

Ethical and Legal Criteria for Consumable Genetic Testing

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BioC 118Q

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Direct-to-Consumer Genetic Testing



Direct-to-Consumer Genetic Testing

- Obtained and administered by consumer without medical doctor
- Results predict likelihood of a disease occurring
 - NOT indicative of a specific diagnosis
 - NOT a guarantee that you will develop the disease

Criticism: Direct-to-Consumer Genetic Testing

- Results might cause stress, depression
 - Lack of governmental regulations
 - Lack of awareness about genetic information
 - Inappropriately act upon results
- Commercialization of human genome



Indian?

Egyptian?

Latina?

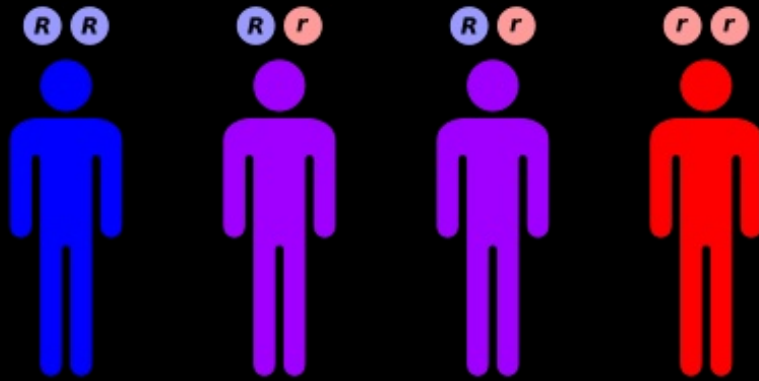
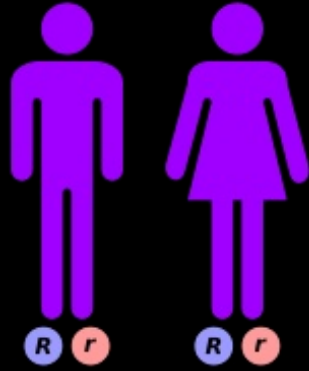


Pakistani?

Russian?

Portuguese?





Ethical Considerations
and
Recommendations

Do genetic test results cause an increase in stress?

- Study: Risk Evaluation and Education for Alzheimer's Disease
- Bloss Study



So what should genetic testing companies do to fulfill their ethical responsibility?

- Beyond the hype
 - Explicitly state that results do not guarantee that a disease will (not) occur
 - Warning: consult a genetic counselor or other medical professional before you take any action based on these results
 - Notify customers of federal regulations

Consumer Privacy and Consent

Criticism of genetic testing companies:

- What do companies do with stored samples?

- How do customers know when their information is shared with other companies, or even sold, for more research and/or profit?

