Introduction

Holly Taylor, PhD, MPH

Research Bioethicist
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.
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

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>Topics</th>
<th>Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9/22/21</td>
<td>Ethical Framework/ Physician-Investigator Role/History of Research Ethics</td>
<td>Taylor, Grady, Joffe</td>
</tr>
<tr>
<td>3</td>
<td>10/6/21</td>
<td>Subject Selection/Inclusion of Pregnant Women/Recruitment and Retention</td>
<td>Wendler, Lyerly, Taylor</td>
</tr>
<tr>
<td>4</td>
<td>10/13/21</td>
<td>Informed Consent/Decision Making/Capacity Assessment</td>
<td>Grady, Kim, Todman, Taylor</td>
</tr>
<tr>
<td>5</td>
<td>10/20/21</td>
<td>Returning Results/Incidental Findings/ Collaborating with Indigenous Communities</td>
<td>Berkman, Jamal, Hull, Claw and Taylor</td>
</tr>
<tr>
<td>6</td>
<td>10/27/21</td>
<td>Vaccines</td>
<td>Grady, Rid, Langford</td>
</tr>
<tr>
<td>7</td>
<td>11/3/21</td>
<td>International Research/Standard of Care/Post-trial Obligations</td>
<td>Millum, Rid, Kamuya</td>
</tr>
</tbody>
</table>

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
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)
- Morain et al. (2019) When Is It Ethical for Physician Investigators to Seek Consent From Their Own Patients
- Session 1 Quiz
  3 pts
Questions

Bioethics-Inquiries@mail.nih.gov
Quizzes

- Key Documents
  - Principles and Benchmarks for Ethical Clinical Research.pdf
  - Registration Quiz (REQUIRED)

- ERACR 2021 - Quizzes
  - Assignment Quizzes
    - Registration Quiz (REQUIRED)
      - Available until Oct 6 at 12:30pm | Due Oct 6 at 12:59pm | 5 pts / 5 Questions
    - Session 1 Quiz
      - Not available until Sep 21 at 10:00am | 3 pts / 3 Questions
    - Session 2 Quiz
      - Not available until Sep 29 at 11:00am | 3 pts / 3 Questions
    - Session 3 Quiz
      - Not available until Oct 6 at 11:00am | 3 pts / 3 Questions
    - Session 4 Quiz
      - Not available until Oct 12 at 11:00am | 3 pts / 3 Questions
    - Session 5 Quiz
      - Not available until Oct 19 at 11:00am | 3 pts / 3 Questions
    - Session 6 Quiz
      - Not available until Oct 31 at 11:00am | 3 pts / 3 Questions
    - Session 7 Quiz
      - Not available until Nov 3 at 11:00am | 3 pts / 3 Questions
# Session 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30-8:45</td>
<td>Introduction to Course</td>
<td>Holly Taylor, PhD MPH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIH Clinical Center Department of Bioethics</td>
</tr>
<tr>
<td>8:45-9:30</td>
<td>Framework for Ethical Conduct of Research</td>
<td>Christine Grady, RN PhD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIH Clinical Center Department of Bioethics</td>
</tr>
<tr>
<td>9:30-9:40</td>
<td>Discussion</td>
<td></td>
</tr>
<tr>
<td>9:40-10:30</td>
<td>Physician/Investigator Roles</td>
<td>Steve Joffe, MD MPH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Interim Chair, Department of Medical Ethics &amp; Health Policy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Art and Ilene Penn Professor of Medical Ethics &amp; Health Policy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>University of Pennsylvania</td>
</tr>
<tr>
<td>10:30-10:40</td>
<td>Break</td>
<td></td>
</tr>
<tr>
<td>10:40-11:20</td>
<td>Conversation about History of Research Ethics</td>
<td>Christine Grady and Holly Taylor</td>
</tr>
<tr>
<td>11:20-11:30</td>
<td>Discussion</td>
<td></td>
</tr>
</tbody>
</table>