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Learning Activity 2:
Teaching Notes for Informed Consent & Payment for Participation in Research
HeLa Cells & HPV Genes: Immortality & Cancer Module
by Katayoun Chamany

In this activity students move through the [7E model of learning](#) proposed by Arthur Eisenkraft (Engage, Elicit, Explore, Explain, Elaborate, Evaluate, Extrapolate) by *eliciting* prior knowledge, *engaging* in discussion of controversial policies, *exploring* secondary literature, infographics, and videos, and *explaining* what they have learned about the biological, ethical, legal, and social dimensions of human subjects research, informed consent, and biobanking. The learning resources consider the arguments for, and against, broad or presumed consent, payment for research participation, and control over the direction of research that involves the collection of biospecimens. These arguments explore the challenges involved in maintaining privacy, determining ownership and rights, and informing research participants of the range of biomedical and scientific activities that utilize biospecimens. This activity is designed to encourage students to *explore* the material on their own and *explain* what they have learned through personalized *timelines*. This approach to teaching and learning is constructivist because the *timelines* reveal what is most important to students and can then serve as reasoning tools in discussing policies for regulating biospecimen collection and banking. As students construct their knowledge they become more self-aware of their own learning. With respect to Blooms Taxonomy, students acquire and remember content knowledge, connect specifics to broader concepts, and synthesize mental models of the information at hand.

Students' visual narratives should not be a replica of the infographics that are assigned but, rather, highlight the biological, ethical, legal, and social issues most important to them and/or a specific community. Using a set of questions provided in the assignment, each student, or group of students, generate(s) a *personalized* visual narrative that highlights the issues most important to them and/or a specific community, including prior knowledge of world history, scientific discoveries, emerging technologies, politics, and human and civil rights movements. It is useful for the instructor to capture their ideas on the board or smart screen. Because the activity draws on personal interest, each group, or student, will respond to the questions differently, highlighting those aspects that are most relevant and meaningful to them. By viewing all timelines, students can see the diversity of responses even within their own class environment. They also begin to realize that biomedical research does not happen in a vacuum and that practices and policies can be influenced by economics, politics, shifting social values, and activist movements. The activity can serve as segue in seminar courses to explore the relationship between science and other academic disciplines, and helps students refrain from segregating scientific knowledge from other forms of knowledge.

STUDENT LEARNING OUTCOMES:

- Map the historical and contemporary trajectory of policies for informed consent and research with human subjects
- Appreciate the challenges in obtaining “consent”
- Understand that “choice” may be contested in the context of opt-out or presumed consent policies

- Compare policies that use “presumed consent,” “community consent,” “broad consent,” “reconsent” or “delayed consent”
- List the challenges associated with storing, tracking, and accessing human biospecimens
- Distinguish between different sectors, public and private, and identify ways in which they are interdependent.
- Provide evidence for opposing views on altruistic donation for human biospecimens

FORMAT

Portions of this activity have been used in a non-majors stem cell course, and a summer bridge course in the Equal Opportunity Program for liberal arts and design students at The New School.

The assignment can involve small group work where each group of students is responsible for reporting out the findings via a visual timeline specific to one topic area presented in the activity’s reading list. Students explore the resources outside of class, develop timelines on their own, and then develop a collective timeline with their peers once they assemble in groups in class. Instructors may also choose to give students time in class to form small groups of 3-5 to discuss among themselves before providing a consensus overview to the remainder of the class. For small group work, see the resources at this site ([Resource One: Group Role Profiles](#)) for role responsibilities that ensure equity in groups, or assign an “equity monitor” who must ensure that all voices are heard in the group and that any missing voices are raised.

Timing

The activity can take 1-4 class sessions. Each of the 4 topics of exploration (Human Subjects History, Contemporary Biobanking, Paying Human Subjects, and “Unknown Consent”) includes a timeline or infographic, a short video, and a collection of readings totaling about 25-32 pages. If the class is split into 4 groups and each one assigned a single topic, all 4 topics can be reviewed in a single class session and the different timelines combined to create a conglomerate timeline. Alternatively, the 4 topics can be explored over 4 different class sessions with students constructing a timeline for each topic.

Readings and Resources

To help students understand the need for improved human subjects research protocols and guidelines, all students read the resources under the topic *Cases for Investigation and Reparations for Human Subjects Research*. The *Nature* editorial titled “[Justice for All](#)” and the Presidential Commission for the Study of Bioethical Issues 2011 Reports titled “[Ethically Impossible](#)” and “[Moral Science](#),” highlight the need to avoid medical injustices inflicted upon the marginalized, or uninformed, and provide a backdrop for the remaining topics. NOTE: the letter exchanges in the Commission Reports are the only assigned reading and in both reports appear on pages v-vi.

