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Learning Activity 3: Ethics Advisory Committees: How They Are Established & What They Do

Stem Cells & Policy: Values & Religion Module

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The five parts to this learning activity involve reading and discussion, and can be used on their own or in combination and require no prior background learning. The series of assignments move through the stages by which an ethics advisory board is established, empanelled, deliberates, and evolves. Parts A, B, and C pay specific attention to the branches of government that create such bodies, the particular goals that are assigned to them, the qualifications of appointees, and the ways in which these bodies replicate and solve the same problems as the public at large. Namely, how do members of diverse background and differing value systems identify common language and understanding to inform policy for the greater good? Parts A, B, and C use reports, testimonies and papers that informed federal policies in the United States. Part D focuses on the issue of dissent within committees and extends to specific state initiatives (NY and CA) for which there is no consensus. Part E uses a “Science and Society” paper from *EMBO Reports* (2015) that reviews the international landscape and proposes a new way forward with regard to ethical oversight that does not make stem cell research the exception. The five parts of this learning activity are:

Part A: What is the Work of an Ethics Advisory Committee?

Part B: Who Sits on an Ethics Advisory Committee?

Part C: Who and What Informs an Ethics Advisory Committee (Resources and Testimony)?

Part D: How is Dissent in an Ethics Advisory Committee Addressed?

Part E: Is It Time to Move Away from Ethical Exceptionalism for SCR?

Learning Outcomes

- Categorize and summarize evidence-based arguments for and against the liberalization of hESCR and the ways in which policy has been shaped by these competing positions
- Analyze how values embedded in the stem cell debate mirror or challenge other values in social culture: utilitarianism, importance of cultural and religious pluralism, separation (or not) of religion and state; and the place of science and knowledge in an individual or societal hierarchy of values
- Categorize the expertise and experience of members appointed to ethics committees
- Recognize the challenge in amassing and understanding a wide range of evidence to inform deliberations of hESCR policy
- List the ways in which dissenting opinions within, or outside, these ethical deliberations are acknowledged
- Understand the responsibility of advisory committees, review boards, and oversight committees
- Trace the history and formation of regulatory structures designed to provide ethical oversight of hESCR
- Categorize and describe central debates for stem cell research exceptionalism

Part A: What is the Work of an Ethics Advisory Committee?

In this activity, you will compare the charters/missions of the [National Bioethics Advisory Commission](#) for the Clinton Administration (1999), the [President's Council on Bioethics](#) (2001) under the Bush Administration and the [Presidential Commission for the Study of Bioethical Issues](#) (2009) under the Obama Administration to gain a better understanding of their charge, their role in shaping policy, and their authority to do so. You will then be asked to compare these committees to those of specific states sponsoring stem cell research with state public funding. For example, unlike the executive ethics committees all of which were created by presidential executive orders, the NYSTEM Ethics Committee was created by the New York state legislature with Public Health Law Article 2, Title 5-A, Sections 265c.

With respect to presidential committees, presidents act with relative freedom in creating and appointing executive committees. A president's decision to do so does not depend on other government officials, and while the president must ultimately answer the voters (and his or her conscience), a president might consciously or unconsciously play to the interests of the particular constituencies that support the president.

The legislative process for ethics committees at the state level is very different. No one legislator can determine policy without the cooperation of other legislators. Even if individual legislators might personally agree with each other on a given issue, they might be answerable to very different constituencies, depending upon the composition of their legislative districts. Committees created by legislation, it might be argued, are far more dependent on consensus and compromise than those created by executive order.

National Bioethics Advisory Commission [Link](#)

President's Council on Bioethics [Link](#)

Presidential Commission for the Study of Bioethical Issues [Link](#)

NYSTEM Statute [Link](#)

Questions

After becoming familiar with the charters for the three executive committees and one state committee, address the following questions by creating a chart with headings for committee composition, reporting structures, charge, authority, etc.

1. Do all the executive committees report *directly* to the President?
2. Examine closely the way the different charters discuss the goals of the committees they form. Are they the same? For example, which of the committees is specifically charged with identifying "broad, overarching principles to govern the ethical conduct of research"? Which of the charters specifically refers to "consensus," and what does it say about it?
3. What specific sorts of work do the charters foresee for these committees? Are committee members given any compensation for this work? How and who funds these committees?

