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Swabbing Students: Should Universities Be Allowed to Facilitate Educational DNA Testing?

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Abstract

Recognizing the profound need for greater patient and provider familiarity with personalized genomic medicine, many university instructors are including personalized genotyping as part of their curricula. During seminars and lectures students run polymerase chain reactions on their own DNA or evaluate their experiences using direct-to-consumer genetic testing services subsidized by the university. By testing for genes that may influence behavioral or health-related traits, however, such as alcohol tolerance and cancer susceptibility, certain universities have stirred debate on the ethical concerns raised by educational genotyping. Considering the potential for psychosocial harm and medically relevant outcomes, how far should university-facilitated DNA testing be permitted to go? The analysis here distinguishes among these learning initiatives and critiques their approaches to the ethical concerns raised by educational genotyping.

Keywords

education; genetic research; human subjects research; IRB (institutional review board); law; medical humanities

Two summers ago, the University of California at Berkeley (UC Berkeley) mailed to more than 5000 incoming freshman and transfer students an invitation to “Bring [Their] Genes to Cal” (Varney 2010). The package included a DNA testing kit, consent forms, a link to an informational video, and coding labels so that students could send their DNA samples to UC Berkeley voluntarily and anonymously, but with the ability to track their personalized results (University of California, Berkeley 2010a). As the research protocol submitted to UC Berkeley’s institutional review board (IRB) explained, this exercise was an educational experiment that involved the use of personalized genetic testing as an educational tool (PGET) (Rhine 2010). The goal was to allow students the opportunity to experience the science and the effects that may result from advancements in personalized medicine firsthand (Rhine 2010, 7–8).

Unsurprisingly, the idea of testing students for genetic markers weeks before the first day of class set off a variety of alarm bells in news outlets and bioethics circles (Vorhaus 2010). Eventually, staunch public disapproval influenced action by the California Department of

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Public Health, which asserted that California law requires a physician to order the genetic tests and that a licensed clinical laboratory must perform the genetic analyses in order for UC Berkeley to be authorized to return the genetic test results to students (University of California, Berkeley 2010b; Vorhaus 2010). Originally students were to receive individualized results related to genetic variations in the LCT (lactose intolerance), ALDH2 (alcohol metabolism), and MTHFR (metabolism of folic acid) genes, but to comply with California law, UC Berkeley modified its program so that students received aggregated results during lectures and panel discussions instead (University of California, Berkeley 2010b).

“LEARN BY DOING”: NEWER PARADIGMS FOR LEARNING ABOUT GENETICS

Although UC Berkeley has made educational DNA testing headline news, it is by no means the first and only school to facilitate personalized genetic testing for educational purposes (Taylor and Rogers 2011). In their recent scholarship, Rogers and Taylor (2011) explain that undergraduate institutions often include student genotyping within a classroom context. And in the past 2 years, university educators have published articles describing their use of genetic testing laboratories on and off-campus to genotype science, pharmacy, and medical students. Collectively, these reports show that institutions are combining the conventional concept of experiential learning with genetic testing technologies that have been increasingly raising questions about the safety and effectiveness of genetic tests (Anonymous 2010; Burke and Evans 2011; Rogers and Taylor 2011; Salari et al. 2011; Taylor and Rogers 2011; Walt et al. 2011). The article here builds on concerns raised about student vulnerability (OHRP 1993), exploitation (Burke and Evans 2011), coercion (Taylor and Rogers 2011; Rogers and Taylor 2011), and the lack of proven clinical validity and utility associated with some genetic tests (Burke and Evans 2011). In addition, it provides a detailed discussion of how these and other key ethical concerns can impact undergraduate and graduate students who participate in PGET activities.

As Table 1 demonstrates, lessons involving PGET can range in terms of who performs the testing (e.g., a commercial laboratory, university laboratory, or classroom laboratory instructor); the format for returning results; the number of single-nucleotide polymorphisms (SNPs) tested; and the scope and goals of different lessons. A few undergraduate institutions have intentionally tested students for genes that predict cancer susceptibility (Rogers and Taylor 2011), and some graduate programs have collaborated with direct-to-consumer genetic testing companies (DTC companies) that test student genomes for a range of complex, multifactorial diseases (Haspel et al. 2010a; Haspel et al. 2010b; Salari et al. 2011).

