

Teaching Notes for Learning Activity 3 Ethics Advisory Committees: How They Are Established & What They Do Stem Cells & Policy: Values & Religion

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The five parts of this learning activity review the development, composition, deliberation, and evolution of ethics committees specifically designed to oversee and guide stem cell research. The five parts can be used in isolation or in combination. Each part requires students to spend time outside of class reviewing resources, and will require at least one class session of discussion, though Parts A and B can be discussed on the same day in class.

Level	Title	Amount of Reading	Student Time
Intro	Part A: What is the Work of an Ethics Advisory Committee?	~15 pages	1-2 hours
Intro	Part B: Who Sits on an Ethics Advisory Committee?	2 pages	1 hour
Intermediate	Who and What Informs an Ethics Advisory Committee (Resources and Testimony)?	17 pages; backgrounders for commission and committee members Interactive Infographic on Stem Cell Sources	3 hours
Intro	Part D: How is Dissent in an Ethics Advisory Committee Addressed?	27 pages; review articles and news articles and one letter	3-4 hours
Intermediate	Part E: Is It Time to Move Away from Ethical Exceptionalism for SCR?	14 pages; policy reviews and news and blog posts	2-4 hours

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

We have not attempted a broad historical and theoretical overview of the character and history of ethics advisory committees. Instructors looking for background on the role of such committees in public policy debates surrounding research on human embryos might wish to consult the summary of Thomas Banchoff's *Embryo Politics: Ethics and Policy in Atlantic Democracies* (Ithaca, NY: Cornell University Press, 2011), which is one of the resources in this unit. We have opted for an approach that emphasizes primary sources, including the charters of four different ethics advisory committees as readings in the unit. Three of these were established at the federal level (the National Bioethics Advisory Commission [NBAC], the President's Council on Bioethics [PCB], and the President's Commission for the Study of Bioethical Issues [PCSB]. We have also provided the act of New York State that created the NYSTEM Ethics Committee. For deliberations regarding the development, implementation, and adaptation of the California Institute of Regenerative Medicine, we recommend sociologist Ruja Benajamin's book *People's Science: Bodies and Rights on the Stem Cell Frontier* (Stanford, CA: Stanford University Press, 2013).

The questions below are directed to the federal bodies and are intended to guide students through texts that are not long, but are written in a bureaucratic language that might seem stilted and off-putting to some students. The ultimate goals of discussion should be the answer to the overarching question –what is an ethics advisory committee and what is its role in public policy. The NYSTEM material is included as a point of contrast to the federal bodies and might be omitted due to time constraints.

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

1. Do all the committees report directly to the President?

All the committees advise or counsel the President, but instructors should point out that the charter of the NBAC is particularly specific about the context for this advice:

“The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, chaired by the President; other appropriate entities and the public, on bioethical issues arising from research on human biology and behavior, and the applications, including the clinical applications, of that research.”

The charter is also more specific about exactly how the NBAC will communicate its findings:

“Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, chaired by the President, and then to the appropriate committees of Congress, and other appropriate entities. The Commission may specifically request a response from the Federal department, agency or other entity within 180 days of publication of such recommendation.

“Executive Summaries of each report of the Commission shall be published in the Federal Register or on the World Wide Web. Such summaries shall specifically list the department, agency, or other entity to which any recommendations are directed and the date by which such summaries are expected.

“An annual report shall be submitted to the National Science and Technology Council and the appropriate committees of Congress. It shall contain, at a minimum, (1) the Commission's function; (ii) a list of members and their business addresses; (iii) the dates and places of meetings; (iv) a summary of the Commission's activities during the year; (v) a summary of the Commission's recommendations made

during the year; and (vi) a summary of responses made by departments, agencies, or other entities to the Commission's recommendations during the year."

Students might note that the NBAC charter not only provides the context for the Commission's reports to the President, but also specifies that those reports will be communicated to Congress, and specific government departments, agencies, and entities. The NBAC even has the power to demand a response from those entities (though not, it seems, from Congress) – its recommendations cannot simply be ignored. The other charters are relatively vague about the ways in which the committees they form communicate the result of their work. Students might ask whether this vagueness affects the efficacy of those committees.

