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THE LEGAL REGULATION
OF BIOBANKS

National Report: Italy



CENTER FOR ETHICS AND LAW
IN BIOMEDICINE





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THE REGULATORY FRAMEWORK OF THE ESTABLISHMENT, MANAGEMENT AND FUNCTIONING OF BIOBANKS IN ITALY

As partners in the European Union Framework Project entitled “GeneBanC: Genetic bio and dataBanking: Confidentiality and protection of data” we are exploring the legal regulations of databanks. (<http://www.genebanc.eu/>) The Center for Ethics and Law in Biomedicine established at the Central European University, Budapest (<http://www.ceu.hu/celab>) aimed to investigate the existing regulatory frameworks of biobanks across the EU and focus on the collection and analysis of legislation and regulation regarding the establishment, management and functioning of classical, population and forensic biobanks across Europe. An important objective was to look at the similarities and differences in such legislation and regulations, in order to formulate recommendations towards a harmonization of European practices and regulations. The European jurisdiction was divided up into two parts between CELAB and the Belgian project partner, the Centre for Biomedical Ethics and Law, K.U.Leuven.

CELAB focused on the regulatory framework of Cyprus, the Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, Romania, the Slovak Republic, and Slovenia. The present booklet is the first one in the series of country reports prepared by CELAB.

In order to familiarize ourselves with the manner in which biobanks actually work, we visited the University of Siena, Faculty of Law, and the Novartis Vaccines & Diagnostics SRL Company, Siena. We also attended the meeting organized by Novartis on Legal Complementary Skills for Life Scientists. Furthermore we launched a questionnaire about the Italian legal framework and we received substantial help from a number of scholars. We would like to express our gratitude to Professors Corrado Angelini, Andrea Monti, Luisa Politano, Elisa Stefanini and Alessandro Spina for providing valuable assistance.

Budapest, 1 September 2009

I. CLASSICAL AND POPULATION BIOBANKS

1. DEFINITION OF BIOBANKS

The only legal reference to biobanks in general is found in Article 3 Section (1) q) of Legislative Decree No. 191 of 6 November 2007, which establishes a broad definition of *tissue bank* as any non-profit health facility, public hospital unit or transfusion service that preserves, stores, distributes or handles human cells and tissues.¹ In the absence of specific legal norms, guidelines adopted by the Telethon Genetic Biobank Foundation² serve as a basis for ethical norms. The Guidelines define a *genetic biobank* as a non-profit service unit created for the collection and storage of human biological material used for research, genetic diagnosis and the study of

biodiversity, and also identifies key distinguishing characteristics, such as the fact that human samples stored in such a bank are associable with the descriptive, genealogic and medical data of the persons from whom they have been isolated.³

2. RELEVANT LAWS

Italy has seen a rapid growth in the number of biobanks in recent years, as the growing interest in the field of biotechnology has led to appreciable developments in the sector here, as elsewhere. Unfortunately, this operational expansion has not led to a corresponding interest of law-makers willing to devise regulations that

¹ In original language: ‘Attuazione della direttiva 2004/23/CE sulla definizione delle norme di qualità e di sicurezza per la donazione, l’approvvigionamento, il controllo, la lavorazione, la conservazione, lo stoccaggio e la distribuzione di tessuti e cellule umani’ available at <http://www.camera.it/parlam/leggi/deleghe/testi/07191dl.htm>

² http://www.biobanknetwork.org/page.php?ID=TheCharter#ethical_guidelines_of_tgb_network accessed 11 September 2009

³ Franca Baldo, Mirella Filocamo, and Lucia Monaco, *Guidelines for Genetic Biobanks*, Italian Society of Human Genetics, Working Group “Genetic Biobanks”, Telethon Foundation Research Services, May 2004, 2, available at http://www.gaslini.org/DPPM/BIOBANK_GUIDELINES.pdf; In original language: ‘Biobanche genetiche: Linee guida’ available at <http://www.sigu.it>; The Telethon Foundation is a network which oversees and coordinates the activities of Italian biobanks. In 2004 it developed an important set of guidelines on the management and activities of genetic biobanks, outlining ethical standards relevant to the processing and use of biological samples for future regulatory statutes; This definition of a ‘genetic biobank’ is replicated in Section 2.3.1 of the Guidelines for the Establishment and Certification of Biobanks, adopted on 19 April 2006; In original language: ‘Linee guida per l’istituzione e l’accreditamento delle biobanche’ available at <http://www.governo.it/biotecnologie/documenti/7.biobanche.pdf>

would help to form a balance between competing societal interests. With the exception of a recent law that introduces measures governing the establishment and management of a forensic DNA Database (dealt with in Part II of the report) there are no legal provisions in Italy which deal expressly with the collection, storage and treatment of biological tissues and DNA. To date no regulatory framework for genetic biobanks has been developed that is global in scope.⁴ Instead these matters are governed by episodic sectoral legislation. However, while the absence of any overarching policy for medical, pharmaceutical or research purposes is conspicuously absent, there are nonetheless a range of laws, by-laws and non-binding instruments that have been adopted over the years in an ad-hoc fashion to govern the collection and use of DNA and human tissue. These are applied in conjunction with provi-

sions specifically targeted to particular biobanks.

The primary pieces of legislation that address the treatment of genetic material, organs and transplantation are Law No. 91 of 1 April 1999 (hereinafter “Provisions for Organ and Tissue Collection and Transplantation”),⁵ Law No. 40 of 19 February 2004 on Human Fertilization,⁶ Law No. 219 of 21 October 2005, which regulates blood transfusions and blood-derived products (hereinafter “Law on Transfusions and Hemo-derivatives”),⁷ Law No. 458 of 26 June 1967 (“Law on Kidney Transplantations between Living Persons”),⁸ and Legislative Decree No. 191 of 6 November 2007 (hereinafter “Decree on the Management of Human Cells and Tissues”),⁹ the transposition of an EU Directive regulating standards of quality and safety.¹⁰ This latter instrument deals specifically with specimens intended for human use,

⁴ Despite the absence of a comprehensive legal framework in this area, the number of facilities that perform genetic testing and provide clinical services in Italy is striking. It has been claimed that Italy is the only country worldwide that can boast of having monitored its genetic testing since the mid-1980s; according to a 2007 census carried out by the Italian Association of Medical Cytogenetics (AICM) and the Italian Association of Genetic Research (AIGM), there were a total of 388 genetic diagnostic laboratories, with 278 facilities handling genetic data (Censimento delle strutture di genetica medica in Italia, anno 2007, Società Italiana di Genetica Umana, 2008).