While some courses provide students with the option of viewing the results of an anonymous classmate, the professor, or an unknown third party, instructors have suggested that those who engage in self-testing may benefit more from the lesson (Haspel et al. 2010a; Haspel et al. 2010b; Krynetskiy and Calligaro 2009; Salari et al. 2011; Silveira 2008). Access to one's genome could immediately challenge some of the assumptions a student might have about what it means personally to know her risk for developing ovarian cancer, for instance, and to have to factor that information into lifestyle goals and choices. In this sense, educational DNA testing could be compared to the viewing of one's credit score as part of a finance course; the student has a personal stake in the report and any supplemental information that may affect his or her lifestyle choices and family.

Do-It-Yourself Genetic Testing: On-Campus and In-Class Generation of Genetic Data

Through the on-campus generation of genetic data, students may participate in genetic testing with or without the ability to access their personalized results. Using classroom technology, students analyze their own DNA samples (Krynetskiy and Calligaro 2009), submit their samples to course instructors for analysis (Johnson and Gallagher 2010; Knoell et al. 2009), send their cheek swabs to a university laboratory licensed to return results under state and federal clinical laboratory laws, or, as the students had done at UC Berkeley, submit the samples to an unlicensed university laboratory typically used for research purposes.

For ethical reasons, instructors usually advise students that actual DNA testing is their voluntary and anonymous choice (Knoell et al. 2009; Krynetskiy and Calligaro 2009; Salari et al. 2011). Students need not label the DNA swabs with identifying information or submit a DNA sample at all. In those cases when genotyping results are returned to students, the students use a bar code or some other tracking mechanism to obtain individualized results without anyone other than the student designated as the intended person being able to receive the genetic test results (Knoell et al. 2009; Krynetskiy and Calligaro 2009). In two doctorate-level pharmacy (PharmD) courses at Temple University and Ohio State University (OSU), for instance, students and instructors used classroom laboratory equipment to conduct a polymerase chain reaction (a technique used to amplify a DNA sequence) on their own DNA, and the professors received and presented only students' aggregate data to the class (Knoell et al. 2009; Krynetskiy and Calligaro 2009). At Temple University 150 students participated in testing and at OSU the instructors requested 10 volunteers (Knoell et al. 2009; Krynetskiy and Calligaro 2009).

Citing previous studies, Temple University was concerned that the relevance of pharmacogenomics, a branch of pharmacology that studies the influence of genetic variation on drug response would be unclear to students, even after completion of a pharmacogenomics course built into the PharmD curriculum (Krynetskiy and Calligaro 2009). To correct for this, instructors added a genotyping component to the pharmacogenomic lectures, which permitted students to analyze their own genetic variations in a classroom laboratory, calculate the frequency of the alleles responsible for those variations, and perform a comparative bioinformatics analysis of their data (Krynetskiy and Calligaro 2009). Students surveyed after the exercise stated that observing genetic diversity among their peers was a useful aid in helping them to understand the link between pharmacogenetics and pharmacy practice (Krynetskiy and Calligaro 2009).

Similarly, instructors at Ohio State University (OSU) engaged students in a genotyping exercise in order to provide them with an opportunity to practice using the terminology and the technology associated with genotyping (Knoell et al. 2009). The OSU students reported that it was difficult at first to grasp the technology associated with identifying patient genotypes and the relevance of pharmacogenomics to clinical practice, but that self-genotyping helped to clarify course content (Knoell et al. 2009).

Educational DNA testing for the reasons highlighted by Temple and OSU are common. As Taylor and Rogers explain, student genotyping is a "popular way to integrate a real world approach and fundamental molecular biology techniques in the teaching laboratory" (Taylor and Rogers 2011, 253). Since students are already naturally curious about their genotype, the "ability to learn one's genetic status by personally conducting the laboratory investigation is even more compelling" (Taylor and Rogers 2011, 254). Generating genetic data in-class has additional advantages. First, because of technological limits, the level of genomic data generated is generally low, allowing professors and their students to have greater control over who has access to the samples and the amount of genetic data that can

be retrieved. Licensed laboratories must comply with state laboratory record retention laws that require them to retain all samples and data for a set number of years (College of American Pathologists 2010), but in-class testing allows universities and students to bypass such laws and reduce the risk of unwanted genetic testing by unknown third parties.

