LAW & GENETICS IN THE UNITED STATES: PROTECTING GENETIC PRIVACY AND GENETIC PROPERTY

Patricia A. ROCHE[1]
George J. ANNAS

SUMARIO: I. *Privacy.* II. *Genetic privacy.* III. *DNA research and privacy*. IV. *Policy recommendations.* V. *Anexos.*

The simultaneous publication of two versions of the human genome may be a major impetus to take the legal, ethical and social policy issues at stake in human genome research more seriously.[2] There are many such issues, the one that has caused the most public concern is the issue of genetic privacy. As DNA sequences become understood as information, and as this information becomes easier to use in digitalized form, public concerns about internet and e-commerce privacy (regarding the security with which their private details are protected) will merge with concerns about medical record privacy and genetic privacy. In this paper, we outline the major public policy issues at stake in the genetic privacy debate by reviewing medical privacy generally, by asking whether genetic information is like other medical information, and by outlining the current controversies over privacy in genetic research. We conclude with some public policy recommendations.

1 Health Law Department, Boston University School of Public Health, Boston, 715 Albany St., MA 02118; annasgj@bu.edu.

2 "International Human Genome Sequencing Consortium, Initial sequencing and analysis of the human genome", *Nature*, núm. 409, 2001, pp. 860-921; Venter J. C. *et al.*, "The sequence of the human genome", *Science*, núm. 291, 2001, pp. 1304-1351.

I. PRIVACY

Privacy is a complex concept involving several different but overlapping personal interests. It encompasses informational privacy (having control over highly personal information about ourselves), relational privacy (determining with whom we have personal, intimate relationships), privacy in decision-making (freedom from the surveillance and influence of others when making personal decisions) and the right to exclude others from our personal things and places. In the U. S., no single law protects all of these interests, and privacy law refers to the aggregate of privacy protections found in constitutions, statutes, regulations and common law.[3] Together these laws reflect the value that US citizens place upon individual privacy, sometimes referred to as " the right to be left alone" and the right to be free of outside intrusion, not as an end in itself, but as a means of enhancing individual freedom in various aspects of our lives. This centrality of individual freedom is evident in state laws that establish a patient's right to make informed choices about treatment, that place an obligation on physicians to maintain patient confidentiality, and that regulate the maintenance of medical records.

Privacy laws in the U.S. are fragmented because of the multiple sources of law, including the federal government and all 50 states. Legislative enactments are also often the result of negotiated agreements among segments of a diverse and oftentimes polarized society, rather than of a real consensus. This is perhaps most readily seen in the rules that govern highly sensitive and personal data in the U. S. Unlike the approach of the European Data Protection Directive, which establishes similar rights and duties relative to different kinds of personal data (health and finance),[4] the U.S has different rights and duties for personal information depending upon the kind of information involved. Even within medical records, there are different rules. For example, the U. S. has laws that govern medical record information generally,[5] as well as separate laws

3 Miller, A. R., "Personal Privacy in the Computer Age", *Mich. Law Rev*, núm. 67, 1968, p. 1091. Standards for Privacy of Individually Identifiable Health Information, 50 Fed. Reg. 250, 2000.

4 Swartz, J. P. M., "European Data Protection Law and Medical Privacy", *Genetic Secrets*, New Haven 1997, pp. 392-417.

5 Cal. Health & Saf, Code sec. 120980 , West, 2000.

that govern specific types of medical information, such as HIV status,[6] substance abuse treatment information,[7] and mental health information.[8] New federal regulations apply the same privacy rules to all medical information except psychotherapy records.[9] Such exceptionalism has been criticized, and the primary argument against specific laws designed to protect genetic information is that such "genetic exceptionalism" would perpetuate the misconception that genetic information is uniquely private and sensitive.[10]

