

August 5, 2010

President pro Tem Darrell Steinberg, Senate
Senate Rules Committee
State Capitol, Room 205
Sacramento, CA 95814

Sen. Gloria Romero, Chair
Senate Education Committee
State Capitol, Room 2083
Sacramento, CA 95814

Sen. Ellen Corbett, Chair
Senate Judiciary Committee
State Capitol, Room 2187
Sacramento, CA 95814

Dear President pro Tem Steinberg and Chairs Romero and Corbett,

We are very concerned by the recent announcement that the University of California, Berkeley has mailed saliva sample kits to incoming freshman and transfer students at the College of Arts and Sciences with which to send in a DNA sample. These DNA samples will be tested on campus for three genes that help regulate the ability to metabolize alcohol, lactose and folates as part of the “On the Same Page: Bring Your Genes to Cal” program. While we support innovative teaching and exploration of science at California’s universities, we are writing to ensure that fundamental rights of students to informed consent and confidentiality are protected.

Newly admitted students have been told that this DNA testing program will benefit their educational experience. However they have not as yet been provided either a sufficient curriculum regarding the complexities of the material, nor have they been given a meaningful opportunity to ask questions concerning the experiment or the procedures required to give fully informed consent under the Common Rule of the Department of Health and Human Services (HHS) Policy for Protection of Human Research Subjects (Code of Federal Regulations, Title 45, Part 46). Ironically, by offering voluntary educational forums only *after* the DNA sample has been collected, the University makes it difficult for students to make an informed decision about whether to participate in the program or how to evaluate the utility of these particular genetic tests. In light of ongoing FDA and Congressional inquiries into similar types of genetic testing services and the consumer protection issues they raise, it is alarming that the University has not taken these steps.

Furthermore, it is concerning that the University has failed to acknowledge well documented ethical concerns regarding the storage of either DNA samples or data containing personal genetic information. As stated in the consent forms, the student’s DNA sample will “become the property of the University of California” until it is destroyed and the University will “save the data for future teaching purposes and for possible publication of the aggregated data and its analysis.” Current science clearly establishes there is no way to make an individual’s DNA profile or his genetic information anonymous, even when de-identified. Thus, claims to privacy and confidentiality cannot be guaranteed, troubling to organizations familiar with information security issues, such as the potential for both intentional and accidental data breaches.

Finally, by conducting the genetic testing at the Genetic Epidemiology and Genomics Lab, headed by Professor Barcellos, Berkeley may be in violation of the California Business and Professions Code Section 1265. Genetic tests of this sort are considered clinical laboratory tests by the California Department of Public Health pursuant to California Business and Professions Code Section 1206(a)(4), and therefore any lab conducting these tests must obtain a license from the Department of Public Health. As far as we know, no laboratory at Berkeley's School of Public Health, including that of Professor Barcellos, has obtained such a license. Furthermore, Professor Barcellos is not licensed as a clinical laboratory director, nor are the members of her lab licensed as clinical laboratory technicians. Therefore, Berkeley's genetic testing program may violate California law.

We, along with many members of the University of California, Berkeley faculty, have attempted to approach University officials with these concerns but have received only descriptions of the program as designed and assurances that it sufficiently satisfies them. It does not. Nor have we received any clarity as to whether there is an outside private funding source for the program, and any conflicts of interest that may result under the California Political Reform Act. We urge you to contact the Regents of the University of California and to request a full accounting of the "On the Same Page: Bring Your Genes to Cal" program. We further urge you request that the Regents delay the implementation of the program until these concerns can be satisfactorily addressed in a transparent and open process.

We welcome the opportunity to work with you to ensure that the best interests of the students of the University of California system are protected.

Sincerely,

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The Council for Responsible Genetics