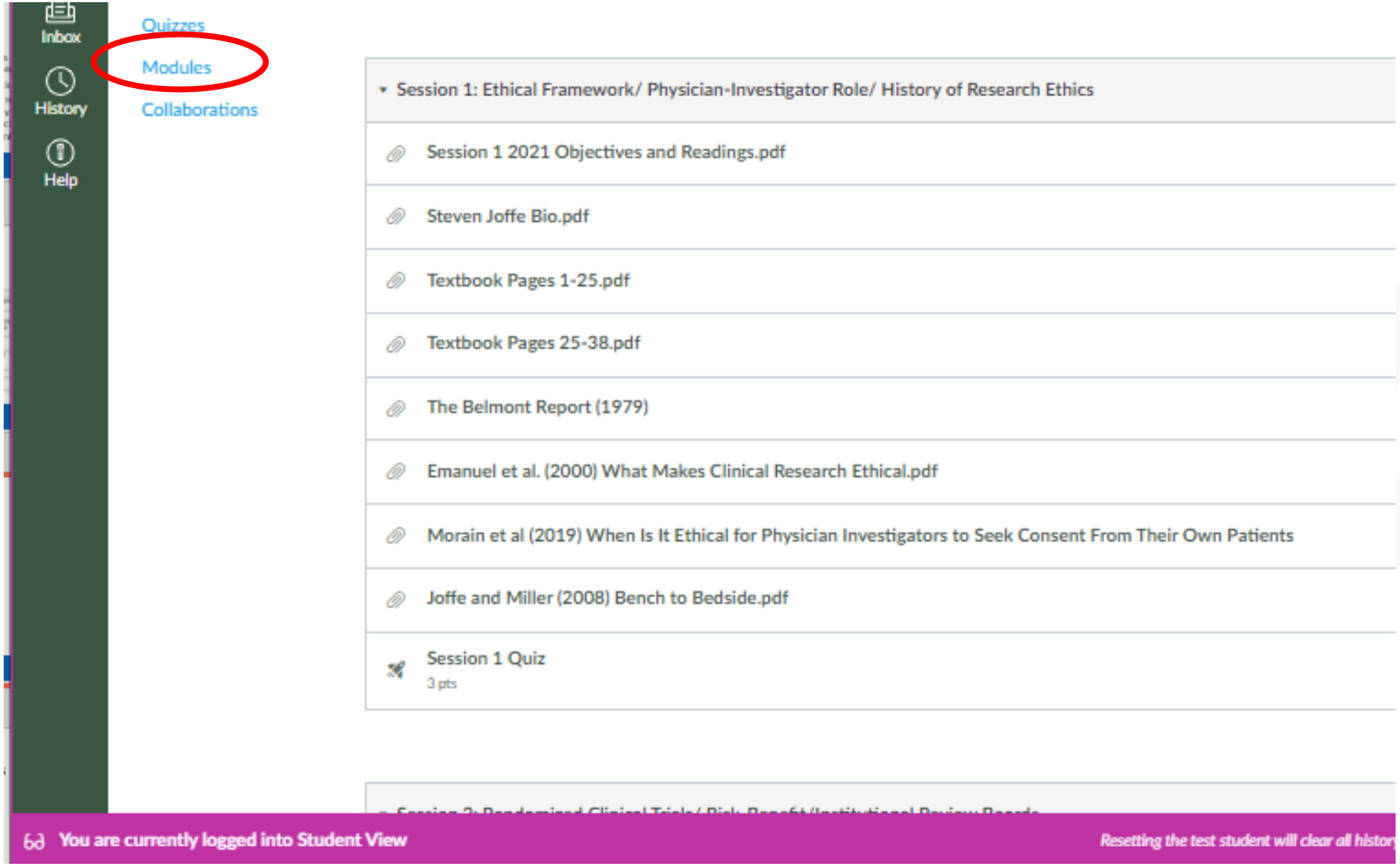
- Attendance

Session Evaluation (link by email)

Pre-Course/Post-Course Assessment (link by email)