In-class SNP testing, however, is not without risks. SNPs that seem innocuous in one sense could have multiple meanings or new meaning in the future as genetic research progresses (Sivakumaran et al. 2011). UC Berkeley, for instance, described the *ALDH2* gene, which causes facial blushing and nausea after alcohol consumption, as “innocuous” in the IRB protocol, but it has also been linked to esophageal cancer (Brooks et al. 2009). In another undergraduate exercise, students examined the *Per3* gene, which affects circadian rhythms and is additionally linked with an increased risk of breast cancer (Taylor and Rogers 2011). As Taylor and Rogers explain, a third university guided students in self-testing related to the *VMAT2* gene, which influences dopamine transportation in the brain (Taylor and Rogers 2011). The goal of this course was to increase students’ genetic literacy, and the genotyping exercise helped them to identify strengths and weaknesses in certain genetic testing methodologies (Silveira 2008; Taylor and Rogers 2011). In a publication about the project, however, the same course instructor noted two reports that linked the *VMAT2* gene to schizophrenia (Silveira 2008; Taylor and Rogers 2011). Although the polymorphisms cited in this report were not the same mutations studied in class, this phenomenon highlights how a seemingly benign genetic mutation can cause significant ethical predicaments, especially if students know one another’s results. In these final examples, students’ DNA data were aggregated, but as explained in the section of this article on nonmedical DNA testing, such precautions satisfy state laws but raise unsettled ethical questions.

Schools That Hire Direct-to-Consumer Genetic Testing Companies: Outside Laboratory Generates Genetic Data

Taking a different approach, several medical schools have partnered with DTC companies to offer genome scans to students at a reduced rate. With the university covering most of the \$400 cost to make testing affordable (students pay \$0–99) (Beth Israel Deaconess Medical Center 2009; Stanford University School of Medicine 2010), commercial companies such as Navigenics and 23 and Me use DNA chips to genotype hundreds of thousands of single-nucleotide polymorphisms related to one’s susceptibility to a range of chronic diseases and phenotypic traits. For example, DTC scans report carrier status, risk factors for diseases like cancer, Alzheimer’s disease, diabetes, students’ likely ancestry, and receptivity to certain drugs. To prevent coercion, students have the option of viewing the results of an anonymous classmate or an unknown third party (Haspel et al. 2010a; Knoell et al. 2009; Salari et al. 2011). Further, university professors typically indicate that they do not know who has chosen to undergo testing and that the students’ choices will have no bearing on their grades (Haspel et al. 2010b; Knoell et al. 2009; Krynetskiy and Calligaro 2009; Salari et al. 2011).

The goals of these programs include educating students on the link between genetic variation and disease, the limits and uses of genomic technology, and the ethical, legal, and social implications of personalized genomic medicine (Haspel et al. 2010a; Haspel et al. 2010b; Ipaktchian 2010; Walt 2011). At Stanford University, an elective course utilizing DTC genetic testing technology introduces students to the relevant ethical, legal, and social issues prior to testing (Stanford University School of Medicine 2010). The curriculum also focuses on the potential of DNA and other biological materials to contribute to clinical decision making and treatment, the methods for interpreting genetic data (Haspel et al. 2010b; Ipaktchian 2010), and the different types of services offered by DTC companies websites (Ipaktchian 2010). Combined courses at Harvard University and Beth Israel Hospital also subsidize the genetic testing of pathology residents by two commercial

companies, but the lessons are tailored to cover the laboratory science in addition to other topics relevant to pathology students (Haspel et al. 2010b).

One of the challenges for universities that facilitate genetic testing as an educational tool is that they must compensate for the well-known problems associated with DTC genetic testing companies: unproven utility for certain tests, inadequate medical guidance and counseling, and ethical questions related to the ownership of data (Berg and Edwards 2008; Evans and Green 2009). An additional concern is that DTC companies' privacy policies and their implications are often inadequate, vague, and inconspicuous (Gurwitz and Bregman-Eschet 2009). DTC companies' privacy and data-sharing policies state, for instance, that the company will save customer data long after account termination (Navigenics 2009) and/or that they will share deidentified data with third parties (23 and Me 2010). This means that the third party conducting the testing is unable to access the client's name or any other personal information except for his or her gender, date of birth, or age (23 and Me 2010).

Two scholars have performed numerous landmark experiments demonstrating the reidentifiability of stored anonymized health data using these very same variables, however (Malin and Sweeney 2000; Malin and Sweeney 2001). Universities that endorse these services or hold themselves out as being capable of advising and educating students on their use arguably take on the obligation of going beyond DTC companies when implementing procedural safety measures and counseling students on the benefits and harms associated with these services, including the discussion about the growing difficulty with upholding deidentification standards.