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?

At first glance, the missions of these three committees look very similar, but the questions attempt to get at one difference that might be significant. The NBAC is charged with identifying broad bioethical principles. This would seem to assume that such principles exist ("truth") and that there is a consensus on what those principles are. Yet, the only one of the charters to mention "consensus" explicitly, that of the President's Council on Bioethics, says that we should not expect consensus from such a body:

"The Council shall strive to develop a deep and comprehensive understanding of the issues that it considers. In pursuit of this goal, the Council shall be guided by the need to articulate fully the complex and often competing moral positions on any given issue, rather than by an overriding concern to find consensus. The Council may therefore choose to proceed by offering a variety of views on a particular issue, rather than attempt to reach a single consensus position." (Executive Order 13237, Section 2.c)

Thus, the Presidential Council was supposed to develop understanding, but that understanding might not lead to any consensus on overarching principles. The Council's findings might appear more balanced in the sense that they represent the diversity of opinions on the issues, but students might ask how the President will be able to use what might be conflicting advice. The instructor might want to solicit students' reactions to the statement of Amy Gutmann, chair of the Presidential Commission for the Study of Bioethical Issues: "Democracies do better to the extent that they allow people to discuss, including robustly argue about, their differences to try to find common ground where possible -- and, where common ground isn't possible, to come to the greatest respect possible for reasonable differences of perspective on controversial issues." (Stein, 2010).

3. What specific sorts of work do the charters foresee for these committees? Are members of the committee given any compensation for this work? From where does funding for these committees come?

The language used to describe the activities of all three committees is largely the same, suggesting an interest in maintaining procedural continuity and consistency. All of the bodies are authorized to conduct inquiries ("research" in the language of the Presidential Commission for the Study of Bioethical Issues), hold hearings, and to develop reports and other materials. They are given the power to organize committees and subcommittees, giving them a good deal of authority to organize themselves autonomously. Nevertheless, the charters do set out criteria for prioritizing their work. In the words of the NBAC charter, "The Commission shall consider four criteria in establishing priority for its activities:

A. The public health or public policy urgency of the bioethical issue.

- B. The relation of the bioethical issue to the goals for Federal investment in science and technology.
- C. The absence of another body able to deliberate fruitfully on the bioethical issue.
- D. The extent of interest in the issue across the government. (The Commission ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)

This language is repeated almost verbatim in the other two charters (with the exception of the last item.)

The members of all three bodies are treated as temporary/intermittent government employees entitled to per diem and travel expenses. This means that the bulk of their personal income likely comes from some other source. In addition, the members of the committee need administrative and clerical help. For all three bodies, such support comes from the Department of Health and Human Services. In general, commissions and committees like these are funded by the agency that requests input, advice, or guidance, however, in rare cases such as seen in Part E for the Committee on Guidelines for Human Embryonic Stem Cell Research, funding is provided from externally from Private Foundations.

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?

As noted above, all three committees are given considerable autonomy in organizing their work and setting their agendas. In one way, or another, all three committees were authorized to take suggestions from other parts of the government and the general public. There is a slight different, in that the NBAC could receive such suggestions from Congress. The other two charters speak instead of other government agencies, or executive (as opposed to legislative) departments and agencies.

That said, each charter suggests possible topics for consideration by the committee it creates. Thus, the charter of the NBAC notes “the rights and welfare of human research subjects” as well as issues surrounding the patenting of human genes as topics of special importance. “Embryo and stem cell research” are named as issues in the charter of the President’s Council on Bioethics – the close association of these terms reinforcing Banchoff’s point that, in the U.S., ethical objections to embryonic stem cell research have tended to focus on the moral status of the embryo. Concern with the status of the embryo might also be behind the reference to “the creation of stem cells by novel means” in the charter for the Presidential Commission for the Study of Bioethical Issues – “novel” referring perhaps to those means that do not rely on the creation and/or destruction of human embryos. None of the committees has the authority to review and approve specific research projects.

To facilitate comparison, the sections detailing the expertise to be sought in appointees to each committee are set out in three columns below.

