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GENETIC INFORMATION, ARTIFICIAL INTELLIGENCE (AI) AND HUMAN RIGHTS: BALANCING INDIVIDUAL AND COLLECTIVE INTERESTS

1. *Genetics and artificial intelligence (AI) as global concerns*

The development of genetic research and applications in different fields has generated a wide range of individual and collective interests related to genetic information: biosafety and biosecurity[1], the fight against crime, terrorism, and international security[2], healthcare[3]. Not only genetic research has a role to play for peace and in the interest of mankind[4] but

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[1] See R. PAVONI, *Biodiversità e biotecnologie nel diritto internazionale e comunitario*, Milan, 2004.
The use of human genetic data in the field of national and international security (for example as a tool to fight terrorism) has also been at the core of international cooperation within the major international organizations and the European Union in the last decade.

[2] The European Union has established cooperation mechanisms between Member States with the purpose of sharing genetic data in the fight against crime, through the creation of DNA databases. There is, however, a risk that the collecting of this kind of information for forensic ends could take place without paying due regard to the protection of fundamental rights. See F. COSTAMAGNA, *Banche dati del DNA e lotta contro il crimine: quale tutela per i diritti fondamentali in Europa?*, in *ISPI Policy Brief*, n. 197, September 2010, pp. 1-10.

[3] For a long time, genetic research and its applications for health purposes have been among the major concerns of States and International Organizations.

[4] See the United Nations General Assembly Resolution n. 3384 (XXX) of 10 November 1975, *Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind*, A/RES/3384 (XXX). The following resolutions are also relevant: General Assembly Resolution n. 46/126 of 17 December 1991, *Human rights and scientific and technological progress*, A/RES/46/126; General Assembly Resolution n. 48/140 of 7 March 1994, *Human rights and scientific and technological progress*, A/RES/48/140; General Assembly Resolution n. 53/152 of 9 December 1998 *endorsing the Universal Declaration on the Human Genome and Human Rights adopted on 11 November 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organization*, A/RES 53/152.

also Artificial Intelligence (AI) is considered as a "common concern of humanity"[5] as emerged in the recent debates[6].

According with the Council of Europe, AI is: «A set of sciences, theories and techniques whose purpose is to reproduce by a machine the cognitive abilities of a human being. Current developments aim, for instance, to be able to entrust a machine with complex tasks previously delegated to a human»[7]. A more articulated and precise definition of AI is provided by the *High Level Expert Group on Artificial Intelligence* set up by the European Commission[8].

It must be noted that scholars often focus on Artificial General Intelligence (AGI) which corresponds to the so-called "strong" AI, the kind that may, one day, be able «to accomplish any cognitive task at least as well as humans»[9]. However, most current advances involve "weak" or "narrow" AI which performs a wide range of specific tasks (e.g. playing a board game, translating between languages, listening and responding to human instructions, etc.).

There is a variety of approaches and techniques in AI development[10]. Especially, in machine learning techniques, the algorithm is enabled to process data independently from explicit human instructions [11]. The result is measured in terms of better performance, but the increasing complexity and the capacity for unsupervised or non–restricted learning of these

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[5] On the concept of "common concern of humanity" see, among others, R. PAVONI, *Biodiversity and Biotechnology: Consolidation and Strains in the Emerging International Legal Regimes*, in F. FRANCIONI, T. SCOVAZZI (eds.), *Biotechnology and International Law*, Oxford and Portland, Oregon, 2006, p. 31 ff.

[6] See the PONTIFICAL ACADEMY FOR LIFE, *Rome Call for AI Ethics*, signed on 28 February 2020 by different stakeholders (e.g. IBM and Microsoft), which set forth ethical standards for the development of AI: «The development of AI in the service of humankind and the planet must be reflected in regulations and principles that protect people – particularly the weak and the underprivileged – and natural environments».

[7] See COUNCIL OF EUROPE, *Artificial intelligence*, in Glossary. As the Council of Europe pointed out, strong AI «would require advances in basic research to be able to model the world as a whole and not just improvements in the performance of existing systems». Other definitions are also describing AI with a good level of approximation. Marvin Lee Minsky, who is considered as one of the founding fathers of AI, defines it as follows: «the science of making machines do things that would require intelligence if done by men. It requires high-level mental processes such as: perceptual learning, memory and critical thinking».

[8] EUROPEAN COMMISSION HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, *A definition of AI: main capabilities and disciplines*, Brussels, 8th April 2019. The definition, that expands the definition proposed within the European Commission's Communication on AI, reads as follows: «Artificial intelligence (AI) refers to systems that display intelligent behavior by analyzing their environment and taking actions - with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications)».

