COMPARATIVE ARCHITECTURE OF GENETIC PRIVACY

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INTRODUCTION: PRIVACY: A CONCEPT

"Perhaps the most striking thing about the right to privacy is that nobody seems to have any very clear idea what it is."[1] Despite that hurdle, or perhaps because of it, privacy has received enormous attention in the literature of numerous disciplines, including law, sociology, anthropology, philosophy, and medicine. Both the definition and the paradigm of privacy can vary depending on the disciplinary lens through which it is viewed.[2] Furthermore, the general absence of a comprehensive legal framework regarding the protection of privacy can make it difficult to develop a common understanding of what interests are protected by privacy rights. This makes it virtually impossible to devise a common concept that covers the full range of considerations across disciplines. Thus, the scope of this Article is necessarily limited. This Article addresses the issue of biomedical privacy and, more specifically, genetic privacy. The information that follows focuses on two related aspects of genetic privacy—informational autonomy and decisional autonomy.

1. Privacy Architecture

Privacy interests and rights are constructed differently across societies. The interplay between the structure and the substantive right can be significant. These variations in the construction of rights have been the subject of some debate regarding the degree of protection afforded those rights by virtue of their architecture. Frederick Schauer has examined the comparative architecture of freedom of speech rights with regard to constitutions, noting that certain constructions render rights "seemingly absolute" while other constructions are qualified, allowing for overrides; some are universal while others are situational and temporal; and some are worded broadly while others are more precise and narrow in their articulation.[3] Schauer's focus on the freedom of expression

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1. Judith Jarvis Thomson, *The Right to Privacy, in* PHILISOPHICAL DIMENSIONS OF PRIVACY: AN ANTHOLOGY 272, 272 (F. D. Schoeman ed., 1988).

2. *See generally* DAVID M. O'Brian, PRIVACY, LAW, AND PUBLIC POLICY (1979).

3. Frederick Schauer, *Freedom of Expression Adjudication in Europe and America: A*

bears some parallels to the topic of this Article. The Fourth Amendment allows a warrant to be issued solely upon the showing of probable cause, and thus it is similar to Schauer's view of free speech privacy rights in that it has also been construed in "absolute terms." Yet we understand privacy to be a qualified right, the contours of which are largely crafted by case law (often tort) and, in the biomedical context, regulatory law and agency guidance that set margins based on countervailing interests. Other legal scholars have considered the architecture of rights pertaining, for example, to enforcement, arguing that the structure of enforcement can affect the meaning of the substantive right.[4] There are several ways counties have structured privacy laws. One of which is the less categorical model.

The less categorical model employed in many European countries recognizes privacy as a fundamental right. However, the less categorical model also accommodates other important competing interests. Resolution of competing interests typically calls for a balancing of interests and rights in which the privacy rights of the individual may be weighed against other interests that fall within certain designated categories, for example, "the public interest."[5] The proportionality rule, a multifaceted test, poses three primary questions: 1) Can the intended action achieve its stated goal?; 2) Is the action necessary in order to achieve the goal, and are there less burdensome means of achieving it?; and 3) If a non-economic right is involved, is the burden on the right an acceptable one?[6] Furthermore, it requires a determination of whether the burden on the right to individual privacy is proportionate to the public interest being privileged. However, it has been demonstrated in several types of analysis[7] that this seemingly more flexible model does not necessarily expose fundamental rights to the subordination of societal interest any more than the "absolute" model. Rather, as this Article explores, certain safeguards protecting the underlying principle of the protections seem to remain fairly intact. What this proportionality model does is make the process and rationale that may result in the override of a fundamental right transparent, ensuring that such override occurs only in certain circumstances and in the least restrictive way possible. Indeed, Schauer notes that critics of the American approach say that the European architecture is more transparent in its open declaration that rights are subject to a weighing process as against other interests, whereas the stringent categorical approach of the U.S. system merely obscures the weighing process that has already occurred in the drafting of the right.[8]

Case Study in Comparative Constitutional Architecture, *in* FACULTY RESEARCH WORKING PAPERS SERIES RWP05-019 1 (2005).

4. *See, e.g.*, Colin J. Bennett & Charles D. Raab, The Governance of Privacy (2003).

5. Council Directive 95/46/EC, Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 31 (30).

6. *See, e.g.*, Francesca Bignami,. *European Versus American Liberty: A Comparative Privacy Analysis of Antiterrorism Data Mining*, 48 B.C. L. Rev. 609, 642 (2007).

7. *See e.g., id.*

8. Schauer, *supra* note 3, at 3.

In the biomedical context, innovative uses of genetic information, and the technologies that use it, implicate a wide range of privacy issues. Because of the nature of genetic information, protection of privacy interests and rights in the biomedical context must be viewed anew; traditional protections do not fit the contours of the new privacy vulnerabilities and interests. Indeed, it has been suggested that, for a variety of reasons (including significant technological innovation), a new taxonomy of privacy is needed in order to more accurately understand modern privacy violations.[9] Consequently, lawmakers and judges have great difficulty articulating the privacy harm in contrast to opposing interests like free speech, market interests, and national security, which are more easily articulated.[10] This skewed articulation of rights and interests may well serve to unseat highly valued privacy rights merely because they are poorly articulated.

This Article examines the comparative architecture of privacy in the biomedical context and analyzes specific aspects of genetic privacy, assessing comparative approaches to three pivotal issues in the biomedical context: tissue use, disclosure of genetic test results, and reduced capacity to consent. I select these issues because they illustrate different levels and aspects of privacy and, as such, suggest a composite picture of both the degree and nature of protections and to what extent architecture affects the meaning of the substantive right. The third issue, reduced capacity to consent, while not exclusively a genetic issue, is addressed because it reveals something of the non-negotiated boundaries of privacy not modifiable by individual consent.

Often, one thinks of medical privacy as being a matter of protection of medical information and confidentiality. These concepts are indeed central to the scope and force of medical privacy, and, like autonomy, are often considered among the fundamental principles of biomedical ethics. Yet, one of the most important aspects of patient rights in this context is a notion that combines both concepts to create a hybrid interest in what I shall refer to as "informational autonomy"—the right to control information about oneself.[11] This encompasses what Brandeis referred to as the right to be let alone.[12] The European Union, in its Data Protection Directive,[13] also adopts a view of privacy that renders this concept a core concern in privacy protections.

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9. Daniel Solove, *A Taxonomy of Privacy*, 154 U. PA. L. REV. 477, 483 (2006).

10. *Id.* at 480.

11. *See, e.g.*, GRAEME LAURIE, GENETIC PRIVACY: A CHALLENGE TO MEDICO-LEGAL NORMS 4 (2002); DAVID H. FLAHERTY, PROTECTING PRIVACY IN SURVEILLANCE SOCIETIES: THE FEDERAL REPUBLIC OF GERMANY, SWEDEN, FRANCE, CANADA, AND THE UNITED STATES 7 (1989); ALAN WESTIN, PRIVACY AND FREEDOM (1970) (for usage of terms describing privacy interests).

12. Samuel D. Warren & Louis Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193 (1890).

13. *See* Council Directive 95/46/EC, Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 31 [hereinafter Directive].

Concepts of both informational and decisional privacy are implicated in this discussion and serve as the focus for this analysis.

Informational autonomy in the biomedical context arises in many forms. In the age of genetic medicine, the genetic information of one patient may be significant for another. Thus, when deciding whether to share an individual patient's medical information, one should attempt to strike a balance between the rights of a patient to keep his medical information confidential and the rights of a patient who may benefit from the release of another's personal medical records. Often the question comes down to whether the patient has a superseding right to make decisions about who has access to his private medical information when others may benefit from knowing it. As biomedical technology proceeds, the question of individual control of medical information arises with increasing frequency in clinical practice, medical research, and even public health and law enforcement. As the cases of both tissue use and storage and disclosure of genetic test results show, the individual privacy right can come into direct conflict with the pursuit of societal benefit.[14] In the former case, the societal benefit derived from the compromise of personal data protections comes in the form of more informed medical research and potential individual and collective benefits to society. In the later case, the interests of a smaller but less speculative circle of potential beneficiaries can come into conflict with those of individual right to privacy.

With the growing case for encroachment on informational autonomy in the name of public interest, it becomes increasingly important to ascertain the force of privacy protections. By examining this question through a comparative analysis of the structure of rights that protect privacy in the biomedical context, some light can be shed on the nature of privacy protections and where the true source of their comparative force lies. As biomedical innovations increase the value of sharing private medical information, identifying and crafting the protective mechanism of privacy rights becomes increasingly important.

2. Overview of the Sources of Privacy Protections

This comparative analysis begins with an identification of the sources of privacy protections and the hierarchy of legal norms regarding privacy rights. The sources of privacy protections, like many laws and regulating mechanisms, do not operate in a vacuum, but rather rely on various institutional, social, and political factors for their implementation and ultimate effect. While not discounting these extra-legal factors, they generally lie outside the scope of this Article.

Starting with European treaties and the Data Protection Directive of the European Union, this analysis examines the European Union Directive 95/46

14. *See, e.g.*, Bartha M. Knoppers, *Confidentiality of Health Information: International Comparative Approaches*, *in* Protecting Data Privacy in Health Services Research, App. D, 180 (Inst. of Med. 2000), *available at* http://newton.nap.edu/html/data_privacy/appD.html#FOOT19.

(Data Protection Directive) and related national legislation to assess the nature and effect of the architecture of privacy protections. Then crossing the Atlantic, the Article examines the U.S. structure of privacy protections in the biomedical context.

2.1 European Union Membership and Its Effect on Member National Law

The European Union was formed as an outgrowth of a number of treaties and agreements with the primary goal of facilitating trade. Beginning with a core membership of eight member nations, it expanded to a membership of 27 by 2007[15]. Membership in the EU held out a number of benefits to member states, particularly economic benefits, and became a foreign policy goal for several post-communist eastern European states.[16] Of course, membership in the EU carries with it numerous obligations, particularly in the observance of EU law and directives. For some relatively late membership candidates, some East European countries, for example, the obligations operated as both a passive and active leverage, resulting in what has been referred to as "asymmetric interdependence."[17] Some countries that joined the EU after the completion of the internal market but were already members of the European Economic Area (EEA) experienced less EU leverage. This is most likely because, as EEA members, they had already complied in principle or practice with general EU norms, particularly those stemming from status as a market economy.[18] This relatively lower degree of leverage may help to explain some aspects of implementation and application of privacy and freedom of speech law in Norway, an EEA member.

2.2 European Convention on Human Rights

The European Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention) was adopted by the Council of Europe in 1950.[19] It articulates the right to privacy in two clear and succinct provisions, arguably leaving no room for suggestion that privacy rights are without meaningful legal basis. Article 8 of the European Convention articulates the right to privacy in two provisions:

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15. *The History of the European Union.* Europa, http://europa.eu/abc/history/index_en.htm (last visited Feb. 13, 2009).

16. MILADA ANNA VACHUDOVA, EUROPE UNDIVIDED: DEMOCRACY, LEVERAGE, AND INTEGRATION AFTER COMMUNISM 108 (2005).

17. *Id.* at 107-10.

18. *Id.* at 111.

19. Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol No.11. Rome, 4.XI.1950. *available at* http://conventions.coe.int/Treaty/en/Treaties/Html/005.htm.

