# Genomics, Big Data, and Broad Consent: A New Frontier for Developmental Scientists

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## Background

- Genomic technologies has enriched our understanding of genetic and environmental factors on the development. Big Data tools link genomic data to health, educational, child welfare, & juvenile 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 developmental scientists as they collect, store or engage in secondary use of potentially identifiable information and biospecimens collected from children.
- Office of Human Research Protections has issued new federal regulations for the protection of human subjects to keep pace with these advances.

## Study Aims

1) Describe regulatory changes and implications affecting traditional informed consent
2) Describe the implications for developmental scientists obtaining broad consent for research with minors
3) Examine challenges for genomic research with children and adolescents

## Regulatory Changes to Informed Consent

| Changes | Implications |
|---|---|
| Identifiable information and biospecimens require the same protections as persons. | ▪ With the evolving ability to re-identify previously de-identified genetic information, how will developmental scientists 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 developmental scientists identify age appropriate key information for different types of research and different participants?<br>▪ At what age is a child considered a reasonable person? |
| Option for "Broad Consent" for secondary use of data/ biospecimens given disclosure of:<br>▪ Nature of information/ biospecimens stored<br>▪ Time period of storage & use<br>▪ Future uses & users<br>▪ Commercial use | How will developmental scientists:<br>• Decide on open-ended broad consent vs. broad consent with specifications and then specifying the terms of the consent?<br>• Identify potential future uses of data?<br>• Engender trust among participants that future researchers will be faithful stewards of identifiable information and biospecimens?<br>• Develop infrastructure to keep obligations to individuals who refused broad consent or agreed with specifications (i.e. biospecimens will be destroyed on set schedule)?<br>• 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? |

## Genomic Data of Minors and Broad Consent

### Challenges for Genomic Studies or Using Broad Consent for Research with Children and Adolescents

- **Long time periods for storage and use of biospecimens collected from minors with guardian permission carries unique implications.** .
  - Future re-analysis may yield findings that were not originally anticipated
  - Developmental scientists 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
- **Families 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 families trying to understand the personal relevance of genomic information.
- **Sharing genetic results with participants incentivizes participation but poses ethical challenges.**
  - Data may contradict assumed attribution of paternity or other biological bases of family relationships
  - Results suggesting minors have possible predispositions to serious mental health or health conditions may carry a lifelong burden and stigma.
  - Parents may treat children differently based on probabilistic data.
  - Parents may feel obligated to share genetic risk with family members.
- **There is limited information on patient perspectives for use of broad consent for minors.**
  - Limited research indicates that parents are concerned about unknown future risks of providing broad consent such as the possibility of limiting medical or insurance provision for their children
  - It is unknown if youth would assent to the secondary use of their data into perpetuity. 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.

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