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## **Learning Activity 2: Informed Consent & Payment for Participation in Research**

### **HeLa Cells & HPV Genes: Immortality & Cancer Module**

*by Katayoun Chamany*

With new advances in biomedical and genomics research, patient autonomy within the practice of informed consent is being revisited. Early on, risk (maleficence) and benefit (beneficence) were confined to side effects and therapeutic outcomes, but later, as protocols for clinical testing and FDA approval emerged, risk and benefit began to expand beyond the area of “health.” Today, healthy volunteers in clinical trials can gain financial benefit in the form of payment or compensation, contributors of genetic information must consider privacy and discrimination risk associated with release of genetic information, and patients must be aware of profits made from research on biospecimens collected as part of diagnosis or therapy.

Standards of ethical conduct are mandated by Institutional Review Boards as required by the National Research Act of 1974, however, these guidelines are in need of updating and revision given the unusual nature of cells as propagating entities or “biologics.” Professional working groups and ethics advisory councils, such as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Office of Management and Budget Working Group to Revise the Common Rule, the National Academy of Sciences, and the American College of Genetics and Genomics have issued statements regarding ethical conduct for research with human subjects and healthcare provider responsibility to inform patients of incidental genomic findings. Not surprisingly, in the era of stem cell research, new oversight committees have emerged, such as ESCROs (Embryonic Stem Cell Research Oversight Committees) and SCROS. Additional oversight has emerged as a means to avoid medical injustices inflicted upon the marginalized, or uninformed, as described in the *Nature* editorial below titled “Justice for All” and the Presidential Commission for the Study of Bioethical Issues 2011 Report titled “Ethically Impossible.”

With respect to compensation for participation in research there are a range of responses. Some believe that that incentives, or financial compensation, can address the need for bioresources to assemble large data sets to advance scientific and biomedical research, while others see biobanking as a civic duty to support a public good, not unlike other requirements in society, such as taxation, catalytic converter requirements for cars, and anti-smoking laws. Those that challenge this latter stance, argue that each individual should be able to act autonomously, and that the choice to participate should be protected or recognized. There also appears to be a level of “bodily exceptionalism,” at play, such that contributions involving internal resources (blood, DNA, cells) appear to warrant a different level of oversight and regulation than contributions involving external resources such as money (taxation) or demographic information (census). Thus, some would argue that it is bodily integrity, not autonomy that is important. The range of responses to these positions, proposals, and practices is varied, reflecting the plurality of opinion even within groups that traditionally hold uniform voice.

**For this activity you will:**

- Read the references listed under *Cases for Investigation and Reparations for Human Subjects Research*. Note: Commission readings only ask that you read the letter exchanges on pages v-vi.
- Review the resources for the topic assigned to you by your instructor
- Create a visual timeline of events, court cases, and policies that have informed research practices and the development of human biobanks.
- Be prepared to collaborate with your peers on a single timeline reviewing all topics and to participate in discussion.

The timelines are designed to frame discussion that responds to the questions below. The timeline should not be a replica of the infographics that are assigned but, rather, your timeline should be personalized including prior knowledge of historical events, scientific discoveries, emerging technologies, politics, and social justice movements that occurred between 1940 to the present. It is important that you highlight those moments in time that are most relevant to you and/or a specific community. You may use hand drawn timelines or review this short slide show, which has a downloadable excel template for timelines and references to online software.

Getman, J. May 3, 2011. Timelines. Teaching with Technology Conference. [Link](#)

**Some of the questions this activity addresses are:**

- What are the central tenets of informed consent?
- Which historical events shaped policies and practices regarding research with human subjects?
- Who should be able to provide informed consent? A government or tribal leader for its people in the case of genome banks? A parent in the case of saviour siblings? A patient with a terminal illness?
- Given the open nature of basic scientific research, how does one provide consent for future uses or applications, or understand the scope of unknown health risks associated with a procedure or drug?
- Should people be compensated for “donating” biospecimens or should non-cash incentives be put in place?
- Should biobanking of human tissues, cells, and DNA be considered a civic duty to support a public good?
- Should the default option for any clinical assessment involve inclusion in public biobanking with no further conversation regarding consent, control over the direction of research that involves the collection of biospecimens, nor any ownership of resources or profits that may result? In this scenario, opting out requires a pro-active option on the part of the patient.
- How can altruistic donations enter the global bioeconomy without donor’s consent?