> 1. Everyone has the right to respect for his private and family life, his home and his correspondence.
>
> 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.[20]

This Convention and its implementing and institutions of enforcement are critical to the protection of privacy interests.[21]

3. European Directive on Data Protection

In 1995, the European Commission enacted the Data Protection Directive (Directive) addressing the member states of the European Union.[22] This document was designed to facilitate the free flow of information among the member states without compromising the privacy of the citizens in each of the member states.[23] The Directive sets forth with greater particularity the provisions that ensure the processing of personal data in a manner that is consistent with Article 8 of the Convention while aiming to assist in the protection of privacy interests in the domestic and international transfer of information. Article 1 ("Object of the Directive") states: "In accordance with this Directive, Member States shall protect the fundamental rights and freedoms of natural persons, and in particular their right to privacy with respect to the processing of personal data."[24]

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20. European Convention for the Protection of Human Rights and Fundamental Freedoms, Art. 8, Nov. 4, 1950, Europ. T.S. No. 5, (*entered into force on* Sept. 3, 1953), *as amended by* Protocol No. 3, Europ. T.S. 45 (*entered into force* Sept. 21, 1970); Protocol No. 5, Europ. T.S. 55 (*entered into force on* Dec. 20, 1971); Protocol No. 8, Europ. T.S. 118 (*entered into force on* 1 Jan. 1990); and Protocol No. 11, Europ. T.S. 155 (*entered into force on* Jan. 11, 1998) [hereinafter European Convention].

21. Taking the 1948 Universal Declaration of Human Rights as its starting point, the European Convention was designed to further the goal of collective enforcement of the Universal Declaration of Human Rights. To that end, the European Commission of Human Rights, the European Court of Human Rights, and the Committee of Ministers of the Council of Europe were set up in subsequent years to enforce the terms agreed to by the contracting states. *See* Universal Declaration of Human Rights, G.A. Res. 217A U.S. GAOR, 3d Sess., 1st Plen. Mtg., U.N. Doc A/810 (Dec. 12, 1948).

22. Council Directive 95/46/EC, Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L 281) 31.

23. *Id.* at 10.

24. Directive, *supra* note 13, at Art. 1.

3.1 Sensitive Information

Although the Directive does not specifically address medical information or research, much can be derived from its provisions with regard to informational privacy protection issues as they arise in the medical arena.[25] Article 8(1) of the Directive on the processing of special categories of data states in relevant part: "Member States shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life."[26]

Thus, although medical research is not specifically addressed by the Directive, Article 8 indicates that personal health information falls into a special category of data deserving of special protections in its processing. This is frequently referred to, both in EU contexts as well as in many national laws, as "sensitive" data.

3.2 Derogations, Exceptions, and Overrides

The protections against the processing of this special category of personal data are not absolute. Indeed, Article 8 subsections (2)-(5) serve to derogate the privacy protections afforded in Article 8(1), stating that Article 8(1) shall not apply to the processing of data relating to offences, criminal convictions or security measures, to exemptions laid down by member states in the "substantial public interest," and notably, to instances in which the processing of data is required for "purposes of preventive medicine, medical diagnosis, the provision of care, or treatment or the management of health-care services."[27] Recital 34 elaborates on the derogation contained in the articles of the Directive stating:

> Whereas Member States must also be authorized, when *justified by grounds of important public interest*, to derogate from the prohibition on processing sensitive categories of data where *important reasons of public interest so justify* in areas such as public health and social protection – **especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system – scientific research and government statistics**; whereas it is incumbent on them, however, to provide specific and suitable safeguards

25. *See, e.g.*, IMPLEMENTATION OF THE DATA PROTECTION DIRECTIVE IN RELATION TO MEDICAL RESEARCH IN EUROPE (Deryck Beyleveld et al., eds., 2004) [hereinafter Research].

26. Directive, *supra* note 13, at art. 8.

27. *See id.*

> so as to protect the fundamental rights and the privacy of individuals . . . .[28]

While the Directive does not specifically address medical research and the use of personal medical information in that context, its inclusion of health data as "sensitive information" and its designated derogations in the public interest (as stated in Recital 34, in the interests of public health, social protection, health delivery and administration, and scientific research), indicate that the architecture of privacy protections as designed in the Directive is such that the protection of substantive rights is not stringent. The list of broad derogations appears to yield no predictable precise boundary for the privacy of health data. Nor does the Directive interpret or direct the precise scope or application of these categories of derogation. Thus, social protection in the public interest may actualize more broadly in some countries as an override of privacy interests than in others. Where this is contested, it may be brought to the European Court of Human Rights or Court of Justice.[29]

In accordance with the proportionality rule, which allows for a balancing of interests and rights, implementing member states may derogate individual privacy rights if the countervailing interests constitute an important public interest, such as public health or social protection, and otherwise meet the criteria of the proportionality principle. However, the protection of fundamental rights figures prominently into the balancing of interests, even in the face of broadly articulated exceptions. In order to prevail over a fundamental right, the proportionality rule requires that the countervailing interest may not be frivolous or dismissive of individual privacy. Thus, the proportionality rule does not open the floodgates; rather it operates within certain confines and assurances that the essential character of fundamental rights is not undermined.[30] Still, health information, while accorded special protected status, in many ways stands to lose some important aspects of that status by virtue of how it is used in the field of health and medical research and how the broadly constructed derogations are interpreted and applied nationally.

As this Article explores, the relevant parameters of privacy are likely to be created and enforced by national legislation, the structure and conception of privacy rights, and by the priority placed on privacy by society.

3.3 Implementation of the Directive

One of the Directive's primary objectives is to harmonize data protection across member states in order to facilitate the use of such data across borders within the EU. Additionally, the Directive also addresses standards and practices regarding data protection among non-member states in order to ensure

28. *See id.* at Recital 34 (emphasis added).
29. *See, e.g.*, Z v. Finland, App. No. 22009/93, 25 Eur. Ct. H.R. (1997).
30. *See* Schauer, *supra* note 3.

an adequate level of protection. This is manifest in the requirement that the transfer of personal data from an EU member state can only be done if the protections in the receiving country are equal to those in the EU, or if not, a certificate of adequacy must be acquired from the appropriate authorities.[31] Each member and EEA state was required to effect implementation of the Directive by 24 October 1998.[32] This deadline for compliance was subsequently extended by amendment until 2001.

The implications of the Directive for medical research are substantial. With increasing transnational collaborative research projects, and the desirability of using existing tissue collections, regulations regarding transferability are pivotal to the medical research enterprise. The commitment to fundamental rights and the protection of individual privacy is really called into question when weighed against the range of societal interests that may fall within the list of derogations.

The process of implementing the Directive, however, was not merely a matter of rubber-stamping of Directive provisions. Indeed, it sometimes required changes that involved numerous procedural, institutional, and political hurdles in the member states. Consequently, when the first report on implementation by member states was to be made in 2001, the slow process of transposition among many member states resulted in delay of the first report[33]. At the end of 1999 the European Commission decided to file against France, Germany, Ireland, Luxembourg and the Netherlands in the European Court of Justice for failure to fully implement Directive 95/46.[34] In 2001 the Netherlands and Germany documented their compliance, and eventually the cases against the remaining nations were closed.

National implementation of the Directive also had to be sensitive to national notions, norms, and practices regarding privacy. Particularly in the context of biomedical research and genetic research, the standards set by the EU provide for a fair margin of discretion for Member States in the substantive implementation of certain areas. This broad discretion is very significant to the protection of sensitive information, particularly regarding health information. For example, one of the consistently mentioned justifications for derogation pertains to scientific purposes and research that presumably benefits society.

Despite the fact that the Directive contains no specific reference to medical applications, the transposition of the Directive by Member States has an effect on the policies and regulations governing significant aspects of

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31. Research, *supra* note 25.

32. *Commission Report on the Transposition of the Data Protection Directive, Analysis and Impact Study on the Implementation of Directive EC 95/46 in Member States, available at* http://ec.europa.eu/justice_home/fsj/privacy/docs/lawreport/consultation/technical-annex_en.pdf (last visited Nov. 11, 2008) [hereinafter *Analysis*].

33. See actions against France, Germany, Luxemburg, Ireland, and the Netherlands, discussed below.

34. *See id.*

biomedical research that use genetic technologies and information.[35] It is generally recognized, although not without controversy, that genetic information has a special character and, at least in some instances, may require separate legislation and oversight.[36] While the Directive does not require this kind of particularized regulation in implementation, several Member States have taken up this matter. In addition, the Commission's Article 29 Data Protection Working Party (Working Party 29) has established a Working Document on Genetic Data in recognition of the concerns arising from the unique nature of genetic information.[37]

Variation with regard to protection of genetic data is considerable. Working Party 29 has noted that regulation of the processing of genetic data is uneven across the EU: "Indeed, while some Member States have explicitly listed genetic data as sensitive data in their Data Protection law with all the safeguards and restrictions associated, in most Member States the issue of the processing of genetic data is not as such regulated by specific legislation."[38] Thus, while some Member States provide for complementary rules in their laws on patients' rights and have enacted legal regulations for the processing of genetic data, the Working Party 29 anticipates a trend toward increased national regulation of the processing of genetic data specifically. For example, in 2005, Portugal, a non-member state, enacted genetic legislation applying many of the principles and safeguards that regulate general medical information, including the nature of permissible overrides.[39]

Where the unique aspects of genetic information have consequence for privacy protections, Member States face the challenge of finding ways to provide the necessary protections, whether in sectoral legislation or broader protective legislation, while leaving sufficient room in which to derive the benefits of developing technologies that challenge the margins of privacy. This Article looks at two largely unsettled issues involving the processing of genetic information – tissue use and storage and disclosure of genetic test results. Regulation of these issues is uneven. The following section provides a very brief view of three national systems of privacy protections pertaining to health information.

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35. *See* Research, *supra* note 25.

36. Sonia Suter, *The Allure and Peril of Genetic Exceptionalism: Do We Need Special Genetics Legislation?* 79 WASH. U. L.Q. 669, 747 (2001).

37. *Article 29 Data Protection Working Party, Working Document on Genetic Data*, 12178/03/EN WP 91 (Mar. 17, 2004), *available at* http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2004/wp91_en.pdf [hereinafter *Article 29 Data Protection Working Party*].

38. *Id.* at 3.

39. Law No 12/2005 of Jan. 26, 2005, Personal Genetic Information and Information on Health [hereinafter Portugal].

4. Europe: National Hierarchies of Privacy Norms

4.1 France

The Constitution of France does not mention privacy or set forth rights of this type.[40] However, by virtue of its declaration of membership in the European Union,[41] France is obligated to abide by the principles of the Directive. There is no single comprehensive privacy provision in France. Provisions for the protection of privacy interests are found in both the civil and criminal codes of this civil law country.