As an alternative to using DTC companies, universities may use an external research biobank to perform the genetic testing, which may offer procedures and methods that are sensitive to the concerns just raised. The School of Medicine at the University of Pennsylvania, for instance, encourages students to submit their samples to the Coriell Personalized Medicine Collaborative (CPMC) (Vence 2010), which performs research on genetic samples and utilizes various expert advisory boards to determine which genes should be tested and when it is appropriate to return genetic test results to participants (CPMC 2008). In addition, the privacy standards implemented by independent nonprofit research organizations, such as CPMC, are often superior to those offered by DTC genetic testing companies—and, if feasible, could be a more appropriate and safer venue to which to send students' samples for testing. This is because these institutions often obtain a certificate of confidentiality under section 301(d) of the Public Health Service Act. Under this law, CPMC has a legal right to withhold participants' records despite a federal, state, or local court order requesting disclosure (CPMC 2008).

As an even safer alternative, some universities may want to use other, less risky forms of educational genetic testing exercises. SUNY Upstate Medical University and the Tufts University School of Medicine, for example, chose not to subsidize student DNA testing, but to provide students with sample genomic data instead (Walt et al. 2011). At SUNY Upstate, the professor provided his students with access to his 23 and Me account (Smith 2010). The students at Tufts University, meanwhile, examined publicly available and anonymous genomes.

CONFLATING RESEARCH, EDUCATION, AND MEDICINE

In the face of so many potential ethical and legal challenges, should university-facilitated DNA testing be prohibited? Critics of UC Berkeley's PGET initiative have noted its frightening resemblance to the nude posture experiments of the 1950s when researchers required incoming freshman at Yale, Mount Holyoke, Vassar, Smith, Princeton, and other elite schools to pose nude for photographs as part of an exercise to examine and improve

student posture (Andrews 2010; Prescott 2002; Vorhaus 2010). These studies were used to assess the health of newly admitted students, as it was believed that poor posture indicated illness (Prescott 2002), but researchers had other motives as well (Prescott 2002) and used the posture experiments to argue that white men born into the upper middle class were physically superior to members of other classes and racial groups (Prescott 2002). Years later, a *New York Times* investigator tracked down the few remaining photos (most of them were burned) and noted the looks of horror and discomfort on students' faces (Rosenbaum 2010). Schools that implemented these programs overlooked the psychological and dignity harms associated with the nude posture experiments well into the 1970s, when the National Research Act instigated the formalization of human subject research protections in the United States. In the case of exercises that incorporate PGET, students usually volunteer to participate or to sign up for the course; however, the danger of conflating distinct activities that merit individual attention is as present here as it was in the case of the nude posture experiments. Specifically, PGET instructors must separately evaluate the ethical, legal, and social issues (ELSI) raised by nonmedical DNA testing, experimental pedagogical activities, and human subject research.

Nonmedical DNA Testing

At this stage, nonmedical DNA testing, and therefore student genotyping, is loosely regulated. The U.S. Food and Drug Administration (FDA) oversees genetic tests that are developed and sold in interstate commerce (FDA 2006) as medical devices or "test kits," so it would not regulate DNA testing that occurs in class or on campus. The regulatory framework for DTC genetic testing, however, is under heavy FDA scrutiny (FDA 2010). FDA is evaluating the challenges raised by DTC genetic tests, including, faulty data analysis and exaggerated clinical claims, and determining what new approach is necessary to ensure that these tests provide the same level of safety and effectiveness as other federally regulated medical products (FDA 2010). Until FDA issues revised guidance, the lack of federal standards and guidelines for nonmedical genetic testing, and therefore educational DNA testing lessons that utilize DTC companies, will continue to lead to controversial and clinically questionable genetic test results.

The Centers for Medicare & Medicaid Services (CMS) have established quality and assurance standards for all laboratories that perform genetic testing through the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (CMS 2011), but these standards only apply to laboratories, and they do not adequately address the issues targeted by FDA. CMS defines a laboratory as "a facility that performs certain testing on human specimens in order to obtain information that can be used for the diagnosis, prevention, or treatment of any disease or impairment of a human being; or the assessment of the health of a human being; or procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in a human body" (42 C.F.R. sec. 493.2). Acknowledging consumers' growing interest in directly accessing genetic testing services, CMS has stated that "CLIA authorizes regulation of laboratories that conduct testing, not the individuals who order the tests or receive test results. State laboratory laws may regulate that issue, and limit the availability of DAT [direct access testing]." Thus, under CLIA, an "authorized person" must provide the laboratory with a written or electronic request for a patient test (CMS 2010), but states may define who is authorized to order and return genetic test results.