[9] M. TEGMARK, *Life 3.0 Being human in the age of artificial intelligence*, New York, 2017, p. 52.

[10] The main techniques are machine learning, deep learning and neural networks. As scholars pointed out, there has been an important shift in AI development, including in healthcare, between the 1970s and now, and especially since 2006. This phenomenon has been described as a shift from "old AI" to "new AI". See S.M. CARTER, W. ROGERS, K.T. WIN, H. FRAZER, B. RICHARDS, N. HOUSSAMI, *The ethical, legal and social implications of using artificial intelligence systems in breast cancer care*, in *The Breast*, n. 40, 2020, pp. 25-32, spec. p. 26.

[11] Algorithms are computer code designed and written by humans, carrying instructions to translate data into conclusions, information or outputs.

algorithms (called "black boxes")[12] lacks of transparency, raising concern about the possible violation of human rights[13].

Scientific literature describes the new frontiers of AI in healthcare both in terms of diagnostics and therapeutic innovations[14], paving the way to effective personalised medicine. The application of algorithms to genetic research does not come as a surprise considering that genetics building blocks have inspired the early development of AI[15]. In a certain sense, AI applications boost-up genetics benefits and risks that need to be carefully addressed.

The problem is whether there is a need to adopt new regulation for AI or not, being it an emerging field for legislators[16]. In this perspective, both the Council of Europe and the European Union are developing specific guidelines[17], and different initiatives are undertaken by intergovernmental and non-governmental organizations as well[18]. However, when it comes to genetics, it can be argued that the existing regulatory framework focusing on HRs

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12 Because «the detail of their operations is not always understandable to human observers», see S.M. CARTER, W. ROGERS, K.T. WIN, H. FRAZER, B. RICHARDS, N. HOUSSAMI, *op. cit.*, p. 26.

13 See the COUNCIL OF EUROPE, *Study on the human rights dimensions of automated data processing techniques (in particular algorithms) and possible regulatory implications*, DGI (2017)12.

14 See, amongst others, D. GRUSON, T. HELLEPUTTE, P. ROUSSEAU, D. GRUSON, *Data science, artificial intelligence, and machine learning: Opportunities for laboratory medicine and the value of positive regulation*, in *Clinical Biochemistry*, n. 69, 2019, pp. 1-7; S.M. CARTER, W. ROGERS, K.T. WIN, H. FRAZER, B. RICHARDS, N. HOUSSAMI, *op. cit.*, pp. 25-32.

15 See D. GRUSON, *Pour une regulation positive de l'intelligence artificielle en génétique*, in *Les nouveaux territoires de la bioéthique. Traité de bioéthique* IV, sous la direction de EMMANUEL ET FRANÇOIS HIRSCH, Toulouse 2018, pp. 555-566.

16 *Ibidem*. On the debate that took place in France and its outcomes, it is interesting to mention the *Ethik IA* initiative aiming at involving professionals and the public on the definition of soft law regulation on AI, with the adoption of a prototype rule encompassing « les 5 clés de régulation de l'IA et de la robotisation en santé». In addition, the French national bioethics committee, *Comité consultatif national d'éthique* (CCNE), adopted its Report on the *États généraux de la bioéthique* on 25 September 2018, devoted to the new frontiers of bioethics including AI and robotics.

17 The Parliamentary Assembly issued a *Recommendation on Technological convergence, artificial intelligence and human rights*, Recommendation 2102 (2017) of 28 April 2017. In addition, the Committee of Ministers adopted a *Declaration on the manipulative capabilities of algorithmic processes*, Decl(13/02/2019)1 of 13 February 2019. With the purpose of developing a specific regulatory framework, the Council of Europe has recently established the *Ad Hoc Committee on Artificial intelligence (CAHAI)*, whose first meeting was held on 18-19 November 2019 in Strasbourg. Other relevant bodies of the COE are working on (or dealt with) specific AI issues as well: the *Steering Committee on media and Information Society (CDMSI)*, the *Committee of experts on human rights dimensions of automated data processing and different forms of artificial intelligence (MSI-AUT),* the *Consultative committee of the Convention for the protection of individuals with regard to automatic processing of personal data (T-PD)*, the *Committee of experts on Internet Intermediaries (MSI-NET)*, that was active from 1 January 2016 until 31 December 2017, and the *Commissioner for Human Rights* who adopted a Recommendation on 14 May 2019 that refers also to other significant guidelines adopted by the COE with regard to AI.
The European Commission has recently adopted the *White Paper on Artificial Intelligence. A European Approach to Excellence and Trust*, COM(2020) 65 final of 19 February 2020, following the Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions *Artificial Intelligence for Europe*, COM(2018) 237 final of 25 April 2018. Furthermore, the *European Group on Ethics in Science and New Technologies (EGE)* has issued a *Statement on AI, Robotics, and Autonomous Systems* on 9 March 2018.