II. GENETIC PRIVACY

Is DNA sequence information uniquely private or just like other sensitive information in an individual's medical record? If it is not unique, existing medical record confidentiality laws should be sufficient to protect genetic sequence information, and no new laws would be needed. Those who support genetic exceptionalism (as we do) emphasize the distinguishing features of DNA sequence information. The DNA molecule itself is a source of medical information and like a personal medical record, it can be stored and accessed without the need to return to the person from whom the DNA was collected for permission. But DNA sequence information contains information beyond an individual's medical history and current health status. DNA also contains information about the individual's future health risks, and in this sense is analogous to a coded "future diary".[11] As the code is broken, DNA reveals information about an individual's probable risks of suffering from specific conditions in the future. Our current obsession with genetic sequence information means that it is likely to be taken more seriously than other information in a medical record that could also predict future risks, like high blood pressure or cholesterol levels. Information about the presence of proteins

6 Conn. Gen. Stat. sec. 19a-583 (West, 1999).

7 42 U. S. Code sec. 290-dd (West, 2000).

8 42 U. S. Code sec. 290-dd (West, 2000).

9 Standards for Privacy of Individually Identifiable Health Information, 50 Fed. Reg. 250 (2000).

10 Murray, T. H. Genetic exceptionalism and "future diaries": Is genetic information different from other medical information in *Genetic Secrets* (Rothstein, M. ed.), Yale University Press, New Haven 1999, pp. 60-76.

11 Annas, G. J., "Privacy rules for DNA databanks", *JAMA*, núm. 270, 1993, pp. 2346-2350.

that specific genes may code for is also different from DNA sequence information because their presence may change over time, and their levels, like cholesterol readings, can only be determined over time by retesting the patient personally. Thus proteomics will not require new privacy rules, but rather enforcement of existing medical records privacy rules. DNA sequence information may also contain information about behavioral traits that are unrelated to health status, although skepticism is called for in this area.[12]

Our use of the "future diary" metaphor has been criticized as potentially perpetuating a mistaken view of genes as deterministic.[13] We understand this criticism, and also reject the idea that genes alone determine our future. Nevertheless, we continue to believe the future diary metaphor best conveys the private nature of genetic information itself. Our future medical status is not determined solely by genetics, any more than our past diaries are the only source for accurate information about our past (or even necessarily reflect it). The DNA information, like the diary, however, is a uniquely private part of our possible future.

An individual's DNA can also reveal information about risks and traits that are shared with genetic relatives, and has been used to prove paternity and other relationships.[14] An individual's DNA has the paradoxical quality of being unique to that individual yet shared with others. Even if one believes that the DNA-sequence information extracted from an individual's DNA is no more sensitive than other medical information, this says nothing about the need to protect the DNA molecule itself. In this regard, we think it is useful to view the DNA molecule as a medical record in its own right. Having a DNA sample from an individual is like having medical information about the individual stored on a computer disk, except in this case the information is stored in a blood or other tissue sample. Like the computer disk, the DNA sequence can be "read" by the application of technology. Thus, regardless of the rules developed to control the use of genetic information that is recorded in traditional paper

12 Billings, P. R., Beckwith, J. & Alper, J. S., "The genetic analysis of human behavior: a new era?", *Social Science & Medicine*, núm. 35, 1992, pp. 227-238.

13 Murray, T. H., Genetic exceptionalism and "future diaries": Is genetic information different from other medical information in *Genetic Secrets* (Rothstein, M. ed.), Yale University Press, New Haven,pp. 1999, pp. 60-76 .

14 Marshall, E., "Which Jefferson was the father?", *Science*, núm. 283, 1999, pp. 153 y 154.

and electronic medical records, separate rules are also needed to regulate the collection, analysis, storage and release of DNA samples themselves. This is because once a physician or researcher has a DNA sample, there is no practical need for further contact with the individual from whom the DNA was obtained, and DNA tests could be done on the stored sample (and thus on the individual). Some of these tests are as yet undeveloped but all will produce new genetic information about the individual.