As UC Berkeley has experienced, states that apply these provisions to genetic testing services occurring within their jurisdictions may interrupt on-campus genetic testing activities that (1) use a laboratory, (2) provide genetic test results to students, and (3) test medically relevant genes. Thus, CLIA's quality assurance standards do not apply to in-class self-genotyping activities just as they do not apply to "do-it-yourself" at-home testing that any individual could conduct using laboratory equipment within the privacy of their own

homes (Angrist 2011). A university may trigger state law, however, if it engages a laboratory that returns results to students. California and New York, for instance, strictly prohibit returning genetic test results to consumers—even so-called “recreational” results—and have enforced state laws against DTC companies within their jurisdictions (Pollack 2008). For the first time, a state also enforced these laws against a university when California challenged UC Berkeley’s program. To avoid agency involvement in their own states, university instructors using an on-campus laboratory should confirm with local agency officials that their student genotyping activities are compliant with state law.

For investigators who do not return results to students, CLIA contains an exemption for “research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease” (42 CFR s. 493.3(b)(2)). Under this provision, university researchers are unable to report incidental findings to research subjects without risking their CLIA exemption, and genetic investigators who use uncertified laboratories may not provide feedback to subject enrollees related to their genetic test results. Although professors would be complying with federal law by aggregating student test results, there has been much debate recently about whether individuals have a moral right to access their personalized genetic data when there is little guarantee that such information will be clinically useful and analytically valid (Evans and Green 2009; Vorhaus and MacArthur 2010).

Within a clinical setting, a medical health professional, such as a doctor or genetic counselor, guides the patient in interpreting genetic test results, and the results are verified by a certified laboratory. But students on both the undergraduate and graduate levels, even those who receive group counseling within the classroom environment, risk exposure to sensitive and medically relevant information without the individualized counsel of a qualified health professional who can access the students’ medical records and family histories. Students who use DTC companies, meanwhile, may mistakenly believe that “alternative methods of genetic evaluation” are “equivalent in their results and analytic rigor” (Eng and Sharp 2010, 2) and forgo counseling related to that information. As Evans and Green argue, “Because information can also cause anxiety, lead to unnecessary medical procedures, and eat-up valuable resources, it can both directly and indirectly cause harm” (2009). Although there is little evidence confirming that individuals who learn of their increased genetic risk for disease suffer severe emotional distress (Bloss et al. 2011; Caulfield et al. 2010), students who receive unexpected or devastating test results will vary in terms of how they respond to their personalized data.

Precounseling by a third party will help assure that the “most emotionally vulnerable” students or those individuals who studies have shown can “become overly anxious” (Caulfield et al. 2010) are identified by an external health care professional. Currently, few instructors require students to participate in both pre- and posttest counseling.

Educational Research Versus Human Subjects Research

Human subject research is governed by Title 45, Part 46, of the Code of Federal Regulations, also known as the Common Rule, and may be the only context within which educational DNA testing programs receive formal oversight. The Office for Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS) is the administrative agency charged with regulating all human subject research utilizing funding from DHHS and occurring at public universities. In most cases, public and private research universities sign federal assurances with OHRP that commit them to conducting both federally funded and non-federally funded research in accordance with the federal rules (45 C.F.R. § 101(f); 21 C.F.R. §§ 56.101(a), 56.103(2002); 45 C.F.R. § 46.101(a)). However, universities are responsible for determining whether their educational DNA

testing activities constitute human subjects research, and if so whether IRB approval is necessary to comply with federal law (Tomkowiak 2004).

OHRP allows investigators to recruit students for research purposes so long as the “investigator has obtained the legally effective informed consent” (45 C.F.R. § 46.116). In addition, an IRB “shall review and have the authority to approve, require modifications in. . . or disapprove all research activities covered by this policy” that apply to human subjects (45 C.F.R. § 46.109). The IRB is responsible for ensuring that the research procedures are sound, minimize risks to subjects, and avoid exposing the subjects to unreasonable harm (46 C.F.R. § 46.111(a)(1)). Further, the risks must be reasonable in relation to the anticipated benefits to the subjects or the knowledge to be gained for the benefit of society (46 C.F.R. § 46.111(a)(2)).