Canvas Course Hub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Session 1: Ethical Framework/ Physician-Investigator Role/ History of Research Ethics
Session 1 2021 Objectives and Readings.pdf
Steven Joffe Bio.pdf
Textbook Pages 1-25.pdf
Textbook Pages 25-38.pdf
The Belmont Report (1979)
Emanuel et al. (2000) What Makes Clinical Research Ethical.pdf
Morain et al (2019) When Is It Ethical for Physician Investigators to Seek Consent From Their Own Patients
Joffe and Miller (2008) Bench to Bedside.pdf
Session 1 Quiz
3 pts
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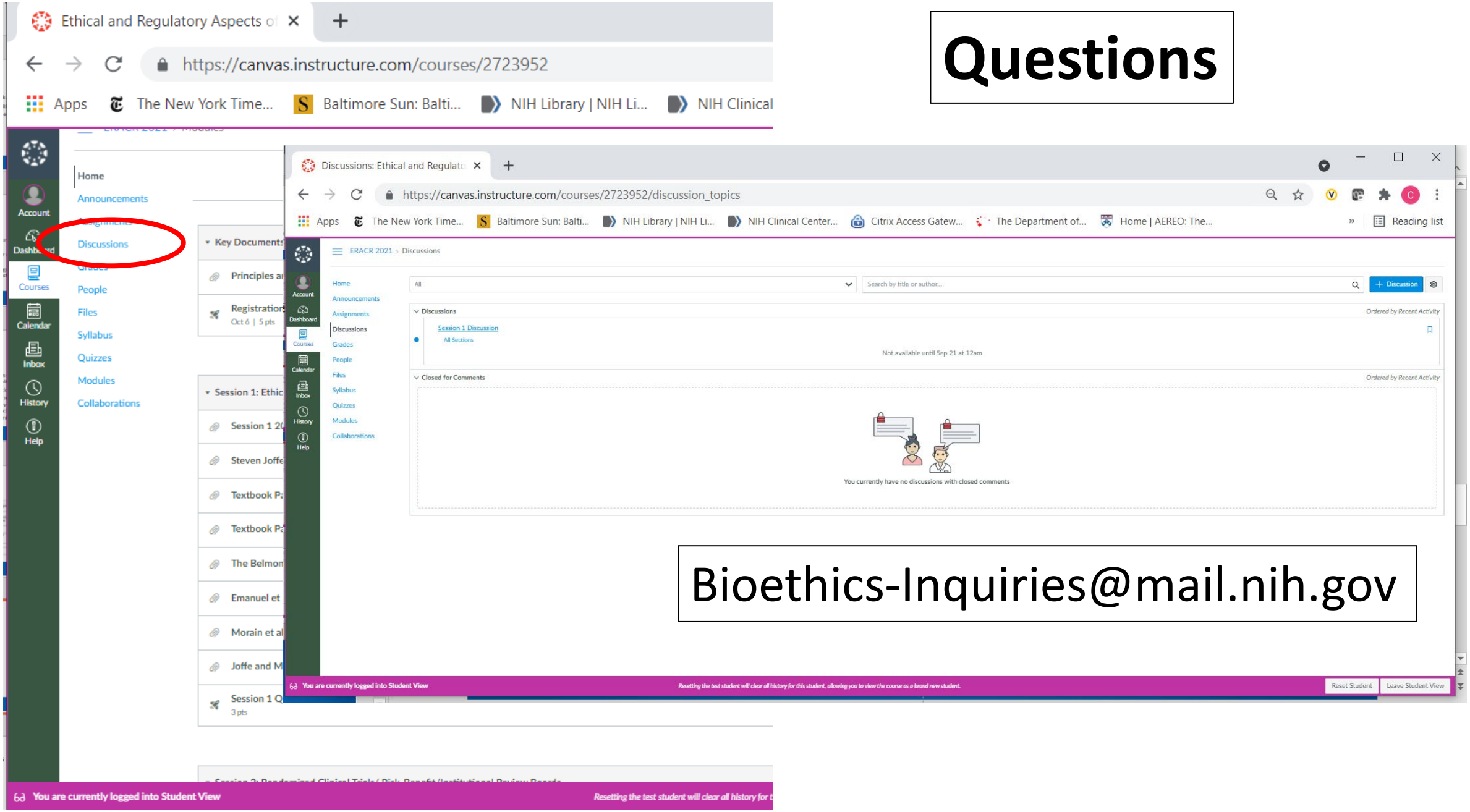
Questions