4. Who determines the agenda for these committees? Which of the charters refer specifically to stem cell research? Do any of these committees have the authority to approve or reject specific research projects?
5. Which charter is the most specific in seeking a balance among the committee members, and what kinds of characteristics does it seek to balance? How are these traits pertinent to bioethical issues? What fields of expertise are sought in appointees? What fields or personal characteristics might be missing?
6. Compare the statute that created the NYSTEM Ethics Committee to the charters of the presidential ethics advisory committees and identify the key differences between them. How might the difference between executive orders and legislative processes explain the differences between the rules governing these bodies?

Part B: Who Sits on an Ethics Advisory Committee?

By now, you are familiar with the rules that govern the creation of ethics advisory committees. Such rules might be considered the ideal, but what about the execution of those ideals in real life? As a first step in thinking about the practical problems of putting together an effective ethics advisory committee, we can start with the members. Study the biographies of the current members of the [Presidential Commission for the Study of Bioethical Issues](#) and the [NYSTEM Ethics Committee](#).

Presidential Commission for the Study of Bioethical Issues [Link](#)

NYSTEM Ethics Committee [Link](#)

Questions

1. In the case of the Presidential Commission, do the biographies seem to correspond to the fields of expertise listed in the charter? Do any areas seem particularly well represented? Do any seem thinly represented?
2. While they are not applicable, these same criteria might provide a point of reference in examining the members of the NYSTEM Ethics Committee. Do the biographies of the members correspond to those criteria? Again, do any areas seem particularly well represented? Do any seem thinly represented? What sorts of academic, professional, and personal experience stand out among the members of the NYSTEM Ethics Committee?
3. While they are not immediately applicable to these bodies, the concerns with ethnicity, gender, and geographical distribution discussed in the NBAC charter and NYSTEM Ethics statute still seem pertinent. What sort of gender and race/ethnicity distribution do you see in the appointees? Do any other characteristics not mentioned in the charter or statute seem to be particularly prominent?
4. Are there points of view that you believe should be represented that are currently absent?

Part C: Who and What Informs an Ethics Advisory Committee (Resources and Testimony)?

The members might come to the work with considerable expertise, but no one member is likely to be familiar with every aspect of the sort of complex issues presented to an ethics advisory commission. Furthermore, the members of the committee must learn a certain degree of cooperation with individuals who possess not only a different area of expertise, but very different political, philosophical, and ethical presuppositions. If the members of the committee are going to be able to deliberate together, they are going to need to digest a great deal of new information very quickly. This is largely accomplished by reading papers and reports prepared for the committee either by its members or by outside experts.

Five papers were prepared for the July 2003 meeting of the President's Council on Bioethics. All five papers were intended to sum up the state of current work on human stem cell research for non-experts. Four of them explain recent scientific developments, while one of them is a review and critique of writing on the ethical issues surrounding that research. While you might want to read all five papers, this exercise will focus on the paper reviewing ethics, written by Paul Lauritzen, and the paper reviewing current hESCR, written by Teneille E. Ludwig and James A. Thomson.

Readings and Resources

Lauritzen, P. 2003. The Ethics of Stem Cell Research. Background Materials for the President's Council on Bioethics. (~14pages) [Link](#)

Ludwig, T. and Thomson, J. 2003. Current Progress in Human Embryonic Stem Cell Research. Background Materials for the President's Council on Bioethics. (~3 pages) [Link](#)

The papers give a sense of the sorts of challenges facing the members of the committee. We strongly suggest that before you read them, you take the time to write down the subheadings the authors use to organize the paper. We also strongly suggest that you note any difficult technical vocabulary and look up the definitions of words with which you are not familiar. Bear in mind that the paper by Ludwig and Thomson reflects the state of scientific research in mid-summer 2003. For a more up to date view see:

Infographics: Chamany, K. et al. 2013. Sources of Stem Cells Radial Infographic. Stem Cells Across the Curriculum. [Link](#). *An information design that integrates the biological, ethical, legal, and social dimensions of embryonic, genetically engineered embryonic, and adult stem cell sources; jpg can be magnified and a downloadable pdf that has hyperlinks to text and video clips.*

Animation Tutorial: University of Michigan. Stem Cells Explained Tutorial. [Link](#)

Questions on the Ludwig-Thomson paper.