Considering these mechanisms and the purpose of IRB review, subjecting the educational program procedures to IRB review would seem to be the obvious solution, but IRB review is not always required or adequate within the context of educational experimentation. In some of the student genotyping exercises, instructors design evaluation forms and attitudinal surveys to evaluate student perspectives on the effectiveness of the courses or to see whether the educational outcomes are different for students who choose not to undergo testing (Salari 2011, 927). Additionally, professors have begun to publish and present on whether their pedagogical goals have been met. While this is clearly research, the Common Rule does not apply to educational research that relies on educational tests or surveys if the responses obtained cannot be linked to the subject (45 C.F.R. § 46.101(b)(2)). Nor do these protections apply if the students’ samples and data “cannot be identified, directly or through identifiers linked to the subjects” (45 C.F.R. § 46.101(b)(4)). Straightforward application of these rules suggests that instructors can anonymize or deidentify students’ DNA data and forgo IRB review, especially if the risks are minimal.

Educational DNA testing raises a few quandaries, however, that these exemptions make it easy to overlook. First, student agreement to participate in research may not always be freely given, and could result from a desire to fit in with one’s peers or to please the professor. OHRP has stated this in its guidance to IRBs:

Students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g. that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming “uncooperative,” not part of the scientific community). (OHRP 1993)

Indeed, the influence of university figures and the compounding consequence of wanting to bond with their peers make students more vulnerable than nonstudents to coercion to consent to personalized genomic testing, even if the students are told up front that participation is voluntary.

Moreover, within the context of educational DNA testing, it is unclear whether the Common Rule’s risk-minimizing conditions for the deidentification exemption can be maintained when the class lesson involves an examination of students’ genetic data. As classroom discussions ensue, the anonymity attached to aggregated results presented on the blackboard or screen could peel away as students disclose details that are revealing about their results. Further, the desire to bond with peers in person and on social networking websites could encourage further student-initiated sharing that makes the deidentification procedures somewhat meaningless. Finally, the potential personal consequences related to remorseful sharing combined with the continued classroom interaction among students, and any

possible hesitation a student might feel about discontinuing the course and losing credit, all work against the aims of the Common Rule.

Examples of these challenges have been described by Rogers and Taylor in their recent article about existing undergraduate PGET exercises. One lesson referenced earlier, for instance, arguably compromised students' identities as students were able to reidentify themselves in class discussions and the published journal article even though the results were provided to students in aggregate form only (Rogers and Taylor 2011; Taylor and Rogers 2011). In this study, student, teacher, and nonstudent volunteers' anonymized DNA samples were tested for mutations in the p53 gene, which has been linked to cervical cancer (Rogers and Taylor 2011, 233; Soto-Cruz and Legorreta-Herrera 2009, 237). However, since the published table of aggregated data included only 29 teachers and 20 students, and provided age and family background information, the deidentified data were ultimately identifiable (Rogers and Taylor 2011, 233; Soto-Cruz and Legorreta-Herrera 2009, 240). Complicating matters, the relevant privacy rules, including the Genetic Information Nondiscrimination Act (GINA), would fail to protect these students from the types of discrimination and stigmatization that can occur among peers and uncovered entities.

It is telling that although students provided informed consent to participate in the educational experiments described by UC Berkeley and Rogers and Taylor, the IRB review teams had not flagged reidentification or the return of ambiguous test results as potential risks. As others have argued, IRBs in general may be ill-equipped to assess medical education research (Dyrbye et al. 2007), especially when that research involves student genotyping exercises. For these reasons, it may benefit students more if universities adopt an alternative model that includes but exceeds IRB review.

Stanford University faculty, for instance, channeled concerns into a task force of scientists, genetic professors, genetic counselors, bioethicists, legal counselors, and students, who spent several months working through the relevant ethical issues and proposing safeguards for students (Stanford 2010). Although the debate on the merits of PGET lessons continues at Stanford, it was partially carried out in the classroom with faculty presenting arguments for and against educational and DTC genetic testing. This format of deliberation and debate could very well be the best way to thoroughly explore the many ethical issues raised by PGET and to engage students in thinking about this controversial and cutting edge application of genomics. To satisfy OHRP's requirements, universities may wish to use this approach to supplement IRB review.

