## OVERVIEW

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<thead>
<tr>
<th>Date</th>
<th>Session</th>
<th>Faculty</th>
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<td>September 23</td>
<td>Session 1: Ethical Framework/ Risk Benefit Assessment</td>
<td>Holly Taylor, Christine Grady, David Wendler</td>
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<td>September 30</td>
<td>Session 2: Informed Consent/Privacy and Confidentiality</td>
<td>Christine Grady, Scott Kim, Ben Berkman, Holly Taylor</td>
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<td>October 7</td>
<td>Session 3: Subject Selection</td>
<td>Holly Taylor, Dave Wendler, Camila Strassle</td>
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<td>October 14</td>
<td>Session 4: Genetics</td>
<td>Ben Berkman, Leila Jamal, Sara Hull, Katrina Claw, Holly Taylor</td>
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<td>October 21</td>
<td>Session 5: IRBs/Trial Design</td>
<td>Robert Troug, Scott Kim, Sara Hull, Holly Taylor</td>
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<td>October 28</td>
<td>Session 6: International Research</td>
<td>Joe Millum, Maria Merritt, Dorcas Kamuya</td>
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<td>November 4</td>
<td>Session 7: COVID</td>
<td>Christine Grady, Nir Eyal, Seema Shah, Annette Rid, Holly Taylor, Anne Barnhill</td>
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Overall Course Objectives

Upon completion of this course, you should be able to:

By the end of this course, participants are able to:

- 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.
- 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, prisoners in research, COVID related research, international research, etc...

Session 1: Ethical Framework, Risk Benefit Wednesday September 23

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
- Identify and apply relevant considerations for assessment of research risks and benefits
**Textbook Reading Assignment**

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. 1-23)

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

Part VI: Clinical Research with Special Populations (Chapter 42; pp. 247-252)

**Additional Readings**


**Optional**


**Session 2: Informed Consent/Privacy and Confidentiality** Wednesday September 30

Objectives:

- Describe the ethical basis of and elements of informed consent, strategies for implementation, and areas for improvement.
- Identify the ethical challenges of including persons in research who have decreased capacity to consent, and discuss the implementation of appropriate additional safeguards Understand the barriers and facilitators to obtaining informed consent from research participants
- Experience drafting key components of informed consent form

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<tr>
<th>Time</th>
<th>Topic</th>
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<tr>
<td>8:30-9:15</td>
<td>Informed Consent</td>
<td>Christine Grady RN PhD NIH Clinical Center Department of Bioethics</td>
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<tr>
<td>9:15-9:25</td>
<td>Discussion</td>
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<tr>
<td>9:25-10:05</td>
<td>Research Involving Persons at Risk for Impaired Decision-Making</td>
<td>Scott Kim MD PhD Department of Bioethics, NIH Clinical Center</td>
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<td>10:05-10:15</td>
<td>Discussion</td>
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</table>
10:15-10:30 Break
10:30-10:50 Privacy and Confidentiality
   Holly Taylor PhD MPH
   NIH Clinical Center Department of Bioethics
10:50-11:20 Repurposing Biospecimens for
   COVID Research
   Ben Berkman, JD
   NIH Clinical Center Department of Bioethics
   and NHGRI
11:20-11:30 Discussion

Textbook Reading Assignment

Part V: Informed Consent in Research (Overview and Chapters 30-33; pp. 189-210)

Part VI: Clinical Research with Special Populations (Chapter 38; pp. 229-233)

Part VII. Special Topics in Research Ethics (Chapter 54; pp. 311-312)

Additional Readings


NIH Policy - Research Involving Adults Who Lack Decision-making Capacity to Consent to Research Participation September 14, 2020

Session 3: Subject Selection Wednesday October 7

Objectives:

- Explore the ethical requirement of fair subject selection and its application
- Identify ethical issues and strategies in the recruitment and retention of subjects.
- Review ethical challenges and strategies for conducting ethical research involving prisoners

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<tr>
<td>8:30-9:10</td>
<td>Fair Subject Selection</td>
<td>Holly Taylor PhD MPH</td>
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<td>NIH Clinical Center Department of Bioethics</td>
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<tr>
<td>9:10-9:50</td>
<td>Recruitment and Retention</td>
<td>Dave Wendler PhD</td>
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Session 4: Genetics  Wednesday October 14

Objectives:

- Identify challenges and opportunities related to genetics research and research with stored samples
- Understand how the rapid development and diffusion of genetic technology influence the conduct of human subject research
- Understand the difference between research findings and incidental findings and the relevant ethical considerations for each
- Appreciate the complexity of conducting genetics research with native populations
- Understand the concept of group harms

