TEACHING GUIDE

Transforming Medical Research: Advancing Modern, Ethical Methods to Help People and Animals

Accompanying Video with Captions



OVERVIEW

In 1974, following unjust human research practices in the United States, the US Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which released <u>The Belmont Report</u> five years later.

Public outrage over human research practices—including the 40-year-long <u>US</u> <u>Public Health Service Syphilis Study at</u> <u>Tuskegee</u> and the 14-year-long hepatitis studies at the <u>Willowbrook</u> State School in New York—prompted Congress to establish the Commission.

Using a broad framework of justice, the publication of *The Belmont Report* highlighted the importance of avoiding actual and potential harms—particularly in research involving individuals who cannot provide consent or those who could be targeted because of their vulnerabilities in society. The Belmont Report transformed directives related to human research through its call for respect for autonomy and duties to justice, beneficence (the principle of "do good"), and nonmaleficence (the principle of "do no harm").

The situation is different for (*nonhuman) animals, which has significant implications for animals, for vulnerable human populations and patients, and for the public's health.

Although multiple disciplines have evolved to better understand the minds and experiences of animals, and scientists have abandoned antiquated <u>Cartesian views</u> about animals, animals continue to be seriously harmed in research.

*While for simplicity we use terms such as "animals" and "nonhuman" to refer to species and individuals other than humans, it's important to remember that humans are animals as well.

OVERVIEW

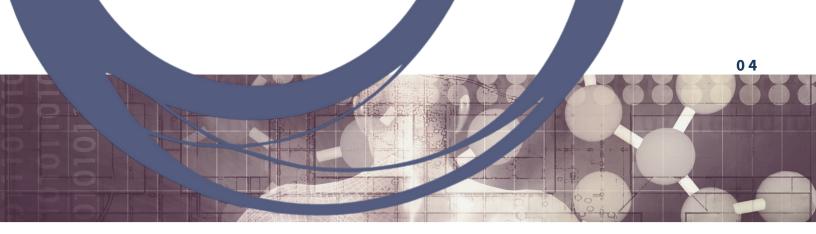
Over time, physicians and scientists have become more <u>concerned</u> with how the pain and distress animals experience in the laboratory may affect interpretations of data obtained through animal research, and there is widespread awareness that animal testing and research can be <u>misleading</u> in determining human therapeutic <u>outcomes</u> and serious life-threatening events including the risks such poor science poses to vulnerable human patients and populations, and the lack of benefit the majority of animal research brings to human health.

Advocates for more modern and effective research methods often cite the fact that most drugs developed in animal trials fail in human trials. Amid this awareness is an existing and everexpanding array of reliable research methods that produce human-specific data. As a result, policy directives have repeatedly called for greater reliance on humancentered, nonanimal methods.

This teaching guide accompanies a <u>captioned</u> <u>videorecording</u> of the 2022 <u>Transforming</u> <u>Medical Research panel discussion</u>. The event was sponsored by <u>Phoenix Zones Initiative</u> and a range of academic cosponsors, and it included experts from medicine, public health, the sciences, and ethics.

The panelists discussed *The Belmont Report* and its principles and applications; the treatment of humans and animals within the context of research; and ways to transform medical research.





LEARNING OBJECTIVES

1) Assess the strengths and limitations of *The Belmont Report*'s ethical principles and existing and potential applications, including as they relate to animals.

2) Describe how the ethical principles described in *The Belmont Report* and technological advancements could be used to transform medical research so that it protects and benefits both people and animals.

3) Identify implementable actions that could advance ethical, evidence-based medical research that protects and benefits people and animals.

TARGET AUDIENCE

The target audience for the activities in this teaching guide includes undergraduate and graduate students and other learners from human and veterinary medicine; the social and biological sciences; public health; and law, policy, the humanities, and ethics.

LEARNING FORMAT

The activities in this teaching guide involve a combination of Socratic and didactic learning methods and discussion, with an accompanying <u>captioned video</u> and optional video clips.



SUGGESTED TEACHING STRATEGIES

The video is approximately 90-minutes long.

If you need to cover the material in a 50–75-minute class, here is a suggested strategy:

1) Ask students to watch the video outside of class time, and to read the two Recommended Readings (see page 11).

