Questions to Consider

Learning Activity 3: HeLa Cells & HPV Genes: Immortality & Cancer

Informed Consent, Compensation, & Ethics

1. When Henrietta Lacks was seeking medical care, guidelines for the use of human subjects in research were not yet established in the US. Rather, in an attempt to revitalize the nation after WWII, the US shifted its focus in scientific research from physics to support military defense to biology in the service of drug and vaccine development. Riding the wave of nationalism, some claim that this was a time of extreme and unquestioned altruism to support biomedical research. Thus, it was considered a time of presumed and blanket consent to use any tissues collected during clinical diagnosis or treatment. Consider those that might view this time differently given the next few decades of social upheaval.

2. In the case of Henrietta Lacks and John Moore were they wronged? Should consent have been sought? Should they have been informed of the research using their bodily tissues and blood? If not, justify the actions of the clinicians and researchers who participated in moving these biospecimens from the clinic/hospital, to the labs, and to markets.

3. Are individuals, or their families, owed anything, if their bodily materials prove essential to developing profitable products? If so, by whom? (whether in the form of a share of profits of damages)

4. How does regulation and monitoring come into play if volunteers are treated as research subjects? What about patients who are also research subjects? Are the protocols different based on different levels of risk and benefit associated with participation by these two very different groups of participants?

5. Are biospecimen providers adequately informed about benefits and risks? Is this different for patients versus “healthy” volunteers?

6. What kinds of information or data need to be made available for individuals to consider contributing biospecimens to research? Does this information exist, or is it being gathered; should it be? Would having this information support a research ethics approach to tissue donation?

Nation, State, or Individual Agency & Autonomy:

7. Should public money be used to support biobanking? If not, what are the alternatives and how might that impact biomedicine, research, and utility to society?

8. Why have various nations adopted public funding efforts to establish biobanks? If not governments, who would construct biobanks? Are there different consequences if the work takes place in the private versus the public sector?

9. Should people have a choice in how their individual bodies serve biomedical research, or should tissue banking be considered a social good in which opt-out models for collection of biospecimens are used? If the latter, should nations, communities, and local leaders, offer some protections to vulnerable populations?

10. 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?

11. As of December 1, 2015 Wales joined the list of countries that uses an opt-out approach to tissue collection from cadavers. In the US several states use an opt-out for collection of blood spots from newborns upon delivery in public hospitals. Governments claim that the resources obtained provide essential data or material to inform public health policies. In places that do not support universal healthcare system, should opt-out programs be put in place? Are they part of the social contract for those countries that invest in universal healthcare?

12. How are these policies and practices reflective of social values? What is being valued or devalued?

Scientific Advances

13. Why is biobanking important for life science research? What are the alternatives; what would be gained/lost in terms of scientific knowledge?

14. When cells are grown outside the body in culture, they adopt different fates, express different genes, why is this important for researchers to investigate? How has this informed culture techniques going forward?

15. Cancer research continues to be dependent on large-scale biospecimen collection for both cell and DNA analyses. How does sample size of the collection influence the research?

16. The use of de-identified samples is seen as a positive for some researchers who may want to use a sample to address multiple scientific questions but other researchers see the de-identification of samples as problematic to public health and life science research. Can you explain both views?

Policy, Law, & Regulation

17. Consider current laws, guidelines, executive orders, and structures for human research subjects, biospecimen (cells, tissues, organs) acquisition, and SCR; consider these at the state, national, and international level. Are these enforceable and, if so, how? Have they been challenged in a court of law or by activists? What are the drawbacks and how can they be mitigated?

18. Are there any policies regarding compensation for bodily goods (gametes, blood, tissues), incentives for public biobanking, and cost coverage for cell transplant therapies?

19. What policies should be implemented to clarify or change the way people are recruited, monitored, and acknowledged for providing biospecimens? Should practices surrounding biospecimen collection and use differ based on purpose; drug development versus research? Where does one draw the line? How has the Bayh-Dole Act complicated matters?

20. Do biospecimen providers have a right to compensation, payment, or some other form of acknowledgement for their services and time? If so, should there be a ceiling or cap on payment and who provides the compensation, and who determines the level of compensation? What is the Wage Payment Model? What other models exist for compensation or payment in medicine or research?

21. What policies should be implemented to clarify or change the way medical samples or human cells are used in research?

Social Justice Perspectives

22. Who decides how biospecimens are obtained, regulated, marketed? Are there ethical concerns about equity, diversity, access, and exploitation?

23. How does the case of Flynn vs. Holder reframe NOTA (National Organ Transplant Act), and what implications does it hold for cell research. Does it border on a loss of human dignity through commodification of bodily tissues? Are there ways to use contract or property law to inform policy?

24. Many different perspectives have been used to address this topic, which ones resonate with you and why? Consider the right to choice, autonomy, equity, and protection of individual rights and the public's health.

25. With Direct to Consumer DNA testing becoming more available through recreational genomics companies such as 23andMe, more and more people are participating and contributing to biomedical research. In 2015, SageBionetwork and Apple launched ResearchKit and shortly thereafter a number of apps were developed to recruit large numbers of participants in research studies focused on Parkinsons, breast cancer, heart disease, diabetes, and asthma. Consider the advantages and disadvantages to collecting data in this way.