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By Amy Maxmen

Web genomics exposes ethics gaps

While connecting SNPs to playful traits such as curly hair and optimism, 23andMe reveals loopholes in the regulation of genomics research

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With contributions from 9,000 web-savvy customers, the personal genetics company 23andMe has linked a suite of genes to eight rather playful traits, such as the ability to smell post-asparagus pee or the tendency to sneeze in sunlight. But in getting the results published today (June 24) in *PLoS Genetics*, they unintentionally illuminated an ungoverned landscape of human genetics research.

The study wasn't previewed by a human research ethics committee, but neither the company nor publishers acted illegally. Participants signed a consent form to have their DNA sequenced for \$399 (now \$499), agreeing that their genetic information



Saliva collection kit from 23andMe

could be used for research by 23andMe. And simple questionnaires that customers, including lead author Nicholas Eriksson, completed on the company's website were voluntary. "It's actually just fun and addictive to take these surveys," said Eriksson, a statistical geneticist at 23andMe in Mountain View, California.

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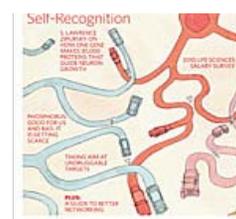
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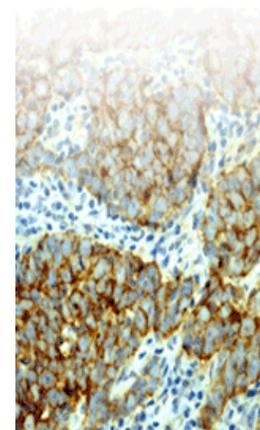
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From surveys, the 23andMe team garnered information about 22 entertaining and heritable traits like curly hair, optimism, and freckles. They discovered new associations between four traits and specific single nucleotide polymorphisms (SNPs). People who sneeze as they step into the sunlight, for example, likely carry two specific SNPs underlying the behavior. And SNPs located near genes for smelling suggest that participants who said they never experienced stinky post-asparagus pee don't smell the stench. Traits like eye color linked to SNPs identified in previous studies, assuring the team that their web-based survey approach was reliable.

"They've reported more statistically significant associations than any genome-wide association study I can think of," said [David Craig](#) at the Translational Genomic Research Institute in Phoenix, Arizona, who is not affiliated with the company but appreciates their unusual choice of traits. "No one wants their tax money to go to sneezing in the sunlight," he said. "But if someone outside of the government funds that research, sure I'm curious to know the result."

Associating traits with SNPs has become a selling point for 23andMe and other direct-to-consumer genetic companies. And as costs drop for sequencing and participant enrollment via the web, these studies will likely be on the rise.

Now is the time to standardize consent and review protocols in human genomic research, write *PLoS Genetics* editors in [an editorial](#) accompanying the manuscript. The study took six months as opposed to 40 days to review, in large part because it lacked an acceptance letter from an institutional review board (IRB), which monitors studies to protect participants' rights and welfare. Without this document, the editors had to evaluate the ethics of the study themselves. "This has caused us to really think about the need for a broader and consistent policy that everyone buys into," said Gregory P. Copenhaver, deputy editor-in-chief at *PLoS Genetics*.

The study was deemed exempt from IRB approval because participants submitted answers over the web rather than in person, and their genetic information was coded. In other words, the study was not "interpersonal" and did not include "identifiable information," qualifying it as a non-human study.

"Since the 23andMe web-based platform, in accordance with federal guidelines, did not technically require IRB approval, we proceeded with data collection and [genome-wide association studies] as part of our service," Anne Wojcicki, 23andMe president and co-founder, wrote in an email to *The Scientist*.

By qualifying as non-human, this study opens a huge loophole for all kinds of research done by investigators who don't directly interact with participants, said [Hank Greely](#), director at the Center for Law and the Biosciences at Stanford. "The scary thing is that if you conclude it's not human subject research, no one has objective oversight."

Further, unlike 23andMe customers who are promised that their genetic information remain private, volunteers contributing DNA to the Personal Human Genome Project and many other genotyping efforts are asked to make their information publically available to researchers -- who may be exempt from ethical review under the current law.

"I think it would make everyone a lot more comfortable to have a general policy of consent and review to guide human genomic research," said Copenhaver.

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A hired IRB concluded that 23andMe's study had been up to par and it will review all studies for the company in the future. Joanne Mountain, senior director of research at 23andMe, said: "What this highlights is the transitional nature of the field."

N. Eriksson et al, "Web-Based, Participant-Driven Studies Yield Novel Genetic Associations for Common Traits," *PLoS Genet*, 6(6): e1000993. doi:10.1371/journal.pgen.1000993

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This is not what should be worrying us.

by Dominique Scalia

[Comment posted 2010-07-01 10:07:02]

The research going on at places like 23andMe is not the research that should be sending us into any kind of frenzy. If this research was not considered "human subjects" under the law, it's because the researchers could not identify the donors of the genetic material. What's more, it's quite clear that those donors freely volunteered, even paid, to participate in the research. This is not the time to get worked up about "unethical" research (which this was not).

The work done at 23andMe appears to comply with federal regulations, and it highlights the very reasonable standards that keep regulations from overstepping and hindering the ability to conduct effectively harmless research. If you want to get up in arms about the regulations not doing enough to protect subjects, then that attention is more rightly focused on other projects that do also follow the law. Consider, for example, the NIH's dbGaP (database of genotypic and phenotypic information). Genetics research funded by NIH is required to submit information to that database, and much of that comes from samples used secondarily originating from donors who did not consent to have their materials databased by the federal government. A review of their consent process is done by an IRB before the information is sent, but it does not require specific consent for dbGaP. Those samples, unlike the ones used by 23andMe, are linked to subject identities by the individual researchers submitting them.