18 See the UNITED NATIONS, *Report of the Special Rapporteur on the promotion and protection of the right to freedom of opinion and expression*, A/73/348 of 29 August 2018 (reissued for technical reason on 26 October 2018). WHO and the International Telecommunication Union (ITU), established a *Focus Group on Artificial Intelligence for Health (FG-AI4H)* in July, 2018. UNESCO *World Commission on the Ethics of Scientific Knowledge and Technology (COMEST)* issued a *Preliminary study on the ethics of artificial intelligence* on 26 February 2019. See also the first meeting of the OECD *Network of Experts on AI (ONE AI)* that was held in Paris on 26-27 February 2020.

(e.g. data protection, privacy, non-discrimination) can be paradigmatic as it is already built on the proportionate balancing of individual's rights and collective interests.

Several international documents (e.g. declarations and other soft law instruments, in addition to conventions) deal with the legal, social and ethical implications of genetics. However, since the adoption of the UNESCO Universal Declaration on the Human Genome and Human Rights (hereinafter: Declaration)[19], in 1997, many things have changed. The scientific and technological progress and the contextual evolution of the international legal framework[20], lead to rethink the relationship between genetic information and human rights[21]. Moreover, the modernisation of the European data protection framework with regards to both the Council of Europe Protocol amending the Convention for the Protection of Individuals with regards to Automatic Processing of Personal Data, adopted in 2018 (not yet in force),[22] and the EU Regulation n. 2016/679[23] provide a more appropriate protection of personal data, in line with the international rules[24].

In this perspective, the paper aims to give an overview on the basic principles of international law related to genetic information elaborated within the context of the international organizations[25], with a focus on the Oviedo Convention on Human Rights and Biomedicine (hereinafter: the Oviedo Convention)[26] and the additional Protocol concerning

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[19] *Universal Declaration on the Human Genome and Human Rights*, adopted unanimously and by acclamation at UNESCO's 29th General Conference on 11th November 1997. The text of the Declaration is available at www.unesco.org. For a general comment of the Declaration see N. LENOIR, *Universal Declaration on the Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level*, in *Columbia Human Rights Law Review*, n. 30, 1999, p. 537 ff.

[20] See the *Universal Declaration on Bioethics and Human Rights*, adopted by UNESCO's General Conference on 19 October 2005.

[21] See F. FRANCIONI, *Genetic Resources, Biotechnology and Human Rights: the International Legal Framework*, in F. FRANCIONI (ed.), *Biotechnologies and International Human Rights*, Hart Publishing, Oxford and Portland, Oregon, 2007, pp. 3-32.

[22] CETS No. 223. The Protocol has been opened for signature on 10 October 2018 by the Contracting States to Treaty ETS 108. It will entry into force upon ratification by all Parties to Treaty ETS 108, or on 11 October 2023 if there are 38 Parties to the Protocol at this date.

[23] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 *on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)*, in the *OJEU* n. L 119 of 4 May 2016, pp. 1- 88. The Regulation does not expressly mention artificial intelligence but instead it regulates automated processing of personal data. See *recitals* 71 and 72, art. 4, para. 4, art. 13 and art. 22.

[24] See the General Assembly Resolution on *The right to privacy in the digital age* of 16 November 2016, A/C.3/71/L.39/Rev.1.

[25] At the international level, the need for concerted or joint efforts, in particular within and outside the United Nations system lead to a stronger action of the Inter-Agency Committee on Bioethics (UNIACB), especially to address regularly the issue of genetic privacy and non-discrimination. See the Economic and Social Council (ECOSOC) resolutions 2001/39 and 2004/9 on genetic privacy and non-discrimination. During the General Segment of the ECOSOC 2012 Session, on 25th July 2012, the Council adopted by consensus the draft Resolution E/2012/L.17 under Item 14(I) entitled: "Genetic Privacy and Non-discrimination". Therefore, the item is now closed.

