

Author: Valerie Racine

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**Class Plan: *Big Data in Genetics/Genomics-The Case of 23andMe and Personal Genomics* (75min.)<sup>1</sup>**

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## Learning Objectives

Students will be able to:

- Evaluate ethical arguments for and against the pursuit of “direct-to-consumer genetics”
- Think critically about the role of informed consent within the context of genetic/genomic research
- Describe how individuals, including scientists, can act on social responsibilities concerning genetic privacy and ownership of genetic data

## 1. Before Class Assignment

### *Assigned Readings:*

Allyse, Megan. “23 and Me, We, and You: direct-to-consumer genetics, intellectual property, and informed consent.” *Trends in biotechnology* 31, no. 2 (2013): 68-69.

Saha, Krishanu, and J. Benjamin Hurlbut. “Research ethics: Treat donors as partners in biobank research.” *Nature* 478, no. 7369 (2011): 312-313.

Seife, Charles. “23andMe is terrifying, but not for the reasons the FDA thinks: the genetic-testing company’s real goal is to hoard your personal data.” *Scientific American* 27 (2013). <https://www.scientificamerican.com/article/23andme-is-terrifying-but-not-for-the-reasons-the-fda-thinks/> Accessed on December 12, 2016.

### *Recommended Readings:*

Alyass, Akram, Michelle Turcotte, and David Meyre. “From big data analysis to personalized medicine for all: challenges and opportunities.” *BMC medical genomics* 8, no. 1 (2015): 33.

McGuire, Amy L., Timothy Caulfield, and Mildred K. Cho. “Research ethics and the challenge of whole-genome sequencing.” *Nature Reviews Genetics* 9, no. 2 (2008): 152-156.

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Robinson, Ann. “DNA-testing kit 23andme: patient powered healthcare or just confusing” *The Guardian*. January 12, 2016. <https://www.theguardian.com/sustainable-business/2016/jan/12/dna-testing-kit-23andme-patient-powered-healthcare-genetics>

Stoeklé, Henri-Corto, Marie-France Mamzer-Bruneel, Guillaume Vogt, and Christian Hervé. “23andMe: a new two-sided data-banking market model.” *BMC medical ethics* 17, no. 1 (2016): 1-11.

Schwartz, Peter H. “The value of information and the ethics of personal-genomic screening.” *The American Journal of Bioethics* 9, no. 4 (2009): 26-27.

Wasson, Katherine. “Direct-to-consumer genomics and research ethics: should a more robust informed consent process be included?” *The American Journal of Bioethics* 9, no. 6-7 (2009): 56-58.

## **2. Introduction (20 minutes)**

### *2.1 Opening conversation (18 minutes)*

Ask students: “Given your readings, what are some kinds of information that individuals can expect to find out from personal genetic/genomic tests?”

Students might list examples of medical and non-medical/personal information: ancestry, predispositions to certain behaviors, diseases, etc.

Then, ask students: “Is acquiring these sorts of information in exchange for providing personal data and bio-specimens to private companies a fair exchange? Why/why not?”

### *2.2 Session overview (2 minutes)*

Outline for students that class today is designed to enable them to think critically about the role of informed consent in genetic/genomic research, especially in the context of “direct-to-consumer” genetic testing. First, they’ll look carefully at a particular case about the “direct-to-consumer” genetic testing company, *23andMe*. Second, they will consider the ethical responsibilities of the individuals participating in these sorts of endeavors (including the scientists pursuing research), as well as the groups and institutions involved in the governance of biobanks.

From *Council for Big Data, Ethics, and Society*:

“Some of the general questions to keep in the back of your mind include:

- What are the boundaries of research? What ethical concerns are unique to researchers and, in the realm of “big data,” how do research practices interact with practices in other sectors (government, business, philanthropic, etc.)?

- Although there are some controversies that are purely about research, many of the major ethical issues emerge when research practices have impact beyond academia. What responsibility do scholars have for thinking about how their data and techniques might get used (or abused)?”

### 3. Activity: Case Study (40 minutes)

#### 3.1 Have students read short case description & accompanying links (10 minutes)

Case Study – “Blurring Research and Practice, Science and Entertainment” - 23andMe and Personal Genomics: boyd, danah and Jacob Metcalf. 2016.