In addition, the proper evaluation of the pedagogical achievements of student genotyping exercises is needed to help set adequate standards for future PGET lessons. Universities have professional obligations that are enforced by accrediting organizations (Diamond 1997), and to receive and maintain accreditation, universities must have procedures in place to assess the educational goals and evaluate the effectiveness of each academic program (Diamond 1997, 16). Accreditors expect clearly stated outcomes, quality teaching and learning, evaluation processes that include the gathering and analysis of quantitative and qualitative data illustrating student achievement, and institutional accountability (Diamond 1997, 17). Unfortunately, despite these requirements, universities still often fall short in providing evidence that their students are actually learning, and accreditors do not always follow up on ensuring that schools meet these particular standards (Diamond 1997).

Considering the ELSI implications associated with student DNA testing, PGET administrators should take special care to satisfy the requirements outlined by accreditors. The pedagogical benefit to students should be clear, as should the methodology to measure what students are receiving in return for donating their DNA samples. As Bonham and

colleagues argue when commenting on the National Collegiate Athletic Association (NCAA) requirement that student athletes undergo testing for the sickle cell trait (to prevent sudden death):

Perhaps it is best viewed as an experiment—one with possible ramifications for other associations, other screening programs, and sickle cell carriers world wide. If it is indeed an experiment, the related data should be collected and analyzed rigorously, objectively, and transparently so that the costs and benefits of testing can be evaluated. (Bonham et al. 2010)

Thorough ethical review and pedagogical analysis is necessary for PGET lessons for the same reasons outlined by Bonham and his colleagues: to justify exposing students to the risks associated with genetic testing and to help develop a viable model for others.

CONCLUSION

When done well, PGET lessons may offer several benefits to students and society. Universities may be able to offer a well-rounded and possibly unbiased context within which students can learn about genetic testing services. In addition, in the long term, greater familiarity with genotyping techniques among students and the families with whom they share their knowledge may increase the number of people able to view their genomic information critically. Among the proponents of the do-it-yourself genetic testing movement are scientists who perform self-testing in their homes and adult consumers who use DTC companies to sequence their DNA (Angrist 2011). Many of them argue that individuals have a right to their own DNA information without needing “permission” from their doctors (Salzberg and Pertea 2010; Vorhaus and McArthur 2010). PGET lessons could help future consumers and physicians not only to peek into their genomes, but also to make better use of available technologies in the future. If other types of institutions adopt the PGET format to train community members to recognize the limits and benefits of genomic testing and technology, then it may enhance any “rights” that individuals have to their genomic data because they will better understand the data they are reviewing; this is especially important as genomic technology advances and becomes cheaper, allowing individuals to access raw genetic data through different mediums.

Still, by facilitating these lessons, instructors have an ethical obligation to be aware of and inform students of the risks associated with genetic testing, especially within a classroom environment where class size is small and students are prone to sharing genetic test results with one another. Moreover, educators have a professional duty to implement policies and practices that will measure and encourage learning in a safe and effective way. Society should not fear educational DNA testing, however. As other authors have found when evaluating the early adopters of DTC genetic testing services, students may be more sophisticated in their analysis and application of their results than we may think (McGowan et al. 2010).

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Table 1
Sample Educational DNA Testing Initiatives

School	Level	Type of testing	Traits	Laboratory
University of California, Berkeley ¹	Undergraduates (including minors)	Metabolism (folic acid, alcohol, and lactose)	3	University Non-CLIA-certified laboratory
Ohio State University School of Pharmacy	Graduate pharmacy students	Drug metabolism	1	Students and instructors perform the testing
Temple University School of Pharmacy	Graduate pharmacy students	Drug metabolism	1	Students and instructors perform the testing
Beth Israel Deaconess Medical Center of Harvard Medical School	Medical residents	SNP scan	Many	CLIA-certified laboratory
Stanford University School of Medicine	Medical/PhD students	SNP scan	Many	CLIA-certified laboratory
University of Pennsylvania School of Medicine	Medical students	SNP scan	Many	CLIA-certified laboratory

¹Table 1 is not exhaustive, but it illustrates that PGET programs can differ greatly procedurally. For a detailed analysis that focuses on undergraduate genotyping programs and the ethical and legal issues they raise, see Rogers and Taylor (2011) and Taylor and Rogers (2011).