Article 9 of the Civil Code recognizes privacy as a fundamental right stating that "everyone has the right to respect for his or her private life."[42] What constitutes private life is not defined, but rather has been a matter for the courts, who have over time constructed a meaning that has been said to include a person's "love life, friendships, family circumstances, leisure activities, political opinions, trade union or religious affiliation and state of health."[43] This protection applies to both public and private spaces. Furthermore, Article 9 authorizes the court to take measures to prevent or halt invasions of personal privacy and, in general, at least regarding publication, privacy protections in France may be among the most protective.[44]

Privacy in the health sector is generally provided for at the national level by the Penal Code in Articles 226-13,14). In the section on "Professional Secrecy," Article 226-13 states that disclosure of secret information by one entrusted with such information by virtue of his profession or position is punishable by a year of imprisonment and a fine of 15,000 Euros.[45] It has been noted that, unlike most obligations of physicians, which are "obligations of means," the obligation of secrecy is an "obligation of result"; thus, it is not only what is explicitly or implicitly communicated, it is also that which is understood.[46] It has been noted that, unlike most obligations of physicians, which are "obligations of means," the obligation of secrecy is an "obligation of result"; thus, it is not only what is explicitly or implicitly communicated, it also refers to that which is understood.[47] Therefore, whatever is "communicated," verbally or non-verbally, to a physician by any means within the context of the

40. 1958 La Constitution (Fr.).

41. Title 15 on the European Communities and the European Union, and its agreement, as a result of the Treaty on European Union signed on 7 February 1992.

42. Code civil [C. CIV.] art. 9 (Fr.).

43. Legal and Technical Office of Information and Communication for the Embassy of France, Embassy of France in Washington, French Legislation on Privacy, http://ambafrance-us.org/spip.php?article640 (last visited Nov. 12, 2008).

44. *Id.*

45. Code penal [C. pen.] art. 226-13 (Fr.).

46. *See* Knoppers, *supra* note 14, at 180.

47. *Analysis*, *supra* note 32, at 24.

doctor-patient relationship is privileged. Thus, protections in France are constructed broadly, resting on both the Data Processing Act and relevant provisions in the Codes.

4.2 Implementation of the Data Protection Directive: Act on Data Processing, Files and Individual Liberties

The French Data Protection legislation[48] came into compliance with Data Protection Directive 95/46/CE in 2004, after having been taken to the European Court of Justice for failure to notify all the provisions of the Directive.[49] The French Act on Data Processing, Files and Individual Liberties does contain a chapter specifically regulating the processing of medical data.[50]

5. Norway

The Norwegian Constitution, adopted in 1814, specifically stating that the "search of private homes shall not be made except in criminal cases,"[51] somewhat resembles privacy protections as expressed in the Fourth Amendment of the U.S. Constitution. Additionally, Article 110(c) of the Norwegian Constitution, which broadly sets forth protections of human rights, sets forth further provisions that pertain to privacy rights.[52]

Giving effect to international agreements requires both ratification and implementation of national legislation. The European Convention on Human Rights was incorporated into Norwegian law by the Human Rights Act of 21 May 1999 no. 30. According to Article 3 of the Human Rights Act, the Convention takes precedence over conflicting legislative provisions. The ECHR does not, however, enjoy constitutional status although it clearly has strong force by virtue of its precedence over conflicting legislative provisions.[53] This provision, not surprisingly, is the subject of some debate.[54] Additionally, as in much of Europe, under "the principle of legality," unwritten norms rooted in customary law may also acquire constitutional status.[55]

Since the European Convention on Human Rights (ECHR) specifically provides for protection of individual privacy and Norway is a signatory to the

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48. Decree No. 2005-1309 of Oct. 20, 2005, Journal Officiel de la Republique Francaise [J.O.] [Official Gazette of France], Oct. 22, 2005, p. 16769.

49. *Analysis, supra* note 32.

50. Decree No. 2005-1309 of Oct. 20, 2005.

51. Grunnloven [Grl] [Constitution] § 102 (Nor.).

52. *Id.* at art. 110(c).

53. Lee A. Bygrave & Ann Helen Aaro, *Privacy, Personality and Publicity--An Overview of Norwegian Law, in* INTERNATIONAL PRIVACY, PUBLICITY, AND PERSONALITY LAWS, 333, 333 (M. Henry, ed., 2001).

54. *See* Synne S. Maehle, *Limits of Rettsanvendelsesskjonn: About the Legal Legitimacy of a Tension Between Flertallsmakt and Rettighetsvern, in* GYLDENDAL ACAD. 285, 285-99 (2005).

55. *Id.* at Ch. 22.

Convention and has passed implementing legislation incorporating the ECHR, those privacy protections set forth in the Convention are protected under Norwegian law. Therefore, under Article 8 of ECHR, provisions relating to privacy protections are incorporated into Norwegian law by way of the Norwegian Constitution.

5.1 Data Protection Directive Implementation: Norwegian Personal Data Act of 2001

Norway, a member of the EEA and not the EU (but similarly required to bring its laws into compliance with the Directive), locates primary protections for personal information in the Norwegian Personal Data Act of 2001[56] (replacing the Data Registers Act of 1978).[57] In the context of medical privacy, other laws, regulations, and provisions interact with the Norwegian Personal Data Act to provide the national standard of privacy protection of medical information. Of particular interest in the realm of genetic privacy is the Biobank Law of 2004, which sets forth regulations pertaining to the use of genetic technologies.

Initially, certain provisions of the draft Norwegian Act proved problematic both with regard to the Directive as well as for certain constituencies in Norway, particularly those concerned with research. It has been argued that the final Norwegian Data Protection Act that was passed in 2001 was modified to satisfy the research community as well as comport with Directive provisions as a result of political idiosyncrasies.[58]

The new Norwegian Personal Data Act occasioned a shift in privacy protections, both in content and, significantly, in underlying orientation.[59] The former Norwegian legislative tradition regarding privacy took its rise from a "model of control" in which privacy, as a responsibility of society and the government, was a matter of external supervision, monitoring, and licensing.[60] The new Act, following the lead of the Directive, is oriented toward a "model of consent" and, according to Bygrave and Aaro, introduces more substantive rules and regulation of specific applications rather than the previously favored "framework legislation."[61] Now the Act includes numerous and more detailed substantive rules and clearly delineates specific principles such as purpose

56. Act of 14 April 2000 No. 31 relating to the processing of personal data (Personal Data Act) *available at* http://www.datatilsynet.no.htest.osl.basefarm.net/upload/Dokumenter/regelverk/lov_forskrift/lov-20000414-031-eng.pdf (last visited Feb. 16, 2009).

57. Vigdas Kvalheim, *Implementation of the Data Protection Directive in Relation to Medical Research in Norway*, *in* RESEARCH, *supra* note 25, at 291.

58. *Id.* at 290 (describing idiosyncrasies such as who participated and controlled the process that formed the final law).

59. *Id*, at 290.

60. *Id.* at 291.

61. Bygrave & Aaro, *supra* note 46.

specification (as may be applied to tissue use and storage).[62]

The Norwegian Personal Data Act has been perceived as not only being consistent with the Directive, but exceeding it in the standards for data protection.[63] It has been observed that the Norwegian Act may actually serve to value privacy over furthering scientific knowledge.[64] To the extent that this is true, it is reasonable to expect that this elevated status of individual privacy is consistent across sectors.

The Norwegian government, through its oversight agency, Datatilsynet, states that the express purpose of the Act is to protect persons from violations of their right to privacy when personal information is processed and to ensure that any processing of personal information is done in a way that accommodates a fundamental respect for privacy rights; it aims to protect personal integrity and private life and ensure that any personal data that is processed meets acceptable standards of quality.[65]

In virtually every aspect of the Norwegian approach to privacy protections, the shift toward consent seems to predominate. Consistent with this is the government website for the Data Protection Act: its implementing government agency, Datatilsynet (Data Supervision/Oversight), has as its headline slogan: "Protection of Persons: Your Right to Choose."[66] Consent is the predominating principle and a decisive factor in much of the processing of personal information in the biomedical context in Norway.

Three pieces of legislation constitute the Norwegian Data Protection Act: 1) The Personal Data Act; 2) Personal Data Regulations; and 3) the Personal Health Data Filing System.[67] However, since this Article looks at specific applications involving biotechnology, such as tissue storage and genetic test results, the Biobank Law, a relatively new piece of legislation implemented in 2004, is also implicated. Together, these regulations provide personal data protection in the biomedical context.

6. United States

It is frequently asserted that there is no fundamental right to privacy in the United States, but rather that it is a social construction,[68] undergirded by no

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62. *Id.*

63. *See* Kvalheim, *supra* note 57, at 290.

64. Kvalheim, *supra* note 57, at 292.

65. Datatilsynet, About the Data Inspectorate, http://www.datatilsynet.no/templates/Page____194.aspx (last visited Feb. 17, 2009).

66. *Id.*

67. Act of 18 May 2001 No. 24 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) *available at* http://www.regjeringen.no/en/dep/hod/Subjects/The-Department-of-Public-Health/Act-of-18-May-2001-No-24-on-Personal-Health-Data-Filing-Systems-and-the-Processing-of-Personal-Health-Data-Personal-Health-Data-Filing-System-Act-.html?id=224129 (last visited Jan. 26, 2009).

68. *See* Frederick Schauer, *Free Speech and the Social Construction of Privacy*, *in* THE

directly relevant constitutional provision.[69] Yet, the Fourth Amendment would seem to protect at least some aspects of privacy interest. It states in part, "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no [w]arrants shall issue, but upon probable cause . . . ."[70] The notion of protection against unreasonable search and seizure has been interpreted to apply to a wide variety of activities, communications, and entities that are not specifically enumerated. Wiretapping is a frequently used example.[71]

One might note that, like First Amendment protection of freedom of speech, there is no list of derogations to the Fourth Amendment; it appears as an "absolute" non-derogable right. Arguably, the warrants that may be issued according to specific criteria may be said to provide the opportunity for the balancing that is transparent in European legislation.

But the reality is that there is no overarching privacy legislation in the U.S. comparable to the European Directive on Data Protection or most of the national implementing legislation following a model of comprehensive data protection. Rather, the U.S. has adopted an approach characterized by sectoral privacy legislation. Thus, in the U.S. there is special privacy legislation regarding, for example, credit, banking, communication, and health.

6.1 Sectoral Health Privacy Legislation: HIPAA

Privacy in the biomedical context is governed by the Health Insurance Portability and Accountability Act (HIPAA).[72] Through this 1996 Act and its subsequent amendments, the U.S. system of privacy protections in the biomedical context would appear to offer a strong statement of protections. Yet, in its application in the context of biomedical research, much of the protection is in fact left to the discretion of implementing agencies. Following guidelines and laws set forth in HIPAA, administrative agencies are charged with oversight of the conduct of medical research within the confines of the law largely as applied by institutional review boards (IRBs).[73] This is especially true in the case of new technologies and the novel ethical and legal issues they raise. Because the process of law-making is so slow, the use and application of new technologies often goes forward without regulatory oversight of the vulnerabilities created by such technology. The lacunae created by the

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JOAN SHORENSTEIN CENTER ON THE PRESS, POLITICS AND PUBLIC POLICY: THE FIRST AMENDMENT SERIES (2000), for an exemplary analysis of the nature of this claim of social construction.

69. *Id.*

70. U.S. CONST. amend. IV.

71. *See, e.g.*, Videotape: In Search of the Constitution: Mr. Justice Brennan (Films for the Humanities & Sciences 1987).

72. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18 U.S.C., 26 U.S.C., 29 U.S.C., 42 U.S.C.) [hereinafter HIPPA].