DNA has also been culturally endowed with a power and significance exceeding that of other medical information.[15] Much of this significance is undoubtedly misplaced, but can be justified in so far as genetic information can radically change the way people view themselves and family members, as well as the way that others view them. The history of genetic testing, particularly in relation to rare monogenic diseases such as Huntington disease, provides us with examples of this impact. Studies of individuals who have undergone testing in clinical settings demonstrate the changes in self-perception caused by positive, as well as negative, test results.[16] Individuals with decreased risk of having a genetic disease have reported difficulty in setting expectations for their personal and professional lives in a more open-ended future. Adjustments appear to have been particularly difficult for those who previously had made reproductive decisions on the presumption that they were at high risk for developing a disease.[17] Consequently, it is good policy to provide genetic counseling before and after testing. And in the interests of protecting the privacy of children and adolescents, some institutions have also adopted a policy of refusing parental requests to test children for late onset diseases when no medical intervention is available to prevent or alleviate the genetic condition. "American Society and American College of Medical Genetics. Ethical, legal and Psychological Implica-

15 Nelkin D., Lindee, M. S., The DNA Mystique: The Gene as a Cultural Icon, W. H. Freeman, Nueva York, 1995.

16 Huggins, M. *et al*., "Predictive Testing for Huntington Disease in Canada: Adverse Effects and Unexpected Results in Those Receiving a Decreased Risk", *Am J. Med Genet*, núm. 42, 1992, pp. 504-515; DudokdeWit, A. C. *et al*., "Distress in Individuals Facing Predictive DNA Testing for Autosomal Dominant Late-onset Disorders: Comparing Questionnaire Results With in-depth Interviews, *Amer J. Med Genet*, núm. 75(1), 1998, pp. 62-74.

17 DudokdeWit, A. C. *et al*., "Distress in Individuals Facing Predictive DNA Testing for Autosomal Dominant Late-onset Disorders: Comparing Questionnaire Results With In-depth Interviews, *Amer J. Med Genet*, núm. 75(1), 1998, pp. 62-74.

tions of Genetic Testing in Children and Adolescents: Points to Consider",[18] Perhaps the major reason why neither DNA sequence information nor DNA samples themselves have been afforded special privacy protection is the strongly-held view of many genetic researchers and biotechnology companies that privacy protections would interfere with their work. One court in the U. S. has addressed whether Constitutional rights to privacy are implicated by genetic testing. In *Norman-Bloodsaw v. Lawrence Berkeley Laboratory* employees of a research facility owned and operated by state and federal agencies alleged that non-consensual genetic testing by their employers violated their rights to privacy. Holding that the right to privacy protects against the collection of information by illicit means as well as unauthorized disclosures to third parties, the court stated: "One can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up".[19]

III. DNA RESEARCH AND PRIVACY

Now that the human genome has been sequenced, attention is shifting to research on genetic variation designed to locate genes and gene sequences with disease-producing or -prevention properties.[20] Some researchers have already taken steps to form partnerships and create large DNA banks that will furnish the material for this research.[21] Others want to take advantage of the large number of stored tissue samples that already exist.[22] In the U. S., for example, the DNA of about 20 million people is collected and stored each year in tissue collections ranging from fewer than 200 to more than 92 million samples.[23] Collections include Guthrie cards on which blood from newborns has been collected for

18 *Am. J. Hum. Genet*, núm. 57, 1995, pp. 1233-1241.

19 Norman-Bloodsaw v. Lawrence Berkeley Lab, 135 F.3d 1260 (1998). At 1269.

20 Kaiser, J., "Environment Institute Lays Plans for Gene Hunt, *Science*, núm. 278, 1997, pp. 569-570.

21 Pollack, A., "Company Seeking Donors for a 'gene trust', *NY Times*, sec A, col. 1, aug. 1 of 2000; Karet, G., Boguslavsky, J., & Studt, T., "Unraveling Human Diversity", *Drug Discovery & Development*, november-december, S5-S14, 2000.