⁵ The law provides for the creation of repositories for the storage of human tissues intended for therapeutic transplantation. In original language: ‘Disposizioni in materia di prelievi e di trapianti di organi e di tessuti. Legge 1° aprile 1999, n. 9,’ available at <http://www.camera.it/parlam/leggi/990911.htm>

⁶ In original language: ‘Norme in materia di procreazione medicalmente assistita’ available at <http://www.parlamento.it/parlam/leggi/040401.htm>

⁷ In original language: ‘Nuova disciplina delle attività trasfusionali e della produzione nazionale degli emoderivati’ available at <http://www.camera.it/parlam/leggi/052191.htm>

⁸ In original language: ‘Legge 26 giugno 1967, n. 458, Trapianto del rene tra persone viventi’ available at <http://guide.supereva.it/diritto/interventi/2001/12/81761.shtml>

⁹ In original language: ‘Attuazione della direttiva 2004/23/CE sulla definizione delle norme di qualità e di sicurezza per la donazione, l’approvvigionamento, il controllo, la lavorazione, la conservazione, lo stoccaggio e la distribuzione di tessuti e cellule umani’ available at <http://www.camera.it/parlam/leggi/deleghe/testi/07191dl.htm>

¹⁰ EC Directive 2004/23/EC; Related Directives 2006/16/EC and 2006/86/EC have not yet been implemented domestically at the time of publication of this report.

defining the domestic legal standards for the procurement, processing, preservation, storage and testing of human cells and tissues, as well as their domestic and cross-border distribution. Governmental guidelines on medical genetics were also adopted on 9 September 2004.¹¹

There are different horizontal modalities of laws for dealing with a broader spectrum of human biological materials such as blood and blood-derivatives used for the purpose of transfusion (regulated by Decree No. 78 of 26 January 2001).¹² Law No. 40 of 19 February 2004¹³ introduced bans on a number of practices in the area of in-vitro fertilization, including assisted reproductive technology, medical research on human embryos, embryo cryopreservation and pre-natal screening of genetic abnormalities.¹⁴

Apart from any diagnostic, therapeutic or research purpose for which it may be used, genetic material also possesses value inasmuch as it potentially contains a great deal of personal information about the indi-

vidual from whom it has been sampled. This feature normally elicits demands for additional legal protection as ethical concerns are brought to the foreground; Italian data protection laws consequently play a significant role in determining the manner in which this material is processed.

All biobank activities, including data and sample conservation and genetic testing, screening and counselling must comply with the provisions of the Data Protection Code (Legislative Decree No. 196 of 30 June 2003),¹⁵ which consolidates a number of earlier decrees dealing with the protection of sensitive data. The principle of personal data protection governs both the processing and transfer of biological samples. Also important are the following pieces of legislation: Agreement on the Treatment of Sensitive Data (Authorization No. 5 of 1997),¹⁶ the Code of Practice for the Processing of Personal Data for Statistical and Scientific Purposes of 16 June 2004,¹⁷ the Agreement on the Treatment of Sensitive Data by Public Bodies of 30 June 2005,¹⁸ the

¹¹ In original language: 'Linee guida per le attività di genetica medica' available at <http://www.governo.it/backoffice/allegati/22925-2077.pdf>

¹² In original language: 'Protocolli per l'accertamento della idoneità del donatore di sangue e di emocomponenti' available at <http://gazzette.comune.jesi.an.it/2001/78/9bis.htm>

¹³ In original language: 'Norme in materia di procreazione medicalmente assistita' Available at <http://www.camera.it/parlam/leggi/040401.htm>

¹⁴ Andrea Dovio et al., The New Italian Law on Assisted Reproduction Technology (Law 40/2004): A Different View, *Journal of Medical Ethics*, 1 Dec 2005.

¹⁵ English language version available at <http://www.garanteprivacy.it/garante/document?ID=1219452>; In original language: 'Decreto Legislativo 30 giugno 2003, n. 196, Codice in materia di protezione dei dati personali' available at <http://www.parlamento.it/parlam/leggi/deleghe/03196d1.htm>

¹⁶ In original language: 'Autorizzazione n. 5/1997 al trattamento dei dati sensibili da parte di diverse categorie di titolari' available at http://www.interlex.it/testi/ag5_97.htm

¹⁷ 'Codice di deontologia e di buona condotta per i trattamenti di dati personali per scopi statistici e scientifici' available at <http://www.garanteprivacy.it/garante/doc.jsp?ID=1556635>

¹⁸ In original language: 'Trattamento dei dati sensibili nella pubblica amministrazione' available at <http://www.garanteprivacy.it/garante/doc.jsp?ID=1144445>

General Authorization for the Processing of Genetic Data of 22 February 2007 (hereinafter "Authorization")¹⁹ and Authorization No. 2/2008 for the Processing of Data Disclosing Health and Sex Life of 19 June 2008.²⁰

The National Bioethics Committee (CNB) initiates parliamentary motions and regularly publishes opinions. In 1999, in conjunction with the Superior Health Institute, it published Bioethical Guidelines for Genetic Testing.²¹ The National Committee for Biosecurity and Biotechnology (CNBB) also regularly publishes opinions, and in 2006 introduced Guidelines on the Certification of Biobanks.²² Also noteworthy are the Guidelines for Cytogenetics for Prenatal Diagnosis and Postnatal Diagnosis²³ of the Italian Society of Human Genetics (SIGU)²⁴ and the Guidelines for Genetic Research Clinical Protocols published in

2006 by SIGU and the Smith Kline Foundation.²⁵

Biobanks in Italy are also naturally subject to a variety of non-binding instruments, which include Council of Europe and European Union recommendations and other international laws and conventions.

The European Convention on Human Rights and Biomedicine was signed in 1997 and ratified with Law No. 145 on 28 March 2001 by Italy,²⁶ however the law has yet to be deposited with the Council of Europe and is therefore absent from the Council of Europe's list of official Convention endorsers. At the time of publication of this report Italy has neither signed nor ratified the Charter on Biomedicine of the Member States of the EuroBioBank Project, although it is a founding partner of the network which presently comprises 18 members.²⁷

¹⁹ In original language: 'Autorizzazione al trattamento dei dati genetici - 22 febbraio 2007' available at <http://www.garanteprivacy.it/garante/doc.jsp?ID=1389918>; on 19 December 2008 this Authorization was prolonged until 31 December 2009.

²⁰ English language version available at: <http://www.garanteprivacy.it/garante/doc.jsp?ID=1642045>; In original language: 'Autorizzazione n. 2/2008 al trattamento dei dati idonei a rivelare lo stato di salute e la vita sessuale' available at <http://www.garanteprivacy.it/garante/doc.jsp?ID=1529389>

²¹ National Bioethics Committee, Bioethical Guidelines for Genetic Testing, available in English at <http://www.palazzochigi.it/bioetica/eng/opinions/genetictest.html>; In original language: 'Orientamenti bioetici per i test genetici' available at <http://www.palazzochigi.it/bioetica/pdf/40.pdf>; A number of their opinions and motions are published in English on the following website: <http://www.governo.it/bioetica/eng/opinions.html>

²² In original language: 'Linee guida per l'istituzione e l'accreditamento delle biobanche' available at http://www.governo.it/biotecnologie/documenti/7_biobanche_1.pdf; For other published documents, see their website: <http://www.governo.it/biotecnologie/documenti.html>

²³ In original language: 'Linee guida per la citogenetica: diagnosi prenatale' and 'Linee guida per la citogenetica: diagnosi postnatale' available at <http://www.cnmr.iss.it/lgui>

²⁴ This network develops quality criteria for Medical Genetics laboratories operating within Italy, contributes to the development of guidelines for research and promotes public awareness of the functions, potential and limitations of diagnostic techniques of Human Genetics (<http://www.sigu.it>).

²⁵ In original language: 'Linee guida per I protocolli clinici di ricerca genetica' available at http://www.movimentodeicittadini.it/documenti/Linee_Guida_Ric_Gen_.pdf

²⁶ 'Legge 28 marzo 2001, n. 145,' available at <http://www.privacy.it/legge2001145.html>

²⁷ EuroBioBank is a Network of DNA, Cell and Tissue Banks for Rare Diseases.

3. ESTABLISHMENT AND MANAGEMENT OF BIOBANKS

According to Article 27 of the Data Protection Code, the “*Garante*” (Guarantor) of the Italian Data Protection Authority must be notified whenever data belonging to high-risk categories are processed. The *Garante* is also responsible for maintaining a record of all such databases. This high-risk category comprises genetic data and any information processed for the purpose of profiling individuals.

As previously pointed out, a gulf exists between the de facto creation and operation of biobanks in Italy and the legal framework needed to regulate them. What serves as a proxy for this is a conglomeration of laws, guidelines and ‘soft law’ instruments. Section 90 of the Data Protection Code requires the establishment of adequate safeguards whenever any processing of genetic data takes place, regardless of their intended usage. In accordance with this provision the Data Protection *Garante* first established a General Authorization on the Processing of Genetic Data pertaining to Health and Sex Life in 1997 with which such activities could be monitored by the Italian Data Protection Authority. Under the terms of this Authorization, such data can only be pro-

cessed for research purposes or if they are considered indispensable for the health of data subjects, third parties or the community, provided that consent is expressly given. Authorization No. 2/1997 has been reissued annually, often in an amended format. Currently General Authorization No. 2/2007 is in force.²⁸

In a corresponding fashion, the Decree on the Management of Human Cells and Tissues also covers a wide range of standards and principles designed to regulate the handling of cells and tissues which pertain, *inter alia*, to their collection, testing, storage, processing and distribution. It also regulates activities involving hematopoietic stem cells, embryonic stem cells and reproductive cells and tissues, however only insofar as the storage of such material is concerned.²⁹

With Legislative Decree No. 14 of 27 February 2009,³⁰ the Ministry of Health extended an earlier decree introducing provisional restrictive measures pertaining to the creation of private biobanks and storage of cells for autologous purposes. This is perceived by some scholars as the government’s attempt to monopolize the cord blood sector by prolonging a 2002 moratorium on the establishment of private biobanks and autologous conservation of cord blood

²⁸ English language version available at <http://www.garanteprivacy.it/garante/doc.jsp?ID=1395420>; in original language: ‘Autorizzazione al trattamento dei dati genetici’ available at <http://www.garanteprivacy.it/garante/doc.jsp?ID=1389918>

²⁹ Paolo DeCarlo, New Human Tissues and Cells Quality and Safety Standards in Italy, *Life Sciences*, February 2008, 53, 6.

³⁰ In original language: ‘Legge 27 febbraio 2009, n. 14, Conversione in legge, con modificazione, del decreto-legge 30 dicembre 2008, n. 207, recante proroga di termini previsti da disposizioni legislative e disposizioni finanziarie urgenti’ available at <http://www.camera.it/parlam/leggi/090141.htm>

stem cells.³¹ It is expected that the Ministry of Health will carry out reforms in this area by December 2009.³²

4. PECUNIARY ASPECTS

The human body or its parts cannot be the object of property rights according to the principle of *res extra commercium*, whereby the human being is viewed as an end in itself and not merely the means to an end. This is a fundamental principle not taken into consideration by the Fascist regime which implemented a regulatory plan whereby the sale of blood was legalized in the 1940s.³³ This practice of remunerated blood donations persisted until it was banned in 1990 with the adoption of the Blood Reform Act.³⁴

The Decree on the Transplantation of Human Tissues, the Provisions for Organ and Tissue Collection and Transplantation and Cells, the Law on Kidney Transplantations between Living Persons and the Law on Blood Transfusion and Hemo-derivatives all provide that any donations of samples, blood or organs must be volun-

tary and unpaid. According to a 13 July 2007 motion on the collection, storage and use of stem cells deriving from umbilical cords made by the National Bioethics Committee, while donations must be made freely, compensation is advocated with respect to reimbursement of expenses incurred for the donation.³⁵

5. CONSENT OF PEOPLE WITH FULL AND LIMITED LEGAL CAPACITY, PROVISIONS ON DECEASED PERSONS

In Italy the normative basis for the principle of 'informed consent' in medical and research settings is found in Article 32 Section (2) of the Constitution. The Italian Code of Medical Ethics outlines the physician's obligation to obtain informed consent in Article 32. Article 39 asserts the necessity for informed consent whenever human biological material is collected from a living person. Article 38 allows for the transplantation of body parts from a cadaver as long as this is done in accordance with current laws.

³¹ Since Legislative Decree No. 191 defines 'tissue bank' as a "non-profit" facility (Article 3 (1) q), private biobanks cannot operate from a legal point of view despite the existence of laws which would permit their establishment. See Massimo D'Auria and Alessandro Spina, *Private Biobanks in Italy: An Overview of the Legal Framework*, 26 July 2009

³² *Ibid.*

³³ Umberto Izzo, *Responding to the HIV-tainted Blood Contamination in Italy, Proceedings of the First meeting on HIV-Contaminated Blood, Policy and Conflict*, Castello di Santa Maria Novella, Florence, 1996.

³⁴ Article 1 (4) of Law No. 107 of 4 May 1990 ("Provisions for Blood Transfusions, Blood by-products and the Production of Plasma Derivatives"); In original language: 'Disciplina per le attività transfusionali relative al sangue umano ed ai suoi componenti e per la produzione di plasmaderivati' available at http://www.ministerosalute.it/imgs/C_17_normativa_1578_allegato.pdf

³⁵ In original language: 'Mozione del Comitato Nazionale per la Bioetica sulla raccolta, la conservazione e l'utilizzo di cellule staminali derivate da cordone ombelicale' available at http://www.palazzochigi.it/bioetica/mozioni/Mozione_cordonali.pdf

All data subjects must be informed of the collection of their personal data, the purpose of collection, its nature (voluntary or obligatory) and the consequences of failure to reply to such notice, according to Article 13 of the Data Protection Code.

Rules concerning consent within the healthcare sector are covered by Article 76 of the Data Protection Code. Here we find a general clause stating that all health care treatment be compliant with the doctrine of informed consent. Additional renewed consent must always be given for the use of samples for purposes different than those for which consent was originally given.

Under Articles 23 and 26 of the Data Protection Code and Article 6 of the General Authorization, genetic data may only be processed if the authority to do so has been granted by both the Data Protection Authority and the data subject who has given informed consent in written form. Such consent is only valid if given without coercion of any kind, and may be withdrawn at any future date. According to the *Garante*, all human tissues destined for medical research must be destroyed once donor consent has been withdrawn.

Since 1999 Italy operates under a system of presumed consent with regard to organ donation following death, that is to say, in the absence of a donor's explicitly communicated objections such consent is presumed. This is regulated by the Criminal Code (Articles 581-585) and the Provisions for Organ and Tissue

Collection and Transplantation. It is said, however, that in practice, prior to organ removal the families of the deceased are often consulted.³⁶

Section 3.1 of the Telethon Guidelines examines different aspects of informed consent in considerable detail. In order to fully respect the decision of the data subject, it is recommended that prior to sampling information is provided in a "simple and comprehensible manner" during an interview, along with the possibility of obtaining additional information or clarifying uncertainties by consulting with parties not implicated in the project. In the case of genetic material, informed consent must be written, adequate information must be offered to the subject beforehand, and anonymity must be guaranteed. In addition, consent must be given for storage of the sample as well as for any possible future uses. The Guidelines also address the issue of population studies, advocating for individual informed consent offered by participants, which must be free from any form of pressure. It charges the relevant local authorities and the bioethics committee whose approval is needed for the study with guaranteeing the accuracy and transparency of the stated research objectives, the development of the research, and potential benefits of the project for the individual and the community.

In addition, the possibility for withdrawing consent at any given moment must be stated openly; under these circumstances any collected sample or related information must

³⁶ Gevers, A. Janssen and R. Friele, Consent systems for post mortem organ donation in Europe, *European Journal of Health Law*, 2004, 11(2), 3.

be destroyed and no further generation of data based on this sample should be permissible (Section 3.1.2). Separate decisions pertaining to authorization of the use and preservation of a sample must be offered, along with the choice of whether or not to be informed about diagnostic possibilities or research results. A countersigned copy of the consent form should also be offered to the data subject.

Consent is not obligatory in all circumstances however. Since a number of registries of biological material were established in Italy prior to the introduction of data protection laws and other forms of regulatory statutes, they sometimes operate under different legal regimes than more recent biobanks.³⁷ This has produced a situation where some of the samples processed and stored today have been obtained without prior informed consent. Under Italian law the concept of ‘personal data’ does not include a biological sample *per se* (i.e., biological material processed in an anonymous format); it is only considered as such when a sample test analysis is associable with an individual.³⁸ Thus consent is not required for the processing of anonymous data.

Article 75 Section (1) of the Data Protection Code includes a provision allowing for personal data to be processed without consent under

authority of the *Garante* if such action is considered to be in the justified interest of a third party or the community at large (this provision is elaborated in Article 85 of the same document). Under normal circumstances, however, the protection of genetic data from being communicated to the subject’s family is guaranteed.

Article 26 Section (4) b) of the Data Protection Code states that sensitive data may be processed without consent if the life or bodily integrity of a third party is threatened. Although a person’s genetic data is considered to be the exclusive property of the one from whom it is derived, it also belongs to members of a legally relevant biological family, who may also be considered stakeholders.³⁹ Subsequent to a pioneering decision made by the Italian Data Protection Authority in 1999, a person’s “right to health”⁴⁰ may prevail over another’s “right to privacy.” The case, which was a first of its kind in Europe, involved a woman who wished to make a reproductive decision based on an informed assessment of the risks of passing on a genetic disease to her future offspring. This required access to her father’s personal data, which was authorized by the *Garante* without his consent.

Although the age of legal competence is 18, Italian law does allow for

³⁷ H. Gottweis and K. Zatloukal, *Biobank Governance: Trends and Perspectives*, *Pathobiology*, 2007, 74: 206-211.

³⁸ 3.1.2.1 (“Samples in the absence of informed consent”) of the Telethon Guidelines.

³⁹ Art. 29 Data Protection Working Party, Working Document on Genetic Data, Paper No. 12178/03/EN WP 91, 2004, 9.

⁴⁰ According to this decision ‘health’ is understood to mean a person’s “psychological and physical well-being” (General Authorization of 22 May 1999, Genetic Data – Data related to the State of Health, Bulletin No. 8).

the possibility of evaluating the individual aptitude of a minor for self-determination on an individual, case-by-case basis, especially where matters of health are concerned (Article 6 of the Authorization). While parental consent is normally required for any processing of personal data, genetic testing or other diagnostic or therapeutic interventions, a minor's obligation to submit to parental authority or legal representative is not absolute, although this matter remains somewhat controversial. In the event that a legal representative of a minor or other person lacking legal capacity refuses to give consent for treatment perceived to be necessary by a physician, the latter must inform the authorities according to Article 33 of the Code of Medical Ethics.

Article 24 Section (1) e) of the Data Protection Code covers situations in which the data subject is unable to provide consent due to physical disability, legal incapacity or inability to discern right from wrong. Under such circumstances consent may be provided (in order of priority) by one of the following: a legal representative, next of kin, family member, housemate or manager of the hosting institution.

We have seen that the right to maintain control of one's personal information is guaranteed under a number of instruments. The right not to be informed is also a legally protected claim in Italy. While the Italian legislator has yet to address this issue head on, both Article 30 of the Italian Medical Code and Article 90 of

the Data Protection Code contain provisions which guarantee that, where documented, the will of a subject not to be informed about the results of predictive testing must be respected.⁴¹

According to Article 6 of the Authorization, genetic testing may be performed on minors or individuals who are incapacitated, mentally or physically, if the direct benefits for such an individual can be justified, and insofar as their opinion is taken into account as far as possible.

6. ACCESS TO DATA AND SAMPLES

The General Authorization for the use of Genetic Data allows access to genetic material to a certain category of professionals (such as physicians, lawyers and scientific researchers) provided that they comply with measures of proportionality and necessity, respect the principle of informed consent of all parties concerned, comply with self-regulatory professional standards, refrain from sharing this data with third parties, and limit the use of the data to the purposes for which consent was originally given. So long as the recipient always uses data for the same objectives for which the donor's consent was initially given, all researchers, legal professionals, partner clinics and biobanks may request such data.

The Data Protection Code also provides for authorized disclosure and processing of personal data by health

⁴¹ See Elisa Stefanini, Biobanks under Italian Law: Mind the Gap! *Aggiornamento*, May 2009, 2.

care professionals and public health care bodies (also within the framework of activities in the substantial public interest pursuant to Article 85 of the Code).

7. STORAGE

The protection provided by the Data Protection Code is general in nature and thus it is applicable in all circumstances where personal data is collected and used. Some of the statute provisions do, on the other hand, specifically address the activities of genetic biobanks. One example of this is Article 90, mandating some form of certification by the *Garante*. Article 55 of the Data Protection Code identifies genetic data banks as facilities where the processing of personal data carries higher risks, to which special processing operations apply (Article 17). In such cases, following a request, the *Garante* must perform a check on the measures and precautions in place prior to any processing activities.

According to Article 4 Section (3) of the Data Protection Authority's Authorization for the Processing of Genetic Data, sensitive personal data may not be stored unless measures are adopted to restrict access. Furthermore, all data transmitted through electronic means must be encrypted, and access to data must only be possible with a special security password. Moreover, data collected and stored in registers must always be coded. The processing of data that takes place subsequent to collection may not allow for the identification of the data subject (even

indirectly via other information).

Chapter VI Section (3) of Authorization No.5/2008 obliges anyone charged with processing sensitive data to ensure that it is kept only for as long as necessary to realize the objectives for which it was originally collected. This provision compels custodians of data to verify on a regular basis that the storage of such data is "relevant, not excessive, and indispensable."

The Decree on the Management of Human Cells and Tissues also requires that all cell- and tissue-related data remain traceable from donor to recipient in a reciprocal fashion, and that any materials that come into contact with these samples be stored for a minimum of 30 years.

8. SUPERVISION, COMPENSATION, PENALTIES

Along with registering all places where sensitive personal data is collected, Article 27 of the Data Protection Code tasks the *Garante* with auditing the facilities where such data is processed or stored, and with enforcing privacy laws.

The Decree on the Management of Human Cells and Tissues authorizes regional administrative bodies to agree to the establishment of facilities which treat genetic data, and to supervise their activities in collaboration with the Ministry of Health, the National Transplant Centre (CNT) and the National Blood Centre (CNS).

According to Article 15 of the Data Protection Code, any harm that may have arisen through the processing of personal data is subject to liability

under Article 2050 of the Italian Civil Code. Any infringements of the processing regulations set out in Article 11 are also subject to compensation for non-pecuniary damages (Article 16). Part III of the Data Protection Code details the sanctions and remedies that are applicable whenever privacy rights are violated.

9. PUBLIC DEBATE

While the normative framework encompassing issues of storage, use and processing of human biological material will always vary with prevailing attitudes, they are often a reflection of the social, cultural and historical circumstances of a society. Accordingly, it is worth considering the attitudes which underlie legal norms. In Italy a dominant concern with privacy and autonomy of the individual and the related apprehension relating to, among others, the threat that genetic modifications may pose to these principles, is a recur-

rent theme on the part of experts in this field.⁴²

Due to increasing concerns about prospective misuse and abuse of new technologies and the potential for exploitation of more vulnerable members of society, in-vitro fertilization is an especially sensitive topic in Italian society, and the majority is adamant about strict regulations in the area of assisted reproduction. In 2004 legislation was adopted that is considered by many professionals working in the field of reproductive technology to be highly restrictive.⁴³ This law generated a great deal of public debate in Italy concerning the ethical and medico-legal aspects of biomedical research and reproductive technology, with some sources claiming that it is a reflection of popular sentiment,⁴⁴ and others alleging that the law ignores contemporary expectations and its adoption was merely the consequence of the disproportionate political influence of the Catholic Church.⁴⁵

There appears to be a strong consensus among practitioners that pub-

⁴² See, for instance, an attempt to capture societal attitudes towards Biobanks in Italy empirically: Virgilia Toccaceli et al., Research Understanding, Attitude and Awareness towards Biobanking: A Survey among Italian Twin Participants to a Genetic Epidemiological Study, *BMC Medical Ethics* 2009, 10 (4), passim; For a discussion of contemporary Italian values relating to genetics and biotechnologies, see also: Carlo Petrini, Cronache di bioetica 2008: fatti, persone, interpretazioni in Italia e nel mondo [Chronicles of Bioethics 2008: Actors, Facts and Interpretations in Italy and around the World], Istituto Superiore di Sanità, 2008.

⁴³ In recent years a great deal has been published on this law and the consequences of the ban on practices for research in this area. For an incisive analysis, see for example Andrea Boggio and Gilberto Corbellini, Regulating Assisted Reproduction in Italy: A 5-year Assessment, *Human Fertility*, 2009, 12 (2): 81-88, passim, and E. Turillazzi and V. Fineschi, Preimplantation Genetic Diagnosis: a Step by Step Guide to Recent Italian Ethical and Legislative Troubles, *Journal of Medical Ethics*, 2008, 34: e21-e21.

⁴⁴ In 2005 there was a failed attempt to modify the law by way of a referendum. For additional information see Mark V. Sauer, Italian Law 40/2004: a View from the 'Wild West', *Reproductive Biomedicine Online*, January 2006, 12 (1): 8-9.

⁴⁵ Andrea Boggio and Gilberto Corbellini, Regulating Assisted Reproduction in Italy: A 5-year Assessment, *Human Fertility*, 2009, 12 (2): 81-88, passim.

lic debate on issues relating to biobanks and their biomedical research activities has not been sufficiently encouraged, with the national media frequently silent with respect to the many social and ethical ramifications of such activities and their potential for abuse. Unregulated practices remain a concern for some segments of the population. It has been alleged, for instance, that the DNA Bank of the RIS (investigative division of the Italian Police Authorities) was established with no public debate and without any legal framework governing its activities or independent monitoring bodies to maintain transparency.⁴⁶

The Italian government has made major investments in databases for population biobanks in order to conduct research on the genetic roots of

diseases. A case in point is the “genetic park,” set up in 2000 by the International Institute of Genetics and Biophysics. The database includes the residents from 10 villages in the South of Italy who are participating in a research study on the identification of diseases which is to be completed by 2010. The database stores a range of data, including blood and DNA samples.⁴⁷ The government project was met by relatively little vocalized opposition compared to other parts of the world where similar population databases were established. But while it is clearly illegal for individual sample donors to profit from the commercial gains that will ensue, some undetermined part of the profits are expected to go to the local communities.

⁴⁶ The RIS DNA Bank of Parma was considered by EDRI as the most invasive technology in 2008 and given a “Big Brother Award.”

⁴⁷ Privacy International Reports: The Italian Republic, 16 November 2004

II. FORENSIC BIOBANKS

1. RELEVANT LAWS

With the adoption, on 30 June 2009, of Law No. 85⁴⁸ on Accession to the Treaty of Prüm⁴⁹ (hereinafter the “National DNA Databank Law”), the Italian government established the legal basis for the creation of a National DNA Databank (NDNAD) and connected central laboratory. This marks an important milestone in relation to governance of the use of genetic profiling in criminal investigations, as regulatory gaps existed in the national legal framework since these techniques were first drawn upon for forensic purposes. The law came into force on 14 July 2009.

The Data Protection Code also applies to some degree to the maintenance and processing of biological materials and data stored and used for forensic objectives. The parts of the Code particularly relevant to forensic biobanks are the following: Title I, Chapter 1 (Processing Operations in the Judicial Sector) (46 – 49); Title II (Processing Operations in the Police Sector) Chapter 1 (53-57); Chapter 2 (Additional Rules Applying to Public Bodies) (18-22); and Annex

A6 (Code of Practice Applying to the Processing of Personal Data for Investigative Purposes). Also pertinent is Decree No. 144 of 27 July 2005 (the so-called “Pisanu Package”). This is a piece of anti-terrorism legislation which amends the Criminal Code to allow forced sampling to take place.

2. MANAGEMENT

Article 16 states that administrative acts must be adopted within four months of the date of entry into force of the National DNA Databank Law addressing issues that range from operational and organizational regulations of the NDNAD and its laboratory to processing methods, access, communication techniques, methods of analysis, storage of samples, and the criteria and procedures for the deletion of profiles and the destruction of samples. It does not enter into detail about technical and administrative matters pertaining to the management of samples and data. Experts, however, underline the importance of more detailed and technical

⁴⁸ In original language: “Adesione della Repubblica italiana al Trattato di Prüm,” available at <http://www.gazzettaufficiale.it/gunewsletter/dettaglio.jsp?redaz=009G0092&datagu=2009-07-13&numgu=160&service=1>

⁴⁹ The aim of the Prüm Treaty is to strengthen cross-border cooperation in combating terrorism, illegal immigration and international crime and promotes the exchange of information including fingerprints and genetic data.

rules: provisions for the establishment of a chain of custody, for instance, are vitally important in preventing the possibility of tampering with or planting samples, as well as with respect to the far-reaching implications of poorly regulated facilities on future reliability of evidence.⁵⁰ Equally important are technical safeguards concerning the proprietary infrastructure of the NDNAD and central laboratory themselves, which are also absent.⁵¹

The central laboratory, located within the Ministry of the Interior, was specially established to work with the biological samples that are analyzed and subsequently stored in the NDNAD according to Article 5 Section (2) of the National DNA Databank Law. The NDNAD will be set up within the Ministry of Justice.

3. PURPOSE AND SCOPE OF COLLECTION

The purpose of the databank, according to Article 7 of the National DNA Databank Law, is for the comparison of DNA profiles derived from samples collected over the course of criminal investigations of serious crimes, or from missing persons, corpses or the remains of unidentified bodies. Facilitating the exchange of data, joint deportations, and running automatic fingerprint comparisons between contracting states are some of the aims

of the databank under the Prüm Treaty, as are standardization and monitoring of data quality. The police authorities have argued along with the judiciary that such a database would increase the speed and efficiency of criminal investigations and the identification of missing persons or victims of natural disasters.

DNA samples collected during a criminal investigation are taken, as a rule, from criminal suspects or volunteers, and from the scene of the crime. Article 9 Section (1) of the National DNA Databank Law details the range of subjects from whom DNA may be sequenced and stored. It stipulates further that samples may be taken from persons held in pre-trial detention or under house-arrest, persons arrested in *flagrante delicto* or subject to detention on suspicion of murder, and convicts serving a fixed prison sentence for a premeditated crime or who are otherwise subject to custodial measures on a provisional or permanent basis. Arrests of persons in *flagrante delicto* and individuals detained as suspects may be sampled only after judicial authorization has been granted.⁵² Sampling may only be completed if proceedings are initiated against the persons who fall into one of these categories for premeditated crimes.⁵³

The scope is also restricted to suspects or persons convicted of crimes of a certain gravity. Thus, Article 9 Section (2) categorically

⁵⁰ For elaboration of this assertion and a critique of the recent law, see Andrea Monti, Italian NDNA Database: The Devil is in the Details, 19/08/2009, available at <http://blog.andreamonti.eu/?p=165>

⁵¹ Andrea Monti, personal communication of 18 August 2009.

⁵² National DNA Database Law, Article 9 Section (3)

⁵³ *Ibid.*, Article 9 Section (2)

excludes processing of data or biological samples for non-violent crimes such as fraud or financial crime.⁵⁴ Samples of persons subject to conviction for a period of less than three years will not be obligatory according to Article 24.

4. SAMPLES AND SAMPLE-TAKING, CONSENT

Specially trained law enforcement staff or health workers are responsible for collecting DNA samples.⁵⁵ Minutes must be taken of the sampling procedure, which is to be performed “with discretion and respect for the dignity and privacy” of the person being sampled.⁵⁶ Immediately following the harvesting of DNA, the samples are sent to the central laboratory for DNA profile sequencing and subsequent dispatch to the DNA databank.

DNA profiles derived from samples taken from crime scene stains may only be stored in a database with permission from a court authority, who decides on a case-by-case basis whether there are sufficient grounds

to warrant such collection.⁵⁷ This provision serves to protect innocent persons, as there is always the possibility that stains at a crime scene will contain their DNA. Nonetheless, it is widely recognized that these laws are not always strictly observed by the Italian police authorities,⁵⁸ which raises a parallel and equally complex problem regarding the storage and use of those DNA profiles which were unlawfully collected by the police before the National DNA Databank Law came into force.

A prosecutor may request a court authorization for forced sampling of a “living subject”.⁵⁹ Once the results of the forensic tests have been established, however, the court is responsible for the immediate destruction of a sample “unless it considers its conservation imperative”.⁶⁰

Article 10 Section (1) of the “Pisanu Package” amended the Criminal Code to allow for the forced removal of oral biological material prior to written or verbal consent from the State Attorney.⁶¹ In light of a 1996 Constitutional Court ruling (discussed in more detail in Section 8 on constitutional review), this provision is unlawful inasmuch as

⁵⁴ While the law appears to exclude economic crimes from the list of offences that would qualify for coercive sampling, it did not eliminate the possibility of storing DNA of persons accused of or prosecuted for offences such as insider trading (Ciro Sbailò, *Trattato di Prüm: Una rivoluzione silenziosa (finora)* [The Prüm Treaty: A Silent Revolution (So Far)], *Forum di Quaderni Costituzionali*, 7/8 August 2009).

⁵⁵ National DNA Database Law, Article 9 Section (4)

⁵⁶ *Ibid*, Article 9 Section (5)

⁵⁷ Van Camp, et al., National Forensic DNA Databases in the EU, *European Ethical-Legal Papers N°9*, Leuven, 2007, 12.

⁵⁸ See for instance, Beatrice Montini, *Dna, 15 mila identità genetiche conservate fuorilegge* [15000 Genetic Identities Preserved Illegally], 17 May 2006.

⁵⁹ National DNA Database Law, Article 25; Article 24 of the same law provides that forced sampling must be by order of a judge.

⁶⁰ *Ibid*, Article 29

⁶¹ In original language: ‘Decreto Legge 27 luglio 2005, n. 144’, available at http://www.italgiure.giustizia.it/nir/lexs/2005/lexs_411968.html

it fails to specify not only the modalities of collection, but also falls short in detailing the precise circumstances under which such derogation would be permissible.⁶² The Court ruled that sample-taking which is done coercively, that is, against the expressed will of the subject, is considered a restriction of a person's personal liberty.⁶³ While the integrity of the person may not be infringed,⁶⁴ the scope of personal freedom may be legitimately narrowed under special circumstances. The Constitutional Court considered Article 224 Section (2) of the Criminal Code, which authorized a judge-ordered infringement of liberty, unconstitutional because it lacked precision about the circumstances under which it would be acceptable, as well as a detailed legal protocol for forced sampling. Furthermore, the Court found that taking samples from non-suspects was also problematic insofar as it violated the principle of equal treatment, guaranteed under Article 3 of the Constitution.⁶⁵

The first Section of Article 24 provides that persons undergoing proceedings for crimes of a premeditated nature, attempted or committed, punishable with a prison sentence of

3 years to life, and for the investigation of which DNA evidence is deemed by a judge to be absolutely indispensable to establishing the facts of the case, must submit to mandatory sampling even if he or she refuses consent. As mentioned previously, the forced sampling of hair, bodily hair or oral mucus for the purposes of determining a DNA profile may only be carried out with an order of the court, or, in the event of an emergency, by the Public Prosecutor (in which case court authorization must follow within 48 hours).

According to Article 24 Section (2), any evidence obtained from the sampling procedure will be deemed invalid if actions have not been taken with respect to the following: identification of the subject undergoing the sampling and of the alleged crime, with a brief description of the facts of the case; explicit information about the sampling and tests to be carried out as well as the reasons for their indispensability to the establishment of the facts; notification of the subject's lawyer or counsel about the procedure; warning of the subject that in the event of failure to appear without legitimate reason forcible

⁶² Ignazio J. Patrone, 'La Cirielli stravolge il diritto penale' [Cirielli Distorts Criminal Law] *Magistratura Democratica News Giurisprudenza*, 28 July 2005; See Section 3.5 of Judgement 238/1996

⁶³ The Court declared that forced sample-taking constitutes an invasion of one's personal sphere of freedom. Section 3.2 of the decision states that such an act compromises "not only the personal sphere ... , the health (including psychological health) and physical integrity ... [but also] "infringes upon a very small, but by no means insignificant, part [of the personal physical sphere of an individual] (Constitutional Court Judgement 238/1996).

⁶⁴ Article 13 Section (2) of the Constitution does allow for limits to personal freedom "in cases and in such a manner as provided by law".

⁶⁵ Constitution of the Republic of Italy, available in English at http://www.senato.it/documenti/repository/istituzione/costituzione_inglese.pdf; In original language: 'La Costituzione della Repubblica Italiana' available at <http://www.governo.it/governo/costituzione/principi.html>

accompaniment may be ordered;⁶⁶ and finally, recording of the place, date and time of the procedure and methods used. The victim, the accused and their respective counsels must be notified of an order of forced sampling at least three days prior to the date fixed for the procedure.⁶⁷ If a subject refuses to give consent, the court reserves the right to authorize the use of physical coercion.⁶⁸ Under no circumstances may the procedure entail actions prohibited by law or endanger the life, health or physical integrity of the person (or unborn child) or cause suffering which would be considered significant in the opinion of a physician.⁶⁹ Finally, “all things being equal, the less invasive method must be employed”.⁷⁰

Under Article 29 of Chapter IV of the National DNA Databank Law (“Amendments to the Criminal Code concerning Verification Procedures which may infringe upon Personal Liberty”) we find the introduction of Article 72 *bis* to the Criminal Code. This deals with the collection of biological samples from or medical assessment of children and persons lacking legal competency. Sampling is permitted with the consent of a legal guardian, who may be present during the sampling procedure. If a parent or guardian is unavailable or is involved in a conflict of interest with the person to be subjected to sam-

pling or assessment, the consent is provided by a guardian specially appointed by the court, who may be present during these operations.

5. ACCESS TO DATA AND SAMPLES

Security measures and access privileges are particularly important in order to respect privacy and preserve the authenticity of evidence. What makes a DNA sample particularly sensitive and elicits a number of legitimate ethical and legal concerns is that it may later be analyzed in a myriad of ways that were not foreseen at the time of physical collection, known as “function creep”. Given the heightened potential for compromising the privacy of an individual (both initially and at a future point in time) stricter precautions are called for to safeguard such information.

Article 12 of the National DNA Databank Law deals with tracking samples as well as processing and accessing data. It begins with a provision guaranteeing the impossibility of direct identification of the subject from whom DNA profiles or samples are derived; these data should “not contain sufficient information”. The entities responsible for maintaining the codes are not clearly specified. Section (4) stipulates that processing

⁶⁶ Article 27 Section (7) of the National DNA Databank Law additionally states that sampling will be considered null and void unless a defence counsel for the subject has been appointed.

⁶⁷ National DNA Database Law, Article 24 Section (3)

⁶⁸ *Ibid*, Article 24 Section (6)

⁶⁹ *Ibid*, Article 24 Section (4)

⁷⁰ *Ibid*, Article 24 Section (5)

of and access to data in the NDNAD and central laboratory are limited to “authorized personnel”.

Authorities from contracting Member States may not automatically access information about stored DNA profiles and fingerprints *per se*, but they will be able to determine automatically whether a DNA profile match is found in a given database through a “hit/no hit” system. Once a match has been established, the information is requested by way of bilateral communication between the countries.

6. STORAGE

The DNA Bank of the Special Investigations Unit of the Italian police authorities (RIS) was established in 2005 without a legal framework to govern its activities. As noted above, it is widely acknowledged that the RIS routinely collected and stored DNA profiles. The national databank, which is said to store a large number of DNA profiles, has frequently been the object of censure from the Data Protection *Garante*.⁷¹ According to Article 17 of the National DNA Databank Law, DNA profiles obtained over the course of criminal proceedings before the date of entry into force of the recent law are to be transferred from the National DNA Database to the newly established databank following court clearance. Regrettably, there are no provisions dealing with review practices on the transference

of DNA profiles previously collected by the RIS, nor any mention of drawing up clear and consistent guidelines to process older records, which include profiles of persons whose samples have been retained in a database without consent, as well as those of persons later acquitted and persons guilty of a crime which would be exempt from inclusion according to Article 9.

Article 13 of the National DNA Databank Law addresses the matters of profile deletion and destruction of samples. The retention period of DNA samples may range from immediate destruction to a period lasting several decades, depending on the circumstances. All DNA profiles collected for the purpose of locating missing persons or obtained from corpses or unidentified remains must be deleted immediately following the successful conclusion of an investigation, and the samples destroyed. As previously stated, both the biological samples of crime suspects and their profiles must be deleted forthwith in the event that the sampling was carried out in violation of the regulations, or if the person from whom the sample was taken has had their charges dropped or been acquitted. In all other cases, the databank retention period for DNA profiles of convicted offenders is determined according to the Data Protection *Garante* in conjunction with the implementation regulations’ established time-frames, but from the moment the decision is taken for it to be included in the data-

⁷¹ See, for instance, the 2006 statement by the *Garante* denying the legal basis for the conservation and use of genetic data stored in the database. In original language: ‘Arma dei Carabinieri–Reparto investigazioni scientifiche di Parma’, available at <http://www.garanteprivacy.it/garante/doc.jsp?ID=1370442>

bank, the period of retention may not be in excess of 20 years for samples and 40 years for DNA profiles.

7. SUPERVISION, PENALTIES

Article 15 of the National DNA Databank Law specifies which authorities and institutions are to supervise the central databank and central laboratory. Control over the NDNAD is exercised by the Data Protection *Garante*, while the CNBB is identified as the body responsible for certifying operational standards and observance of regulations. According to Article 19, the Ministry of the Interior and the Ministry of Justice must inform the Parliament on an annual basis of the activities of the NDNAD and central laboratory.

According to Article 14 of the National DNA Database Law, public officials who are charged with misuse of the data or violation of the provisions found in Chapter II may be sentenced to between 1 and 3 years of imprisonment.⁷² The penalty may be up to 6 months of imprisonment when such crimes are considered to be the result of negligence.

8. CONSTITUTIONAL REVIEW

In Italy the issue of sample collection has received considerable attention from criminal law jurists.⁷³ In 1996 the Constitutional Court departed from an earlier judgement (No. 54/1986, which recognized the forced removal of DNA samples), when it found Article 224 Section (2) of the Italian Criminal Code unconstitutional.⁷⁴ The Court found that the provision under review lacked clear-cut instructions pertaining to the circumstances under which a judge may impose a limitation on a person's right to liberty.⁷⁵ This case is known as the "Madonna of Civitavecchia" as it concerned a statue alleged to have shed tears of blood. Over the course of a criminal investigation into "pious fraud," forensic experts revealed that the liquid found on the statue was that of a male. The Public Prosecutor subsequently requested DNA samples from the owner of the statue (the suspect) and from all the male members of his family in order to test for matching genetic polymorphisms. The suspect and his family objected to the court-ordered testing and the case reached the Constitutional

⁷² According to Monti (2009) a guilty plea combined with favourable "generic circumstances" could reduce such a sentence to as little as 6 months of imprisonment or a fine.

⁷³ Lucia Scaffardi, Legal Protection and Ethical Management of Genetic Databases: Challenges of the European Process of Harmonization, European Legal Integration: The New Italian Scholarship, Jean Monnet Working Paper, 19 August 2008, 16.

⁷⁴ See Judgement No. 238/1996 in original language: 'Sentenza 238/1996 della Corte Costituzionale' available at

<http://www.cortecostituzionale.it/giurisprudenza/pronunce/schedaDec.asp?Comando=RIC&bVar=true&TrmD=&TrmDF=&TrmDD=&TrmM=&iPagE1=1&iPag=1>

⁷⁵ Lucia Scaffardi, op. cit, 32, fn. 120.

Court. Article 13 of the Constitution guarantees the inviolability of personal freedom, understanding bodily examinations taken by means of coercive measures to be a form of violation. The forced sampling of a third party was said to breach Article 3, which obliges the state to remove all obstacles that “constrain the freedom and equality of citizens,”⁷⁶ along with Article 32 Section (2), according to which “the law may under no circumstance violate the limits imposed by respect for the human person”.⁷⁷

Genetic information is not purely individual since it possesses features shared by other people; the 2002 “Fronthaler Case” illustrates some of the thornier legal implications of this particular characteristic.⁷⁸ A profile of a homicide suspect was derived from stains taken from a crime scene in a village in Northern Italy; subsequently, the male inhabitants of the village were asked by the Prosecutor to volunteer DNA samples. On the basis of their analyses, the investigators discovered a close match with the father of the accused, who was eventually convicted as a result of his father’s sample. The event raised issues of informed consent and mass screening when the father of the defendant objected to the fact that he had unknowingly given evidence convicting his son (according to Article 199

of the Criminal Code, close relatives of a defendant may withhold potentially damaging evidence during a trial).⁷⁹ This case exemplifies some of the profound implications of the storage of genetic profiles.

A number of 2003 rulings are also relevant to forensic databanks. One decision by the Council of State recognized the right of any administrative body responsible for sensitive data to determine, on a case-by-case basis, whether privacy rights may be limited under circumstances that necessitate access to such data in order to establish a claim (No. 4002/2003).⁸⁰ The Council of State also ruled that if, in criminal proceedings, records containing sensitive data are required in order to establish a defence, this may take precedence over the right to privacy (No. 9276/ 2003).⁸¹ In addition, the Constitutional Court ruled that non-pecuniary damages must be awarded to persons who have had their personal freedom compromised through the unlawful collection of personal data (No. 8828/2003).⁸²

9. PUBLIC DEBATE

According to the RIS, issues of data privacy should not stand in the way of the security of Italian citizens and a forensic databank is indispensable as

⁷⁶ Constitution of the Republic of Italy

⁷⁷ *Ibid.*

⁷⁸ Lucia Scaffardi, *op. cit.*

⁷⁹ *Ibid.*, 17

⁸⁰ 2006 Privacy International Report on Italy, 18 December 2007.

⁸¹ *Ibid.*

⁸² *Ibid.*

a crime-fighting tool.⁸³ As is the case elsewhere, a large segment of the population tends to support this opinion. However, the National DNA Databank Law also has its opponents. Some experts believe that the public is frequently misled about the advantages it would offer, which is especially important when combined with a lack of technical knowledge necessary to assess its social and ethical implications. Concerns have been raised about the scarcity of legal and scientific public debate that this piece of legislation demands, concerns which are amplified by the normative challenges such a law represents; others have expressed fears

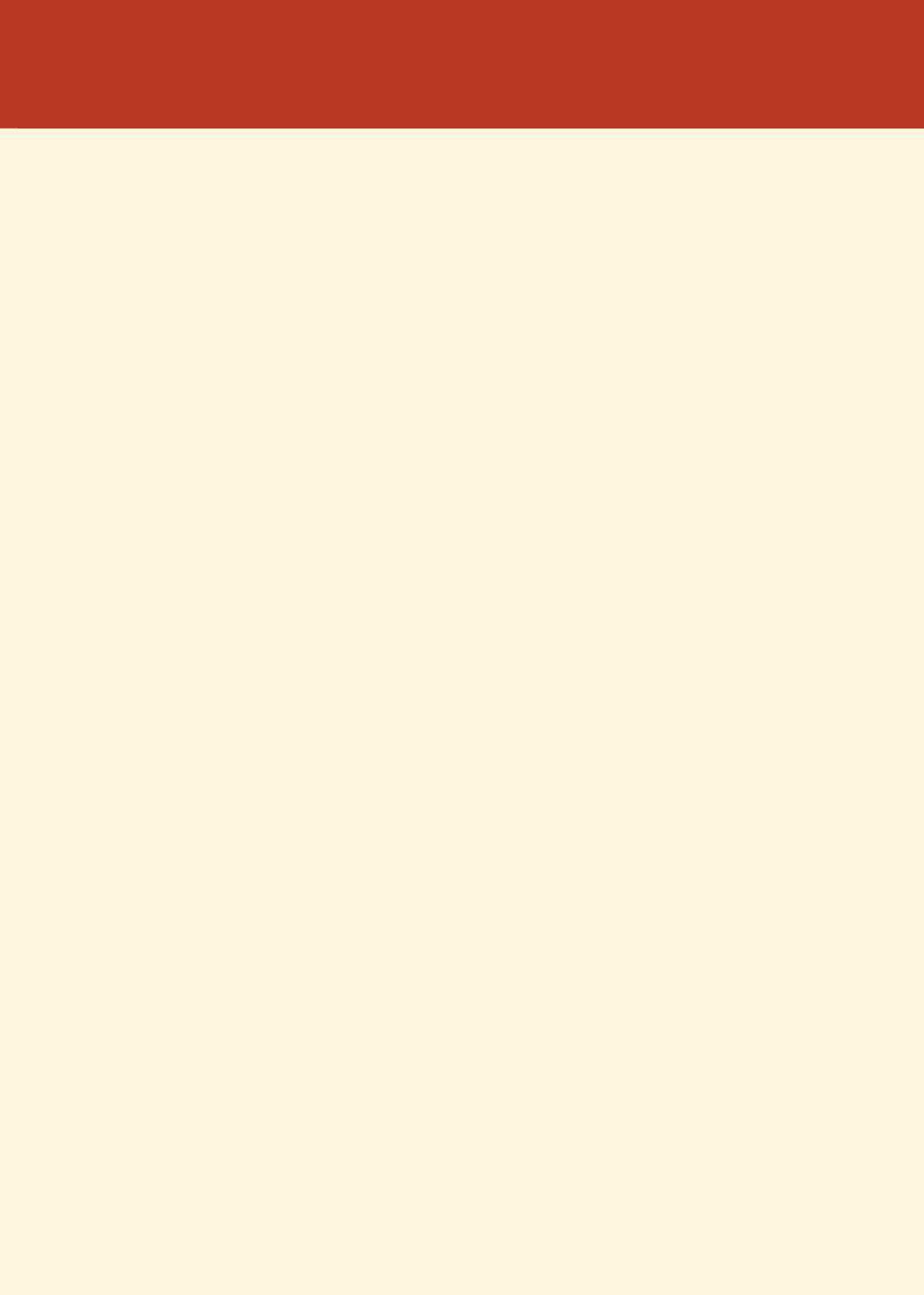
ranging from the danger of theft of genetic data to retention time frames of DNA profiles and processing protocols that are susceptible to abuse.

Regarding the recently adopted National DNA Databank Law, there are some legal analysts who contend that its lack of provisions concerning safeguards and its imprecise wording make the law defective in important ways. For instance, provisions addressing admissibility criteria of DNA samples collected from a crime scene are absent,⁸⁴ as are provisions detailing measures that may be taken by innocent persons whose samples have been illegally included in the databank.⁸⁵

⁸³ Chris Asplen, *Progress in Southern Europe, Forensic News: Legislation Corner*, February 2008

⁸⁴ Andrea Monti, *Italian NDNA Database: The Devil is in the Details*, 19 August 2009.

⁸⁵ Ciro Sbailò, *Trattato di Prüm: Una rivoluzione silenziosa (finora)* [The Prüm Treaty: A Silent Revolution (So Far)], *Forum di Quaderni Costituzionali*, 7 August 2009.





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