73. 45 C.F.R. § 46.107 (2005).

outpacing of ethical analysis and the regulation spurred by the scientific developments are considerable. One area where this is very apparent is that of tissue use and storage, and the derivation, compilation, and storage of personal data taken from such tissue. The significance of the fact that HIPAA makes no specific reference to genetic data is unclear. HIPAA does not distinguish among different types of personal medical information[74]. However, because of the structure of rights, permissible processing of this data will not necessarily be the same. A use that falls through the cracks in HIPAA legislation and, therefore, might go unregulated in Europe will still receive rigorous analysis if it burdens a fundamental right.

Under HIPAA, protected health information (PHI) refers to individually identifiable health information. This includes information such as demographic information relating to a person's past, present or future health state; the provision of care, payment for health care, or anything that otherwise makes it possible to identify the individual. Common identifiers include birth date, social security number, name, and address.[75]

6.1.1 Explicit Exceptions

Along with the protections, HIPAA contains an extensive list of exceptions to non-disclosure of PHI.[76] This list includes disclosures: 1) for public health activities; 2) about victims of abuse, neglect, or domestic violence; 3) for health oversight activities; 4) for judicial and administrative proceedings; 5) to avert a serious threat to health or safety; 6) for specialized government functions; 7) for research purposes and; 8) for law enforcement purposes.[77] These categories of exceptions are carved out in the legislation, reflecting, as Schauer points out,[78] that the balancing has taken place in the drafting of the legislation. Importantly, these are also distinguishable from the broad derogations characteristic of European legislation precisely because of their specificity and the largely absent opportunity for further balancing.

This absence of opportunity for further balancing is not absolute regarding the use of private health data. The carved-out exceptions allow for some flexibility for the arbiter of disclosure. Thus, "research purposes," for example, absent a specific provision to the contrary, could allow a wide range of practices that would normally be considered in violation of privacy rights. However, typically, an IRB will have the opportunity to conduct a form of balancing[79]. The important point that distinguishes this kind of balancing from

74. *See* HIPPA, *supra* note 72.

75. 45 C.F.R. § 160.103 (2005).

76. 45 C.F.R. § 164.512 (2005) (providing: "Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required").

77. 45 C.F.R. Section 164.512 (a)-(f).

78. Schauer, *supra* note 3.

79. *See, e.g.*, Nat'l. Inst. of Health, Nat'l. Comm'n. for the Protection of Hum. Subjects of Biomedical and Behav. Res., The Belmont Report: Ethical Principles and Guidelines for the

that performed in accordance with the proportionality principle is that the nature of the balancing at this level is rarely transparent. As a result, it is often not clear what interests are being balanced and what weight is being accorded them. Thus, a decision by an IRB to permit a waiver of consent for the indefinite storage and use of existing genetic samples in an ongoing study may be justified by an oversight committee based on the inconvenience to the research staff, time constraints, or even on the reputation of the researcher, not to mention personal idiosyncrasies of a given IRB in which members expressing reservations about a study may be subjected to subtle (and not so subtle) expressions of disapproval.[80] Still, HIPAA provides a baseline level of protection, which is viewed by some, particularly researchers, as "overly protective."[81]

7. *Genetic Information in Research*

It is widely recognized, although not undisputed, that genetic information has characteristics that set it apart from other medical information.[82] For example, if one parent carries the genetic mutation for Huntington's disease, the children have a fifty percent chance of developing the same fatal and untreatable disease. Information about this genetic information can be of great interest to the offspring as well as siblings.[83] The power of information on a single gene disorder like Huntington's can be overwhelming, but when multifactorial diseases also carry genetic markers which can be tested for, the value of the genetic test result becomes more speculative. For example, questions arise regarding whether a forty-five-year-old who tests positive for the genetic mutation associated with colon cancer should be compelled to disclose this to family members in the interest of providing health benefits.

The ability to access and interpret genetic information as a biomedical tool can offer a range of benefits by virtue of the kinds of information it can provide and interventions to which it might lead. However, genetic technology also presents enormous complexities regarding the use of this information. Indeed, genetic information can trigger the involvement of interests, obligations, and rights of persons that extend beyond those of the individual whose genetic information is at issue. Furthermore, as the Article 29 Data Protection Working Party points out, genetic information can provide personal

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Protection of Human Subjects of Research (1979) *available at* http://ohsr.od.nih.gov/guidelines/belmont.html#goc2.

80. Sohini Sengupta & Bernard Lo, *The Roles and Experiences of Nonaffiliated and Non-Scientist Members of Institutional Review Boards*, 78(2) ACAD. MED. 212, 212-218 (2003).

81. *See, e.g.*, Robert E. Erard, *Release of Test Data Under the 2002 Ethics Code and the HIPAA Privacy Rule: A Raw Deal or Just a Half-Baked Idea?* 82 J. PERSONALITY ASSESSMENT 23 (2004).

82. *See, e.g.*, Sonia M. Suter, *The Allure and Peril of Genetic Exceptionalism: Do We Need Special Genetics Legislation?* 79(3) Wash. U. L. Q. 669 (2001).

83. *See, e.g.*, ALICE WEXLER, MAPPING FATE: A MEMOIR OF FAMILY, RISK, AND GENETIC RESEARCH (1995).

information relevant throughout an individual's remaining life.[84]

As personal information that, in most circumstances, falls in the category of "sensitive information," such as health data, it is also subject to derogation. The assurance of the protection of personal data that is paramount in the Data Protection Directive is tested in new ways in the context of the collection, use, and dissemination of genetic information. Inasmuch as the Directive lists "the public interest" among the categories of overrides that may be used to justify exemption from certain privacy provisions,[85] individual genetic information may routinely be caught in the paradoxical position of being classified both as "sensitive information" and as information whose benefit to society outweighs the potential harm to the individual's privacy interests and, thus, is less deserving of protection than even non-sensitive personal data.

The rationale for the selection of these two issues is manifold. First, there is no consensus on the resolution of either issue and there is considerable variability in the current approaches to these issues[86]. Second, these issues present profound questions regarding the future of privacy protections. Third, policies regarding tissue use and storage will have long-term effects on privacy interests and the weight of the countervailing potential benefit derived from incursions on those privacy interests[87]. Finally, these two questions gauge different levels of privacy protections as well as suggest key aspects of the nature of the application of the proportionality rule in the balancing between individual rights and third party benefit.

This Article also references the issue of research involving persons with reduced or no capacity to consent. I shall refer to this category of persons as "incapacitated persons." The reasons for the selection of this issue are related to its place as a largely unsettled and controversial aspect of biomedical research and to what it tells us about attitudes toward privacy. In a sense, the issue of research on incapacitated persons forces clarity on the limits of privacy since consent, as a mobile parameter, is not available. As this Article explains, the current trend is to limit research on such persons to that which will provide a direct benefit, and in some instances, only when a surrogate decision-maker has provided consent. This has been a very unpopular policy with researchers, and many countries are re-examining their position on this issue. This issue calls forth a declaration of the balance between incursion into the private sphere without consent and the weight of the public interest. So, while this particular issue is governed primarily by Directive 2001/20/EC (Clinical Trials Directive), the privacy implications are significant, and, in the case of incapacitated persons, the policy resolution of the balance between individual privacy and

84. *Article 29 Data Protection Working Party*, *supra* note 37, at 4.

85. Directive, *supra* note 13, at recital 34.

86. *See, e.g.*, Privireal.org, http://www.privireal.org/index.php (A European Commission Framework 5 Project on the Implementation of the Data Protection Act among Member States).

87. *See, e.g.*, E.W. Clayton, et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 J. Am. Med. Ass'n 1786 (1995).

public benefit can be very telling.

7.1 Tissue Use and Storage

Medical research has taken on new ethical and legal challenges with the advent and development of genetic technologies and various computerized database and advanced sequencing capabilities. Some of the most promising developments are tissue banking and biobanking. The former is generally understood to refer to the storage and processing of human biological material ("HBM"), e.g. blood, tissue, saliva, etc.; whereas the latter is primarily concerned with the collection of data derived from the tissue. A biobank allows for the processing (for research purposes) of HBM and known phenotypic characteristics and thus may include both. This kind of banking allows for longitudinal studies as well as studies on related or unrelated diseases or other epidemiologic phenomena. Tissue and biobanking potentially implicate property and privacy interests, while data-banking more strongly implicates privacy interests, although not exclusively. In most instances, it is the *information* derived from the tissue that is the basis for the privacy concerns.[88] It is this coupling of information and tissue into a "biobank," an optimal research tool, that is the primary focus of this inquiry. Interestingly, as far back as the 1970's, there was growing concern about the increase of data banks of various sorts, which permit "computerized pools of information" about virtually every aspect of people's lives.[89]

Several issues have proven controversial with regard to various aspects of biobanking. First is the issue of informed consent as a mechanism of both decisional and informational privacy.[90] One of the great benefits of biobanking – the ability to analyze the same tissue over time for various characteristics as scientific developments would merit – also constitutes one of the great dilemmas of the enterprise.

The Helsinki Declaration[91], embraced by the European Convention on Human Rights, declares that informed consent is a foundation for biomedical research on human subjects.[92] A typical scenario in biobanking involves a subject (human participant) agreeing to participate in research that involves the taking of a tissue sample for analysis for a specific research project. However, it is increasingly common for researchers to acquire a sample with the idea of

88. The most notable exception to this would be the use of tissue that results in patent. *See, e.g.*, Moore v. Regents Univ. of Cal., 793 P.2d 479 (Cal. 1990).

89. *See* Hyman Gross, Privacy—Its Legal Protection 100 (1976).

90. *See, e.g.*, E.W. Clayton, et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 J. Am. Med. Ass'n 1786 (1995).

91. World Medical Association, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, (2008) *available at* http://www.wma.net/e/policy/b3.htm.

92. Research on identifiable human tissue is generally considered human subject research (*See, e.g.*, 45 CFR 46.102(f) and 45 C.F. R. 46.116). Variations on this construction do exist and I examine them here as appropriate.

storing that sample so that it may be analyzed at a later date either for a related study or for a completely new purpose, which may be unforeseen at the time the sample was taken.[93] In order to secure a sample that can be used both for the instant research and for unspecified future uses, the researcher must obtain informed consent from the prospective participant. Herein lies the dilemma: it is much debated whether or not an individual can actually give "informed" consent to unspecified future uses since a participant would be consenting to something about which he is not actually informed at all. There is little resolution about the ethical nature of "blanket consent." However, there is considerable discussion about the degree to which restrictions on blanket consent hinder research efforts.[94]

A second related issue involving informational privacy is that of the identification and anonymization of data derived from HBM, as well as links to other information about the donor, e.g. phenotypic information (observable properties) or family history. Identification and anonymization in this context unfold into a fairly complex set of configurations that is designed to enable the researchers to link analyzed data to individual phenotypic characteristics (possibly the optimal research resource scenario), while simultaneously protecting the privacy of individuals. Simply put, samples can be identified (labeled with a person's personal identifying data), coded (linkable to personal identifying information not readily available to researchers), de-identified (collected with identifiers, but subsequently stripped of all identifying information and links) and anonymized (collected and stored with no identifying information). Among the most central issues on which there is variation in regulation are: 1) which form of identification constitutes human subject research; 2) whether blanket consent can be given to use of identifiable samples; and 3) whether new use of an identifiable (coded) sample requires re-consent, and under what circumstances it can be exempted.