[26] 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, Oviedo, 4 April 1997, CETS No.: 164. The Convention has entered in force on 1 December 1999. The text of the Convention and the additional Protocols are available at www. coe.int. In the literature, see, among others, BOMPIANI, *Consiglio d'Europa, diritti umani e biomedicina. Genesi della Convenzione di Oviedo e dei Protocolli*, Roma, 2009; ZANGHÌ, PANELLA (a cura di), *Recenti sviluppi in materia di bioetica. In margine al progetto di Convenzione sulla bioetica del Consiglio d'Europa*, Torino, 1996; ROSCAM ABBING, *The Convention on Human Rights and Biomedicine. An Appraisal of the Council of Europe Convention*, in *European Journal of Health Law*, 1998, 377-387.

genetic testing for health purposes (hereinafter: Protocol)[27]. The analysis will focus also on guidelines applying to AI that have been recently affirmed at the international level.

The main concerns related to both the AI collection and the algorithmic processing of genetic and healthcare information regards the need to identify and to address different human rights violations. Not only States and national healthcare systems have the knowledge and the power to collect and to process personal and genetic data for different purposes but also private bodies and groups have an interest therein. This can possibly challenge the traditional tools for the protection of HRs, like informed consent and the non-discrimination principle.

The evolving jurisprudence of the European Courts related to the collection of genetic information, that affirms the need to balance different human rights in this field, is crucial to address the present and future challenges of AI.

2. *Genetic information, AI and human rights*

Individual human rights related to the use/manipulation of genetic information are mostly aimed at protecting genetic identity, genetic privacy and genetic diversity.

The protection of genetic diversity is related to the individual as depositary of the genetic code. It ensures the protection of collective interests through individual empowerments. Different legal constructions have emerged in the attempt to protect the genetic identity of the human species: namely, the prohibition of practices contrary to human dignity (e.g. reproductive human cloning); the right to genetic integrity and the right to a non-modified genetic heritage; the right to uniqueness of the embryo; and the principle of non-discrimination[28].

The right to genetic privacy has been considered commonly as encompassing all legal problems related to the protection of genetic information. In other terms, privacy protects the right of the individual to control information that is intrinsically linked to his/her identity. Two different rights which are presented as autonomous need to be considered: the right to know (Article 5 of the Declaration) and the right to confidentiality (Article 7 of the Declaration). The right to know and its corollary the right not to know in genetic testing[29], recognized in Article 5 of the Declaration, reflect the natural extension of individual autonomy and are considered essential guarantors of the individual's ability to choose his/her lifestyle. At this regards it is important to underline that it is difficult to place limits on the right to know. However, it is essential to consider the uncertainties of genetic testing because predictive genetic testing can give little guidance as to the disclosure of the positive information of a pre-symptomatic diagnosis[30].

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[27] Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, CETS No.: 203. The Protocol entered into force on 1 July 2018; the States parties are only 6 on 25 April 2020 are: Czech Republic, Montenegro, Norway, Portugal, Republic of Moldova and Slovenia. See H. D.C. ROSCAM ABBING, *Editorial*, *Genetic Testing for Health Care Purposes*, in *European Journal of Health Law*, Vol. 15, 2008, pp. 353- 359; D. MARRANI, *Genetica, tutela della salute e diritti umani: il Protocollo addizionale alla Convenzione di Oviedo relativo ai test genetici a fini medici*, in *La Comunità internazionale,* n. 2, 2012, pp. 303-329.

[28] For a wide analysis on these topics, see H. BROUSSARD, *cit.*, p. 256 ff.

[29] See below at para. 3.

[30] It may be difficult for individuals to appraise the risks of genetic testing as misleading test results may be further complicated by deceptive marketing. I am referring to direct-to-consumer genetic testing which proves

It should be observed that these concerns have already, though partially, been addressed in the last decades. Several international and European instruments (conventions, declarations and generally soft law regulations) deal with genetic research, genetic information and human rights[31]. Such instruments underline the need to reconcile different individual (the genome or the genetic sequence owner) and collective interests (the benefit of genetic research for others and for society) involved in genetic research[32]. Especially, Article 14 (b) of the UNESCO International Declaration on Human Genetic Data is aimed at protecting genetic data, thus balancing confidentiality with the interests of society[33].

The recent developments of AI in genetics research and applications may strongly affect the respect of human rights. First, genetic testing for healthcare purposes are becoming more usual for many different reasons (e.g. genetic testing is not as costly and time consuming as in the past). Second, AI fuelled by big data (i.e. genetic data of a high number of patients undergoing genetic tests) makes it possible to infer intimate and detailed information about individuals from readily available data (e.g. individual health conditions, lifestyle, customer habits, online and offline behavior, etc.), including genetic data. This supports the sorting of individuals/patients into categories (e.g. groups of patients owing to benefit from innovative therapies), thus implying a deterministic choice[34]. A further characteristic of the groups generated by algorithms is that people do not know the other members of the group, differently from people belonging to groups that are the traditional targets of discriminatory practices. Consequently, scholars suggested a broader notion of discrimination.