**At the completion of this activity you will be able to:**

- Map the historical and contemporary trajectory of policies regarding 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” or “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

## Resources

### *Cases for Investigation and Reparations Regarding Human Subjects Research*

1. September 2011. Presidential Commission for the Study of Bioethical Issues. Letter Exchange between the Commission and President Barack Obama. *In Ethically Impossible: STD Research in Guatemala from 1946-1948*: v-vi. [Link](#)
2. December 2011. Presidential Commission for the Study of Bioethical Issues. Letter Exchange between the Commission and President Barack Obama. *In Moral Science: Protecting Participants in Human Subjects Research*. v-vi. [Link](#)
3. Anonymous. 2012. Justice for all. *Nature*. 484 (7394):287. [Link](#)
4. Eliot, C. 2012. Justice for injured research subjects. *NEJM*. 367:6-8. [Link](#)

### *Human Subjects Research History*

1. University of Nevada. History of Research Ethics. Research and Graduate Studies UNLV. (1pg) [Link](#)
2. GAO. March 26, 2009. HIGHLIGHTS: Human Subjects Research. Undercover Tests Show the Institutional Review Board System is Vulnerable to Unethical Manipulation. Government Accountability Office. (1/2 pg summary) [Link](#)
3. **Infographic**: Chamany, K. et al. 2013. History of Human Subjects Timeline. *Stem Cells Across the Curriculum*. [Link](#)
4. **Video**: UNM. 2014. UNM Paper: Would Frankenstein's experiment fly today? KRQE.com Youtube. (2:20 min) [Link](#)
5. Wentworth, K. Oct 7, 2014. Frankenstein and the Institutional Review Board. UNM Newsroom. [Link](#)
6. Harrison, G. and Gannon, W. Sept 2014. Victor Frankenstein's Institutional Review Board Proposal, 1790. 1-19. *Science and Engineering Ethics*. [Link](#)
7. Hudson, K. and Collins, F. Oct 28, 2015. Bringing the common rule into the 21<sup>st</sup> century. *NEJM.org* [Link](#)

### *Contemporary Biobanking*

1. **Video**: April 21, 2011. Medical Innovation: Biobank. BMJ Innovations. Youtube. (7:49) [Link](#)
2. **Infographic**: Chamany, K. et al. 2013. Adult. Adult Cell Source. Blood Stem Cells ZoomGraphic. *Stem Cells Across the Curriculum*. [Link](#)
3. Emanuel, E., et al. 2011. Reforming the regulations governing research with human subjects. *The New England Journal of Medicine*. 365:1145-1150. [Link](#)
4. Moran, N. Jan 2013. Banking iPS cells. *NatureBiotechnologyNews.com*.31:11. [Link](#) and [StemBancc](#)
5. Mohapatra, S. Fall 2013. Cutting the cord from private cord blood banking: Encouraging compensation for public cord blood donations after Flynn v. Holder. University of Colorado Law Review. 84: 932-934 and 970-983. [Link](#) *Note that this article is very long, and you are being asked to read ONLY the abstract on the first two pages and the last 13 pages.*
6. Maxwell, A. Jan 2015. Biobanks and Donors: How to Understand What is Understood. ThermoFisherScientific. [Link](#)
7. Botkin, J. et al. 2014. Proposed regulations for research with biospecimens: Responses from stakeholders at CTSA consortium institutions. *American Journal of Medical Genetics*.164(4): 892-897. [Link](#)

8. Caulfield, T. et al. March, 2014. A review of key issues associated with the commercialization of biobanks. *Journal of Law and Bioscience*. 1(1):94-110. [Link](#)
9. Mcgrary, C. Oct 15, 2015. ResearchKit at 6 months; 100,000 people now using medical apps. *MacWorld*. [Link](#)