Another set of concerns relates to unforeseen subsequent use. The issue of secondary uses is somewhat less controversial than the issues of consent. Some policies limit secondary use to related research, yet a determination must be made about what constitutes "related" research. This determination must generally be made on a case-by-case basis. Additionally, uses by third parties is a very important issue implicating both informational and decisional privacy, particularly given the Directive's concern with the free flow of information across borders.[95] If consent is given to a particular researcher, a determination must be made about whether that consent extends to a third party who also

93. Philip Reilly, et al., *Ethical Issues in Genetic Research: Disclosure and Informed Consent*, 15 Nat. Genetic 16-20 (1997).

94. *See, e.g.*, Sandra Chandros Hull, et al., *Genetic Research Involving Human Biological Materials: A Need to Tailor Current Consent Forms.*, 26 IRB: Ethics & Hum. Res. 1, 1, 6 (2004).

95. *See* Council Directive 95/46, On the Protection of Individuals with Regard to the Processing of Personal Data and On the Free Movement of Such Data, 1995 O.J. (L 281) 31.

wants to use the sample and data. Clearly, the reasons that may motivate a person to permit one researcher to use her tissue and data may not apply at all to an unknown third party. Various approaches have been taken in this regard, with a common policy being to state this possibility of third-party transfer in the consent form. There is an argument that when a new use of a sample is proposed that the researcher should obtain the participant's re-consent. Matters of practicality have resulted in different approaches to this issue, with perhaps the greatest variation being in who makes the determination of whether an exemption for impossibility or impracticability should be permitted.[96]

Participants' post-consent control over samples is complex. Consistent with basic principles of research ethics, a participant must be able to withdraw from research at any time.[97] Accordingly, a participant is generally allowed to withdraw her sample at any time, up until it has become anonymized or until the data derived from an individual's sample has been compiled with others.

Another related issue is that, given the nature of genetic research, analysis of genetic data could reveal information that would be of beneficial interest to the donor-participant. It is far from resolved whether a researcher should re-contact a research participant to inform them of an incidental finding of a genetic mutation that indicates the likelihood of serious disease with the possibility for early intervention.[98] This issue implicates an interesting aspect of privacy in two ways: 1) the right not to know; and 2) the right to access information being processed about oneself. There are both practical and ethical reasons for not adopting a contact-and-inform[99] approach. Difficulty of follow-up and the need to respect persons' right not to know are just two of the critical considerations.

Finally, another unsettled issue involves the handling and processing of samples taken from minors. In many countries, a parent can consent to the involvement of a minor child in research if certain conditions are met (usually requiring the child's assent).[100] However, when a sample is taken from a minor, some policies permit the indefinite retention of that sample without obtaining consent from the donor when she reaches the age of majority.[101] While there are legitimate issues of practicability, the implications for individual autonomy and privacy are significant. Indeed, if such recruitment occurs on any significant scale, a substantial collection of data could be obtained and stored indefinitely without the consent of the participants.

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96. *See* Research, *supra* note 25.

97. *See, e.g.*, 45 CFR 46.116 et seq.

98. *See* E. W. Clayton, *Incidental Findings in Genetics Research Using Archived DNA*, 36 J.L. MED. & ETHICS 286 (2008).

99. *Id.*

100. *See* Marina Cuttini, *Proxy Informed Consent in Pediatric Research: A Review*, 60 Early Hum. Dev. 89 (2000).

101. *See, e.g.*, Partners Healthcare System Research Consent Form (2005), *available at* http://healthcare.partners.org/phsirb/consfrm.htm (follow "Tissue Repository Consent Form" hyperlink). [Hereinafter Healthcare].

The challenge presented by the ability to access genetic information that provides information about probable future health states of individuals complicates considerably the analysis of privacy implications and optimal resolutions. Although there is general agreement on the governing principles, the regulation of tissue use and storage is far from harmonized. Principles of self-determination, decisional autonomy, and "control over information about oneself" tend to drive many policy approaches. Yet, even within application of these principles, there is a perhaps surprisingly wide berth for variation in implementation. This Article isolates just a few of the issues involved in tissue use and storage. I intend for these issues to serve as indicators of privacy orientation, sensibilities, and how the architecture serves to create, enforce, or fail to establish substantive boundaries.

7.2 National Approaches to the Regulation of Biobanking: Tissue Use and Storage Issues

Biobanking regulation is still very much in flux. A major debate has been underway in Norway between researchers and those charged with regulating and overseeing human subject research. Countries like the U.K., Estonia, and Iceland have undertaken the establishment of national biobanks for research purposes, sometimes facing considerable resistance.[102] While other countries have not (yet) initiated efforts to establish national biobanks, the establishment of smaller-scale biobanks is undertaken more frequently and involves some of the same issues.[103]

Resolution of issues involving national databases impacts many of those smaller-scale projects. One of the most controversial issues regarding informed consent in national biobanks arose with the DeCode project. The Icelandic Health Sector Database initially instituted a model of "presumed consent." Presumed consent requires that the potential participant opt out of participation. The default is inclusion and use of the sample, so that if the potential participant does nothing, his sample and information are included in the databank. Perhaps not surprisingly, this issue eventually became one of the most contentious of the DeCode project and the model was ultimately modified.

Another of the more problematic issues was the blending of data/samples collected in the health care or therapeutic context and data/samples collected specifically for research.[104] This distinction between residual tissue and tissue

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102. S.B. Haga & L.M. Beskow, *Ethical, Legal, and Social Implications of Biobanks for Genetics Research*, 60 Advances in Genetics 505 (2008). The DeCode project in Iceland moved swiftly in the beginning, but as concerns mounted, the project was substantially slowed down and forced to address many of the concerns. *See* Skuli Sigurdsson, *Yin-Yang Genetics, Or the HSD deCODE Controversy*, 20 New Genetics and Soc'y, 103 (2001).

103. *E.g.* Jocelyn Kaiser, *NIH Ponders Massive Biobank of Americans*, 304 Sci. 1425, 1425 (2004); *College of Medicine and First Genetic Trust Form Biobank*, How. U. Capstone, June 2, 2003, *available at* http://www.howard.edu/newsroom/capstone/2003/June/news2.htm.

104. Jacquelyn Ann K. Kegley, *Challenges to Informed Consent*, 5 EMBO Rep. 832, 833

collected specifically for research is an important one in European regulatory and ethical analysis.[105] Consent regulations frequently differ for the two types of tissue collection and storage, typically with fewer restrictions on the collection and storage of clinical samples. (There is some suggestion that the norm in many European countries is to treat clinically-derived samples as "abandoned."[106])

The establishment of smaller-scale biobanks creates a number of challenges for researchers, depending on the governing regulations. As mentioned, one of the highest hurdles is that of protecting individual privacy while facilitating legitimate and potentially beneficial research efforts. The issues most heavily implicated in this attempted balance are: 1) the limitation of use to the original research purpose; 2) blanket consent; 3) permissible duration of storage; 4) right to withdraw one's sample after initial consent; and 5) re-consent for new uses. Below is a snapshot of policy positions on these issues among two European Union member states, Norway, and the U.S.

Table 1 Tissue Use and Storage[107]

	Limited to Original Purpose w/o Explicit Consent	**Blanket Consent To Un-Specified Future Use Permitted**	**Permissible Duration of Storage**	**(Re)Consent Exception approved by**
France	Yes	Yes	Necessary	CNIL
Germany	Yes	No	Only as long as necessary	Supervisory Auth[108]
Norway	Yes[109]	No	Only as long as necessary to achieve purpose	Dept, REC
United States	No	Yes	Indefinite	REC

7.3 European Union: Data Protection Directive

The provisions of the Directive suggest that their direct application to the above-mentioned issues of tissue use and storage would result in the regulations

(2004).

105. Ben-Evert van Veen, Letter to the Editor, *Human Tissue Bank Regulations*, 24 Nature Biotech. 496, 496 (2006).

106. *See, e.g.*, Bartha Maria Knoppers, et al., *Ethical Issues in International Collaborative Research on the Human Genome: The HGP and the HGDP*, 34 Genomics 272, 274-75 (1996).

107. Admittedly, this and other tables in this paper grossly oversimplify the nature of the policies and otherwise fail to reflect the nuance of both the underlying reasoning and the application. Nevertheless, as a summary, it serves as a useful point of departure.

108. *See* Bundesdatenschutzgesetz [Federal Data Protection Act], Jan. 1, 2002, § 38 (F.R.G).

109. Biobankloven [Biobank Law], 20 Juni 2008 nr. 44 § 13 (Nor.) [Hereinafter Biobank Law].

contained in Table 1. Notably, with the exception of Norway (which amended its policy effective in 2007), the policies suggested by the Directive are the most restrictive. Article 6(1)(c) and Recital 28 require that member states ensure that the processing of personal data is "adequate, relevant and not excessive in relation to the purposes for which they are collected/further processed." This would suggest that it would be impermissible to keep tissue and data beyond the time necessary to accomplish the original research purposes. Yet, France does not adopt this approach[110]. The architecture of privacy rights in Europe can, in large part, answer why the policies of the member states can be less restrictive. The derogations in Article 13 and Recital 29 affect the Directive provision prohibiting the processing of personal data without the consent of the individual. The basis for different policy outcomes are within the interpretation and applications of these derogations, particularly the "public interest" and "historical, statistical, and scientific" purposes. If application of a provision permitting blanket consent to unspecified future use were permitted and consequently challenged in ECHR, the court would employ the proportionality test to determine the legality of the act.

Consider the following scenario: Claude, a French citizen, voluntarily participates in a diabetes study in which DNA samples are taken in addition to other information, although genetic associations are not the primary focus of this study. Claude, who may have perceived a direct benefit in the form of close monitoring of his health, gave blanket consent to use of his health information. Several years later the French research project sells the samples with personal information to an Estonian research enterprise whose study intends to explore a genetic link between diabetes and alcoholism. Claude reads about the transfer in the newspaper and objects. His success in blocking the transfer in France is not guaranteed. In a similar situation in Norway, Claude would likely prevail. In the U.S., Claude would almost surely lose. I examine resolution of this scenario below.

7.3.1 Specific Provisions Regarding Medical Research (Tissue Use)

7.3.1.1 France

The national legislation of France regarding data protection requires a description of the purpose, population, and nature of data to be involved in the study and processing.[111] This legislation explains some of the reasoning for the determination that blanket consent may be permissible.

The French National Consultative Ethics Committee (CCNE) has taken up the question of tissue storage and use in Opinion No. 77, "Ethical issues

110. Decree No. 2005-1309 of Oct. 20, 2005, *supra* note 48.

111. Decree No. 2005-1309 of Oct. 20, 2005, Journal Officiel de la République Française [J.O.] [Official Gazette of France], Mar. 25, 2007, p. 16 (Fr.).

raised by collections of biological materials and associated information data: 'biobanks' and 'biolibraries."' The CCNE has determined that blanket consent to unspecified future use is acceptable if the sample is "scrupulously anonymized." This blanket consent is allowable partly because of the impracticality of re-contacting a participant, but primarily for the research value of such tissue and data information.[112] Basing its reasoning on a principle of "solidarity," the CCNE states that "[t]he principle of solidarity would in this case be a justification for concessions regarding the rules observed to safeguard individuals, but it would be true solidarity dependent on voluntary decisions."[113]

The answer to this seeming contradiction can be found in the architecture of French privacy rights. Claude's case against the transfer of his data via blanket consent could conceivably go either way depending on a number of factors. Article 39 of the French Data Processing Act requires consent. The CCNE, while condoning blanket consent, does emphasize that the participation must be voluntary. Claude's case becomes considerably stronger, however, if the sample has been transferred with any identifying information. As the CCNE has stated, blanket consent is acceptable only if the sample is "scrupulously anonymized." Therefore, even with consent, Claude's sample could not be transferred with any personally identifying information. The Directive also requires that the receiving country have the equivalent protections as the transferring country, or at least provide proof of adequate protections. Here, Estonia, as a member of the EU that has ratified the provisions of the Directive, meets the requisite criteria for a receiving country. Thus, if Claude's sample is anonymized, its sale and transfer would be considered legal by a French Court, even if the sample was linked to (unidentifying) phenotypic information.