Consumer Privacy and Consent

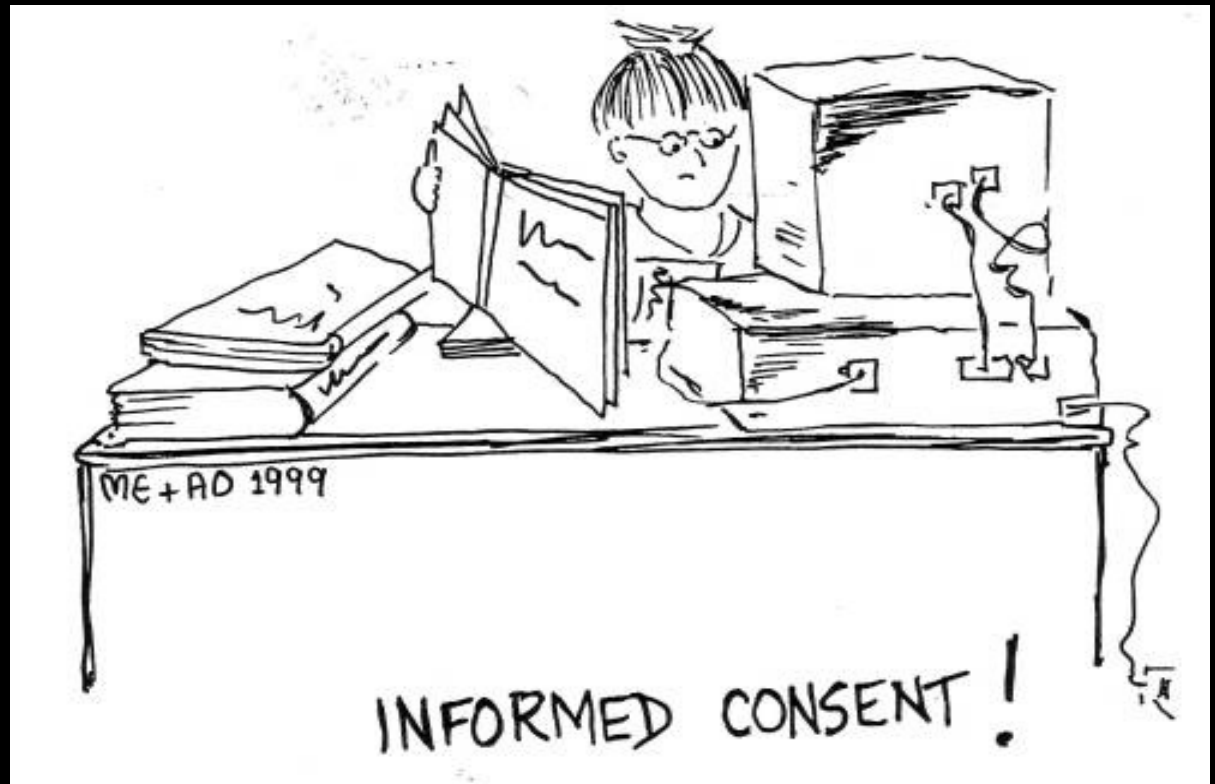


- Genomic Biobanks
 - Not enough information provided
 - Do not obtain informed consent for specific uses

The Common Rule is a federal policy on Human Subjects Protection. It requires that researchers obtain and document informed consent.

Consumer Privacy and Consent

- How should we approach consent?
- Do consumers have a right to clinically important information?



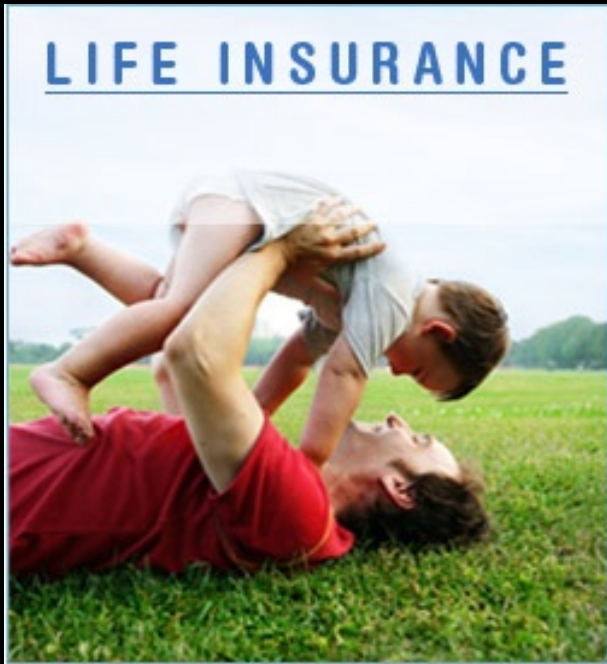
Legal Considerations and Recommendations

Genetic Information Nondiscrimination Act of 2008

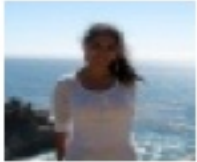
- Title I: Genetic Nondiscrimination in Health Insurance
- Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information



Exceptions to GINA



Exceptions to GINA



Eileen Wright

zomg my genetic test results say that I'll die when I'm 23 from obesity complications :(

6 minutes ago ·  · Like · Comment

 Arielle Isabel Garcia likes this.



Arielle Isabel Garcia Umm... You. Are. So. Fired.

3 minutes ago · Unlike ·  1 person



Eileen Wright :(

2 minutes ago · Unlike ·  2 people



PHOTO-ILLUSTRATION: JOSHUA DALSIMER

patientslikeme

YOU HAVE A CONDITION
WE CALL 'NOTUS
ENOUGHUS INSURANCE'



Legally ensure that *all* people are insured despite potential genetic-related health risks



Questions?



Sources

23andme.com

Nytimes.com

http://www.nytimes.com/2010/06/12/health/12genome.html?_r=1<http://www.fda.gov/Me>
[htm](#)

Green, Robert. *Disclosure of APOE Genotype for Risk of Alzheimer's Disease.*

N Engl J Med 2009; 361:245-254 [July 16, 2009](#)

Greely, Hank. The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks. *Annu. Rev. Genomics Hum. Genet.* 2007. 8:343–64 First published online as a Review in Advance on June 5, 2007.

Lee, Sandra Soo-Jin. HumBio 3B Lecture. 24 Feb 2011.