<p>NBAC (page 2): “At least one member shall be selected from each of the following categories of primary expertise: (1) philosophy/theology; (ii) social/behavioral science; (iii) law; (iv) medicine/allied health professions; and (v) biological research. At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and non-scientists. Close attention will be given to equitable geographic distribution and to ethnic and gender representation.”</p>	<p>The President's Council on Bioethics (page 2): “The Council shall include members drawn from the fields of science and medicine, law and government, philosophy and theology, and other areas of the humanities and social sciences.”</p>	<p>President's Commission for the Study of Bioethical Issues (page 3): “The Commission members will be drawn from fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, or other areas of the humanities or social sciences.”</p>
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Once again, the provisions of the NBAC charter are far more specific than those of the other two committees. Not only does it make clear that there must be at least one representative from each area of expertise, but it also seeks parity between scientists and non-scientists on the committee. In addition, it takes into consideration issues of gender, ethnicity, and geographical distribution. The pertinence of these first two issues might be obvious to students who have worked on the modules dealing with oocyte donation, or who have read *The Immortal Life of Henrietta Lacks* by Rebecca Skloot. But what do students make of the concern with geographical representation? Students might also want to consider whether the gender, ethnicity, or geographical origin of committee members would be predictive of their stances on any given issue.

While these personal traits are only mentioned in the NBAC charter, there are five terms that are repeated in all three charters regarding the desired fields of expertise among appointees: law, medicine, philosophy, social science, and theology.

“Law” is both coupled with and distinguished from “government” in the charter of the President’s Council on Bioethics. The NBAC couples social science with “behavioral science,” a term that disappears from the other two charters. Likewise, the reference to “biological research” in the NBAC charter seems to have been replaced by the more generic “science.” In the charter of the Presidential Commission, the reference to generic science is supplemented with equally generic references to engineering and technology. Does the switch to generic “science” represent a broadened awareness of the unexpected ways in which different lines of research in different scientific fields might influence each other – or a decreased awareness of the ways that ethical issues in biology might be different from those in another scientific field, like physics? Likewise, does the introduction of engineering and technology to the list represent greater awareness of the practical ways in which applied science poses ethical issues, or an impatience with the more “theoretical” approaches of “pure” science?

Similar questions might be asked about the terms “philosophy” and “theology.” The two terms are closely associated in all three charters – in the charter of the NBAC, they are separated by a mere slash, as if they were essentially interchangeable. The charters of both the President’s Council and the Presidential Commission seem to consider “philosophy and theology” as parts of the humanities and social sciences. But note how important something as seemingly innocuous as a conjunction can be. The charter of the President’s Council follows up its reference to philosophy and theology with “and other areas of the humanities and social sciences” that might supplement philosophy and theology. The charter of the Presidential Commission follows the reference to philosophy and theology with “or other areas of the humanities or social sciences,” as if these other fields could replace philosophy and

theology. Students will probably have questions about the distinction between philosophy and theology. Some might also ask whether the inclusion of theology does not violate the “separation of church and state.”

But perhaps the single most important development in the list of fields of expertise is the introduction of the term “bioethics” in the charter of the Presidential Commission. While the term “bioethics” features prominently in the name of all three committees, bioethics as a recognizable field of study is a relatively recent development. The introduction of bioethics into the desired fields of expertise corresponds to the appearance of bioethicists, individuals who have pursued specialized study and degrees in a new area of knowledge.

While students might identify other differences, the authors feel that discussion of the NYSTEM Committee should touch on the following three points. First, unlike the presidential committees, which directly advise the executive branch of government on a broad range of topics, the NYSTEM Ethics Commission advises the NYSTEM Finance Committee on a more limited range of issues arising directly from stem cell research.

Part B: Who Sits on an Ethics Advisory Committee?

One personal characteristic that seems to be missing from the list of the NBAC appointees, at least to the authors of this module, is personal experience with disability or chronic illness. But it must again be asked whether such personal experience would necessarily indicate that member’s stance on a given issue. Students might come up with unexpected suggestions for fields of expertise or personal characteristics that they feel are missing from those listed in these charters.

Instructors might want to share CHART 1 that indicates academic and professional degrees of appointees to the Presidential Commission for Issues in Bioethics as comparison.