However, this case might be handled differently in the European Court of Human Rights. The Directive states that storage of personal information is limited to that period and purpose necessary to effect the original goal. The court's application of the proportionality rule would determine: 1) if the intended action can achieve its goal; 2) if the action is necessary to achieve the goal; and 3) if the burden on the right is proportionate to the public interest being privileged at the expense of the right. Here, the issue is whether the burdening of Claude's right is proportional to the public interest being served at the expense of his right. If the sample is anonymized, the right involved is only that of decisional privacy. Although Claude has given blanket consent, he can now claim that this use of the sample is not permissible, since Claude would not have given permission to the use of his sample in a study connected to

112. Nat'l Consultative Ethics Comm. for Health and Life Scis., Opinion n° 77: Ethical Issues Raised by Collections of Biological Material and Associated Information Data: "Biobanks," "Biolibraries" 19 (2003) [hereinafter Ethical Issues Raised by Collections of Biological Material], *available at* http://www.ccne-ethique.fr/docs/en/avis077.pdf.

113. *Id.* at 16.

genetics and alcoholism, especially if the study took place in a foreign country. In this case the burden on decisional privacy may be viewed as either minimal or considerable – minimal in that a completely anonymized sample cannot cause Claude direct harm by virtue of disclosure of sensitive information; considerable since Claude knows that he is now participating in research that he does not support. His right to withdraw his sample has been lost since the sample has been anonymized. Thus, while the harm is minimal, one could argue that a dignitary violation has occurred from which the psychological burden could be considerable. Therefore, although Claude's claim is likely to lose in a French court, it is quite possible that he could prevail in the ECHR.

7.3.1.2 Norway

The Biobank Law largely governs tissue use and storage.[114] The Norwegian law has been regarded as very restrictive as compared to its European counterparts.[115] The problematic restrictions invalidate blanket consent and serve to limit the involvement of incapacitated persons. In April 2006, the Norwegian government announced some important changes to the Biobank and Patients Rights Laws[116] in response to a very public controversy. The controversy concerned researchers decrying the degree of restrictiveness regarding consent and the accompanying short and long term negative effects on the conduct of biomedical research in Norway. [117] The changes to DeCode will allow the collection of HBM from persons who do not have the capacity to give consent, including in circumstances of emergency medicine, or in cases of persons with physical or mental disturbances, dementia, or developmental limitations.

Therefore, if Stein, a Norwegian citizen, also wishes to claim that his sample may not be used for a purpose not related to that of the original study, Stein need only show that the researchers acted in violation of the law. Violations will be relatively easy to prove, as Norwegian law prohibits blanket consent, limiting the storage and use of samples to the original purpose.

7.3.1.3 United States

Tissue use and storage in the United States has been something of a maelstrom for the past five years. As recently as 2004, the annual convention of research ethics committees had as its focus the regulation of tissue use and storage, with part of the program designed to solicit input on what the policies

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114. Biobank Law, *supra* note 109.

115. Kvalheim, *supra* note 57, at 291.

116. Ot.prp. nr. 64 (2005-2006) Om lov om endringar i pasientrettslova og biobanklova (helsehjelp og forsking – personar utansamtykkekompetanse), http://odin.dep.no/filarkiv/277845/Otp0640506-TS.pdf (last visited Dec. 1, 2006).

117. Johan Votvik, *Åpner For Forskning Uten Samtykke*, Helserevyen Online, Apr. 11, 2006, *available at* http://www.helserevyen.no/index2.asp?newsid=3797.

should be.[118] Guidelines were issued in August 2004[119] but were non-binding and have been interpreted in inconsistent ways across IRBs. For example, some IRBs permit both blanket consent and indefinite storage of identifiable tissue of minors without attempts to consent upon the age of majority,[120] while others restrict the use of blanket consent and limit storage of minor HBM until the donor reaches the age of majority. While the European Directive permits variation in the application of blanket consent, indefinite storage of the tissue of minors seems well outside the scope of the permissible boundaries of European law. Indefinite storage would occur after the original research purpose was achieved, violating the law. Additionally, other aspects of the proportionality test would likely fail. For example, the necessity component would seem to present insurmountable challenges to this practice. Balancing the burden on the right versus the goal to be achieved would likely also cut against indefinite storage.

Consider the following scenario: Debbie, a U.S. citizen, has a family history of alcoholism and objects strongly to the use of her sample in the study. In the United States, although the National Bioethics Advisory Committee has criticized blanket consent, there is no enforceable provision prohibiting it. The terms of the permissible future use of Debbie's sample may be different depending on the identifiability of the sample. However, even if the sample is identified or identifiable, the transfer may still be permissible if the researcher can show that re-consent is impossible or impracticable and the harm is minimal. Thus, Debbie may only have a case if she is likely to suffer actual harm from the further use of her sample and the approval of that use and processing was negligent.

7.4 Unconsented Disclosure of Genetic Tests Results to Relatives

It is widely recognized that genetic test results may provide important information for the person undergoing the test regarding his possible future health state. However, the same test results may be of significant interest to relatives of the tested individual. A test result indicating the presence of a mutation associated with a hereditary disease can have enormous implications for certain relatives, both in terms of future health risks and the possibility of initiating interventions. Indeed, this issue highlights the tension between individual privacy rights and the interests of others in a most dramatic and profound way. To honor the proband's right to control the dissemination of information about him is to disregard an opportunity to confer a potentially life-

118. Public Responsibility in Medicine and Research (PRIM&R), an organization whose mission is to create, implement, and advance "the highest ethical standards in the conduct of research." *See* http://www.primr.org/.

119. Off. for Hum. Res. Protection, Guidance on Research Involving Coded Private Information or Biological Specimens (2004), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.

120. *See* Healthcare, *supra* note 101.

saving benefit on the relative. Strong arguments can be made on either side. One pro-disclosure argument makes the point that disclosure to relatives does not violate an individual's privacy since family members share genetic information. The conflict between the individual's right to control information about herself and a relative's interest in having access to information that could potentially afford the opportunity for life-saving measures is one that has not met an easy solution.

Consider the case of Grete, a Norwegian citizen, who has received a positive indication of the presence of the BRCA mutation associated with breast cancer. Knowing that at least one grandmother died from breast cancer, she opted to take the test. Her doctors urge her to tell her three sisters and also two daughters who are considering starting a family. Grete refuses, knowing that her sisters will immediately have prophylactic surgery if they are informed. Grete also does not want to have her daughters live their lives in fear of developing the disease. She has been unable to return to her normal life and deeply regrets having taken the test. The doctor feels strongly that Grete should inform family members since interventions are available, and decides to inform Grete's family members himself.

In Norway, France, and the United States, her doctor would be required to honor Grete's wishes; and in France particularly, the doctor could be subject to criminal penalties for breaching confidentiality. In Portugal[121] and Italy[122], for example, the doctor might be allowed to disclose based on permissible breach of confidentiality to save the lives of third parties. The physician is prohibited from disclosure,[123] but may not be penalized for doing so if he can show that it was necessary to save a life.

7.4.1 Background

In 1992 the Council of Europe took a position that straddled both sides. While recognizing the need for confidentiality, its recommendation called for consideration of disclosure to family members in the case of serious disease risk. Principle 9 of Recommendation on Professional secrecy No. R (92) 3 on Genetic Testing and Screening for Health Care Purposes stated that:

> . . . in the case of a severe genetic risk for other family members, consideration should be given, in accordance with national legislation and professional rules of conduct, to informing family members about matters relevant to their

121. *See* Helena Moniz, *Privacy and Intra-Family Communication of Genetic Information*, 21 L. Hum. Genome Rev. 103, 103-24 (2004).

122. *See Article 29 Data Protection Working Party*, *supra* note 37 at 4.

123. *See* Portugal, *supra* note 39.

health or that of their future children.[124]

This recommendation seems to imply that in certain situations, e.g. in the case of severe genetic risk, that professional secrecy may be, *and even ought to be,* breached. It is important to note, however, that this 1992 recommendation predates the Directive on Data Protection.

Relevant provisions in the Directive could be interpreted to draw a clear line against any unconsented disclosure of genetic test results to anyone. Genetic test results clearly fall within the category of health data and, as such, constitute sensitive information deserving of special protections. The Article 29 Data Protection Working Party also notes that genetic data can also be used to contribute to the identification of a person's ethnic identity.[125] In the United States, recent studies have claimed not only to be able to identify a person's ethnicity or race, but also identify the degree of admixture.[126] The Working Party makes the point that even though this information may not be health data, as an indicator of race and ethnicity, this type of genetic data nevertheless falls in the category of sensitive information[127] deserving of special level of protection.[128] Thus, novel issues deriving from the implications of test results revealing racial or ethnic information could also present problematic complexities. For example, a test result that reveals admixed membership in an ethnic group known to have a higher risk of a particular disease, e.g. breast cancer in Ashkenazi Jews or sickle cell anemia in African-Americans, could also have implications for the future health states of relatives.

In such an instance, the architecture of the protections may actually have significant impact on both the substance and procedure of handling of such a matter. By contrast, a European proportionality model could accommodate such a situation. The Working Party currently advocates a case-by-case approach that could allow disclosure in some instances but not in others, albeit at some sacrifice of predictability and universal application. Because of the practice of defensive medicine in litigious societies, discretionary disclosure is likely to lose much of its discretionary quality.[129]

One of the exceptions to the Directive's prohibition of processing sensitive data is when such processing is required "for the purposes of

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124. Comm. of Ministers, Council of Eur., Recommendation No. R (92) 3 on Genetic Testing and Screening for Health Care Purposes (1992), http://www1.umn.edu/humanrts/instree/coerecr92-3.html (last visited Jan. 9, 2009).

125. *Article 29 Data Protection Working Party*, *supra* note 37 at 4-5.

126. Mark D. Shriver, et al., *Skin Pigmentation, Biographical Ancestry and Admixture Mapping*, 112 Hum. Genetics 387, 387 (2003).

127. Directive, *supra* note 13, at Art. 8(1).

128. This issue is further complicated by predictions in the scientific literature claiming that it may soon be possible to draw links between degree of ancestral admixture (suggesting racial and ethnic identity) and disease predisposition.

129. Khadija Robin Pierce, Setting Margins for Genetic Privacy (June 2007) (unpublished Ph.D. dissertation, Harvard University) (on file with the Harvard Kennedy School Library).

preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services." This exception is subject to national codes of professional confidentiality and other relevant provisions and safeguards.[130] Therefore, as the Working Party points out, in many European countries, an individual's genetic data could conceivably be processed under one of the exceptions of Article 8(3).