The readings in the remaining 5 topic areas include about 20-35 pages of reading alongside one video and one infographic. These resources were intentionally chosen to highlight the processes involved in shaping policy including public comment, consensus building around model informed consent forms, and research investigating the extent to which the informed consent process is effective. Instructors may want to assign the second category, *Human Subjects Research History* to a group or to the entire class depending on background of the students as it traces the history but brings us up to date to 2015.

For instance, under *Contemporary Biobanking* the [Emanuel et al. article](#) details the process of proposing a revised human subjects protocol, the [Botkin et al. study](#) analyzes the public comments to this proposal, the Maxwell piece reviews a research study that demonstrates that participants are not well informed despite these protocols, and the [Caulfield et al.](#) points to future challenges involving commercialization of biobanks.

Additionally, the last section of the [Mohapatra article](#) connects to payment and incentives for cord blood banking specifically for under represented minorities. NOTE: only the first two pages and last 13 pages of this article are assigned as it a very long in its entirety.

Under the *Paying for Belabor or Biological Resources* topic [Lacetera](#) et al. and [Truog](#) et al. both provide examples of situations where human research subjects are paid for their contributions or where altruistic donation is incentivized.

Under the *Unknown Consent* topic the discussion is expanded to egg and sperm providers and those seeking IVF and PGD through fertility centers highlighting the difference in informed consent practices in the clinical versus research setting and the cross talk between private industries and publicly funded research. The [optional reading by Wolfson et al.](#) in this section would be well suited to an engineering, epidemiology, or computer programming class as it demonstrates how answers to social problems can sometimes be solved by innovations in science and mathematics.

The references under the *Broad Consent & Data Sharing* topic connect to those under *Contemporary Biobanking* and address the changing landscape regarding ethical oversight with human tissues beyond the specifics of 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 processes allow for public input, and in some cases, activism and lobbying 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](#)).

The activity's readings mesh well with the chapters in *The Immortal Life of Henrietta Lacks* by Rebecca Skloot or articles detailing the case of John Moore and Ted Slavin. These two individuals sought ownership of their biological specimens and challenged the idea that informed consent had been achieved when they were seeking medical care.

If instructors want to focus on the **media's coverage** and the public deliberation of privacy issues regarding genomic data, Chris Brainard's article highlighting Rebecca Skloot's criticism of the media's coverage of the HeLa Genome data breach is a wonderfully rich analysis of this and excellent for students interested in education, outreach, social media, and journalism.

Brainard, C. March 28, 2013. HeLa-cious Coverage: Media Overlook Ethical Angles of Henrietta Lacks Story. *Columbia Journalism Review*. [Link](#)

If instructors would like to assign **only one article** that touches on biobanking, federal laws, and the case of **Henrietta Lacks and John Moore**, the paper by Gail Javitt provides a good deal of information though it does not address the Havasupai and DNA banking, nor does it address the race, class, and gender perspectives.

Javitt G. 2010. Why Not Take All of Me? Reflections on The Immortal Life of Henrietta Lacks and the Status of Participants in Research Using Human Specimens. *Minnesota Journal of Law, Science & Technology*. 11(2):713-55. [Link](#)

Another option would be the article by Hannah Landecker, Science, Technology and Society scholar, that addresses the notion of **race and bioslavery**, but does not expand to contemporary biobanks.

Landecker, H. 1999. Between beneficence and chattel: The human biological in law and science. *Science in Context*. 12 (1): 203-225. [Link](#)

The most up to date article addressing genetic data sharing was published in response to a series of legislative measures regarding “broad consent.” These measures would allow researchers to share genetic data for secondary research questions without requiring re-consent and the authors specifically address populations that have in the past not only been marginalized, but harmed by biomedical practices.

Arias, J., et al. 2015. Trust, vulnerable populations, and genetic data sharing. *Journal of Law and Biosciences*: 1-7. [Link](#)

Alternatively, these views can also be addressed by showing the 15-minute video of Radhika Rao’s presentation at *The Challenge of Informed Consent in Times of Controversy Symposium*, hosted by UC Irvine Law School on Nov 11, 2015.