22 Grody, W. W., "Molecular Pathology, Informed Consent, and the Paraffin Block, *Diagn. Mol. Pathol*, núm. 4, 1995, pp. 155-157.

23 "National Bioethics Advisory Commission", *Report on the Use of Human Biological Material in Research: Ethical Issues and Policy Guidance*, 1999.

phenylketonuria screening since the 1960s, paraffin blocks used by pathologists to store specimens, blood bank samples, forensic specimens, and the U. S. military's bank of samples for use in identifying bodily remains.[24]

Several factors have contributed to the proliferation of DNA banking: the relative ease with which DNA can be collected, its coincidental presence in bodily specimens collected for other reasons, and its immutability. Regardless of the original purposes for storing specimens, however, as the ability to extract information from DNA increases and the focus of research shifts to genetic factors that contribute to human diseases and behaviors, repositories containing the DNA of sizeable populations can be "gold mines" of genetic information. Thus it is not surprising that there is considerable interest on the part of biomedical researchers, companies that market genomic data, and the pharmaceutical industry to stake claims on these informational resources and to exploit them for their own purposes.[25]

Commercial enterprises, as well as academic researchers, have equally strong interests in making it relatively easy to get access to DNA samples that can be linked to medical records for research purposes. Representatives of these constituencies have been vocal in arguing that requirements for informed consent and the right to withdraw data from ongoing research projects (two aspects of genetic privacy) would greatly hamper their research efforts.[26] 29 When U. S. federal rules apply to such research—as is the case with federally-funded projects and any projects related to obtaining FDA approval to market drugs or devices—the local Institutional Review Board (IRB) must approve the research protocol. IRBs should not waive basic federal research requirements on informed consent (nor exempt researchers from them) except when the IRB determines that the research will be conducted in such a way that the subjects cannot be personally identified.30 If existing research rules were consistently and diligently applied perhaps we could confidently state that the

24 Pezzella, M., "DNA Satabases Take Shape at Firms on Two Coasts", *Biotechnology Watch*, september 18 of 2000, at 2000 WL 7388705.

25 Pezzella, M., "DNA Databases Take Shape at Firms on Two Coasts, *Biotechnology Watch*, september 18 of 2000, at 2000 WL 7388705.

26 Korn, D., "Genetic Privacy, Medical Information privacy, and the use of human tissue specimens in research in Genetic Testing and the Use of Information (Long G, ed.) pp. 16-83 (Washington, American Enterprise Press, D. C., 1999).

privacy of research subjects is adequately protected.[27] Today, however, such confidence would be misplaced.[28]

None of the privacy and consent issues are limited to the U. S. (see anexo 1) The most internationally discussed DNA-based project has been deCODE in Iceland, a commercial project which has been opposed by the Iceland Medical Association, among others, for ethical shortcuts, including "opt out" provisions instead of requiring informed consent of subjects.[29] The deCODE project, which has been endorsed by two acts of the Iceland parliament, involves the creation of two new databases: the first containing the medical records of all Iceland citizens, and the second DNA samples from them (a third database, of genealogical records, already exists) deCODE intends to use these three databases in various combinations to seek out genetic variations that could be of pharmaceutical interest. The major ethical issues raised by this project are 1) the question of informed consent for inclusion of personal medical information in the database, which is currently included under the concept of presumed consent, which requires individuals to actively opt out of the research if they do not want their information in the database; 2) informed consent for the inclusion of DNA in the DNA databank in an identifiable manner (whether encrypted or not, and no matter which entity holds the encryption key) and 3) whether the right to withdraw from the research (including the right to withdraw both the DNA sample itself from the databank and all information generated about it) can be effectively exercised. Other issues include the security of the databases, and community benefit from the research project itself.[30] Iceland provides a type of ethical laboratory that helps identify the major issues involved in population-

27 "Office of Inspector General U. S. Department of Health and Human Services", *Institutional Review Boards: A Time for Reform*, 2000.