7.4.2 The Finality Principle

The Article 29 Working Party takes an interesting approach to the applicability of the Data Protection Directive in the reference to Article 6(1)(b) and (c). The Working Party states that implementing national legislation must provide that personal data may only be "collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with purposes."[131] The Working Party adds that personal data must be "adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed."[132] The Working Party subtitles the latter segment of the provision as the "proportionality principle" and the former, the "finality principle."[133]

Application of the "finality" rule to the question of unconsented disclosure suggests that test results collected for the specific purpose of diagnostics of the individual submitting to the test should not be further processed for some other purpose. That the Directive specifically prohibits processing that is incompatible with the original purpose begs the question of whether disclosure to the proband's family constitutes incompatible processing. Moreover, even the permitted processing for purposes of various health care services as set forth in Article 8(3) renders such processing subject to norms of professional secrecy. Yet, a plausible rationale for disclosure may be that members of a proband's biological family share this information and, as such, may be considered "data subjects" with the attendant rights.[134] Though plausible, this argument is unpersuasive given that the relatives have neither consented to the test nor voluntarily assumed any risks associated with taking the test. Such a convenient but flawed construction of their status in order to confer rights rapidly unravels. The alternative rationale put forth by the Working Party[135] that family members could assert a right based on the potential effect on their personal interests is more convincing. However, this reasoning currently has no legal basis for superseding the rights of the tested individual.[136] The Working Party concludes that the complexity of the balance

130. Directive, *supra* note 13, at art. 8(3).
131. *Id.* at art. 6(1)(b).
132. *Id.* at art. 6(1)(c).
133. *Article 29 Data Protection Working Party*, *supra* note 37, at 5-6.
134. *Id.* at 8.
135. *Article 29 Data Protection Working Party*, *supra* note 37 at 7.
136. The Working Document on Genetic Data does reference an Italian case in which a

of interests and rights is such that no clear resolution has yet emerged and that "at this stage" a case-by-case approach should be considered.

It is not entirely clear what the implications are for resolving the conflicts inherent in the unconsented disclosure of genetic test results to relatives. Arguments asserting that a new legally relevant social group has emerged in the biologic family[137] have not found widespread acceptance. Many European countries have adopted a policy that disclosure is desirable in certain specified circumstances, but that rules of confidentiality and privacy prohibit such disclosure where the patient has not consented. However, the option to consider the weight of countervailing interests would permit an individual act of discretionary disclosure. See Table 2 below.

Table 2 Unconsented Disclosure of Genetic Test Results to Relatives

	Absolute Confidentiality
European Union (WP)	Unsettled—case-by-case
France	Generally No-case by case
Norway	Yes
United States	Yes
Portugal[138]	Generally No—case by case

7.5 Approaches and Architecture

The French National Consultative Ethics Committee for Health and Life Sciences (CCNE) has issued an opinion on the question of disclosure of test results to relatives. The opinion takes a very careful approach in which it weighs the nature of the patient's interests and those of the family, finding merit in both. However, as with disclosure of HIV status,[139] CCNE holds fast to the principle of absolute confidentiality. Opinion 76 carefully outlines procedures to prepare a proband for disclosing to family members, but it stops short of taking the decision out of the hands of the tested individual, stating that "a strict application of the principle of medical confidentiality, as well as utilitarian attitudes, argue against systematic breaching of confidentiality."[140]

Despite the unsettled nature of the balance between individual rights and

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woman sought disclosure of her father's genetic data so that she could make "a fully informed reproductive decision." The relevant authorities granted the woman's request despite her father's refusal to consent, stating that the "father's right to privacy was to be overridden by the daughter's right to health – the latter meaning her 'psychological and physical well-being.'" *Id.* at 9.

137. *Id.*

138. Portugal is included here for purposes of illustration as a country that does not distinguish between genetic and other medical information in its privacy protections.

139. Nat'l Consultative Ethics Comm. for Health and Life Scis., Opinion n° 76: Regarding the Obligation to Disclose Genetic Information of Concern to Family Members in the Event of Medical Necessity 6 (2003), http://www.ccne-ethique.fr/docs/en/avis076.pdf (last visited Jan. 9, 2009).

140. *Id.*

the interests of biologic family members, the legal order seems to favor an individual rights model that allows persons to control the flow of information about themselves. Application of a proportionality approach may be seen in some instances, e.g. Sweden, where disclosure is discretionary under specified circumstances if the benefit outweighs the potential harm to the patient and that harm is minimal.[141] In Portugal, genetic data, like other medical information, can be disclosed without consent if the benefit will outweigh the harm and the harm is minimal.[142] Sweden and Portugal implemented the Data Protection Directive in 2003 and 1998, respectively.[143] These widely divergent implementations of the Directive speak to several aspects of the dilemma. First, the categories justifying the overriding of the privacy protections are flexible in their interpretation. Secondly, the issue is very complex with strong competing interests, both of which can find support in the wording of the Directive. Thirdly, the categories of derogation are constructed such that national cultural, legal, and professional norms may resolve the dilemma in a manner most suitable to the national context.

7.5.1 Analogy: HIV Notification

The European Court of Human Rights has not taken up the issue of unconsented disclosure to genetic test results, but one of the few cases involving medical secrecy, *Z versus Finland*,[144] decided by the European Court of Human Rights, may provide some insight on the court's likely position. Given the paucity of case law in this area in Europe, this analysis is well-served by examination of analogous issues. In *Finland*, a husband stood accused of rape. The HIV status of the accused's wife was disclosed, without the wife's consent, to the alleged rape victim. This disclosure was undertaken for the benefit of criminal proceedings against the husband. The wife filed suit, alleging that this unauthorized disclosure of her HIV status to the alleged rape victim constituted unauthorized disclosure of confidential personal data in violation of Article 8 of the Convention. While the court acknowledged the highly sensitive nature of HIV status, it reasoned that an overriding public interest could justify unauthorized disclosure, and thus the burdening of a right to special protection of sensitive information.[145] Here, striking the balance between protecting sensitive information and facilitating the public interest was a complex one. This complexity was due in part to the nature of the information and the weight of that privacy interest, but also to the context in

141. Lag (1998:544) om vårdregister [Health Data Law] (Swed.).

142. Eur. Comm'n, Genetic Testing: Patient's Rights: Insurance and Employment: A Survey of Regulations in the European Union 100 (2002), ftp://ftp.cordis.europa.eu/pub/life/docs/genetic_testing_eur20446.pdf (last visited Jan. 9, 2009).

143. *See* Report on the Implementation of the Data Protection Directive 95/46/EC http://ec.europa.eu/justice_home/fsj/privacy/lawreport/index_en.htm.

144. Z v. Finland, App. No. 22009/93, 25 Eur. Ct. H.R. (1997).

145. *Id.*

which the information was sought and the possibility that additional judgments (such as how important the information was to the investigation) would have to be made.[146]

The court in *Finland* applied a version of the proportionality test in which the burdened right of privacy was outweighed by the state's interest in resolving the criminal investigation.[147] It was not just that the public interest in resolving a criminal investigation was sufficient to override protection of this sensitive information, but that the probative value of this information was significant enough to justify the override. Therefore, it is unlikely that sensitive information that would merely assist in the resolution of a criminal proceeding would be subject to disclosure. Rather, that information, albeit by local standards, must have high probative value, and presumably, must not be obtainable by less burdensome means.

This case may have significant implications for unconsented disclosure of genetic test results to relatives. Like HIV status, information about a genetic disease may be probative regarding someone other than the individual who has been tested. *Finland* suggests that highly sensitive information may lose its protection in the face of its value to a criminal proceeding going to the question of manslaughter.[148] However, because of the mode of transmission of a genetic disease, it is unlikely that an action of manslaughter would ever lie based on the knowing transmission of a genetic disease. However, if a scenario could be constructed in which the genetic information of a relative were probative in a criminal trial, it is possible that this might create the outer bounds for permissible disclosure of highly sensitive information.

Still, one can imagine a situation in which a breadwinner knows that he carries the genetic mutation associated with Huntington's disease, a neurodegenerative disorder. He takes out several major unsecured loans and gives the money to his girlfriend. These gifts result in a criminal proceeding against the girlfriend in which the breadwinner's genetic test results (indicating the presence of the mutation associated with Huntington's disease, which has roughly 99% penetrance) are relevant and highly probative. *Finland* would suggest that the privacy interests of these test results would be outweighed by the public interest.[149] Furthermore, here, unlike in *Finland*, the tested individual is also culpable in some way even though he may not at the time of trial be alive or competent.

By contrast, the process of adjudication of the case of *Finland* in the United States would be very different, largely because of the architecture of the privacy protections. As noted earlier, HIPAA provides for the unauthorized disclosure of personal health information in certain circumstances that are

146. *See e.g., id.*
147. *Id.*
148. *Id.*
149. *Id.*

outlined in section 164.512 of the Code of Federal Regulations.[150] This list includes disclosures for judicial and administrative proceedings as well as for law enforcement purposes.[151] Thus, even though these exceptions have their parameters, the exceptions have been carved out in advance, presumably as a result of a balancing between the weight of the privacy right and the countervailing public interest.[152] The result in this case is probably the same, but one could easily imagine a less clear case in which the PHI of an innocent third party could be disclosed simply by virtue of one of the exceptions; whereas in Europe, a balancing of the rights and interests could conceivably result in a different outcome regarding the permissibility of disclosure. In recent years, a few courts have authorized the subpoena of medical records and other personal data (believed to be of a genetic nature) of the parents of child plaintiffs in lead paint cases, thus allowing a defendant to pursue a defense alleging that the low I.Q. of the plaintiffs was inherited and not the result of lead poisoning.[153] The architecture of the rights, the transparent balancing of the proportionality rule versus the "absolute" articulation with carved out exceptions (e.g. relevance) can, indeed, affect the degree of privacy protection.

The more likely scenario is that involving a civil action. At least one such case has been litigated at the national level in Europe. As noted earlier, the Data Protection Article 29 Working Party mentions an Italian case in which a daughter seeks disclosure of her father's genetic test results to assist her in reproductive decision-making.[154] The court determined that the father's test results should be disclosed to the daughter even against the wishes of the father.[155] How ECHR would resolve this case would probably turn on such factors as the gravity of the heritable disease and the extent to which disclosure burdens the father's privacy interest. However, based on the Working Party recommendations, it seems unlikely at this time that the court would find an overriding interest in preventing a speculative genetic disease. Furthermore, since the override would require a determination that a less burdensome alternative was not available, i.e. that infringement on the right was necessary, the fact that individuals can seek out a genetic test themselves may preclude the authorization of disclosure. This preclusion should at least be the case in instances where gatekeeping arrangements do not rely on the known presence of the disease or mutation in a relevant biological relative. However, in the case of autosomal recessive diseases, genetic testing of the parents may be inadequate to inform the degree of risk.

It is important to note that case law, as a source of rights, does not play

150. 45 C.F.R. § 164.512 (2008).

151. *Id.*

152. *Id.*

153. *See, e.g.*, State v. Idellfonso-Diaz, Tenn. Crim. App. 2006, 2006 WL 3093207 (unpublished).