Rao, R. The Challenge of Informed Consent in Times of Controversy Symposium. UC Irvine School of Law. November 13, 2015. [Video Link](#). Please note that the video is 8 hours in length, but Radhika and others speak towards the end at 5 hour:48 minutes – 6 hours:03 presentation AND at 6:31- 7:07 for clarification in Questions and Answers. An agenda can be found here. [Link](#)

Videos

Showcasing videos during class can be useful if the class is broken into four groups and each group is addressing a single topic. In this way, the entire class can quickly get up to speed before seeing each group’s timelines. The [first video](#) under *Human Subjects Research History* by UMN is a news piece that highlights how far ethical conduct has come since 1790, using the novel by Mary Shelley *Frankenstein*. The second video “[Medical Innovation](#)” under *Contemporary Biobanking* is produced by the *British Medical Journal* and describes the UK Biobank containing samples from over 500,000 altruistic donors. The [video](#) under *Paying Human Subjects* details a court case resulting in bone marrow donors being compensated for their contributions. This court case challenged the assumption that bone marrow donation is regulated by the National Organ Transplant Act. The last [video](#) under *Unknown Consent* also addresses a lawsuit, but one that was settled out of court concerning genetic testing of the Havasupai with respect to lineage and schizophrenia without their consent. In this last video, the Henrietta Lacks case is also discussed.

Bioethics

In bioethics four principles guide research practice: autonomy; nonmaleficence; beneficence; and justice. The process of informed consent is designed for potential research participants to exercise autonomy in choosing to participate in research based on an analysis of risk and benefit. The notion of justice is addressed through “just participant selection” such that the population that would benefit the most is selected for the research participant pool and that no one population experiences disproportionate risk or burden.

Instructors may need to remind students that protections for human subjects research in the US were not put into place until the National Research Act was signed into law in 1974. This history is provided in the

shared readings section under Human *Subjects Research History*. Following the publication of the Belmont Report, authored by a presidential commission, informed consent was effectively put into practice in 1981 as “The Common Rule.” It is also important to note that this policy only regulates publicly funded research using human research subjects, not privately funded research. Thus, the informed consent process was not in place at the time that cells were removed from Henrietta Lacks’ cervical cancer biopsy, though there was general consensus emerging post-WWII that research subjects should participate voluntarily as stated in the Nuremberg Code (1948) and be informed as to risks and benefits as stated in the Declaration of Helsinki (1964).

Instructors may want to provide students with an abbreviated overview of quotes from these standard resources:

The voluntary consent of the human subject is absolutely essential.-*Nuremberg Code 1948*

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject’s freely-given informed consent.-*Declaration of Helsinki 1964*

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.-*Belmont Report 1979*

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.-*The Common Rule 1981*

- [Protection of Human Subjects — 45 CFR 46](#)
- [The Belmont Report](#)
- [The Nuremberg Code](#)
- [Institutional Review Board Guidebook](#)
- [World Medical Association Declaration of Helsinki](#)
- [Compilation of National Policies](#)

It may be useful for instructors to confront unethical practices in biomedical research openly and illustrate the ways in which current regulation comes up short and the struggle to maintain oversight and retribution for such practices continues. In light of the report of unethical practices conducted on human subjects during the Guatemalan STD study conducted by the US Public Health Service in the 1940s, President Obama requested that a review be conducted on human subjects research. The letter exchanges between the President and the Presidential Commission for the Study of Bioethical Issues is instructive, as recommendation #7 calls for education at the undergraduate and graduate level on human subjects research and bioethics. The Executive Summary is in the first 28 pages. In July 2012, an editorial in *The New England Journal Medicine* titled “Justice for injured research subjects” references this report and speaks to proposals to bring the United States policies and practices surrounding research with human subjects in line with those of other developed countries to address injuries sustained as a research participant ([Elliot, 2012](#)). A new set of proposed guidelines for the Common Rule has been reviewed and open to comment over the last three years and some significant changes are reviewed the references published in 2015 and assigned to students.

PREPARING FOR PRIOR KNOWLEDGE FROM STUDENTS

Instructors may benefit from reviewing the [HeLa Cells & HPV Genes Primer](#), as many students will have alternative histories regarding research conducted on minorities, the incarcerated, and orphans. For

instance, Harriet Washington's book *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present*, Michele Goodwin's book *Regulating Contestable Commodities in the Global Body Market: Altruism's Limits* and Dorothy Roberts' *Killing the Black Body: Race, Reproduction, and the Meaning of Liberty* are popular texts in some Gender and American Studies courses. Similarly, the authors of *Achieving Justice in Genomic Translation: Re-Thinking the Pathway to Benefit* evoke a responsive justice framework to call on researchers to take greater responsibility in protecting subjects and communities, specifically addressing redistribution and recognition with respect to underserved communities (Burke, et al. 2011; page 3-20 in Google Books). Likewise, Ruha Benjamin's book *People's Science: Bodies and Rights on The Stem Cell Frontier* specifically addresses procedural justice with respect to who participates in life science research, as a scientist, research subject, policy maker, activist, or lobbyist. Her case analysis centers on the political process behind the establishment of the California Institute of Regenerative Medicine (CIRM) and reveals the complex network of stakeholders behind this initiative. She challenges the notion that health inequity is the by-product of a competitive edge, and ends the book with a proposal for a more equitable way forward that simultaneously promotes biomedical innovation and equity.