A point of contrast: the NYSTEM Ethics Committee

Unlike the members of the presidential ethics committees, who are all vetted by the President, the power to appoint members to the NYSTEM Ethics Committee is distributed among the governor, the temporary president of the NY Senate, the speaker of the NY Assembly, and to the minority leaders of the Senate and Assembly. Students might want to examine more closely the exact number of each appointees that each officer is authorized to make. Can they provide a reasonable explanation for those differences?

This leads to the third significant difference between the NYSTEM Ethics Committee and the presidential ethics committees. While the charters of the latter spell out key areas of expertise desired in the members of the committee, the statute creating the NYSTEM committee provides no criteria for appointment. Students might want to consider more closely the reasons for the absence of such criteria. One possibility is that since the other bodies discussed above are appointed directly by the President, he is able to articulate criteria for selection to the bodies, while appointment to the NYSTEM committee is in the hands of five different elected officials whose criteria might differ and who might actually appoint members to offset the perceived biases of members appointed by other officials. This might lead to a further question: which system of selection seems more likely to produce diversity and/or balance among committee members – the NYSTEM Ethics Committee or the various presidential advisory bodies? Which seems more likely to be representative of the general public?

Again, instructors might want to ask students to review the expertise and experience of appointees to the NYSTEM Ethics Committee, paying close attention to academic and professional degrees as detailed in **CHART 2**.

Part C: Informing an Ethics Advisory Committee (Resources and Testimony)

The two essays used in this exercise might prove challenging for some college-level students. Indeed, one goal of this exercise is to impress students with the technical challenges faced by the members of an ethical advisory committee, as well as giving students some tools in analyzing difficult texts. Alternatively, instructors could take a case-based approach, and ask students to read the following papers to showcase dissenting opinions or criticisms on processes intended to support democratic deliberation. In the first set the focus is the NYSTEM initiative to pay for oocyte provision to support embryonic stem cell research. The Roxland article describes the process used to arrive at the state decision, while the Sulmasy article challenges the committee's deliberations more generally. The Baylis article below looks at differing perspectives on the ability to support public desires with respect to the UK agency regulating embryo, chimera, and stem cell research. Collectively these shorter articles allow students to develop a critical eye towards governance and public consultation on matters of biomedical research.

Sulmasy, D. P. 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](#)

Roxland, B. 2012. New York State's landmark policies on oversight and compensation for egg donation to stem cell research. *Regenerative Medicine*. 7(3):397-408. [Link](#)

Baylis, Francoise. March 2009. The HFEA public consultation process on hybrids and chimeras: Informed, effective, meaningful? *Kennedy Institute of Ethics Journal*. 19 (1):41-62. [Link](#)

Questions on the Ludwig-Thomson paper.

- 1. While this paper is intended to review recent developments in hESC research, 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?**

The Ludwig-Thomson paper starts out by introducing themes that might seem almost obvious to students at this point in the course – the isolation and culturing of human embryonic stem cells has opened up exciting new opportunities for research and therapies. While they do not use this language, the authors are introducing the goods (or potential goods) promised by this line of research. At the same time, they acknowledge the ethical objections that have been raised against this research, issues historically linked to IVF and at least temporally resolved in President Bush's statement of August 9, 2001. Students might try to compare this historical frame with the one offered by Banchoff. There is at least partial agreement, though Banchoff would take the debate back even further, to at least *Roe v. Wade* and the controversies triggered by the Supreme Court decision to legalize abortion.

- 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?**

Essentially, the implicit line of argument in this paper is that the potential good obtained by research on human embryonic stem cells outweighs the potential evils of destroying human embryos in order to obtain them. (Or, perhaps, that the Bush decision implicitly ended the debate on the use of hESC by opening a restricted number of human embryonic stem cells lines.) The argument in this section reinforces the overall argument of the paper. The first part of the analysis might go like this:

- I. Understanding how to prevent or how to correct serious evils is good. (Unstated premise)
- II. Infertility, birth defects, and miscarriage are serious evils. (Unstated premise)
- III. “[*Lines of research using*] Human ES cells offer a new and unique window into the early events of human development, a period critical for understanding [*and, by implication, preventing or correcting*] infertility, birth defects, and miscarriage.”
- IV. Therefore, research using Human ES cells is good. (Unstated conclusion)
- V. This section also addresses a potential and implicit objection to the argument outlined above.
- VI. As noted at the beginning of the paper, there are serious ethical objections to the use of human ES cells in research.
- VII. Experimentation with non-human tissues, for example mouse tissue, does not pose the same ethical objections.
- VIII. Therefore, the use of non-human tissues, for example mouse tissue, is to be preferred to the use of human ES cells.
- IX. To this implicit objection, this section of the responds.
- X. The use of non-human tissue, for example, mouse tissue, might avoid the ethical objections raised against the use of hES cells, if they could provide the same level of understanding as the latter. (Unstated premise)
- XI. However, embryonic development in mice differs significantly from that of humans.
- XII. Therefore, the use of non-human tissues, for example mouse tissue, is not to be preferred to the use of human ES cells. (Unstated conclusion)

Note that this implicit objection – that the same kind of results can be obtained from research on animal tissue as from human tissue, without the concomitant ethical objections – is implicitly raised and dismissed in the following two sections (“Cardiovascular Differentiation” and “Neural Differentiation”).

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?

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. Does this prediction strengthen the sort of implicit argument made in the previous sections? Has it proven true so far?

Here is Ludwig and Thomson's prediction: "However, given the pace of advances in developmental biology over the last decade, it is likely that in the next five to ten years, it will be possible to routinely generate clinically useful quantities of b-cells from human ES cells." Note the first word of the sentence – "however." The authors are answering another potential objection to the use of hESC in research and therapy, namely, that ultimately, the research will not fulfill the promises it raises. The response appeals to the inevitability of scientific progress, but the problem then becomes the basis of such optimism. How can the authors –and their audience – know that such results are coming? Does the five to ten year frame given here provide a point at which the research should be reconsidered, and if the problems have not been resolved, should this line of research be abandoned?

Questions on 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 hESC research, a statement that you saw in the Dees case study. What points does Lauritzen make about the statement and philosophical response to it? How does his analysis of this dialogue support his main argument concerning philosophical discussion of the moral status of the embryo and hESC research?**

Lauritzen sets out the main thrust of his critique of discussion of the moral status of the embryo at the beginning of the second subsection, entitled appropriately "Beyond Questions of Embryo Status": "This passage from Zoloth helps to illustrate the point I wish to make in arguing that the stem cell debate has been too focused on questions of embryo status and that we must move beyond status questions if we are fully to do justice to the moral questions raised by technological developments associated with stem cell work." This criticism is derived in part from arguments developed by Lisa Sowle Cahill regarding the abortion debate, which she says has focused too narrowly on questions of rights, understood very individualistically, and that this narrow focus has obscured other important issues (and possible solutions).

A key point in Lauritzen's argument is that the debate on human embryonic stem cell research has been framed in terms derived from the abortion debate. (Compare this to the statement at the beginning of the Ludwig-Thomson paper and in Banchoff.) To support this part of the argument, Lauritzen cites the statement of the Vatican Academy for Life, which was also cited in the Dees case study. Lauritzen provides a fairly detailed analysis of the statement. One of the more interesting things that Lauritzen says about the statement is that, "One reason the Catholic church has played such a major role in framing the stem cell debate is that, in defending its position, it combines the two claims we have just noted, neither of which is explicitly religious. First, the early embryo is an individual person with rights and, second, the fact that the embryo is an individual person is confirmed by modern science." This touches on the issue of religion in public policy deliberation. Whether one agrees with them or not, the authors of the Vatican statement claim that their position is not grounded in a religious position peculiar to them, but is backed by science and perceivable to all reasonable people.

Lauritzen discusses recent ethical work on hESCR largely in reference to the sort of argument made in the Vatican Academy statement. It might be noted that dissent to this position has come from both Catholic and non-Catholic sources. His criticism of the narrowness of this approach is succinctly expressed in the statement, "Yet, whether writers are responding more or less directly to Catholic discourse, or not at all, the important point is that the stem cell debate has been remarkably preoccupied with the question of whether the early embryo is an individual person and whether and how the minute details of embryological development help us to answer this question. This is one reason why a fair amount of the ethics literature

on the topic reads like a textbook on embryology.” While he notes that good bioethics depends on sound science, at the very least he raises questions about the role of science in informing the deliberation.