154. *Article 29 Data Protection Working Party, supra* note 37, at 9.

155. *Id.*

the same role in Europe as it does in the United States. This is particularly true in the area of health privacy law. Health privacy law tends to be statutory and regulatory. To a lesser degree this is also true of U.S. medical privacy. Doctor-patient confidentiality has a line of case law beginning as early as 1920.[156]

The issue of disclosure of genetic test results has appeared in American courts. Interestingly, U.S. case law has demonstrated a leaning toward embracing the importance of disclosure to relatives, but has stopped shy of imposing a duty. The closest the court has come is in *Safer v. Estate of Peck.*[157] In *Safer*, the court found that the physician did owe a duty to the daughter of his patient who had a hereditary disease; however, because the daughter was put on notice by other means, the physician was not held liable.[158] The important thing about these cases, of which there are very few, is that the closest the courts have been willing to come is in the case of vertical disclosure – disclosure to an offspring. No case has embraced horizontal unconsented disclosure to siblings or other related non-offspring. Consequently, if the courts move toward unconsented disclosure of genetic test results to relatives, it is likely to be in the case of offspring wanting to avert serious illness or death or, more likely, to assist in reproductive decisions.[159]

Nevertheless, there are strong reasons why ECHR would hesitate to take this step even in the cases set forth above involving offspring. One of the most important aspects of privacy law is its relationship to cultural and social norms. Unconsented disclosure of a hereditary disease to other family members could be disastrous in some cultures and situations. A decision by ECHR that such disclosure is permissible, and thereby implicitly creates a duty, would mean that all national laws would have to be consistent. Thus, a Norwegian or German court could not deny disclosure to a son or daughter wishing to know the genetic test results of a parent in certain circumstances. Such a decision, while possibly saving lives, may serve to unravel fundamental aspects of social relations and cultural norms. It is not clear that the EU, which was originally created to facilitate trade and pursuit of economic interests, is ready to take this step. Furthermore, permitting unconsented disclosure to relatives further erodes protection of sensitive data.

Finally, it can be argued that this private sphere may be more appropriately regulated by cultural and social norms. The pressure imposed by the norms may be sufficient to achieve the described result in most instances. Additionally, it may be excessive and unnecessary to impose a legal burden on the privacy right in order to force disclosure in the rare cases where it would not

156. Simonsen v. Swenson, 177 N.W. 831, 832 (Neb. 1920) (statutory doctor-patient privilege must be subject to a public health exception).

157. Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super Ct. App. Div. 1996).

158. *Id.*

159. This would also be consistent with principles of the duty to rescue between a parent and a minor child where such statutes are in force (e.g. Vermont).

otherwise occur.[160]

8. Conclusion: Measuring the Force of Privacy Protections: Architecture or Substantive Law?

8.1 France

The story told about France by the analysis of these two medical indicators is one of interesting paradoxes, but it is consistent with a host of social and political contextual aspects. We can deduce three key points from the foregoing analysis.

First, the permissibility of blanket consent for future unspecified uses of tissue may suggest a more permissive research climate regarding protections. The architecture of French privacy rights probably contributes to this result by virtue of the heavy reliance on CNIL as an oversight body charged with considerable active and practical regulatory authority and with the administration of privacy protections. Furthermore, the French Data Processing Act looks to the cultural climate of "solidarity" to embrace a risk-benefit calculation when determining whether to allow the processing of sensitive data.[161] This embrace suggests that the processing of sensitive data is allowable because of the use of strong oversight.

Second, the use of a risk-benefit analysis in the case of incapacitated persons rather than a requirement of direct benefit may be inconsistent with a policy of absolute confidentiality honoring the proband's right to control the flow of information about himself. However, as openly stated by the French national ethics committee, a strong value of "solidarity" and the "public interest" may be behind this policy. The policy of absolute confidentiality of genetic test results helps to define the limits of "group consciousness."

Third, consent is exempted when it is impracticable or impossible to obtain; however, saving the life of a relative does not justify unconsented disclosure of genetic test results. Interestingly, this could suggest that the right of privacy receives the greatest protection when it is exercised.

8.2 Norway

The picture we get about privacy protections in Norway shows a strong allegiance to individual rights and autonomy. This may seem surprising, given that Norway has been a highly functioning social democratic welfare state for several decades. However, strong protections of individual rights permeate Norwegian law.

First, Norway's previous prohibition of the involvement of incapacitated

160. Pierce, *supra* note 129.

161. *See Article 29 Data Protection Working Party, supra* note 37.

persons in medical research is that of a tiny minority in the western world. This approach departs from two of the other leading views: 1) research that provides a direct benefit to the incapacitated person is permissible; and 2) the European Union's risk-benefit calculation. However, as mentioned, this law was changed in 2006. Second, the disallowance of blanket consent and the limiting of tissue use to those uses necessary for the original purpose for which it was collected both depart from the European approach. Norway's departure represents a firm commitment to individual autonomy and informed consent. The policy against unconsented disclosure of genetic test results is also consistent with this commitment, even in its convoluted articulation. Third, the approval of any consent exemptions for impracticability or impossibility must come directly from a government entity, consistent with the former Norwegian approach to privacy that relied heavily on government oversight and protection rather than the model of individual consent.[162]

Health privacy practices, the scant case law, and analogous rulings in Norway reveal a strong national commitment to the protection of individual rights even in the face of strong countervailing societal or third party benefit. Recent cases involving freedom of speech have upheld the right of individuals to engage in hate speech, receiving considerable criticism from the rest of Europe.[163] Synne Sæther Mæhle, a legal scholar on judicial review, has explained that the rigidity of the Norwegian Constitution and the privileging of that document over European texts help to explain this result. [164] There are indications that Norwegians may be unwilling to open the door to derogations of the freedom of speech.[165]

Indeed, the rationale for changing the law regarding participation in research by persons with reduced capacity to consent was ostensibly based on the fact that the former degree of restrictiveness made it impossible to include such persons in research. Not including such persons in research hindered the ability to investigate methods and interventions that may improve the services that could be offered to them.[166] Thus, arguably it was not societal benefit that served to outweigh individual privacy rights, but a move towards better serving individual rights by providing a direct benefit.

Thus, it seems reasonable to conclude that the approach to privacy in the biomedical context, even with the recent changes, remains on the restrictive end of the European continuum. The Norwegian human subject research regulations, which incorporate by reference the Patients Rights Law, were recently legalized.[167] (They had "guidance" status up until December 2005.)

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162. Kvalheim, *supra* note 57, at 289-290.

163. *See* Hvit Valgallianse-kjennelsen, Rt. 1997 s. 1821, Høysterett. 2004; and Boot Boys-dommen. Rt. 2002 s. 1618.

164. Interview with Synne Sæther Mæhle in Bergen, Norway (Dec. 2005).

165. *See* Hvit Valgallianse-kjennelsen and Boot Boys-dommen, *supra* note 163.

166. Johan Votvik, *supra* note 117.

167. *See* De nasjonale forskningsetiske komiteer [Norwegian Regional Ethics Committee], http://www.etikkom.no/English/NEM/REK (last visited Jan. 9, 2009).

These regulations provide that "historical, statistical, and scientific" reasons, as well as "important societal benefit" can exempt data from the data protection provisions. Thus, the balancing does occur in Norwegian decisions involving a burden on individual privacy, but the scale seems to tip in favor of individual rights. However, the scale does not tip in favor of individual rights unless two elements are present: 1) a clear and convincing need to burden the right in order to achieve an important benefit, as in the case of permitting research on persons who do not have the capacity to consent; and 2) the state, through some responsible agency, can provide effective oversight, as was the case before its adoption of the individual consent model upon the passing of the Data Protection Directive.

That a change in this regard has been legislated may represent a move toward a more permissive approach in support of the biomedical research enterprise. In a climate in which public hearings are being held to discuss whether the ban on stem cell research should be lifted, it may well be that Norway is taking steps toward the research imperative. Arising perhaps from the earlier "oversight model"[168] of protection, it is possible that the model of consent with relaxed application may be sufficient to assure society that the research enterprise is not necessarily at odds with individual rights.

8.3 United States

The reality of privacy in the United States, as constructed by the analysis of the three medical indicators, puts forward a sectoral model containing absolute privacy protections with carved out exceptions, along with a heavy reliance on individual consent. This may actually result in fewer privacy protections than the seemingly more elastic proportional approach taken in the European Union.

First, the permissibility of blanket consent for unspecified future uses suggests a "market model" of research participation. There is no overarching oversight body with administrative and enforcement powers, thus leaving the injured plaintiff to file a private tort action as his primary recourse. Unlike in France, the permissibility of blanket consent is not accompanied by a strong oversight body, but rather is left to application and monitoring by individual research ethics committees that employ different standards and policies to review in-house research proposals.

Similarly, that samples/data may be stored indefinitely if the participant has given consent suggests a very strong reliance on individual consent as the mechanism for privacy protections. Official guidance suggests that blanket consent is ethically problematic;[169] yet, to date, this issue remains largely without enforceable regulation.

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168. *See* Kvalheim, *supra* note 57.

169. Nat'l Bioethics Advisory Comm'n, Research Involving Human Biological Materials: Ethical Issues and Policy Guidance, 1, at 33 (1999).

Third, the requirement that incapacitated persons may participate in medical research only if they will directly benefit from the research suggests a boundary that may be more a matter of historical sensitivity to vulnerable populations than a clear commitment to privacy boundaries. Finally, where the sectoral legislation and exceptions do not specifically address issues arising from new technology, there is no reliable protection of privacy rights.

9. *Concluding Observations*

There are reasons to believe that architecture does matter in the force of privacy protections. In the United States, a stringent prohibition of physician disclosure of genetic test results to relatives does not allow for breach in even the most compelling of circumstances. To permit discretionary disclosure by the physician would require a legislative act carving out an exception (even in specified circumstances) or a high court ruling rendering such disclosure permissible. By contrast, in Europe, even legislative provisions prohibiting discretionary disclosure can be overridden on the basis of the weight of the countervailing interests. However, this same flexibility allows a country like Norway to maintain a policy of strict confidentiality and countries like Sweden and France to decide on a case-by-case basis. Thus, the architecture does matter.

The case of human biological material exemplifies this well. Policies allowing permissive use of HBM, from blanket consent to indefinite storage of a minor's tissue have determined that the balance weighs in favor of competing research interests against individual privacy interests. In contrast, in Europe, the fundamental right of privacy can only be overridden when countervailing interests are found to be greater, thus maintaining the essential privacy right while allowing for circumscribed exceptions with adequate oversight, as in the case of France. That Norway tends to maintain the privacy line speaks to the ability of the European model to accommodate national norms. This leaves us with the conclusion that national law and norms determine the strength of privacy protections in Europe, but that this is enabled by the architecture. Furthermore, the regard for privacy as a fundamental right may be what ultimately sets the margins for privacy.[170] Thus, while the architecture accommodates a range of policy positions, from the very restrictive to the permissive, it is the regard for privacy as a fundamental right that ensures that limits remain regarding how much this essential right may be burdened by countervailing interests.

170. The phrase "sets the margins for privacy" comes from the title of Khadija Robin Pierce's Ph.D. dissertation, Setting Margins for Genetic Privacy. Pierce, *supra* note 129.