2) In class, break the students into small groups and assign each group specific items from the Discussion Questions. Additionally, instruct each group to create a new question of their own.

3) Come back together as a class, and have each small group lead the discussion on their assigned questions and pose the new question to the others. Encourage students to integrate what they learned from the assigned reading into the discussion.

4) Once the discussion has concluded, have students, alone or in small groups, choose one implementable action that could help transform medical research so that it protects and benefits both people and animals and assess its benefits and challenges—via an essay, an infographic, or another medium. Invite students/groups to share.

If you need to cover the material over more than one teaching session, here are some suggested strategies:

1) Ask students to watch a portion of the video (or the entire video) during one session, and facilitate discussion in the next session(s), guided by the Discussion Questions and the Recommended Reading. Consider facilitating discussion using a mixture of small-group and class discussion.

2) Ask students to read the Recommended Reading in advance, and then, in class, ask them to watch selected portions of the video that correspond most with the Recommended Reading. Use the discussion questions that pertain most to ethical principles to guide class discussion. Consider facilitating discussion using a mixture of small-group and class discussion.

See also the suggested questions and activities for deeper investigation on page 9.

SUGGESTED CLIPS FOR BRIEF EXPLORATIONS

If time is a factor, we recommend having learners watch the following clips from the virtual event:

<u>5:38-8:23</u> – <u>Dr. Hope Ferdowsian</u> introduces *The Belmont Report* and why we need a Belmont Report for animals.

10:50-14:33 – **Dr. Charu Chandrasekera** highlights innovative technologies for advancing ethical medical research.

<u>38:56-43:53</u> – <u>Dr. Jessica Pierce</u> discusses the ethical and scientific harms of captivity.

<u>44:15 – 49:02</u> – <u>Dr. Agustín Fuentes</u> discusses the need to weigh the risks and rewards of medical research.

<u>1:01:59-1:08:16</u> – **<u>Dr. Syd Johnson</u>** discusses how to turn innovative ideas into concrete action.



DISCUSSION QUESTIONS

- What was the central point of the Transforming Medical Research panel discussion?
- Throughout the discussion, the moderator and panelists referred to comparisons between human research standards and animal research standards. Did these comparisons resonate with you? Why/why not?
- The moderator and panelists referred to ethical principles, including respect for autonomy, beneficence (do good), nonmaleficence (do no harm), and justice. Describe these principles and what they mean to you in everyday life and during extreme circumstances, such as a personal health crisis or a global pandemic. In what ways could you implement these principles in your life?
 - Some of the panelists discussed how the ethical principles that guide human research could be applied to decisions about animals. What do you think of these potential applications?
 - How can transparency and accountability both uphold ethical principles and facilitate innovation?
- Conversations about the historical and modern treatment of humans and nonhuman animals can be difficult and polarizing. Does starting from basic principles (such as respect for autonomy, beneficence, nonmaleficence, and justice) help overcome these difficulties and potential polarization? Why/why not?
- Discuss the role of consent in medical research for humans and other animals. Consider: are there ever times when a level of social good might outweigh an individual's or group's consent? When might overriding consent for an individual's own good factor in? When might the need for consent be irrefutable? Now apply the role of consent to the larger context of our healthcare system: why is consent so important to our individual and collective health and wellbeing?

DISCUSSION QUESTIONS



Think about a time that you were able to justify a behavior that caused harm to others. What allowed you to make that justification?

How does the ability to justify causing harm in medical research hamper our ethical growth and our ability to innovate?

Some of the panelists discussed human exceptionalism. What is human exceptionalism, and how does it manifest in research and in other areas of society? How is it useful to consider whether concepts such as human exceptionalism influence decisions about others?

What reaction did you have to learning about some of the nonanimal methods available in medical research today? As a group, list at least three nonanimal methods mentioned by the panelists. Do you believe these methods will provide better healthcare to humans in the future? Why/why not? Choose one of these methods to discuss in more depth.



Should the existence of new research technologies, such as organs on a chip, influence the moral permissibility of using animals in research? If so, how? Is there a moral imperative to develop these technologies? If so, how?