28 "Office of Inspector General U. S. Department of Health and Human Services", *Institutional Review Boards: A Time for Reform*, 2000.

29 Greely, H. T., "Iceland's plan for genomics research: facts and implications", *Jurimetrics*, núm. 40, 2000, pp. 153-191; Jonantansson, H., "Iceland's Health Sector Database: a significant head start in the search for the biological holy grail or an irreversible error?", *Am. J. Law. Med.*, 2000, núm. 26, pp. 31-67; Annas, G. J., "Rules for research on human genetic variation-lessons from Iceland", *NEJM*, núm. 342, 2000, pp. 1830-1833.

30 Annas, G. J., "Rules for research on human genetic variation-lessons from Iceland", *NEJM*, núm. 342, 2000, pp. 1830-1833.

based genetic research, as well as helping to inform us as to why international privacy rules are desirable.

Although Icelanders themselves do not seem overly concerned with the adequacy of deCODE's plans to protect their personal privacy, other countries have not been as disposed to giving away the autonomy and privacy of their citizens so readily. Both Estonia and the U. K., for example, have announced that their population-based DNA collections and research projects will contain strong consent and privacy-protection provisions.[31] The privacy problems inherent in large population-based projects could be avoided altogether by stripping DNA samples of their identifiers in a way that makes it impossible to link personal medical information with DNA samples (at least by using standard identifying methods). Of course, most researchers want to retain identifiers to do follow-up work or confirm diagnoses.[32] Such identification retention, however, puts individuals at risk for breach of confidentiality and invasion of privacy, and these risks are why both informed consent and strong privacy protection protocols are ethically necessary for genetic research.[33] These considerations also apply to criminal DNA databases, since even convicted felons have privacy rights.

Risks of disclosure of personal genetic information are so high that some prominent genetic researchers, including Francis Collins and Craig Venter, have suggested concentrating not on privacy rules, but rather on anti-discrimination legislation designed to protect individuals when their genetic information is disclosed, and insurance companies, employers, or others want to use that information against them.[34] We agree that anti-discrimination legislation is desirable, but it does not substitute for privacy rules that can prevent the genetic information from being generated in the first place without the individual's informed authorization.

A law recently enacted in Massachusetts, a state with a population more than 20 times larger than Iceland's,[35] for example, mistakenly cha-

31 Annas, G. J., "Rules for research on human genetic variation-lessons from Iceland", *NEJM*, núm. 342, 2000, pp. 1830-1833; Frank, L. "Storm brews over gene bank of Estonian population", *Science*, núm. 286, 1999, pp. 1262-1623.

32 McKie, R., "The gene collection", *BMJ*, núm. 321, 2000, p. 854.

33 Clayton, E. W. *et al*., "Informed Consent for Genetic Research on Stored Tissue Samples", *JAMA*, núm. 274, 1995, pp. 1786-1792.

34 CBS News: *This* Morning, 27 de junio de 2000, Federal Document Clearing House transcript at 2000 WL 6654407.

35 Massachusetts Acts Chapter 254, 2000.

racterized in the press as "a sweeping set of genetic privacy protections, "illustrates this point. Under this new law, written informed consent is a prerequisite to predictive (but not diagnostic) genetic testing, and to disclosing the results of such tests by entities and practitioners that provide health care. The law also limits the uses that insurers and employers can make of genetic information. However, it places no limitations on how researchers and biotech companies that engage in projects that require the use of identifiable samples and identifiable genetic information conduct their activities. Apparently those who drafted the statute were under the impression that they need not be concerned about protecting research subjects because research with human subjects is regulated by the federal government, failing to recognize that many activities of genomic companies do not fall under the jurisdiction of the federal regulations.