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 this article Caulfield, T. & 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).**

“Commodification of the body” refers to the process by which the body comes to be seen as alienable property that can be bought or traded without regard to its human origin or independent from considerations of personhood. Historically, the issue of commodification of the body arose in regard to the donation of tissues and organs for transplantation. Legally, these body parts must be donated by individuals or the families of the recently deceased – they may not be sold. But it has been pointed out that once tissue or an organ has been donated to a tissue bank, even a non-profit tissue bank, it can later be sold for what amounts to a profit for the bank. If the tissue is then used in research that results in patentable products, the original donor, or his or her heirs, are not entitled to royalties.

It has already been noted that the problems associated with commodification have now extended to the circulation of IVF embryos that have not been used for reproductive purposes either because they were in excess, carry undesirable traits, or created specifically for the purposes of research. But Lauritzen points out that problems raised by commodification are just as pertinent when it comes to adult stem cell research as to research on embryonic stem cells. In fact, he argues that arguments about commodification are likely to represent the next phase of debate on stem cell research, making a prediction that might be compared to the one made by Ludwig and Thomson regarding developments in pancreatic research (see above.) He also makes an interesting distinction between questions of policy and questions of ethics, though he notes that there are ethical issues involved in commodification, specifically the kind of argument regarding justice made by Karen Labacqz.

In their more recent publication in 2012, bioethicists Caulfield and Ogbogu also raise the issue of “definitional baggage” as it relates to the term “commodification.” They argue that a vague definition prevents sound ethical reasoning, something necessary for sound policy. Within the context of their review, they present conflicting and inconsistent policy positions with regard to the inalienable referring to gene patents, altruistic organ donation, and compensation for gametes. Since the publication of this paper, there have been more inconsistencies that may hold precedent for hESCR policy. The court decision in *Flynn v. Holder* challenges decades of policy that prohibited compensation for bone marrow in an effort to address the lack of diversity in existing public banks.

3. **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?**

Lauritzen cites a paragraph from a then unpublished work of Catherine Waldby and Susan Squier that might prove difficult for some students, who may not be familiar with terms like ontogenesis (“coming into existence”), contingency (“a future event that is possible but cannot be predicted with certainty”), and

teleological (“intended for a distinct end”). But he does provide an explanation of the salient point of their argument, namely, that the cultivation and use of hESC effectively negates the notion that the concepts has a “narrative arc,” the sort of biography that is part of being a human person.

Students might reasonably ask why this matters. Lauritzen answers by citing the work of writers like Meilaender, Kass (who was the chair of the President’s Council), and Fukuyama, arguing that if stem cell therapies live up to their promise, they could largely rewrite what is understood to be the “natural” course of human life, one that ideally ends in old age and death, replacing it with an indeterminate increase in longevity that would pit older generations against younger generations in competition for resources. He returns to another point raised by the writing of Waldby and Squier and the article of Patricia Piccinini and Eduardo Kac that raise questions about the boundary between the human and non-human. Here instructors may want to exhibit some of these artists work. See Media and Infographics on the SCAC website and Piccinini’s “The Young Family.”

Lauritzen sees the possible consequences of this blurring of boundaries in Martha Nussbaum’s essay “Compassion & Terror,” which argues that the human experience of compassion is closely tied to a sense of shared human identity. In effect, we see in others the suffering that we might, in other circumstances, have to endure. But that sense of shared human identity, she argues, is threatened by the feeling of disgust and revulsion that overcomes us, oftentimes when we are confronted by the suffering of those who are somehow perceived as being “other,” and therefore not representative of our shared humanity. Lauritzen suggests the stem cell research, and the sorts of changes it might make in our perceptions of the body, threaten to erode our sense of shared humanity, and from there, the feeling of compassion. This compassion is the good that Lauritzen seems to advocate—a good that in many ways is not different from the good advocated in the Ludwig-Thomson paper.