“Example “Big Data” Research Controversies.” Council for Big Data, Ethics, and Society. Accessed November 29, 2016. <http://bdes.datasociety.net/council-output/example-big-data-research-controversies/>

23andMe – Core Values statement: <https://mediacenter.23andme.com/our-core-values/>

23andMe – Privacy Statement: <https://www.23andme.com/en-int/about/privacy/>

23andMe YouTube Channel: e.g. <https://www.youtube.com/watch?v=-1gJNUzABAY>

#### 3.2 Small group brainstorming (10 minutes)

Break class into groups of 3-6.

Have each group discuss the following questions:

1. Should there be regulations restricting the collection and sale of genetic/genomic data for “entertainment” (non-medical) purposes? Why/why not?
2. How should we apply the bioethical principle of autonomy/respect for persons to the ethics of biobanks and related research?

#### 3.3 Discuss questions as a class (20 minutes)

Notes for instructor to guide discussion:

Critics of “direct-to-consumer” genetic tests (Allyse, Seife):

- Informed consent is reduced to disclosure (Allyse). As a result, both for-profit and non-profit enterprises that collect genetic/genomic data might fail to ensure honest and open communications with their participants. In turn, that might make it even more difficult to build biobanks large enough for useful genomic research.
- There’s no such thing as an “anonymous genome” (Seife). Should hesitate to trust any company/organization with one’s genetic information, especially those with a profit motive.

Advocates of “direct-to-consumer” genetic tests (Saha & Hurlbut):

- 23andMe demonstrate “that individuals who lack the strong motivation and resources of disease advocates will nevertheless participate in exploratory biobanking, *if the terms are right.*”
- Example: gene related to Parkinson’s disease
- Companies like 23andMe has achieved participants’ trust, while protecting their privacy, according to Saha and Hurlbut – “The result is that participants have chosen to give more than minimum. They are rewarded by witnessing scientific progress in process – including what new knowledge means for them as individuals.”

Tensions about notions of informed consent and its relation to the bioethical principle of autonomy (Mittelstadt & Floridi 2015):

- Informed consent is problematic in research that makes use of big data because it does not, and cannot, explicitly cover all future investigations, or future instances of sharing and aggregating data across research communities.
- More liberal notions of consent that have been proposed: “open,” “broad,” “blanket,” or “tiered” consent.
- Those approaches have been criticized for limiting participants’ autonomy (Mittelstadt & Floridi 2015; Master et al. 2014).
- Some have proposed a shift towards emphasis on concept of solidarity (bioethical principles of justice and beneficence) over the concept of consent (bioethical principle of autonomy). This approach relies on the participation of “information altruists” concerned with the public good.
- That approach has been criticized for being “paternalistic,” and placing undue burdens on individuals to participate in research, but it might also shift the focus from the moral duties of researchers to “do no harm” towards their moral responsibilities to ensure the just distribution of any benefits and the minimization of risk of harm that might result from their research.

#### **4. Activity: How can scientists act on social responsibilities? (10-15 minutes)**

Transition: The emerging concepts of consent under negotiation within this research context, and the emphasis on researchers’ duty to benefit research participants and their communities more widely, as well as the research participants’ duty to contribute to the public good, are areas of ethical deliberation intended to maintain the public’s trust in the medical profession, and scientific institutions more broadly.

Considering what you know about “direct-to-consumer” genetic tests and biobanks, and McFarland’s framework\* for analyzing social responsibility in science and engineering, do

scientists who work on developing and managing biobanks have social responsibilities to the research participants (those who donate their genetic information) and to the public more generally?

<b><i>Factors</i></b>	<b><i>Has this characteristic?</i></b>
<i>Critical need</i>	
<i>Proximity</i>	
<i>Absence of other sources that can help</i>	
<i>Ability to help effectively, without substantial harm to self</i>	

\* McFarland, Michael C. "The public health, safety and welfare: an analysis of the social responsibilities of engineers." *Technology and Society Magazine*, IEEE 5, no. 4 (1986): 18-26.

### **5. Wrap up (5-10 minutes)**

Ask students to think about the main arguments for and against "direct-to-consumer" genetics and biobanks. Then, ask students to draw up a short list of (2-3) ethical questions representative of the core issue(s) in the ethical disagreements about the governance of these biobanks.

### **Required Materials and Equipment**

- One short video:
  - Excerpts from 23andMe YouTube channel
- One activity handout:
  - Case study & discussion questions
- Discussion activities
  - whiteboard to keep track of discussion