IV. POLICY RECOMMENDATIONS

We have argued in the past that a major step to achieving genetic privacy would be the passage of a comprehensive federal genetic privacy law.[36] The primary purpose of such a law is to give individuals control over their identifiable DNA samples and the genetic sequence information extracted from them. The model we suggest explicitly provides that individuals have a property interest in their own DNA and this property interest gives them control over it. Control could also, however, be obtained by requiring explicit authorization for collection and use, including research and commercial use. We believe that in the absence of authorization no one should know more about an individual's genetic makeup than that individual chooses to know, and the individual should also know who else knows (or will know) their private genetic information (see anexo 2) Current U.S. state laws at best offer some economic protections, and a patchwork of genetic privacy protections. But existing state laws have significant gaps and inconsistently regulate those who engage in DNA banking and genetic research. Nevertheless, existing privacy laws

36 Annas, G. J., Glantz, L. H. & Roche, P. A., *The Genetic Privacy Act and Commentary*, 1995 (Available by Request from the Health Law Department, Boston Mass., Boston University School of Public Health, and at http://www.busph.bu.edu/Depts/HealthLaw/); Roche, P. A., Annas, G. J., Glantz, L. H., "The Genetic Privacy Act: A Proposal for National Legislation", *Jurimetrics*, núm. 37, 1996, pp. 1-11.

provide models and a foundation that can be built upon to protect genetic privacy and empower individuals in this genomic era. But until comprehensive federal legislation is passed in the USA, US citizens will have to rely upon those who create and maintain DNA banks to design, implement and enforce self imposed rules to protect individuals.

One proposal to deal with privacy issues and individual control over genetic information is to have DNA samples and medical records collected by a "third party broker" of genetic information who would then, with the informed consent of the individual, make this information available to researchers in a coded form. A for-profit company, First Genetic Trust, has been formed in the U. S. to try out this model.[37] Individuals are solicited via the internet to participate in the Trust and all communication with those who participate, including consent to new studies, will take place over the internet. The purpose of the Trust is to assure individuals that no one would be able to use their DNA or their personal medical information associated with it without the individual's authorization. Some have criticized this approach as going too far in protecting participants, noting that consent is not generally necessary for IRB-approved research that does not involve identifiable data. Regardless of the fact that First Genetic Trust itself will not be engaged in research, as long as data held by the Trust is linkable to individuals, we think authorization should be required and that proposals like this one are a step in the right direction.

Whether arrangements like these will lead to significant public participation in genetic research remains to be seen. Despite the availability of tests for genes that predispose individuals to several diseases, including Huntington disease and some forms of breast and colon cancers, the number of people who choose to undergo clinical genetic testing has fallen far below the expectations of the companies that sell tests and physicians who believe their patients would benefit from them.[38] Why is the public, which is on the one hand fascinated with each advance in mapping the genome and the identification of particular genes and the possible association of a gene with particular human characteristics, simultaneously reticent to undergo genetic testing? Explanations that individuals give for avoi-

37 Marshall, E., "Company Plans to Bank Human DNA Profiles", *Science*, núm. 291, 2001, p. 575.

38 Kolata G., "Public Slow to Embrace Genetic Testing", *NY Times*, 27 de marzo de 1998, available at www.nytimes.com.

ding genetic tests include fear of discrimination, concern over the impact on family members, lack of effective treatments, and preference for uncertainty about the future.[39] Privacy protections have little, if any, impact on attitudes towards the future. Nevertheless, by regulating the creation, maintenance and disclosure of information, they can reduce privacy risks and provide some reassurance to those who might not otherwise participate in genetic research or clinical testing.

Once individual interests in privacy and in being treated fairly on the basis of genetic information have been addressed, only property issues remain. Individuals can be thought of as having a property right in their DNA, including, among other things, the right to restrict others from "trespassing" on their property without permission.[40] One U.S. state, Oregon, incorporated an individual's right of ownership in DNA into its laws in 1995.[41] Objections that this law would inhibit research in that state echoed objections researchers and industry have made elsewhere to explicit and strict privacy rules.[42] Acknowledging property interests in DNA need not impede research anymore than respect for individual privacy would. To the contrary, individuals are free to grant researchers property rights in their DNA, and are much more likely to do so if their privacy can be guaranteed (as it can be if identifiers are not retained).