Several panelists mentioned a resistance in the scientific and medical research systems to shifting to nonanimal, human-centered research methods. Do you agree? Why/why not? How do you think a Belmont Report for animals would be received? What kind of push back might there be, and why?



What were your reactions to some of the stories that panelists shared? Discuss any aspects of the panel that surprised you. Have you changed your attitudes, opinions, or behaviors since watching and/or listening to the panel? If so, how?



How can you as students influence the trajectory of research ethics? What support can faculty offer? What systemic changes are needed?

QUESTIONS AND ACTIVITIES FOR DEEPER INVESTIGATION

- Up to half of all premature deaths in the US are attributable to preventable factors, even though the US spends more on healthcare that does any other industrialized nation. Our current healthcare system doesn't necessarily prioritize public health research and primary prevention (preventing diseases before they occur). Consider what a healthcare system focused on primary prevention could look like and outline the role a modern, ethical research framework could play in such a shift.
- Dr. David Wendler discusses net risk research and two of the ethical questions it raises: Is it ever ethical to expose individuals, particularly those who can't consent, to risks for the benefit of others? And, if it is okay in certain conditions, what are the requirements that should be satisfied for such research to go forward? How would you answer those questions?
- 3 Dr. Jessica Pierce discusses "the harm of captivity," which is often ignored or dismissed when considering the harms of animal research. Find at least two articles that discuss the physical and psychological harms of captivity on nonhuman animals, and write a summary and assessment of what you've learned. How should these scientific revelations inform our research policies and practices?
 - Dr. Agustín Fuentes says the following in his segment: "We need a serious and global reassessment of how, why, and whether we harm other animals...We need a better roadmap for navigating those landscapes, and we need to constantly highlight the data and the structures, and the outcomes, not obfuscate them...and lean into the science that shows us that we are in a position where, just like with *The Belmont Report* for humans, there is moral, ethical, scientific, methodological, and theoretical justification to redo the way in which we think about, enable, fund, and reward research."

Outline what you think the first steps of such a global reassessment and roadmap should be.

09

QUESTIONS AND ACTIVITIES FOR DEEPER DISCUSSION

- Dr. Syd Johnson discusses the necessity of a commitment to the principles of *The Belmont Report* for both people and animals in medical and scientific research. How could such a shift happen, given the role that human exceptionalism could play in preventing the adoption of those principles?
- Make a list of at least three of the implementable actions discussed by the panelists that can transform medical research. Then do a little research and find at least two additional actions or strategies that could advance medical research following the principles of *The Belmont Report* for both humans and other animals. Which actions seem easiest to implement? Most challenging? Most impactful? Choose one action and briefly outline what would be needed to successfully implement that action.

Investigate the current laws that exist to regulate the use of animals in research. How well are these current laws protecting animals?

8

Access the <u>text for the Animal Welfare Act</u> and make a list of which animals are legally considered "animals" and who is not. Review the history of why the USDA made this distinction. Now look at the data available for the numbers of animals used for the most common species who are used in research. What have you noticed? Now do a little research into the cognition, emotions, and sentient qualities of the individuals from the species most used in research. What questions does all this data and information raise, from both a scientific and ethical viewpoint?

Investigate the historical and existing differences between the intended and actual roles that Institutional Animal Care and Use Committees (IACUCs) and Institutional Review Boards (IRBs) (for human research) play. How do they differ? Are they effective in ensuring scientific justification and ethical practices?



Given the lack of transparency inherent in the medical and scientific research systems, what tools and strategies can be used to ensure transparency and accountability from both a scientific and ethical perspective?



What practical steps can be taken to codify the principles of a Belmont Report for animals into law?

RECOMMENDED READING & ADDITIONAL RESOURCES

RECOMMENDED READING

Ferdowsian, Hope, L. Syd M Johnson, Jane Johnson, Andrew Fenton, Adam Shriver, and John Gluck. "<u>A Belmont Report for Animals?</u>" *Cambridge Quarterly of Healthcare Ethics* 29, no. 1 (January 2020): 19-37.

Ferdowsian, Hope, Agustín Fuentes, L. Syd M Johnson, Barbara J. King, and Jessica Pierce. "<u>Toward an Anti-Maleficent Research Agenda</u>." *Cambridge Quarterly of Healthcare Ethics* 31, no. 1 (January 2022): 54-58.