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| 8:30-10:15 | Ethics of Genetics Research and Incidental Findings        | Ben Berkman, JD, MPH
NIH Clinical Center Department of Bioethics and NHGRI
Lelia Jamal, PhD, ScD, CGC
NIH Clinical Center Department of Bioethics and NCI |
10:15-10:30  Break

10:00-10:30  Enrollment of Native Populations: Key Considerations  Sara Hull *in Conversation* with Katrina Claw  University of Colorado Anschutz Medical Campus

10:30-10:40  Discussion

10:40-11:30  Case Discussion: Arizona State University Diabetes Project  Sara Hull/Holly Taylor

**Readings**


**Session 5: Trial Design/IRBs Wednesday October 21**

Objectives:

- Identify ethical issues in the design and conduct of randomized controlled trials, and explore meanings and issues related to clinical equipoise
- Understand the basis of the role and responsibilities of an Institutional Review Board
- Discuss ethical considerations in the design and conduct of pragmatic clinical trials.
- Discuss the purpose and function of IRBs, and current challenges

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| 8:30-9:15| Randomized Clinical Trials: Clinical Equipoise | Robert Truog MD  
Director, Harvard Center for Bioethics  
Frances Glessner Lee Professor of Legal Medicine, Professor of Anaesthesia (Pediatrics) Harvard Medical School |
| 9:15-9:25| Discussion                               | Scott Kim MD PhD  
Senior Investigator  
NIH Clinical Center Department of Bioethics |
| 9:25-10:10| Pragmatic Trials                        |                                                                        |
Textbook Reading Assignment

Part III: The Ethics of Trial Design (Chapter 11; pp. 103-107, Chapters 13-15; pp. 113-126)

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

Additional Readings


Common Rule, 45 CFR 46 (2018) https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML


Session 6: International Research Wednesday October 28

Objectives:

- Appreciate challenges with conducting human subject research in low and middle income countries
- Understand the meaning of standard of care in the context of human subject research
- Understand the obligations investigators, sponsors have to research participants after trial completion (e.g. post-trial access)
- Apply IRB assessment tool to research proposal
8:30-8:55  Introduction and Standard of Care  Joseph Millum PhD  NIH Clinical Center Department of Bioethics and Fogarty International Center

8:55-9:10  Discussion

9:10-9:35  Ancillary Care Obligations  Maria Merritt PhD  Visiting Scholar  NIH Clinical Center Department of Bioethics  Johns Hopkins Bloomberg School of Public Health  Johns Hopkins Berman Institute of Bioethics

9:35-9:50  Discussion

9:50-10:05  Break

10:05-10:35  Perspectives from Kenya  Joe Millum in Conversation with Dorcas Kamuya, PhD, MPH  Head of Health Systems and Research Ethics  KEMRI-Wellcome Trust Research Programme  Nairobi, Kenya

10:35-11:30  Mock IRB: Study TBA  Joe Millum/Holly Taylor

Readings


Optional:


Session 7: COVID Vaccines Wednesday November 4

Objectives:

- Explore key course topics in the context of COVID
- Appreciate differences in methods and strategies, and the associated ethical challenges in testing experimental vaccines.

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<tr>
<td>8:30-9:00</td>
<td>Approaches to Vaccine Trial Design</td>
<td>Christine Grady RN PhD NIH Clinical Center Department of Bioethics</td>
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<tr>
<td>9:00-10:00</td>
<td>Ethics of Controlled Human Infection Trials</td>
<td>Seema Shah, JD Northwestern University</td>
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<td>Nir Eyal, PhD Rutgers</td>
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<td>Moderator: Annette Rid MD, PhD NIH Clinical Center Department of Bioethics</td>
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<td>and NIAID</td>
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<tr>
<td>10:00-10:15</td>
<td>Break</td>
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<tr>
<td>10:15-10:35</td>
<td>Obligations to COVID Vaccine Research Subjects</td>
<td>Holly Taylor, PhD, MPH NIH Clinical Center Department of Bioethics</td>
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<tr>
<td>10:35-10:45</td>
<td>Discussion</td>
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<tr>
<td>10:45-11:20</td>
<td>Vaccine Dissemination</td>
<td>Anne Barnhill, PhD Research Scholar Berman Institute of Bioethics Johns Hopkins University</td>
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<tr>
<td>11:20-11:30</td>
<td>Discussion</td>
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Readings


Key criteria for the ethical acceptability of COVID-19 human challenge studies. 2020