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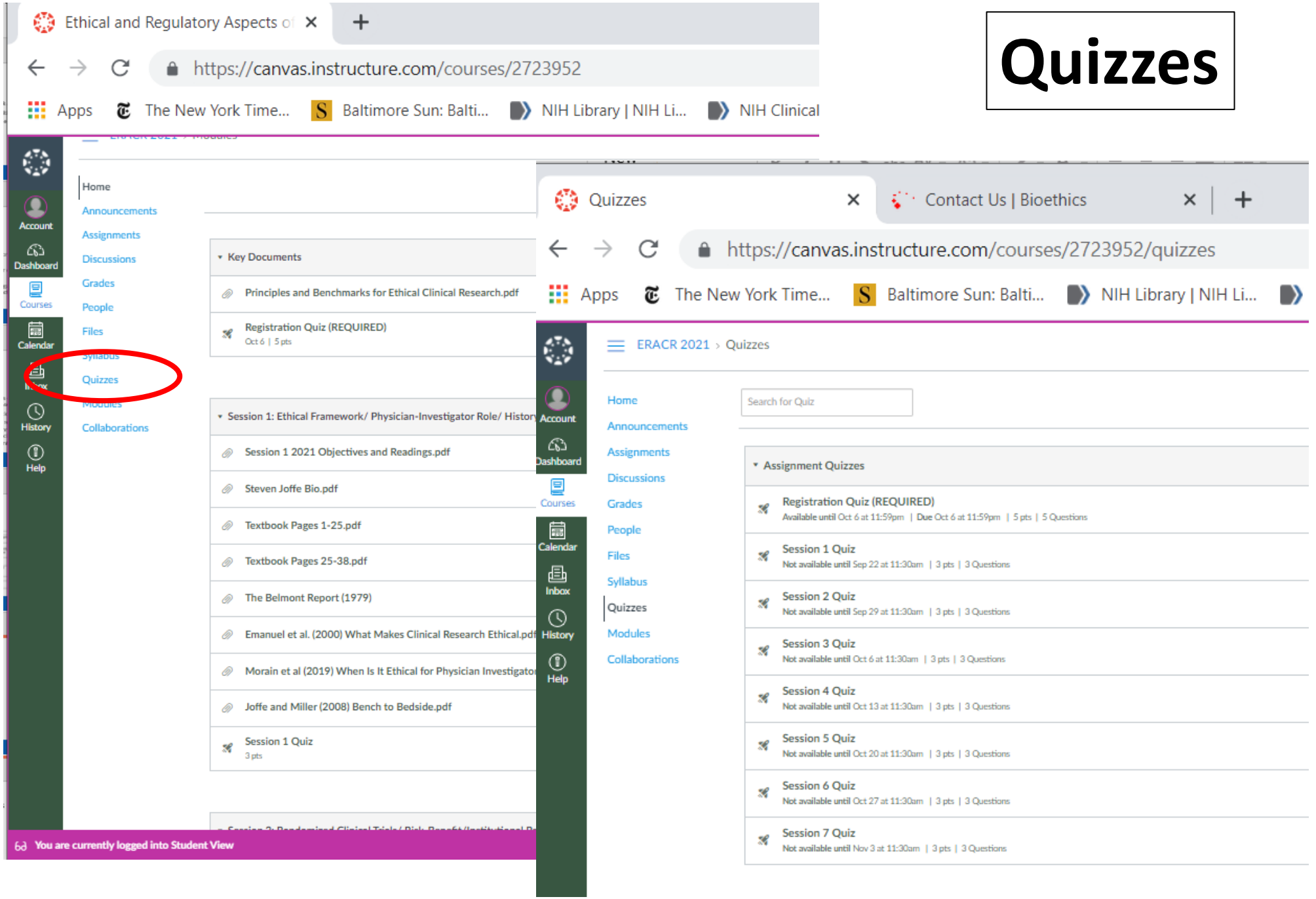
Quizzes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Key Documents
Principles and Benchmarks for Ethical Clinical Research.pdf
Registration Quiz (REQUIRED)
Oct 6 | 5 pts
Session 1: Ethical Framework/ Physician-Investigator Role/ History
Session 1 2021 Objectives and Readings.pdf
Steven Joffe Bio.pdf
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Registration Quiz (REQUIRED)
Available until Oct 6 at 11:59pm | Due Oct 6 at 11:59pm | 5 pts | 5 Questions
Session 1 Quiz
Not available until Sep 22 at 11:30am | 3 pts | 3 Questions
Session 2 Quiz
Not available until Sep 29 at 11:30am | 3 pts | 3 Questions
Session 3 Quiz
Not available until Oct 6 at 11:30am | 3 pts | 3 Questions
Session 4 Quiz
Not available until Oct 13 at 11:30am | 3 pts | 3 Questions
Session 5 Quiz
Not available until Oct 20 at 11:30am | 3 pts | 3 Questions
Session 6 Quiz
Not available until Oct 27 at 11:30am | 3 pts | 3 Questions
Session 7 Quiz
Not available until Nov 3 at 11:30am | 3 pts | 3 Questions

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	
9:40-10:30	Physician/Investigator Roles	Steve Joffe, MD MPH Interim Chair, Department of Medical Ethics & Health Policy Art and Ilene Penn Professor of Medical Ethics & Health Policy University of Pennsylvania
10:30-10:40	Break	
10:40-11:20	Conversation about History of Research Ethics	Christine Grady and Holly Taylor
11:20-11:30	Discussion	