Part D Addressing Dissent in an Ethics Advisory Committee

The five resources used in this exercise reveal the ways in which committee members and citizens voice dissent in scholarly journals, blog posts, and publications that advocate a particular message. It is important for instructors to highlight the year and type of publication and remind students of the Three Question Heuristic if Learning Activity 2 was used.

It is also of note that New York was the first and, as of the date of this publication, the only state to allocate state funds to compensate oocyte providers for stem cell research. The Roxland piece provides a staff member’s overview of the NYSTEM Ethics Committee deliberation process in arriving at this decision and the Sulmasy piece questions the authenticity of this process, while the letter from Senator Ruben Diaz compares the work of the NYSTEM initiative to that of Joseph Mengele in Nazi Germany.

1. What happens when members of an ethics committee disagree? How is dissent among members communicated to the public and are these venues effective?

Blackburn claims that because she was the sole voice of “science” and divergent in her views regarding human embryonic stem cell research from those of other members, she was not asked to serve again on the PCBE. It is important to note that title of her piece “Reason as our Guide” and perhaps return to Learning Activity 1: Word Play in a Pluralistic Society, and ask students whether the title invites discourse or mocks any opposing views as “unreasonable.” It might also be useful for instructors to remind students of the degree to which science has been self-regulated in the US and the origins of such an approach by reading an excerpt from Vannevar Bush’s *Science the Endless Frontier*. Published in 1945 in response to a call by President Roosevelt to invest in science for the public good.

In the case of Sulmasy, his piece tells a very different narrative than the one published by Roxland in the *World Stem Cell Summit journal*. Students should be aware that the World Stem Cell Summit is an annual event that gathers patient advocates, philanthropists, industry executives, clinicians and stem cell researchers to “connect, collaborate and cure”. Though Roxland’s overview emphasizes the ethical issues as related to informed consent, health risk, and financial benefit, there is no address of moral status of the embryo. Where this could be introduced is in the section on the “need for fresh oocytes”, however, this is the only tangential mention of such concerns:

“The Committee also discussed alternative forms of research that do not require oocytes, including induced pluripotent stem cell research (commonly referred to as “iPSC research”), in which adult somatic cells are reprogrammed to a pluripotent state. While the field of iPSC research is promising the Committee asserted that the existence of alternative forms of research does not require foreclosing funding for other potentially valuable forms of stem cell research. It also noted that iPSC research was in a relatively nascent stage and that iPS cells have shown limitations in certain studies.”

That discussions regarding the question of status of the embryo was not introduced or mentioned suggests that the committee did not raise these issues. Thus, Sulmasy questions the weight given to each member of the committee. That the committee strives for consensus but forms advises based on majority is a conflict raised in the Sulmasy piece that is not adequately addressed in the Roxland piece.

2. What role should staff members have on ethics committees?

Both Judy Doesschate and Beth Roxland participate in the NYSTEM Ethics Committee meetings and often take the lead in crafting the agenda and inviting experts to provide background materials. That NYTEM Ethics Committee Members are not permitted to work outside the confines of the monthly meeting means that much of the behind the scenes work and agenda making is conducted by staff members. They are also prohibited from discussing any ethics matters presented to the committee with recipients of NYSTEM funding. Students should consider this operational scheme very closely.

3. Comment Senator Ruben Diaz’s letter addressed to NYSTEM Staff member Judy Doesschate by Senator Ruben Diaz.

The emotions in this letter are strong, as is the language so students can again revisit Learning Activity 1: Word Play in a Pluralistic Society and also consider the responsibilities of policy makers with regard to their constituents. Instructors might want to provide students with additional information regarding a lawsuit against the state for funding oocyte provision for stem cell research brought forward by Feminists Choosing Life NY. The case was dismissed in 2011 but demonstrates yet one more form of communicating dissent by members of the NY community.

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 or piece of legislation?

All Ethics Committee Meetings are public, yet attendees must provide advance notice of attendance and cannot engage in deliberations or speak, though they may view recorded meetings on line or request transcripts. They are simply allowed to observe. In the case of the new guidelines on human embryonic stem cell research at the federal level, open comment was permitted on the guidelines for months but few were aware of this online opportunity. Instructors may choose to juxtapose the approach to support oocyte compensation in California via the Bonilla Bill, with that of New York. This bill was approved by the California congress yet, the advocacy that followed eventually led to its veto by Governor Gerry Brown as is detailed in the Ikemoto review of 2014.