DNA can rightly be seen as containing uniquely personal, powerful and sensitive information about individuals and their families. Some individuals want to know as much of this information about themselves as possible, and may be willing to share this information with their families and beyond. Others would rather remain ignorant about their own genetic makeup, and thus their risks for future illnesses, or at least to keep others ignorant of such information. We believe that individual choices are best served by policies that place primary control over an individual's DNA

39 Gettig, B., "Survey Reveals Attitudes Towards Genetic Testing", *The Marker*, núm. 10, 1997, pp. 6 y 7; Hall, M. A. & Rich, S. S., "Genetic Privacy Laws and Patients Fear of Discrimination by Health Insurers: the View of Genetic Counselors", *Journal of Law Medicine & Ethics*, núm. 28, 2000, pp. 245-257.

40 Kolata G., "Public Slow to Embrace Genetic Testing, *NY Times*, 27 de marzo de 1998, Available at www.nytimes.com.

41 Oregon Revised Statutes 659.715, 1998.

42 O'Neill, P., "Researchers Fight to get a Piece of You, *Portland Oregonian*, 11 de julio de 1999 WL 5358096; Rosenberg, R., "Biotechnology: a Study in Data Collection, Genomics Companies go Abroad to Obtain Samples Citing Obstacles in the United States, *Boston Globe*, D4 (1o. de noviembre de 2000).

and genetic information in the hands of individuals. We also believe privacy protections will prove as necessary for the future of genetic research and clinical applications as they will be for the future of e-commerce. We believe the sooner reasonable genetic privacy protections are in place, the better it will be for all of us.

V. ANEXOS

1. *Anexo I*

Enterprises that Raise Challenging Issues

A) DeCODE Genetics plans to computerize the national health service patient records of Iceland, and collect DNA samples from members of the population for genetic linkage analysis and association studies on common diseases. Results will be cross referenced with information from publicly available genealogical information. Subscriptions to these databases are sold to researchers, and information is entered into them on the basis of presumed consent.

B) The UK Population Biomedical Collection, a joint initiative of the Medical Research Council and the Wellcome Trust, which plans to focus on understanding the interactions between genes, environment and life styles in cancer and cardiovascular conditions. Their goal is to collect samples of up to 500,000 people and link these samples to an ongoing collection of the individuals'medical data. Investigators may be granted access to results of genotyping, but not to the DNA samples.

C) Ardais Corp., a startup biotechnology company that intends to enter into agreements with several major hospitals in the U. S. under which surgical patients will be asked for tissue left over from operations. These samples will be linked to records detailing the patient's medical history and family information. Tissue libraries and data will be licensed to researchers.

2. *Anexo II*

Assessing Genetic Privacy

Laws or policies that purport to protect genetic privacyshould, at a minimum, do the following:

A) Recognize individual genetic rights, particularly:

- *a)* The right to determine if and when their identifiable DNA samples are collected, stored or analyzed.
- *b)* The right to determine who has access to their identifiable DNA samples.
- *c)* The right of access to their own genetic information.
- *d)* The right to determine who has access to their genetic information.
- *e)* The right to all information necessary for informed decision making in regard to the collection, storage and analysis of their DNA samples and the disclosure of their private genetic information.

B) Limit parental rights to authorize the collection, storage, or analysis of a child's identifiable DNA sample so as to preserve the child's future autonomy and genetic privacy.

C) Prohibit unauthorized uses of individually identifiable DNA samples, except for some uses in solving crimes, determining paternity or identifying bodily remains.

D) Prohibit disclosures of genetic information without the individual's explicit authorization.

E) Strictly enforce laws and institutional policies.

F) Provide accessible remedies for individuals whose rights are violated.

G) Institute sufficient penalties to deter and punish violations.