1. While this paper is intended to review recent developments in human embryonic stem cell research (hESCR) it is being delivered to an ethics advisory committee and makes several implicit ethical arguments. How does the introduction frame the ethical argument of the paper?
2. What is the implicit argument of the subsection entitled "Human ES Cells as a Model of Early Human Development."? Does that argument extend to the other subsections of the paper?

3. The subsection entitled ‘Pancreatic Differentiation’ makes a prediction regarding expected results of research on uses of hESC in therapies for type-1 diabetes, as well as the time-frame for such work. How does this prediction strengthen the sort of implicit argument made in the previous sections? Has it proven true so far?

Questions for the Lauritzen paper.

1. Like Ludwig and Thomson, Lauritzen is not only setting out a survey of recent ethical literature – he is also making a critique of the way philosopher’s discuss those issues. As part of his argument, he gives a detailed discussion of the statement of the Vatican Academy for Life on hESCR. What points does Lauritzen make about the statement and philosophical response to it? In what ways does his analysis of this dialogue support his main argument concerning philosophical discussion of the moral status of the embryo and hESCR?
2. The second section of Lauritzen’s paper discusses stem cells in terms of “commodification” of the body. Explain what Lauritzen and the authors he cites mean by “commodification.” How does this part of the argument support Lauritzen’s larger argument that too narrow a focus on status of the embryo obscures other issues surrounding stem cell research? If you have completed Learning Activity 2 you may also choose to draw upon the following articles by health law scholars Timothy Caulfield and Ubaka Ogbogu.
3. Caulfield T. and Ogbogu, U. 2012. Stem cell research, scientific freedom and the commodification concern. EMBO reports. 13(1): 12-16. This policy paper analyzes how the word “commodification” is used to uphold notions of human dignity as it applies to stem cell research practices and policies and also introduced a new type of ethics committee; the embryonic stem cell research oversight committee (ESCRO). [Link](#)
4. The third section of Lauritzen’s paper discusses the problem of the boundaries of human nature and the ways stem cell research might erode those boundaries. In his argument, he refers to the works of Waldby and Squier and of Martha Nussbaum. Can you reproduce the points these authors raise?

Part D: How is Dissent in an Ethics Advisory Committee Addressed?

As Part C illustrates, most members of ethics committees hold degrees or have expertise in health policy, philosophy, theology, bioethics, and/or medicine. Few ethics committees include scientists in their membership and this is partly an effort to balance out the membership between committees that address social values related to the research and those that address the scientific value or merit of the research. For instance, most grant review committees for government funding are made up primarily of scientists because peer-review is essential in determining which projects warrant funding based on scientific merit. There have been some exceptions to this division and the President’s Council on Bioethics (PCBE) is one such example. The PCBE in its original composition included scientists, but in later iterations chose not to renew these members as can be seen in the Blackburn piece below. While this article and the prior activities in this assignment focus on the question of the status of the embryo, the issue of compensation for human eggs destined to create human embryos for stem cell research has raised additional ethical

challenges with regard to autonomy, social justice, and health risk, and clinical trials for stem cell treatments pose a new set of concerns regarding access and informed participation. The NYSTEM Ethics Committee deliberated for approximately eighteen months before deciding that the state should offer compensation for human eggs (oocytes) in the context of human embryonic stem cell research, yet there are some NYSTEM members who felt their voices were not heard and some policy makers who felt that the committee did not reflect the values of their constituents. New York is not the only state navigating emerging ethical challenges associated with stem cell research. Sociologist Ruja Benjamin, in her book *The People's Science*, reviews some of the deliberations and challenges that emerged as a result of Prop 71 in California; namely that state bonds are used to fund stem cell research and that no funds can be used to provide payment to oocyte providers. Benjamin also considers how community voices are either silenced or amplified by specific characters that claim to represent a particular stakeholder group in her article regarding the Stem Cell Research and Cures Act. California underwent a series of legislative attempts to reverse the policy on egg provision, which is detailed in the [Eggs & Blood: Gifts & Commodities](#) Module associated with this curriculum.