#### *Paying for Biolabor or Biological Resources*

1. Anonymous. 2003. Eggs shared, given, and sold. *The Lancet*. 362(9382): 413. [Link](#)
2. VanderWalde, A., & Kurzban, S. 2011. Paying human subjects in research: Where are we, how did we get here, and now what? *Journal of Law, Medicine & Ethics*. 39(3):543-558. [Link](#)
3. Truog, R. et al. 2012. Paying patients for their tissue: The legacy of Henrietta Lacks. *Science*. 337:37-38. [Link](#)
4. Anonymous. Jan 18, 2012. Court Asked to Reconsider Ruling on Bone Marrow Compensation. *Los Angeles Times*. Nation Now. [Link](#)
5. **Infographic:** Chamany, K. et al. 2013. History of Policies and Human Tissues Timeline. *Stem Cells Across the Curriculum*. [Link](#)
6. **Video:** Schmitz, A. and Naggiar, S. March 15, 2013. Mom of Girl in Need of Transplants Wins Fight to Compensate Bone Marrow Donors. Rock Center with Brian Williams. NBC.com. Rockcenter.com. (7:56min) [Link](#)
7. Lacetera, N. et al. 2013. Economic rewards to motivate blood donations. *Science*. 340(6135): 927-928. [Link](#) podcast [Link](#)
8. Cyranoski, D. May 15, 2013. Human stem cells created by cloning. *Naturenews.com*. [Link](#)
9. April 28, 2015. Thank you for sharing. *Nature*. 520: 585. [Link](#)

#### *"Unknown" Consent*

1. **Video:**Thirteen/Education Broadcasting Corporation (Producer.) June 25, 2010. Religion & Ethics Weekly: Informed Consent and Medical Research. (7:22 min) [Link](#)
2. **Video:** Informed Consent: Genomics Video & Resources. *Stem Cells Across the Curriculum*. [Link](#)
3. Couzin-Frankel, J. April 30, 2010. DNA returned to Tribe, Raising Questions About Consent. *Science*. 328(5978):558. [Link](#)
4. Wadman, M. June 15, 2010. Disease cells fail to win approval. *Nature News*. [Link](#)
5. **Infographic:** Chamany, K. et al. 2013. History of Biomedical Research Timeline. *Stem Cells Across the Curriculum*. [Link](#)
6. Chapman, A., & Wyndham, J. 2013. A human right to science. *Science*. 340(6138):1291. [Link](#)
7. Lehrman, S. Jan 16, 2013. Shifting Roles, Shifting Research: Collaborative Genetic Studies with Indigenous Communities. SACNAS. [Link](#)
8. Garrison, N. March 2013. Genomic justice for Native Americans: Impact of the Havasupai case on genetic research. *Science, Technology, & Human Values*. 38(2):201-223. [Link](#)
9. Kaiser, J. Feb 7, 2013. Did sperm and egg donors unwittingly contribute to NIH-approved stem cells? *ScienceInsider*. [Link](#)
10. Kaiser, J. 2013. Agency nixes deCODE's new data-mining plan. *Science*. 340(6139): 1388-1389. [Link](#)
11. Petrini, C. 2014. Umbilical cord blood banking: From personal donation to international public registries to global bioeconomy. *Journal of Blood Medicine*. 4(5):87-97. [Link](#)

12. **Optional:** Wolfson, M., et al. 2010. DataSHIELD: Resolving a conflict in contemporary bioscience - performing a pooled analysis of individual-level data without sharing the data. *International Journal of Epidemiology*. 39(5):1372-82. [Link](#)

#### *Broad Consent & Data Sharing*

1. Brainard, C. March 28, 2013. HeLa-cious Coverage: Media Overlook Ethical Angles of Henrietta Lacks Story. *Columbia Journalism Review*. [Link](#)
2. Garrison, N. et al. Nov 19, 2015. A systemic literature review of individual's perspectives on broad consent and data sharing in the United States. *GeneticsinMedicine*: 1-9. [Link](#)
3. Chamany, K. Nov 19, 2015. New Rules Proposed to Address Privacy and Trust in the Precision Medicine Initiative. *Biopolitical Times*. Center for Genetics and Society. [Link](#)
4. Feldwisch-Drentrup, H. Dec 19, 2015. E.U. frees up data for science. *ScienceInsider*. [Link](#)
5. Merson, L., et al. 2015. Trust, respect, and reciprocity: Informing a culturally appropriate data-sharing practice in Vietnam. *Journal of Empirical Research on Human Research Ethics*. 10(3): 251-263. [Link](#)
6. Arias, J., et al. 2015. Trust, vulnerable populations, and genetic data sharing. *Journal of Law and Biosciences*: 1-7. [Link](#)