Students should also consider when public comment is being secured. If public comment is only requested after a draft proposal or set of guidelines are issues, then procedural justice may not be met. If the policy making does not begin with a desire to include diverse viewpoints and in particular public views, it can prove challenging to amend or revise a proposed plan after the fact. The Benjamin article regarding a Race for Cures addresses this shortcoming using three very different cases.

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?

This is an open-ended question, but instructors may choose to use the Powerpoints associated with this learning module to stimulate discussion through imagery. The civil disobedience ppt, contains photography from a public protest on the UC Santa Cruz campus regarding stem cell research and animal rights that was in response to a firebombing of a faculty member's home.

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

The four resources in this exercise illustrate the ways that emerging biotechnologies have demanded hyper scrutiny by the public and government officials. This scrutiny is partly the result of budget allocations at the federal and state level and the desire to maintain economic accountability. But perhaps more obvious, is the desire to avoid egregious violations of human rights in the name of biomedical science as has happened in the past (Guatemala Sexually Transmitted Diseases Study, and Tuskegee Syphilis Trial).

Bioethicist Hank Greely, "Assessing ESCROs: Yesterday and tomorrow" details the unusual circumstances that led to the establishment of the Committee on Guidelines for Human Embryonic Stem Cell Research, from its source of external funding, to its member composition, to the ways in which it has or has not promoted advances in this field. This short review provides both instructors and students with an excellent and succinct history of other oversight committees and boards established to regulate and deliberate ethical aspects of animal research, human subjects research, and recombinant DNA research. In this same 100th anniversary issue of the [American Journal of Bioethics](#), other scientists and scholars provide their perspectives on the topic.

The two short news pieces one in *Nature Medicine* and on the CIRM blog suggest a split in the scientific community about proposed next steps with some scientists eager to dismantle the ESCRO mandate and others urging continued caution and guidance by such committees.

The Caulfield et al. (2015) article is the most recent and also provides an international view on how funding mechanisms, the existence of public stem cell banks, and laws prohibiting reproductive cloning in countries other than the U.S. may make it easier for such countries to forego the need for yet another committee to specifically oversee human embryonic stem cell research. 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.

It is important for instructors to highlight the year and type of publication and remind students of the **Three Question Heuristic** if *Learning Activity 2* was used.

The assignment here is a rather cursory one requiring students to categorize and outline 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. The assignment could be easily adapted for a dialogue where students represent specific scholars/ practitioners

views in class discussion or write letters to the editor responding to a recent commentary by Caulfield et al. (Caulfield et al., 2015) article in *EMBO Reports*.

It is important that students be made aware of the changing landscape regarding ethical oversight with human tissues beyond the specifics of stem cell research. In 2015, both the US and the European Union considered applying broad consent to the collection and use of biological specimens in large-scale national projects. In the US, the Common Rule guides the process of informed consent and is mandatory for federally funded research using human research subjects. The Advanced Notice of Proposed Rulemaking regarding the Common Rule involves public deliberations to apply revisions to the Rule and may expand its reach to those projects funded by private dollars and abandon broad consent for de-identified specimens ([Chamany, 2015](#)). The European Union, which had taken a similar approach, reversed its position at the end of 2015 drafting legislation that would grant researchers access to data for which patients or research subjects provided broad consent ([Feldwisch-Drentrup, 2015](#)). Both the ANPRM and the EU legislative process allows for public input, and in some cases, open letters are influencing the final outcomes. In the E.U. the European Data in Health Research Alliance, which included the Wellcome Trust, pushed hard for the reversal using the URL “[Datasaveslives.com](#).” In the US, the National Institutes of Health funded a project to collect public opinion through [surveys](#) informed by a meta analysis of patient and research subjects’ views via the eMERGE consortium working group ([Garrison et al., 2015](#)). More resources regarding these revisions and the history of the Common Rule can be found in the teaching notes to Learning Activity 2 in the [HeLa Cells & HPV Genes: Immortality & Cancer](#) module.

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