Genomics, Big Data, and Broad Consent: A New Frontier for Psychologists

Deborah M. Layman, M.A. and Celia B. Fisher, Ph.D.
Fordham University, New York, USA

ETHICS @ FORDHAM Center for Ethics Education

#FordhamADP Applied Developmental Psychology

Abstract

The growing field of genomic technologies has enriched the contributions of psychological science for understanding the unique and interacting roles of genetic and environmental factors on the development of behavioral risk and individual responsivity to prevention and intervention programs. Big Data tools link genomic data to health, educational, criminal justice, and other personal information stored in large integrated datasets. Advances have created a new frontier of ethical challenges for psychologists' as they collect, store or engage in secondary use of potentially identifiable information and biospecimens. New federal regulations for the protection of human subjects requires new informed consent format, content, and transparency requirements online posting of the consent document for "clinical trials" and a new mechanism This poster describes challenges and present recommendations for psychologists responding to regulatory changes affecting traditional informed consent formats, requirements for obtaining broad consent, and calls for public transparency in ways that enhance the scientific and ethical dimensions of psychological science.

Background

Genomic technologies has enriched our understanding of genetic and environmental factors on development. Big Data tools link genomic data to health, educational, child welfare, & criminal justice. These tools foster research on the dynamic roles of genetic and environmental factors in academic achievement, sexual risk behaviors, substance use, internalizing and externalizing disorders and responsivity to educational and development promoting preventive interventions. Advances have created a new frontier of ethical challenges for psychologists as they collect, store or engage in secondary use of potentially identifiable information and biospecimens. Office of Human Research Protections has issued new federal regulations for the protection of human subjects to keep pace with these advances. Study aims include:

1) Describe regulatory changes and implications for psychologists

2) Examine challenges for genomic research and research psychologist's using Broad consent

Regulation Changes	Implications for Psychologists
Identifiable information and biospecimens require the same protections as persons.	▪ With the evolving ability to re-identify previously de-identified genetic information, how will psychologists keep abreast of continuously changing definitions of identifiable information and biospecimens?
New concise summary of key information on the first page(s) of the informed consent document	▪ How will psychologists identify appropriate key information for different types of research and different participants? ▪ At what age is a child considered a reasonable person?
Option for "Broad Consent" for secondary use of data/ biospecimens given disclosure of: ▪ Nature of information/ biospecimens stored ▪ Time period of storage & use ▪ Future uses & users ▪ Commercial use	How will psychologists: • Decide on open-ended broad consent vs. broad consent with specifications and then specify the terms of the consent? • Identify potential future uses of data? • Engender trust among participants that future researchers will be faithful stewards of identifiable information and biospecimens? • Develop infrastructure to keep obligations to individuals who refused broad consent or agreed with specifications (i.e. biospecimens will be destroyed on a set schedule)? • Evaluate whether data repositories have the infrastructure to honor obligations made during broad consent?
Broader definition of "clinical trial' & requirement to publicly post the informed consent	• How will an investigator identity whether their socio-behavioral prevention study qualifies as a "clinical trial" and therefore requires posting of the consent form(s) on federal website like clinicaltrials.gov?

Challenges for Genomic Studies or Using Broad Consent

- **Long time periods for storage and use of biospecimens carries unique implications.**
  - Future re-analysis may yield findings that were not originally anticipated
  - Psychologists must consider if child participants when they become legal adults be notified as to where their biological materials are stored and conditions in which they will or will not have a right to re-consent or withdraw permission for further use
  - Psychologists working with American Indian Alaskan Native communities should consider the implications of tribal prohibitions on body fragmentation, that is, biospecimens living outside the body or after death. Psychologists should consult with tribal leaders to specify conditions for the time period for storage, destruction, and blessing before destruction of biospecimens.

- **Individuals vary in their genetic literacy.**
  - Rapid technological advances can outpace the average person's knowledge further complicating the informational needs of the "reasonable person"
  - Complex and probabilistic nature of information collected from genetic data may confuse participants trying to understand the personal relevance of genomic information

- **Sharing genetic results with participants incentivizes participation but poses ethical challenges.**
  - Data may contradict assumed paternity or other biological bases of family relationships
  - Results suggesting predispositions to serious mental health or health conditions may carry a lifelong burden and stigma.
  - Participants may feel obligated to share genetic risk with family members.

- **Willingness to consent to broad consent varies by the study's privacy protections and background of the prospective participant.**
  - Majority of people are willing to consent for altruistic reasons if adequate privacy protections are in place
  - Parents, African-Americans, individuals with less education, and those with a history of drug abuse were less likely to consent to broad consent
  - There is sparse research on youth attitudes toward broad consent.

Recommended Reading

Fisher, C. B, (2017). Ethical risks and remedies in social behavioral research involving genetic testing. In: S. Bouregy, E.L., Grigorenko, S.R Latham & M. Tan (eds). *Current Perspectives in Psychology: Education, Ethics, and Genetics*, (pp. 263-283). New York: Cambridge University Press.

Fisher, C. B. Brunquell, D. J., Hughes, D. L., Liben, L. S., Maholmes, V., Plattner, S., Russell, S. T. & Sussman, E. J. (2013). Preserving and enhancing the responsible conduct of research involving children and youth: a response to proposed changes in federal regulations. *Social Policy Report, 27(1)*, 1, 3-15.

Fisher, C. B. & Layman, D. M. (2018). Genomics, big data, and broad consent: A new ethics frontier for prevention science. *Prevention Science, 19*(7), 871-879,

Fisher, C. B., & McCarthy, E. L. H. (2013). Ethics in prevention science involving genetic testing. *Prevention science, 14(3)*, 310-318.