Reading:

Blackburn, E. & Rowley, J. April 2004. Reason as our guide. *PLoS Biology*. 2 (4):1-3. [Link](#)

Benjamin, R. 2014. Race for cures: Rethinking the racial logics of 'trust' in biomedicine. *Sociology Compass*. 8(6): 755-769. [Link](#)

Fowler, Jack. June 13, 2008. Pro-Life Dem Lawmaker Blasts Embryonic Stem Cell Research Plan. *The National Review*. [Link](#)

Roxland, B. 2012. New York State's landmark policies on oversight and compensation for egg donation to stem cell research. *Regenerative Medicine*. 7(3):397. [Link](#)

Roy, Y. Dec 13 2011. Suit to block stem cell fund dismissed. *Newsday.com*. [Link](#)

Sulmasy, D. March 2009. Deliberative democracy and stem cell research in New York State: The good, the bad, and the ugly. *Kennedy Institute of Ethics Journal*. 19(1):63-78. [Link](#)

Questions

1. What happens when members of an ethics committee disagree? How is dissent among members communicated to the public and are these venues effective?
2. What role should staff members have on ethics committees?
3. Comment on the letter addressed to NYSTEM Staff member Judy Doesschate by Senator Ruben Diaz.
4. How can members of the public weigh in on deliberations? How are calls for open comment on pending proposals made? Who can participate in amending an existing proposal?

5. What qualifies as civil disobedience? When ethics committee members hold the floor, or speak at length on an issue for multiple meetings is it akin to congressional filibustering? Is this considered civil disobedience?
6. How is input from a community gathered in the context of procedural justice (the procedures and protocols that pertain to donor recruitment, biobanking, and policy making) and distributive justice (access to the goods and products of research). Who has voice, and whose voices are silenced?

Part E: Is It Time to Move Away from Ethical Exceptionalism for SCR?

In 2005, the U.S. National Academies published guidelines requiring ethical oversight specific to hESCR, which led institutions receiving federal funding to create Embryonic Stem Cell Oversight Committees (ESCROs). In January 2013, the *American Journal of Bioethics* celebrated its 100th anniversary and chose to focus on stem cell research and in [that issue](#) they asked several legal, ethics, and scientific scholars to weigh in on existing approaches used to navigate ethical challenges associated with the field and to imagine the best way forward. The papers here raise concerns about current practices that promote stem cell research exceptionalism. Like Part D, the papers suggest that there is not yet consensus on the best way forward. The article authored by Stanford bioethicist, Hank Greely, discusses the formation, composition, funding, and charge of the Committee on Guidelines for Human Embryonic Stem Cell Research and suggests that the guidelines should be revisited. The Dolgin news piece reviews the Greely proposal in light of differing national approaches and Caulfield and his colleagues review existing practices across the globe. These authors argue that the last fifteen years of stem cell research have provided us with a wealth of information that can be used to assess the legitimacy of ethical oversight standards and bodies unique to this field of research. However, some members of the California Institute for Regenerative Medicine (CIRM) do not agree.

After reading the pieces below, draft a brief statement that outlines the arguments for and against the continuation of local or national ESCROs as opposed to shifting ethical oversight to existing, or new bodies, in charge of human subjects research, emerging biotechnologies, and animal research.

Reading:

Greely, H. 2013. Assessing ESCROs: Yesterday and tomorrow. *American Journal of Bioethics*. 13(1):44-52. [Link](#)

Dolgin, E. 2013. Time to ditch stand-alone stem cell oversight panels, experts say. *Nature Medicine*. 19(3): 250. [Link](#)

Lomax, G. Jan 16, 2013. CIRM supporting a remarkable experiment in research ethics. *CIRM Blog*. [Link](#)

Caulfield T. et al. 2015. Research ethics and stem cells: Is it time to re-think current approaches to oversight? *EMBO Reports*. 16(1): 2-6. [Link](#)