TIMELINE CONSTRUCTION

All students will need to engage with graphic representations of information, whether graphs, maps or diagrams. However, instructors should not assume that students always know how to interpret or use these appropriately. Making their own versions helps to develop a more sophisticated understanding of the relationship between symbolic representations and what is being described. Instructors may want to explore pedagogical resources that demonstrate how the use of timelines can improve student retention of content knowledge. Verbal encouragement for the utility of visualizations and diagrams and practice in class suggests that students may be more motivated to generate such learning tools spontaneously and enhance learning in two ways; by highlighting what aspects of the topic are relevant to students and to represent the simultaneous push and pull that can occur across wide sectors of society. If students need an example that is HeLa specific instructors may want to show them this beautiful one created by Walbaum for *Wired* magazine.

Biba, E. Jan 25, 2010. Henrietta Everlasting: 1950s Cells Still Alive, Helping Science. *Wired*. [Link](#)

A short bibliography is provided below that reviews strategies and tools to promote this kind of activity.

Lin, C., et al. 2010. Making science vivid: Using a historical episodes map. *International Journal of Science Education*, 32(18), 2521. [Link](#) *This paper has a number of visual examples.*

Getman, J. May 3, 2011. Timelines. Teaching with Technology Conference. [Link](#) *A short slide show highlighting some easy to use timeline software, including an excel template and Dipity.*

Ainsworth, S. et al. Aug 2011. Drawing to learn. *Science*. 333 (6046): 1096-97. [Link](#) and response by Manalo and Uesaka [Link](#)

Dietz, K. 2012. Storied Infographics: Why Do They Fail? *In* Why Data and Infographics Help. E Marketing 101 Serving a Need. [Link](#)

Ridley, P. and A. Rogers. 2010. Drawing to Learn in the Arts and Humanities. Centre for Learning and Teaching University of Brighton. [Link](#)

Uesaka, Y. et al. 2010. The effects of perception of efficacy and diagram construction skills and students' spontaneous use of diagrams when solving math word problems. *Lectures Notes in Computer Science. In* Diagrammatic Representation and Inference. 6170:197-211. [Link](#)

FURTHER LEARNING: Instructors and students would benefit from combining this activity with [Learning Activity 1](#) or following this activity with [Learning Activity 3](#) (elaborate, evaluate, extrapolate) or assigning the [Primer](#) associated with this module. A collection of [Discussion Questions](#), [Timelines](#), [PPT slide sets](#), [Essential Resources](#), and [Infographics](#) tracing the trajectory of technologies and policies are also available.

NOTE of IMPORTANCE REGARDING INTERSECTIONAL ANALYSIS

As many will be unfamiliar with intersectional analysis and the alternative narratives of Henrietta Lacks, instructors are encouraged to review the [Pedagogies and Philosophies](#) document on the *Stem Cells Across the Curriculum* website and the [Primer](#) associated with this module. The [Primer](#) provides a comprehensive view of many of the topics that will emerge during discussion with learners from diverse backgrounds.

ASSESSMENT: A rubric can be constructed based on the goals of the course and shared with students beforehand. For instance, students can be directed to provide 3 significant events on the timeline for each of the following categories: biological discoveries, technological advances, policy, activism, legislation, or the assignments can be more general, suggesting a total of 10 events that span those areas.

An example (fig 1) on the next page in which the prompt and resources were slightly different is provided to highlight the ways in which students bring their lived experience to the timelines. As can be seen, students recognized that emerging threats such as polio and small pox propelled the vaccine movement and a need for a suitable model cell line for testing. They rightly place the civil rights movement *after* the establishment of the HeLa cell line. Additionally, they provide commentary regarding their interpretation for why congressional representatives were requesting acknowledgement for altruistic donation from Henrietta Lacks. So though this timeline does not have many events, the choices behind those that are included provide insight as to how students' mental schemas are being developed and shaped. The outcomes also reveals how students move from situational interest (an assignment that an instructor deems important) to personal interest as can be seen by the layering of new knowledge onto prior knowledge that is meaningful to them. In a [seminar-based course on stem cell research at Eugene Lang College](#), students had completed the *HeLa Cells & HPV Genes: Immortality and Cancer* Module and were in the midst of the *Eggs & Blood: Gifts & Commodities* Module and were asked to collectively construct a timeline (fig 2) of important events regarding the use of human cells, bodies, or embryos in research. As can be seen the government oversight regarding embryos is outlined in purple ink, but a number of other laws are depicted regarding human subjects research in the US, embryo research in the UK (HFEA), and human embryonic stem cell research at the state level. This timeline is much more focused on events central to the course and has less prior knowledge of larger social movement, history, and events.