ADDITIONAL RESOURCES

Aguilera, Bernardo, and David Wendler. "<u>Commentary: Should the Belmont Report Be</u> <u>Extended to Animal Research</u>." *Cambridge Quarterly of Healthcare Ethics* 29, no. 1 (January 2020): 58-66.

Bekoff, Marc, and Jessica Pierce. "<u>Human Behavior Toward Animals Hasn't Caught Up to the</u> <u>Science</u>." The Cut, April 2017.

Chandrasekera, Charu. "It's Time to Think Outside the Cage." YouTube video, 14:21.

Ferdowsian, Hope. "<u>Ethics in Animal Research</u>." *Issues in Science and Technology* 38, no. 1 (Fall 2021).

ADDITIONAL RESOURCES

Ferdowsian, Hope, and John Gluck. "<u>The Ethical Challenges of Animal Research: Honoring</u> <u>Henry Beecher's Approach to Moral Problems</u>." *Cambridge Quarterly of Healthcare Ethics* 24, no. 4 (October 2015): 391-406.

Ferdowsian, Hope, and Agustín Fuentes. "<u>Harms and Deprivation of Benefits for Nonhuman</u> <u>Primates in Research</u>." *Theoretical Medical Bioethics* 35, no. 2 (April 2014): 143-156.

Ferdowsian, Hope, and Debra Merskin. "<u>Parallels in Sources of Trauma, Pain, Distress, and</u> <u>Suffering in Humans and Nonhuman Animals</u>." *Journal of Trauma & Dissociation* 13, no. 4 (2012): 448-468.

Ferdowsian, Hope. "<u>Stop Torturing Animals in the Name of Science</u>." *Scientific American*, September 16, 2021.

Fuentes, Agustín. "<u>The Humanity of Animals and the Animality of Humans: A View from</u> <u>Biological Anthropology Inspired by J. M. Coetzee's *Elizabeth Costello*." *American Anthropologist* 108, no. 1 (2006): 124-132.</u>

Fuentes, Agustín. "Politics of Species." YouTube Video, 14:05, March 2, 2014.

Fuentes, Agustín. "<u>Commentary: Other Animals as Kin and Persons Worthy of Increased Ethical</u> <u>Consideration</u>." *Cambridge Quarterly of Healthcare Ethics* 29, no. 1 (January 2020): 38-41.

Johnson, L. Syd M, and Andrew Fenton. "<u>COVID-19 Animal Research Reveals Ethical</u> <u>Shortcomings</u>." Impact Ethics. September 25, 2020.

Johnson, L. Syd M. "<u>Pigs as Spare (Human) Parts</u>." Impact Ethics. October 26, 2015.

Johnson, L. Syd M. "<u>The Road Not Mapped: The Neuroethics Roadmap on Research with</u> <u>Nonhuman Primates</u>." *AJOB Neuroscience* 11, no. 3 (July 2020): 176-183.

ADDITIONAL RESOURCES

Jones-Engel, Lisa. "<u>Commentary: Trust But Verify</u>." *Cambridge Quarterly of Healthcare Ethics* 29, no. 1 (January 2020): 42-45.

Kantin, Holly, and David Wendler. "Is There a Role for Assent or Dissent in Animal Research?" *Cambridge Quarterly of Healthcare Ethics* 24, no. 4. (October 2015): 459–472.

King, Barbara J. "<u>Grief and Love in the Animal Kingdom</u>." Filmed April 2019 in Vancouver, Canada. TED Video, 14:33.

King, Barbara J. "<u>My Cancer Scars Map the Pain of Animals Held in Research Labs</u>." *Psyche*, May 2021.

King, Barbara J. "<u>A Spider Shows the Way Towards Greater Compassion for Animals</u>." *The Montréal Review*, July 2021.

Wendler, David. "<u>Should Protections for Research with Humans Who Cannot Consent Apply to</u> <u>Research with Nonhuman Primates?</u>" *Theoretical Medical Bioethics* 35, no. 2 (April 2014): 157-173.

Find out more about <u>Phoenix Zones Initiative</u> and our efforts to <u>transform medical research</u>.

Connect with us:

