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CONSENT TO THE USE OF GENETIC INFORMATION: RESPECT OF PRIVACY AND PROTECTION OF OTHER FUNDAMENTAL INTERESTS

Abstract: The international and national legal sources provide a protection on genetic information of individuals, on the ground of the legislation concerning the personal data, especially in Europe through the Directive 95/46/EC. The Directive, as well as the international legal instruments approved by the Council of Europe and by UNESCO, uses an individualistic approach to ensure the control of the personal genetic information, through the consent or the anonymisation.
However this scheme does not grant the solution of all problems concerning the genetic information, because of the special status of this kind of data. Furthermore, the individualistic approach prevents the balance between the will of the individual and the other fundamental interests protected by the legal system, such as the rights of other individuals (in particular the persons owning the same genetic information), the solidarity and the freedom of research.
Therefore, a protection of genetic information should be achieved, alongside with future and eventual legislative interventions, also trough a better equilibrium between right to consent and the other interests, as well as by means some alternative legal techniques.

Summary: 1. The consent within the legal sources. — 2. Legal protection of genetic information. — 3. The protection of genetic information through the discipline of privacy. — 4. Consent for processing genetic information. — 5. Exemption and limitations concerning consent. — 6. The particular status of genetic information. — 7. Genetic information and the rights of other subjects. — 8. The right to know own proper genetic origins. — 9. Other cases of insufficiency of the informed consent. — 10. Conclusive observations.

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1. — *The consent within the legal sources.*

The legal obligation to require the consent of an individual involved in an activity that could affect his or her interests is relatively recent.

It is only after World War II that legal sources have begun to consider this issue, usually in cases of medical treatment.

The Italian *Costituzione* of 1948, which establishes the obligation of consent to medical treatment (see Article 32 of the Italian Constitution) [1] constitutes an example.

Other Constitutions, directly or indirectly, provide for consent, as in the case of Article 7 of the Constitution of Finland and the paragraph 2, pt. 2 of the German Constitution, where they recognize the right to personal liberty [2] or in the Swedish Constitution which prohibits physical violations of the person (see Article 6).

More recent, on the other hand, is the need of consent for a person's involvement in scientific activities.

That issue, as all linked to the ethical aspects of research, received attention from the scientific community immediately after World War II. In fact this period had seen a highly offensive use of science against human dignity, as in the laboratories of Nazi scientists.

Symbolically, the first document in the field of research was adopted by the medical scientific community in Nuremberg, the place of the proceedings against Nazi criminals, including several scientists and physicians.

The so-called «Nuremberg Code» concerning the «Permissible Medical Experiments» set as absolutely essential for the medical experimentation the voluntary consent of the person concerned.

However the issue of informed consent has been absorbed in the medical practice and, therefore, over the following years the legal sources gave no

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[1] See the judgement of *Corte costituzionale* of 23 December 2008, n. 438, in *Foro it.*, 2009, I, c. 1328.

[2] H. Nys et al., *Genetic Testing Patients' rights, insurance and employment. A survey of regulations in the European Union*, (Office for Official Publications of the European Communities) Luxembourg, 2002, pp. 38 and 54.

relevance to the will in scientific activity on assumptions other than medical treatments.

In fact only the most recent, or recently modified, Constitutional charters take into consideration the consent in the specific field of scientific research.

This is an evolution that depends on a new cultural and also legal sensitivity about the importance and risks of techno-science (i.e. science impacting the world through technology).

Thus, within the Swiss Constitution, Article 118b, entered into force on March 7, 2010, disciplines informed consent in the research on humans. Also in the Constitutions of Bulgaria in 1991 (Article 29), Slovenia (Article 18), Hungary (Article III, § 2) and Croatia (Article 23) prohibit medical or scientific experimentation without the consent of the person concerned.

In other cases, at the level of national law, consent is disciplined by ordinary legislation or other rules.

Among the national legislations, is the French law which devotes several provisions to consent in the scientific and health sectors. In particular several laws have been approved in the field of bioethics, which have modified the Civil Code, introducing in Book I «*Des personnes*», Title I (*De civils droits*), the Chapter II «*Du respect du corps humain*» (Articles of 16 to 16-9), the Chapter III «*De l'examination des caractéristiques Génétiques d'une personne et de l'identification d'une personne par ses empreintes Génétiques*» (sections 16-10 to 16-13), and the Chapter IV «*De l'utilization des techniques d'imagerie cérébrale*» (Article 16-14).

Regarding the field of biomedics, the French Code requires the consent of the persons for all medical treatments (Article 16-3, paragraph 2 Civil Code), which collect their genetic information (Articles 16-10, 16-11, 16-12 Civil Code), and this requirement also applies to brain imaging techniques (Civil Code Article 16-14) [3].

At the continental level the matter makes parts of the competences of the European Union law and of the system of the European Convention on Human Rights (herein referred to as «ECHR»). The European Union, in the

[3] Also in Netherlands the fundamental discipline of the consent is provided by the Civil Code, see Article 7:450.

last two decades, has developed the theme of the knowledge society, that's to say a society in which research and technology play a key role [4]. EU law addresses both the opportunities and risks of a Society of research-based knowledge and technology. The issue of informed consent is considered as a pivotal dimension of European society [5].

In particular, the bio-legal topic is regulated at the constitutional level in the Charter of Fundamental Rights, which acts as a sort of a «bioethics constitution», because takes into consideration the need to protect the fundamental interests in the framework of economic, therapeutic and scientific activities.

In particular, Article 3 of the Charter sets out that human dignity has to be respected in medicine and biology, especially granting that in such activities the free and informed consent of the person concerned is required, in the manner defined by law.

The informed consent is not directly disciplined by the ECHR, but the European Court of Human Rights (hereinafter «Court ECtHR») derives the regulation on consent from the Article 8 ECHR (Right to respect for private life and family).

Furthermore, the Council of Europe has elaborated a specific regional convention concerning biomedicine, the «Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine», made in Oviedo on 4 April 1997(hereinafter «Convention on Biomedicine» or «Convention of Oviedo»). That Convention was supplemented by additional protocols on specific topics: the additional Protocol concerning organ transplantation and tissues of human origin (Strasbourg, 24 January 2002); the additional Protocol concerning biomedical research

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[4] See the papers B.E. Sosa Morato, *Un humanista ante el umbral de la Sociedad del Conocimiento. Un esfuerzo por comprenderla*; V. Colcelli, *El «conocimiento» en la tradición del derecho privado europeo*; R. Cippitani, *El Derecho privado de la Unión Europea desde la perspectiva de la Sociedad del Conocimiento*; M.I. Álvarez Ledesma, *Sucintas reflexiones en torno al derecho de la sociedad del conocimiento*, in R. Cippitani (edit. by), *El Derecho de la Sociedad del Conocimiento*, Roma-Perugia, 2012.

[5] See A. Sassi, *Consentimiento informado*, in M.I. Álvarez Ledesma and R. Cippitani (coord.), *Diccionario analítico de Derechos humanos e integración jurídica*, Roma-Perugia-México, 2013.

(Strasbourg, 25 January 2005); the additional Protocol concerning genetic testing for health purposes (Strasbourg, 27 November 2008).

Within the above mentioned context, it is important to underline the case-law of the ECtHR which in some judgments refers to the Convention of Oviedo to enforce the norms arising from the ECHR [6], even where the State concerned has not signed or ratified the Convention yet [7].

Furthermore, the Institutions of the Council of Europe, such as the Committee of Ministers and the Parliamentary Assembly, adopt instruments of softlaw as recommendations and resolutions relating to the Oviedo Convention and its Additional Protocols.

The Convention of Oviedo, in particular, states the «general rule», according to which «An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it» (Article 5). The need for consent is also provided on all matters regulated by the Convention on Biomedicine, as scientific research (Article 15) and the donation of human organs or tissues (Article 19).

Moreover, with regard to scientific research in the bioethics matter, it is important to mention the Additional Protocol to the Oviedo Convention of 25 January 2005, which focuses on informed consent, in particular, through Article 13 and following dispositions.

Under the European law, informed consent is not provided only in respect to the biomedical fields.

The entire discipline for the protection of personal data, for example, requires as essential for the lawful processing of such data the consent of

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[6] See, H. Nys, *Towards an international treaty on human rights and biomedicine? Some reflections inspired by UNESCO's Universal Declaration on Bioethics and Human Rights*, in *European Journal of Health Law*, 2006, p. 7; E. Glad, *The global significance of the Convention on Human Rights and Biomedicine*, in J.K.M. Gevers et al., *Health Law, Human Rights and the Biomedicine Convention. Essays in honour of Henriette Roscam Abbing*, (Martinus Nijhoff) Leiden, 2005, p. 44.

[7] See for example ECtHR, 10 April 2001, Cyprus v. Turkey; Id., 9 March 2004, Glass v. UK; Id. 8 July 2004, VO v. France; Id., 10 April 2007, Evans v. United Kingdom; Id., 11 November 2007, Özalp v. Turkey; Id., 16 December 2008, Ada Rossi a.o. v. Italy. See H. Nys, *The European Convention on Human Rights and Biomedicine: a European Patient Rights Instrument,* in *www.coe.int*.

the persons concerned. This as provided by Article 8, § 2, Charter of Fundamental Rights and by the EU law, mainly by Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to treatment of personal data and the free movement of such data.

2. — *Legal protection of genetic information.*

An important set of information which can be collected during therapeutic and scientific research is the genetic data concerning human subjects [8].

The genetic data for each individual is contained in his or her billions of cells, making up the human body and in particular the molecules and structures such as DNA, RNA and chromosomes. They determine several features of the natural persons, such as eye colour, blood type, height, as well as several diseases or other characteristics.

That information may be inherited or acquired during cell division and influence subsequent generations («germinal genetic data») or cells and tissues («somatic genetic data») [9].

From a legal point of view, defining the genetic information is not only a scientific question, but it is a task needing the political and legal choice of the interests to be protected [10].

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[8] More correctly, «Data represents material for analysis. Information is what fallows from that analysis. The significance of the data that we perceive is it is interpreted », see M. Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, (Cambridge University Press) Cambridge, 2012, p. 56. Anyway the Directive 96/45/EC (see Article 2, letter a) uses data as information: «"personal data" shall mean any information relating to an identified or identifiable natural person ("data subject")».

[9] See the definitions provided by in E. McNally, A. Cambon-Thomsen et al., *Ethical, legal and social aspects of genetic testing: research, development and clinical applications*, Bruxelles, 2004, report by the independent expert group to the Commission, *http://ec.europa.eu/research/conferences/2004/genetic/pdf/report_en.pdf.*

[10] See J. Gerards, *General Issues concerning Genetic Information*, in J.H. Gerards, A.W. Heringa and H.L. Janseen, *Genetic Discrimination and Genetic Privacy in a Comparative Perspective*, (Itersentia) Oxford, 2005, pp. 5 ff. and 11.

In the last decades many national, supranational, international legal sources are protecting the genetic information, as an important expression of the personality of the individual and, therefore, from a legal point of view, as object of the fundamental rights.

A first legal definition of «genetic data» was provided by the Article 1, of the Recommendation of the Committee of Ministers of Council of Europe, No. R (97) 5 on the Protection of Medical Data (of 13 February 1997).

Among the «medical data», that's to say the «personal data concerning the health of an individual»,there is also the genetic data which is the «data, of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals».

This definition is very huge and includes any kind of information concerning the «hereditary characteristic» of the persons, independently from the source of the information [(11)].

More specific is the definition contained within the « International Declaration on Human Genetic Data» of 2003 of UNESCO (hereinafter «Declaration of UNESCO»), which distinguishes (at the Article 2) human genetic data as «Information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis», «human proteomic data» («Information pertaining to an individual's proteins including their expression, modification and interaction»), and in general the «biological samples», concerning «Any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are present and which contains the characteristic genetic make-up of an individual».

The Council of Europe in 1997 adopted the Convention on Human Rights and Biomedicine signed in Oviedo April 4, 1997, which dedicates Chapter IV to the human genome, establishing, above all, the prohibition of discriminations based on genetic heritage (Article 11) and of the interventions on genome aiming at introducing modifications in the genome of any descendants (Article 14).

[(11)] See C.S. Diver and J.M. Cohen, *Genophobia: What Is Wrong with Genetic Discrimation?*, in *U. Pa. L. Rev.*, 2001, 149, p. 1451.

Several Additional Protocols to the Convention of Oviedo make references to genetic information such as: the Protocol of 1998 on the Prohibition of Human Cloning; that of 2001, on Transplantation of Organs and Tissues of Human origin; the Protocol of 2005 concerning the Biomedical Research, and finally the most recent, which is the focus and topic studied in this paper, the Additional Protocol to the Oviedo Convention concerning Genetic Testing for health adopted in Strasbourg on 27 November 2008.

The above mentioned EU Charter reaffirms the prohibition of discrimination based, among others, on genetic characteristics (Article 21) and imposes the ban of the eugenic practices, in particular those aiming at the selection of persons, as well as the reproductive cloning of human beings.

At national level, usually the Constitutions do not provide coverage to genetic data.

As matter of fact, genetic data falls within the more general protection of the fundamental rights [(12)]. Specifically, the most significant constitutional references on the subject can be observed in the legal protection of values of human dignity, physical integrity and personal freedom [(13)].

In this respect, two interesting examples, within Europe, are represented by the constitutions of Switzerland and Portugal which both contain specific references to the protection of the genetic data.

The Constitution of the Swiss Confederation, already before the update of 1999, stated in article 24 novies specific rules on the use of human reproductive and genetic material. Following the constitutional amendment of 1999, Article 119 establishes the general principle that the human being must be protected from abuse of reproductive medicine and genetic engineering.

In application of this principle, in particular it is provided that the genetic makeup of a person can be analysed, recorded, or detected only with the consent or on the basis of legal prescription and each person has access to his/her genetic data.

[(12)] A. Ruggeri, *«Nuovi» Diritti fondamentali e tecniche di positivizzazione*, in *Pol. dir.*, 2, 1993, p. 183.

[(13)] A. Falcone, *La tutela del patrimonio genetico umano, fra Costituzione e diritti, verso la formazione di un* Corpus Iuris *sul genoma umano*, (Rubbettino) Catanzaro, 2012, p. 17.

With respect to the Portuguese Constitution of 2 April 1976, as amended by on 1997, the Article 26.3 second paragraph sets out the right to genetic identity.

At the level of the sub constitutional legislation, the matter of genetics is regulated, for example, by the French and Austrian laws, which were the pioneering laws in Europe.

In particular, the French Law regulates the use of genetic data, through the above mentioned Chapter III of the Title I of the Civil Code devoted to «*De l'examen des caractéristiques génétiques d'une personne et de l'identification d'une personne par ses empreintes génétiques*» (examining the genetic characteristics of a person and the identification of a person using genetic prints), which was introduced by the laws concerning bioethics, the last one being the Law no. 2011-267 of the 14 March 2011 [(14)].

Other countries have adopted a specific legislative framework [(15)].

Otherwise, some national systems, such as Italy, prefer soft law instruments as guidelines and recommendations of the Ethics Committees [(16)].

3. — *The protection of genetic information through the discipline of privacy.*

Usually, the main legal means for the protection of genetic data is considered to be the discipline of privacy.

[(14)] About the French *loi de bioétique*, see R. Cippitani, *Principi e metodo nella revisione della normativa francese relativa alla bioetica*, in *Dir. fam.*, 2012, pp. 1836-1865; Id., *La nueva ley Francesa en tema de bioética en el contexto europeo*, in *Criminogenesis*, 2011, pp. 199-214.

[(15)] According to the Swiss Law, see the Federal Law on Human Genetic Testing, approved on 2004 and entered in force on 1st April 2007. In Germany in the last years a Law concerning the Genetic Diagnostic has approved (*Gendiagnostikgesetz* - GenDG), entered into force on 1st February 2010. See A. Diurni, *Esperienze di regolamentazione della diagnostica genetica*, in *Danno e resp.*, 2010, p. 660.

[(16)] According to Italy see the document of the Comitato Nazionale per La Bioetica, *Orientamenti Bioetici per i Test Genetici* del 19 novembre 1999 and *Linee-guida per le attività di genetica medica* enclosed to the *Agreement between Italian Ministry of Health and Regions* of 15 July 2004.

At the European level, the first regulatory intervention was put in place on 1981 by the Council of Europe with the Strasbourg Convention on the Protection of Individuals with regard to Automatic Processing of Personal Data.

Such a Convention includes the basic principles that govern even today the treatment of personal information, and therefore also of genetic data.

In particular, article 5 of the Convention provides that «Personal data undergoing automatic processing shall be: a. obtained and processed fairly and lawfully; b. stored for specified and legitimate purposes and not used in a way incompatible with those purposes; c. adequate, relevant and not excessive in relation to the purposes for which they are stored; d. accurate and, where necessary, kept up to date; e. preserved in a form which permits identification of the data subjects for no longer than is required for the purpose for which those data are stored».

According to the European Union law such a protection is granted by the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. This directive has allowed the establishment of a European notion of privacy regarding personal information [(17)], in a field where the national definitions may be many [(18)].

The Directive on privacy is related to all personal data considered as «any information relating to an identified or identifiable nature of a person», where «an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity» (Article 2, § 1).

The Directive does not make reference to the genetic information, but

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[(17)] M. Simoncini, *Legislazione antiterrorismo e tutela della privacy,* in *Riv. trim. dir. pubbl.*, 2007, p. 963.

[(18)] P. Roberts, *Privacy, Autonomy and Criminal Justice Rights: Philosophical Preliminaries*, in P. Alldridge and C. Brants, *Personal Autonomy, the Private Sphere and Criminal Law: A Comparative Study*, (Bloomsbury Publishing) London, 2001, p. 49 ff.

it refers to data which could represent genetic information. In particular the Article 8, § 1, of the Directive takes into consideration «personal data revealing racial or ethnic origin, and (…) data concerning health». Such data are considered «sensitive» because they reveal particular and intimate aspects of the life of a person. As a consequence of this, the processing of those data can be prohibited or subject to particular discipline, in order to grant the reinforced protection provided by the Directive.

The qualification for genetic information as personal data is confirmed by the literature [19] and by the documents approved by the authorities dealing with privacy.

Among these documents appears a very interesting one, the «Working Document on Genetic Data», adopted on 17 March 2004 by the «Article 29 Data Protection Working Party» [20].

According to the Working document there is no doubt that genetic information content must be considered as personal data (§ III, p. 5). In fact genetic information could lead in many cases to the identification of a person, associating with a given person through the examination of DNA samples.

4. — *Consent for processing genetic information.*

In consequence of the above mentioned qualification, it would be possible to apply to genetic information the discipline concerning consent in collecting, processing and storage of personal data, especially those which are to be considered as sensitive.

According to the definition contained within the Article 2 of the Declaration of UNESCO mentioned above, the consent is «Any freely given specific, informed and expressed agreement of an individual to his or her genetic data being collected, processed, used and stored».

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[19] M. D'AMICO, *Il trattamento pubblico dei dati sensibili: la disciplina italiana a confronto con il modello europeo*, in *Il diritto comunitario e degli scambi internazionali*, 4, 2002, p. 817 ff.

[20] Available at the following address: *http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2004/wp91_en.pdf*.

The subsequent Article 6 (letter d) provides that «It is ethically imperative that clear, balanced, adequate and appropriate information shall be provided to the person whose prior, free, informed and expressed consent is sought».

Therefore, the requirements for a valid consent on the use of the genetic information are the following: a) they are requested for specific and lawful purposes; b) the information provided has to be adequate from both subjective and objective points of view; c) the consent has to be free; d) it must also be explicit and formal.

a) The purposes

According to the Article 6 of the Directive 95/46/EC personal data must be collected only in order to achieve specific proposes and must be processed in a way compatible with those purposes (so called «Finality principle»). In addition, personal data must be adequate, relevant and not excessive in relation to the purposes for which they are collected and further processed (Proportionality principle).

As above mentioned, being sensitive data, not all the purposes may be acceptable in order to process the genetic information [21].

The respect of the finality and proportionality principles implies a clear determination of the purpose for which genetic data are collected and further processed.

To avoid incompatible re-use it is essential that the purposes for processing genetic data are clearly defined.

Furthermore, an evaluation of the respect for proportionality and the respect for legitimacy is necessary, taking into account the risks for the protection of fundamental rights and freedoms of individuals and notably whether or not the intended purpose could be achieved in a less intrusive way.

According to Article 6 of the of the Declaration UNESCO the scope available for the use of genetic data are as follows: (i) diagnosis and health care, including screening and predictive testing; (ii) medical and other scien-

[21] The processing of genetic information for purposes not recognised by the law may be punished by the criminal law, as it happens in French for those requesting genetic testing on himself or others, outside of cases authorized by law (see Article 226-28-1 penal code).

tific research, including epidemiological, especially population-based genetic studies, as well as anthropological or archaeological studies, collectively referred to hereinafter as «medical and scientific research»; (iii) forensic medicine and civil, criminal and other legal proceedings; (iv) any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and the international law of human rights.

Consent is also needed in cases of the cross-matching of the human genetic data «stored for diagnostic and health care purposes and for medical and other scientific research purposes, unless otherwise provided for by domestic law for compelling reasons and consistent with the international law of human rights» (see Article 22).

The admissibility of aims of research, health treatments and judicial procedures are also established within the supranational legislation (Article 8, § 3, of the Directive 95/46/EC) and by the national laws (see Article 16-10 and 16-11 French «*Code Civil*»; see also Italian «*Garante per la protezione dei dati personali*», General Authorisation No. 8/2012 of 13 December 2012, § 3).

b) Adequacy of the information provided

Generally speaking, consent must be informed, that is to say based on information that allows the evaluation and understanding of the facts and consequences of an action [22].

To this end information should be provided in an adequate manner (Article 13, § 1, Additional Protocol Biomedical Research), both from subjective and objective viewpoints.

From the subjective point of view, the information is appropriate if provided by qualified professionals and researchers.

The Helsinki Declaration (§ 14) states that information is communicated by« physician or another appropriately qualified individual» [23]. On the other hand, in cases of research activities, Article 3, § 2.b Directive 2001/20/

[22] *WP131 - Working Document on the processing of personal data relating to health in electronic health records*.

[23] World Medical Association, *Declaration of Helsinki*, *Ethical Principles for Medical Research Involving Human Subjects*, in *www.wma.net*.

EC [24] provides that consent is collected by research staff members.

Furthermore, information is adequate from the subjective point of view, if expressed in an understandable way (Article 13, § 1, Additional Protocol to the Biomedical Research), taking into account the personal situation and context (especially the social, cultural and economic ones) [25]. This also applies if the person concerned is a professional expert (see the judgment of ECtHR, Csoma v. Romania).

According to the contents of the information to be provided, Article 10 of the Directive no. 95/46/EC requires that: (a) the identity of the controller and of his representative; (b) the purposes of the processing for which the data are intended; (c) any further information such as the existence of the right of access to and the right to rectify the data concerning him are communicated.

With specific respect to genetic information, Article 6 (letter d) of the Declaration UNESCO establishes that the following information must be provided:

– the context in which the activity is performed: the objectives and nature (see items 2.j Directive 2001/20/EC, Article 5 Oviedo Convention), including funding sources if scientific research (see Article 13, § 2: VIII), as well as the conditions under which the intervention will take place (Article 3, paragraph 2, letter b), Directive 2001/20/EC);
– the risks and consequences of the processing (see also Article 2.j Directive 2001/20/EC; Article 5 Convention of Oviedo) [26];
– other issues such as the measures in order to implement the respect of

[24] Directive 2001/20/EC of The European Parliament and of The Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

[25] See mainly the document of the European Group of Ethics and New Technologies, *Ethical aspects of Clinical Research in Developing Countries*, Opinion no. 17, 2003, § 1.29.

[26] Article 13 of Additional Protocol refers to the specific biomedical research is necessary to identify «the arrangements for responding to adverse events or the concerns of research participants», as well as «the arrangements for fair compensation in the case of damage».

privacy and the confidentiality of personal data (see the Additional Protocol to the Oviedo Convention on biomedical research).

c) Form of the consent

As general rule, the consent must not be ambiguous (see Article 7 of the Directive on the protection of personal data) and it may consists in «any freely given specific and informed indication of his wishes» (Article 2.h).

However, with respect to sensitive data the Directive requires that the consent is not only clear, but also explicit [27].

This, because it is recommended that the form of expression of consent should depend on the importance of the interests to be protected [28].

Therefore, only some legal texts clearly envisage that the consent has to be expressed in writing.

The Convention of Oviedo refers to the need for written consent in the case of participation of the person in scientific research (see Article 16, v) or in the case of obtaining organs and tissues from living donors and transplantation (see. Article 19, paragraph 2, which provides that the consent is given in writing to an official).

In this context, the written consent is provided in particular to process genetic information (see the General authorization no. 8/2012 § 6; see also Article 16-10 of the *Code Civil*, second intend and also in French Law the Article L. 1131- 1 Code Santé Publique, hereinafter «CSP»).

d) The freedom of consent

As above mentioned, usually the legal documents affirm that consent must be freely provided.

The person concerned is entitled to choose whether or not to accept the activity which receives the information [29]. Furthermore, this right includes

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[27] See *WP131 – Working Document on the processing of personal data relating to health in electronic health records (EHR).*

[28] See § III.A.3 of *Opinión 15/2011 on the definition of consent*, ref.

[29] See *Opinion 15/2011 on the definition of consent*, ref.

also the right to know and the right to not know the results of the genetic testing, as specifically provided by the Article 10, § 2, of the Convention of Oviedo (within the French Law, see Article L. 1111-2 CSP).

To be effectively free, the consent can only be considered valid only if no intimidation, coercion or threat of negative consequences were put in place [30].

Coercion and intimidation may be exercised in many ways, through social, economic and financial factors [31].

Manipulations should also be avoided, i.e. «that it seeks to alter people's behaviour by influencing them in ways that somehow bypass rational agency; rather than influencing them through reason and argument, we (typically through some 'sleight of hand') seek to change their mind by appealing (consciously or otherwise) to non-autonomous and/or non-rational parts of the person» [32].

It is specifically prohibited any threats of sanctions or refusal of medical treatment or other benefits.

As well as financial incentives or taking advantage of economic or personal situation (see in particular Articles 8, letter a and 9 of Declaration UNESCO; Articles 4, letter d, 5, letter d) Directive 2001/20/EC) [33].

A particular case is the employee's consent. This is a situation which can be difficult for consent to be effectively free. So special care should be given in the assumption of an acquisition of consent in the context of an employment relationship. In particular the consent should not be linked to chances of winning or losing jobs or careers [34].

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[30] *Ibidem*.

[31] Véase *WP131 – Working Document on the processing of personal data relating to health in electronic health records*.

[32] European Commission, *European Textbook on Ethics in Research*, (Publications Office of the European Union) Luxembourg, 2010, p. 38.

[33] See Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries*, London, 2002, in *www.nuffieldbioethics.org*.

[34] See *WP48 on the processing of personal data in the employment context* y *WP114 - Working document of the Article 29 Working Party on a common interpretation of Article 26(1) of Directive 95/46/EC* of 24 October 1995.

Furthermore, the consent is free if it can be withdrawal in any moment (see in particular Article 9 of Declaration of UNESCO).

Other aspect of the freedom of consent is its «granularity» [35] in the sense that it is provided only to activities and very limited and specific contexts [36].

It is what emerges from the recommendation of the Committee of Ministers of the Council of Europe Rec (2006) 4 of 15 March 2006, which refers to research on biological material of human origin. Article 12, § 1, requires that biological material collected for purposes other than scientific research (ex for therapeutic purposes) can't be used without consent or authorization. This is when the subsequent activity is «substantially different» with respect to that authorized [37].

The granularity of consent has as a consequence a need for adaptation of the consent to changing situations that refer to the same person (ex a child becomes a teenager) [38].

Also if consent can't be attributed for a long period of time. EU documents advise those responsible for the processing of personal data to re-ask the person to confirm or refuse consent [39].

5. — *Exemption and limitations concerning consent.*

The legislation concerning the protection of the personal data, which is also applicable to genetic information, provides some cases where the consent is not needed or has not be provided directly by the data subject.

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[35] See § III.A.1 de la Opinión 15/2011 *on the definition of consent*, ref.

[36] *Ibidem*.

[37] Council of Europe, *Explanatory report to the convention on human rights and biomedicine*, 1997, § 214.

[38] *Working document 1/2008 on the protection of children's personal data, WP 147* 18 february 2008.

[39] See also the Article 29 Working Party Opinion no. 171 *on online behavioural advertising*, of 22 June 2010.

a) The consent of vulnerable persons

The legal sources, including those on the use of genetic information, specifically refer to the cases where the persons are not capable to provide consent [(40)].

In this type of case the main rules applicable are the following:

– Legal representative. Article 8 (letter b) of the Declaration of UNESCO establishes that where «a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law».
In particular, the Italian Authority on Privacy (see § 6 of the General authorization above mentioned) states that consent may be provided, along with the legal representative, also by «a next of kin, a family member, a person cohabiting with the data subject, or – failing these – the manager of the facility where the data subject is domiciled».

– The best interest. According to the above mentioned Article 8 (letter b) of the Declaration of 2003 «The legal representative should have regard to the best interest of the person concerned».
The best interest of the vulnerable is not left to the mere opinion of the legal representative. Therefore the interest of the vulnerable person refers to a needed health treatment (or in case of the risk of a genetic disease) or a scientific research, but only in some specific cases (The research is aimed at improving the health of other individuals that either are in the same age group or are affected by the same disease; A research for similar purposes may not be carried out by processing data related to individuals that can provide their consent; The research does not entail significant risks to the data subject's dignity, rights, and fundamental freedoms, see § 6 of the General Authorisation of the *Italian Garante*).

[(40)] For an overview on the legal sources on this matters, see, among others, K. Hens, H. Nys, J.J. Cassiman and K. Dierickx, *Biological sample collections from minors for genetic research: a systematic review of guidelines and position papers*, in *European Journal of Human Genetics* (2009), pp. 1-12.

– The participation of the vulnerable persons. In the case of an adult incapable of giving full consent, he/she should as far as possible take part in the authorization procedure. On the other hand the opinion of a minor should be taken into consideration in proportion to age and degree of maturity (see Article 8, letter c, Declaration of UNESCO; see also § 6 of the General authorization of the *Italian Garante*).
This principle is consistent with the provision of Convention of Oviedo (se Article 6, § 3) and of Additional Protocol of genetic testing (Article 11, § 1). In particular the latter explicates the right to the vulnerable person to receive the adequate information.
It also needs to be underlined that Article 9 of the Convention of Oviedo provides that the previously (before the situation of the incapacity) expressed will of the incapable person has to be taken into consideration.
In particular with reference to the issue of participation, it is important to specify that the incapacity considered by the legal sources is not that provided by the civil law concerning the patrimonial relationships. The Italian Civil Code, as well as other national legislations, provides that persons are not able to act in contractual relationships before a specific age (in general 18).
The modern legislation, when personal interests are affected, oversees the civil law rule of the absolute incapacity of the person to act.
In Article 12 of the UN Convention on the Rights of Persons with Disabilities establishes provisions that state that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life (see § 2). This is applied especially in the case of personal issues as those relating to informed consent.
The European system of protection of human rights provides that such persons must be guaranteed the greatest possible autonomy (Grand Chamber in Stanev v. Bulgaria of 17 January 2012) and that restrictions on their autonomy must be strictly necessary (Shtukaturov v. Russia, of 27 March 2008, parr. 90, 93-95) and respect the principle of proportionality (Salontaji-Drobnjak v. Serbia of 13 October 2009).

b) Limitations or absence of the right to consent

In some cases the treatment of the genetic information, as other sensitive data, may be allowed without the consent of the subject data.

In particular, in accordance with Article 8 of that Convention, consent is not requested in case of an emergency when «any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned».

The same approach is followed also by the European Principles of Medical Ethics (adopted by the International Conference of Medical Associations and Organizations on 6 January 1987, seethe Article 4).

The case of emergency is not explicitly mentioned in the field of medical experimentation (Article 20 of the European Principles of Medical Ethics). A reference to urgency cannot be found in Directive 2001/20/EC or instruments of the Council of Europe dealing with scientific research.

However, the proposal for a regulation of the European Union that will replace Directive 2001/20/EC [41] (see Article 32) provides for the possibility, in an emergency situation, that consent would be required after the start of the experiment, confirming that in normal situations consent must be previously acquired.

The situation of emergency is defined as the case in which, for example, a patient has had a life-threatening condition due to multiple traumas, strokes or seizures heart, requiring immediate medical intervention (the recital 23 of the proposed Regulation).

Furthermore, Article 32, § 1 of the proposed regulation provides some additional conditions to be met: a) it is impossible to obtain prior consent, or is impossible to provide prior information; b) is not available a legal representative; c) the person has not previously declared his objection and this is known to the researcher; d) research has a direct connection with the situation that causes the impossibility of obtaining informed consent.

However the person (or their legal representative) has the right to be

[41] See *Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.*

informed and give consent as soon as possible, when situations of impossibility end (see Article 32, § 2 proposed Regulation).

Further limitations to the right to consent may be admissible to safeguard other interests recognised by the constitutional norms. This is the case of the freedom of expression. According to Article 9 of Directive no. 95/46/EC which establishes that Member States are entitled to approve exemptions or derogations from obligations arising from the discipline of the protection of personal data for the processing of personal data carried out solely for journalistic purposes or the purpose of artistic or literary expression.

More in general, the national legislation may impose limitations on some rights to protect personal data, for reasons such as national security; defence; public security; the prevention, investigation, detection and prosecution of criminal offences, or of breaches of ethics for regulated professions; an important economic or financial interest; and moreover the protection of the data subject or of the rights and freedoms of others (see Article 13).

c) Anonymisation

According to the definition of «personal data», to be protected by the law, the information taken into consideration is linked to an identified or identifiable person.

Thus, if a data might not be associated to a specific person, it is outside the protection of the legislation and it can be processed without the consent of the data subject.

The data are considered anonymous taking into account « all the means likely reasonably to be used either by the controller or by any other person to identify the said person » (see 26th recital of the Directive 95/46/EC).

The data may be collected in a non anonymous way and subsequently then can be anonymised. With this respect the Directive argues that the codes of conduct (see the definition of Article 27) «may be a useful instrument for providing guidance as to the ways in which data may be rendered anonymous and retained in a form in which the identification

of the data subject is no longer possible» (see 26th recital of the Directive 95/46/EC) [42].

The data « are anonymised if all identifying elements have been eliminated from a set of personal data. No element may be left in the information which could, by exercising reasonable effort, serve to re-identify the person(s) concerned» [43].

The European documents admit pseudonymisation, as one form of anonymisation. This is where the identifiers are replaced by one pseudonym, and the data cannot be identifiable without the possession of the decryption key [44].

With respect to the specific case of genetic information, the Declaration of UNESCO states that genetic data when «collected for the purposes of scientific research should not normally be linked to an identifiable person. Even when such data or biological samples are unlinked to an identifiable person, the necessary precautions should be taken to ensure the security of the data or biological samples» (Article 14c).

The link to an identifiable person may be acceptable «only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law » (Article 14d) and for a period which does not exceed the time needed for achieving the purposes for which they were collected or subsequently processed (Article 14.e).

6. — *The particular status of genetic information.*

Although genetic information is protected by the legislation concerning

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[42] See for example, United Kingdom Information Commissioner's Office (2012), *Anonymisation: managing data protection risk. Code of practice*, available at *www.ico.org.uk/ for_organisations/data_protection/topic_guides/anonymisation.*

[43] European Union Agency for the Fundamental Rights, *Handbook on European data protection law*, Luxembourg, 2014, p. 44.

[44] See Council of Europe, *Explanatory Report to Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data*, Article 42.

personal data, the Declaration of UNESCO, as well as other documents (see the Working document on privacy out (§ II), recognises them with a «particular status».

As matter of fact, at least the following main features may be observed in relation to genetic information:

a) Immutability. Genetic information identifies in a permanent way a specific individual, also even if the concerned person does not know his or her data.

b) Predictability. They are predictive of genetic predispositions of each individual; anyway some information contained in the genetic data may have a «significance» which is not necessarily known or knowable at the time of the collection of the biological samples.

This implies that they are not only able to define what the individual is, but also what they can become. Genetic data have unique characteristics, provide or will provide in the future, scientific, medical and personal knowledge valid for the entire life of the individual to which they refer.

c) Genetic family membership. «While genetic information is unique and distinguishes an individual from other individuals, it may also at the same time reveal information about and have implications for that individual's blood relatives (biological family) including those in succeeding and preceding generations, furthermore, genetic data can characterise a group of persons (e.g. ethnic communities); genetic data can reveal parentage and family links» (see the Working document on privacy, § III). DNA can show a variety of information about a person, including his family history, in the meaning of the persons of the same genetic line [45].

Some scholars do not agree with the particularity of the genetic information, which would be overestimated, increasing the resistance of the public

[45] On the co-shared nature of the genetic information see M.J. Taylor, *Data Protection, Shared (Genetic) Data and Genetic Discrimination,* 8 *Med L. Int'l* 51 (2006).

opinion with respect to genetic technologies [46].

Indeed, it has been criticised the so called «genetic exceptionalism», due to the exaggerated view of the significance of genetic information in lives of the persons, based on an unacceptable genetic determinism and genetic reductionism [47].

Nevertheless, the above mentioned special status of genetic data may be observed in relation to several cases.

For example, the General authorization no. 8/2012 of *Italian Garante* imposes that the individual, before the genetic testing, has to be informed also on the possible results of such a testing, especially «with regard to unexpected findings» (§ 5.b). That cautions should not be necessary in the processing of other kinds of sensitive data (as the political opinion or the health situation).

With respect to the use of the genetic data in the criminal investigation, it has been argued that «DNA samples or profiles are intrinsically 'more private' objects or their collection involves greater infringement of bodily integrity than, for example, fingerprints or photographs» [48].

In fact, unlike fingerprints or other biometric identifier, which may be put in relation only to a specific individual, genetic information identifies information (for example a predisposition to genetic-linked diseases) of the other members of the genetic family. DNA is akin to a «future diary» of the persons (it contains information about our present and future medical conditions), and the right of the protection from unwanted «readership» must be imperative in order to maintain autonomous control of personal and sensitive information [49].

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[46] M.P.M. Richards, *How distinctive is genetic information*? *Studies in the History and Philosophy of Biological and Biomedical Sciences*, 2001, 32, pp. 663-687.

[47] T.H. Murray, *Genetic Exceptionalism and Future Diaries: Is genetic Information Different from Other Medical Information*, in M.A. Rothstein, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era*, (Yale University Press) New Haven, 1997, pp. 60-73, in part. p. 71.

[48] R. Williams, P. Johnson and P. Martin, *Genetic information and crime investigation: social, ethical and public policy aspects of the establishment, expansion and police use of the National DNA Database. Project Report. Durham University*, (School of Applied Social Sciences) Durham, 2004, § 6.2.2, p. 78.

[49] G. Annas, *Genetic Privacy. The Technology of Justice: DNA and the Criminal Justice System*, (John F. Kennedy School of Government) Harvard, 2001.

The above mentioned features of genetic information should lead to a specific protection, also taking into account the great risks of misuse and/or re-use for various purposes and the risks of discriminations and stigmatization which may affect the individual.

Moreover, some authors underline that the discipline of privacy is able to cover only some aspects of the protection of the genetic information and the related rights [50].

7. — *Genetic information and the rights of other subjects.*

As above mentioned, genetic information belongs not only to a specific person, but it is shared between persons of the same genetic group.

According to Article 11 of the Directive 95/46/EC, the data subject also has a right to receive information from the controller (or his representative) when the data has not been obtained from the said data subject.

In consequence of this aspect of genetic information, a physician or other health professional, who found a risk of a genetic disease examining the biological material of a person, might be confronted with the following dilemma: on one hand he could be bound by the obligation of secrecy, as well as the right to not know of the person concerned. On the other hand he/she could be obliged under article 11 to provide information to the data subject, who are the relatives sharing the same genetic line.

There is a not clear answer to that question within the discipline concerning the privacy, nor in the supranational and international legal sources.

According to the Article 18 of the Additional Protocol to the Convention of Oviedo on genetic testing, «Where the results of a genetic test undertaken on a person can be relevant to the health of other family members, the person tested shall be informed».

Anyway it is not clear the consequences and the conditions of that information.

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[50] In particular See M. Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, ref., *passim*.

According to the Working document on privacy above mentioned at least two scenarios may be imagined «One is that other family members could also be considered as "data subjects" with all the rights that follow from this. Another option is that other family members would have a right of information of a different character, based on the fact that their personal interests may be directly affected».

At the national level, legislations are focused on the protection of the privacy of the personal data subject, requiring his or her consent to disclose the information to the relatives [51].

Within Europe, an interesting solution is provided by the French Law.

Before the last version of Law concerning bioethics (Law 814-2011), the legislation previously in force established a procedure for communicating to family members the results of a genetic testing (s. Article L. 1131-1, 5th alinéa, CSP), without providing any consequence in case the person had not informed his/her relatives [52].

Such an exclusion of liability had appeared in conflict with the constitutional principles. As argued by the Constitutional Council «*le droit français ne comporte, en aucune matière, de régime soustrayant à toute réparation les dommages résultant de fautes civiles imputables à des personnes physiques ou morales de droit privé, quelle que soit la gravité de ces fautes*» [53].

The *Conseil d'Etat* in its document on the review of the law concerning bioethics had then proposed to make explicit the responsibility to inform family members about genetic abnormalities, while respecting medical confidentiality [54].

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[51] B. Godard, T. Hurlimann, M. Letendre and N. Égalité and Inherit Brcas, *Guidelines for disclosing genetic information to family members: From development to use*, in *Familial Cancer* (2006) 5, pp. 103-116.

[52] See J.R. Binet, *Le nuoveau droit de la bioéthique*, in *LexisNexis*, Paris, 2005, p. 30 ff.

[53] See the judgement of the *Conseil constitutionnel* n. 82-144 DC of 22 October 1982, in *www.conseil-constitutionnel.fr.*

[54] Conseil d'État, *La révision des lois de bioéthique*, Paris, 2009, cap. IV «*Examen des caractéristiques génétiques: respecter la volonté des personnes et renforcer leur information*». According to the *Conseil* the Swiss approach – allowing the physician to be authorised by the public authorities to contact the relatives if the patient refuse to inform them – might affect the trust relationship between the professional and the patient.

Article 1 of the new law adds to the *Code de la santé publique* the Article L. 1131-1-1, which requires upon an examination of genetic characteristics it becomes the duty of the physician to inform the person of the risks for family members in cases of a diagnosis of a serious disease, if they were not properly informed (1st *alinéa*).

The disposition states also the duty of the person concerned to prevent the consequences of genetic abnormalities of the relatives, when measures of prevention will be adopted (3th sub§).

The person may also decide not to be informed about the results of the diagnosis. In this case, as in the case where the persons concerned do not feel they are able to make the communication, the physician is requested to inform the relatives (4th alinéa). In any case, the doctor will not reveal the name of the patient, nor the genetic abnormality, or the risk associated with it. Basically the physician has to invite family members to take a genetic test, envisaging the existence of a potential risk.

8. — *The right to know own proper genetic origins*.

Other potential ethical dilemmas related to the consent on the use of genetic information concerns the reproductive field.

According to the ECtHR, Article 8 ECHR recognises a right to become or not to become a parent [55].

This implies the right to adopt a child [56] and also that to access to the techniques of medically assisted procreation [57], among which the heterolo-

[55] See EctHR, *Evans v. the United Kingdom* [GC], no. 6339/05, § 71, ECHR 2007-IV; Id., *A, B and C v. Ireland* [GC], no. 25579/05, § 212, 16 December 2010; Id., R.R. v. Poland, no. 27617/04, § 181, ECHR 2011.

[56] ECtHR*, Rieme/Sweden*, in *E. Ct. H. R.*, 22 April 1992, series A, no. 226-B.

[57] See EctHR, *Dickson v. the United Kingdom* [GC], no. 44362/04, § 66, ECHR 2007-V. According this case-law the Court of Strasbourg hold as illegitimate, in accordance with the Article 8 ECHR, to provide the applicants – a prisoner and his wife – with facilities for artificial insemination.

gous fecundation [58].

The discipline on privacy would recognise to the donors and to the genetic parents the strict right to the anonymity and, only eventually on a voluntary basis, the consent that third parties may have access to their genetic information.

However the right to anonymity and to consent to the access to the personal information may be in conflict with the rights of the child adopted, not recognised or born in consequence of the heterologous donations of

In particular within the last years the ECtHR case-law has identified the own proper origins.

On the ground of this principle, for example, the Court of Strasbourg condemned Italy (see case Godelli vs. Italy, judgment of 25 September 2012) for violation of Article 8 ECHR in relation to the discipline of «anonymous birth» (see law 184/1993).

In fact, the Italian law establishes the right of the mother to not be mentioned in the birth certificate, without any chance for the child to access the information about the birth mother, even if she is not identified, or to the mother to change the choice of anonymity.

The Court in its judgment Odièvre vs. France of 2003 [59] points out that Article 8 ECHR protects the right to identity and personal development, to establish and deepen relationships with other human beings. According to the other judgment Godelli, the exercise of the right to personal development, the person needs knowledge of details of his identity and in particular those concerning their parents [60].

The circumstances of birth belong to the private life of the child, then of the adult.

Thus, according to the ECtHR Italy has not carried out a balancing of the interests involved, especially that of the child to know his/her origins

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[58] See ECtHR, *S.H. and Others v. Austria* [GC], no. 57813/00, § 82, ECHR 2011.

[59] ECtHR, 13 February 2003, Application no. 42326/1998, *Odièvre c. France*. See J. Long, *La Corte europea dei diritti dell'uomo, il parto anonimo e l'accesso alle informazioni sulle proprie origini: il caso Odièvre c. Francia*, in *Nuova giur. civ. comm.*, 2004, II, pp. 283-311.

[60] ECtHR, *Mikuli v. Croacia*, no. 53176/99, § 53, CEDU 2002 I, §§ 54 and 64.

and to protect his/her health, and the right to anonymity of the mother.

On the contrary, in the case Odièvre the French legislation concerning anonymous birth was found as compliant with Article 8 ECHR, because it provides the retention of not identifying the genetic information of the birth mother, as well as it establishes the possibility of eliminating anonymity with the agreement of the biological mother [(61)].

Furthermore, with respect to the heterologous fecundation, in most countries, the principle of anonymity is relative: the child can only access data not identifying (Brazil); he/she can access data identifying and, exceptionally, the identity of the donor (Spain, Greece, Portugal). Other countries have a mixed system: in Belgium the anonymity rule applies to the donation of embryos and sperm, but not oocyte. In Hungary anonymity is expected in the case of donor sperm, but is not expected to oocytes.

Another kind of limitation of anonymity and consent is the *post mortem* testing in order to identify the genetic parent of a person. In its case-law ECtHR, while confirming the principle of consensus [(62)], admits the post-mortem examination, if this is in the interest of the person requesting the genetic analysis, taking also into account the lack of invasiveness of the examination [(63)].

Therefore, as recommends the case-law and the document of the Article 29 Working Party, the above mentioned situations cannot be dealt with only from the perspective of the rules on the privacy of personal information, but through a balance between the interests, with a particular attention on the interests of children.

[(61)] See also ECtHR, 10 January 2008, *Kearns v. France*, no. 35991/04.

[(62)] ECtHR, *Mikulic v. Kroazia*, 7 February 2002, no. 53176/99; see the commentary contained in V. Colcelli, *La tutela della vita privata e familiare attraverso il diritto di conoscere le proprie origini*, in *https://diritti-cedu.unipg.it.*

[(63)] See ECtHR, *Jäggi v. Swiss*, 13 July 2006, n. 58757/00; see also ECtHR, *Hereditary Succession of Kresten Mortensen v. Denmark*, n. 1338/03, 15 May 2006. See, in relation to the Italian case law, B. Bottalico, *Familiarità dei caratteri ereditari e diritti individuali: un caso davanti al Tribunale di Milano*, in *Nuova giur. civ. comm.*, 2009, II, p. 399 ff.

9. — *Other cases of insufficiency of the informed consent.*

The rules concerning privacy are not able to regulate several other hypotheses related to the use of genetic information.

a) Identification of a third person.

The first set of questions arises from the possibility of identifying a third person through the examination of the genetic data.

This possibility is put in place in criminal or other judicial investigations, in order to identify the offender, the victims of a murder, missing persons or, in the civil law field, to establish paternity.

In such cases the discipline of privacy admits that the use of the genetic information of a third person is possible without consent, subject to the control of the public authority to satisfy important interests. Anyway, also in such a case, some general principles have to be observed such as that of proportionality [(64)].

Nevertheless, the proliferation of Internet-based offers of genetic tests aimed especially at establishing fatherhood has as consequence other important questions.

In particular the consent of the data subject does not prevent the use of genetic or further personal information of the other persons. Although the legal father would give his consent to the genetic testing, in case the analysis will establish that he is not the genetic father, this will have as consequence that the genetic information related to a person who has not given his consent.

A solution may be the absolute ban of this kind of test, but this may affect the right to know one's own proper genetic origins. The right to claim

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[(64)] The above mentioned document of the Article 29 Working Party provides the example of the Spanish Data Protection Authority (DPA) which considered disproportional the creation of a file of genetic samples to identify new-borns through DNA testing, in order to prevent mother-infant mismatches. As matter of fact the same result could be reliably obtained with other means e.g. identity bracelets or footprints.

a judicial control could be deprived of effectiveness if it were forbidden any form of extrajudicial previous test. Indeed, in absence of test, the judicial claim should be grounded on other evidences.

b) Genetic testing in employment and other contractual relationships

The genetic profile of a person may influence his/her responses to the workplace and, in particular, the probability to develop a future disease relevant for the employment contract.

Therefore the employers could be interested in the results of a genetic screening of employees.

The interests of the employers may be justified by economic reasons (to avoid great levels of absenteeism or poor efficiency) but also in order to prevent the emergence of a disease which could affect the health of the employers.

Several ethical concerns may arise from gathering and processing of the genetic information in employment relationships: the actual freedom of a person subject to a hierarchical relationship or who is searching for a job; the actual reliability and predictive value of the testing; the discrimination; the right to not know; etc.

In such cases the solutions of the ethical issues are inspired only by the application of the discipline of the consent in order to protect the privacy of personal data. As matter of fact it is needed to provide a balance between interests as health of the employees or of third parties and, on the other hand, the right to privacy and to the protection of the personal data.

The consent, within the above mentioned context, may not be considered either as condition sufficient or necessary.

Indeed, Article 8, par 1.b, of the Directive no. 96/45/EC explicitly provides that «processing is necessary for the purpose of carrying out the obligations and specific rights of the controller in the field of employment law in so far as it is authorized by national law providing for adequate safeguards».

For example Article 29 Working Party in its Opinion 8/2001 and in its concluding of 24 September 2003 argued that the processing of genetic

data in the field of employment should be prohibited in principle and admitted only under really exceptional circumstances.

The European Group on Ethics in Science and New Technology in its Opinion no. 18 concerning «Ethical Aspects of Genetic Testing in the Workplace» of 2003, although if underlying the risks and the not sure predictability, provided several suggestions in order to find equilibrium between the different interests.

The Group (see § 2 of the Opinion no. 18), argues that the legitimate duties and rights of employers concerning the protection of health may be fulfilled through medical examination but without performing genetic screening.

However, in exceptional cases, the use of genetic screening could be considered when it may be necessary to guarantee health protection of workers or protection of third parties

Anyway, the medical examination should not be a criterion of selection. It should take place after the phase of selection.

In any case the principles of proportionality and non discrimination must be observed.

c) The relativity of anonymisation

The option of anonymisation, as an alternative to consent, has to be considered as not absolute.

For example, in case of processing of data for historical, statistical or scientific purposes, the Article 6, § 1 letters b) and e), of the Directive 95/46/EC admits that the personal data may be kept in a form which permits identification of data subjects for extended periods, subject to safeguard instruments established in the national law. With respect to such activities, the controllers are not obligated to inform the data subject in case of gathering information from a source different from the data subject him/her self (see Article 13, § 2, Directive). This is when the provision of such information proves impossible or would involve a disproportionate effort.

Today is diffuse the constitution of the bio-banks, that's to say to large

collections of human biological samples and associated data such as the genetic information [65].

The bio-banks are established for various reasons: criminal investigation, therapeutic treatments, and research activities.

In the case of the bio-banks the consent is required depending on the nature of the activity, public or personal interests, the degree of anonymity, etc.

The common interests (together with the private such as pharmacological industries) can be to maintain for many years the genetic information on bio-banks and some identifiable data. The research activities could be carried out in the future is not even foreseeable.

This makes it particularly difficult to require the consent for a specific purpose and during all the time needed to carry out the research.

Furthermore, the anonymity is relative because of technical reasons. The anonymisation processes are likely reversible and in principle any anonymised data can be linked to a person. The situation might occur in cases of pseudonymisation [66].

As it has been underlined within the scientific community «No responsible scientist can guarantee absolute privacy» and that «Privacy and confidentiality are important principles. But being identifiable has some benefits, and

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[65] For an overview on the European, international and national legislations relating to the biobanks, see among the others: I. Vivas Tesón, *Bioresearch, Biobanks and Informed Consent from Vulnerable Donors in Spanish Law*, in *Europa dir. priv.*, 2013, p. 1069 ff.; L. Scaffardi, *Legal Protection and Ethical Management of Genetic Databases: Challenges of the European Process of Harmonization*, in *European Legal Integration: the New Italian Scholarship, Jean Monnet Working Paper* 19/08, (New York University School of Law) New York, 2008; B. Godard, J. Schmidtke, J.J. Cassiman and S. Aymé, *Data storage and DNA banking for biomedical research: informed consent, confidentiality, quality issues, ownership, return of benefits. A professional perspective*, in *European Journal of Human Genetics* (2003) 11, Suppl. 2, S88-S122.

[66] Article 29 Data Protection Working Party, Opinion 4/2007 on the concept of personal data, Adopted on 20th June 2007, p. 18 stating that «Retraceable pseudonymised data may be considered as information on individuals which are indirectly identifiable. Indeed, using a pseudonym means that it is possible to backtrack to the individual, so that the individual's identity can be discovered, but then only under predefined circumstances».

being anonymous has some costs; science will be better off when it acknowledges this reality» [67].

According to some documents the risk of re-identification posed by genetic data would be considered as low.

As Article 29 Working Party argues, treating the matter of the pseudonymisation «In that case, although data protection rules apply, the risks at stake for the individuals with regard to the processing of such indirectly identifiable information will most often be low, so that the application of these rules will justifiably be more flexible than if information on directly identifiable individuals were processed» [68].

However this interpretation refers to the present state of the technique and does not take into consideration that it is possible to establish an association between the genetic information and other pieces of information, in a way leading to the identification of a person.

As demonstrated in an interesting research published on *Science* [69], it is possible, from sequencing of genetic data without identifiers, to recover the surnames by profiling short tandem repeats on the Y chromosome and querying genetic genealogy databases (as for example *www.ysearch.org* and *www.smgf.org*). Then a specific person can be targeted by combining the surname with other types of metadata, such as age and state, easily and freely available on Internet resources.

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[67] M. Angrist, *Genetic privacy needs a more nuanced approach*, in *Nature*, 7 February 2013, vol. 494, p. 7.

[68] Article 29 Data Protection Working Party, Opinion 4/2007 on the concept of personal data, Adopted on 20th June 2007, p. 18, stating that «Retraceable pseudonymised data may be considered as information on individuals which are indirectly identifiable. Indeed, using a pseudonym means that it is possible to backtrack to the individual, so that the individual's identity can be discovered, but then only under predefined circumstances».

[69] M. Gymrek, A.L. McGuire, D. Golan, E. Halperin and Y. Erlich, *Identifying Personal Genomes by Surname Inference*, in *Science*, vol. 339, 18 January 2013, pp. 321-324.

10. — *Conclusive observations*.

The features of the genetic data show that their processing cannot be limited to a question of privacy.

In particular, as mentioned in the previous paragraphs, the legal techniques to provide a free and informed consent or anonymisation are not always the solutions to the problems arising from the processing and storage of genetic data.

Some questions above mentioned and many others should be the objectives of new rules, at the international and national levels.

Anyway, the approach to the questions concerning the use of genetic information (as well as other kinds of data) [70] should take into account some aspects concerning both the contents and the methodologies in the protection of public and private interests.

From the viewpoint of the contents, the idea that the privacy is an absolute value should be subjected to a revision.

In particular the consent, the main instrument together with anonymity to protect the privacy, derives from the principle of autonomy and from a «proprietary» logic concerning if not the entire human body, at least its parts [71].

Furthermore, «In the European Convention on Bio-medicine as well as in the Universal Declaration on Human Genome, the approach to protecting data confidentiality would appear to be based on an individualistic concept» (Working Party, Working Document on Genetic Data, p. 8).

This approach is justified by the attempt to protect the persons from the great risks arising from the massive use of techno-science and in particular of the ITC technologies.

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[70] See V. Mayer-Schönberger and K. Cukier, *Big data: A Revolution That Will Transform How We Live, Work and Think*, (John Murray) Boston-New York, 2013, p. 165, who argue that «In the context of big data, the tried and trusted concept of notice and consent is often either too restrictive to unearth data's latent value or too empty to protect individuals' privacy».

[71] See for example, J. de Witte and H. Have, *Ownership of genetic material and information*, in *Soc. Sci Med.*, 1997 Jul; 45(1):51-60.

However, the ownership itself, according to the modern legal systems, has to comply with a social function, protecting the interests of the third persons and the society as a whole. The aim of the legal systems is no longer the egoism, as Jhering argued in his *Der Zweck im Recht*, but on the contrary the principle of solidarity [72].

Indeed, as it has affirmed «If we protect privacy effectively, we will not reduce ethics to autonomy, and autonomy to data ownership. Reducing ethics to ownership comes at a high price: ethics that care only about ownership and consented transfers are, by exclusion, indifferent to distributional justice and optimizing social outcomes» [73].

Privacy should be coordinated with other important freedoms or rights recognised by the constitutional norms, as the freedom of research (see, for example, Article 13 Charter of the Fundamental Right of the European Union) [74].

As matter of fact, the solution of genetic data [75], may lead to affect the scientific genomic research activities [76].

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[72] R. Cippitani, *La solidarietà giuridica tra pubblico e privato*, Roma-Perugia, 2010, *passim*.

[73] P. Taylor, *When consent gets in the way*, in *Nature*, 6 November 2008, vol. 456, pp. 32-33.

[74] See C.F. Molina del Pozo and C. Archontaki, *Libertad de artes y de Investigación Científica, Libertad de Cátedra*, in M.I. Álvarez Ledesma and R. Cippitani (coord.), *Diccionario analítico de Derechos humanos e integración jurídica*, Roma-Perugia-México, 2013; R. Cippitani, *La libertad de cátedra y de investigación en el ámbito de la autonomía universitaria*, in A.F. Buenrostro Ceballos, *La libertad de cátedra y de investigación en el ámbito de los derechos humanos*, (Universidad Autónoma de Baja California) Mexicali, pp. 129-188.

[75] W.W. Lowrance and F.S. Collins, *Identifiability in Genomic Research*, in *Science*, 3 August 2007, vol. 317, pp. 600-602.

[76] See the conclusions of M. Gymrek, A.L. McGuire, D. Golan, E. Halperin and Y. Erlich, *Identifying Personal Genomes by Surname Inference*, ref.; and also the editorial of Nature concerning the research on Science entitled Genetic privacy. The ability to identify an individual from their anonymous genome sequence, using a clever algorithm and data from public databases, threatens the principle of subject confidentiality, in *Nature*, 24 January 2013, vol. 493, p. 451.

Anyway, within the legislation in force already it is possible to find principles able to establish a balance between the rights to consent on the other fundamental interest.

In this respect, Article 26 of the Convention of Oviedo allows limitations of rights arising from that Convention, if such limitations «are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others».

As the legal doctrine holds, on the grounds of the international and constitutional principles, the right to provide the consent and the right to not know, in particular when such rights are related to genetic information [77], may be subject to the limitations needed to protect the rights of the others [78], in particular the health or the procreative choices [79].

From the methodological point of view, it would be advisable, also in respect to the balance of different interests in a field so complex, to put in place various strategies and new instruments [80].

Consent should not be considered as a rigid and monolithic form of opt-in/opt-out, but it may be conceived as a set of legal instruments for participating in the activities which may concern not only the interests of the «data subject», but also those of third parties and of the community.

In particular with respect to the use of genetic data, those instruments are various and multiplies, comprising detailed express consent; enlarged or broad consent (for a range of broadly defined uses); the presumed consent

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[77] R. Andorno, *The right not to know: an autonomy based approach*, in *Journal of Medical Ethics*, 2004, 30, pp. 435-440, in particular p. 437.

[78] In respect to the conditions to limit the fundamental rights, see M.I. Álvarez Ledesma, *La libertad de expresión en el sistema electoral mexicano desde una perspectiva jurídica*, in G. López Montiel and E. Tamés Muñoz (coord.), *Libertad de expresión en el proceso electoral 2012*, Tecnológico de Monterrey-Coparmex, PNDU/ONU, (Porrúa) México, 2013.

[79] See M. Petrone, *Trattamento dei dati genetici e tutela della persona*, in *Fam. e dir.*, 2007, p. 853 ff.

[80] See L. Villani, *Biobanche e test rivelatori di informazioni genetiche: spunti di riflessione per un nuovo consenso informato*, in *Resp. civ.*, 2010, p. 140.

(where people who do not want to be involved have to voluntarily opt out); the blanket consent, etc.

The consent could also include the decision to voluntary sharing of information as a common good [81].

It would be also stressed the procedural aspect of the consent: the quantity and quality of information to be provided; the time to take the decision; the kind of the decisions to be taken, etc., should be adequate to the situations [82].

From a subjective point of view, consent should not be only considered as individual, but it would be advisable to define the consent of the members of a group (as a family) and techniques to involve communities more huge.

In any case, the level and the kind of consent should be adapted to the interest of the parties in play and which could be put placed at risk.

For example, the International Bioethics Committee of UNESCO, in its document «Human Genetic Data: Preliminary Study by the IBCon its Collection, Processing, Storage and Use» of 15 May 2002, affirms that «Many tests which reveal genetic information will not have a great deal of significance for the person tested (…). Other tests, however, will have major

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[81] See the document *Ethical, legal and social aspects of genetic testing: research, development and clinical applications*, ref., p. 41 ff., esp. p. 42.

[82] See E.M. Bunnik, A.C.J.W. Janssens and M.H.N. Schermer, *Informed Consent in Direct-to-Consumer Personal Genome Testing: the Outline of a Model Between Specific and Generic Consent*, in *Bioethics*, 2012, pp. 1-9. The paper, in respect to the «Personal Genome Testing», uses a «combined tiered-layered-staged model for informed consent» which may be more suitable. This combined « is tiered to provide consumers with options, so as to enable them to choose what types of information on what (categories of) diseases they wish to receive, and especially to opt out of receiving information they do not wish to receive. Layering of information will help limit the otherwise overwhelming quantity of information offered to all consumers in the first layer of the consent process, while it also strives for an 'individual consumer-based' consent, as it offers additional information for those who need that information in order to consent. Finally, a staged set-up of the pre-test information provision process can serve educational purposes and improve the quality of consent. Moreover, subsequent renewal of consent will be required as new test outcomes become available as a result of ongoing genomics research. A combined tiered-layered-staged model for informed consent in PGT would allow for relevant information provision that is both sufficiently complete and sufficiently understandable».

implications, both for the individual and for relatives. The principle stated above sets out the consent requirements. For practical reasons, it would be unrealistic and unnecessary to require that there be specific consent to the genetic component in any test unless the consequences of this are sufficiently serious enough to justify this» (§ 59, p. 15) [83].

Another important instrument to face the ethical problems concerning the use of the genetic information is the control carried out by the ethics committee or other third subjects. This would occur in all cases where individual consent may not be sufficient in protecting the interests at risks or when such an individual consent is not available or possible.

For example the documents dealing with genetic screening for the recruitments of employees recommend requiring the prior assent of the appropriate labour organisation and a specific ad hoc authorization by an independent committee. Indeed, the person may be compelled to consent to the screening in order to be recruited by the employer [84].

According to some legal sources in the field of health, like the discipline on clinical trials, the expression of consent has to be subject to the control of independent bodies, through ethical committees, agencies or other bodies that allow the evaluation of the activity (see Article 6, § 3, Directive 2001/20/EC).

Other instruments for assuring the accountability and the quality of the establishments and of the professionals dealing with the genetic information are to be refined and developed [85].

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[83] As UK Human Genetics Commission affirmed «the difficulties involved in tracing and securing re-consent for different forms of medical research may make obtaining fresh consent impractical and would seriously limit the usefulness of large-scale population databases» (Human Genetics Commission Inside Information (May 2002).

[84] See the European Group on Ethics in Science and New Technology in its Opinion no. 18 concerning *Ethical Aspects of Genetic Testing in the Workplace* of 2003, § 2; see also the document *Ethical, legal and social aspects of genetic testing: research, development and clinical applications* of the 2004 elaborated for the General Directorate of Research Commission by a group of independent experts.

[85] The 5 Article of Additional Protocol to the Oviedo Convention concerning Genetic Testing for health adopted in Strasbourg on 27 November 2008, already stipulates that

More in general, it is necessary that the consent form part of a governance framework of « trust, responsibility and accountability », in which the involvement of institutional review boards would be essential [86].

States must ensure that «a genetic tests meet generally accepted criteria of scientific validity and clinical validity; b a quality assurance programme is implemented in each laboratory and that laboratories are subject to regular monitoring; c persons providing genetic services have appropriate qualifications to enable them to perform their role in accordance with professional obligations and standards».

[86] T. Caulfield, R.E.G. Upshur and A. Daar, *DNA databanks and consent: A suggested policy option involving an authorization model*, in *BMC Medical Ethics*, 2003, 4:1.