It should be noted that the protection accorded by the principle of genetic non-discrimination[35] has been considered weak for many different reasons. Especially, art. 11 of the Oviedo Convention and the Protocol discipline are limited in their scope[36], and the

problematic in terms of protection of consumers and respect of human rights. The so-called "genome wide association" can be misleading or with no utility without considering in addition important environmental and social factors that impact on genetic diseases. With the purpose to avoid misleading practices, different governmental bodies have taken a strong position on this issue. See the United States Government Accountability Office statement (GAO-10-847T) *Direct-to-consumer genetic tests. Misleading Tests Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices*, July 22, 2010.

[31] For a comment on these international instruments, see amongst others, I.R. PAVONE, *Diritti dell'uomo e genetica*, in *Enciclopedia giuridica Treccani,* Roma, 2006, p. 1 ff.

[32] See H. BROUSSARD, *Individual Human Rights in Genetic Research: Blurring the Line between Collective and Individual Interests*, in MURPHY (ed.), *New Technologies and Human Rights*, Oxford, 2009, pp. 246-271.

[33] See the International Declaration on Human Genetic Data, adopted by UNESCO on 16 October 2003, especially Article 14 (Privacy and Confidentiality): «*Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential*».

[34] As scholars pointed out: «La capacité d'orientation de l'IA peut, dans cette configuration, acquérir un tour significativement plus déterministe». Without introducing specific regulation, the consequence of the large use of AI in healthcare would be: «la derive eugénique deviendrait davantage qu'une possibilité technique. Elle serait même sans doute la consequence logique du processus». See D. GRUSON, *op. cit.*, p. 562

[35] See C. CAMPIGLIO, *Il principio di non discriminazione genetica nella recente prassi internazionale*, in *Diritti umani e diritto internazionale*, n. 3, 2008, pp. 513-534.

[36] The Protocol applies only to genetic testing for health purposes and does not regulate genetic testing in other relevant fields such as labor and insurance where discrimination may strongly affect the individuals' rights. At this regard, the Council of Europe Recommendation Rec(2016)8 *on the processing of personal health-related data for*

Protocol has been ratified by a limited number of State Parties. Moreover, the European Court of Human Rights has only a consultative competence on these accords. In the EU legal order, Article 21 of the EU Charter of Fundamental Rights, stipulating that: «Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, *genetic features*, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited» applies only to the EU institutions. Therefore, according to primary law, genetic discrimination by privates or companies falls behind the scope of the EU.

With the purpose of addressing these concerns, the Parliamentary Assembly of the Council of Europe adopted Recommendation 2102(2017) asking the Committee of Ministers «to instruct the relevant bodies of the Council of Europe to consider how intelligent artefacts and/or connected devices and, more generally, technological convergence and its social and ethical consequences related to the field of genetics and genomics, neurosciences and big data, challenge the different dimensions of human rights» (para. 8)[37].

In *the Declaration by the Committee of Ministers on the manipulative capabilities of algorithmic processes* of 13 February 2019[38], the Committee of Ministers (CM) observes that the sorting of individual into categories reinforces «different forms of social, cultural, religious, legal and economic segregation and discrimination». (para. 6). Indeed, the CM draws the attention on «The effects of the targeted use of constantly expanding volumes of aggregated data on the exercise of human rights in a broader sense, significantly beyond the current notions of personal data protection and privacy» (para. 7). Accordingly, the CM encourages Member States, *inter alia*, to address this threat «considering the need for additional protective frameworks related to data that go beyond current notions of personal data protection and privacy and address the significant impacts of the targeted use of data on societies and on the exercise of human rights more broadly» (*sub b*).

Moreover, the recent *Recommendation of the Committee of Ministers to member States on the human rights impacts of algorithmic systems* of 8 April 2020[39] recommends the governments of member States to «review their legislative frameworks and policies as well as their own practices with respect to the procurement, design, development and ongoing deployment of algorithmic systems to ensure that they are in line with the guidelines set out in the appendix to this recommendation…»[40]. As underlined by the Committee of Ministers: «In addition to the intrusion on individuals' privacy and the increasing potential of highly personalized manipulation, tracking at scale can have a serious adverse effect on the exercise of human rights, which must be considered throughout the entire life cycle of an algorithmic system,

insurance purposes, including data resulting from genetic tests, adopted by the Committee of Ministers on 26 October 2016, is an example of a proportionate balancing of the insured person's human rights with collective interests (insurers, society).

[37] Recommendation on *Technological convergence, artificial intelligence and human rights* of 28 April 2017, cited above (footnote 17). The Assembly proposed also to elaborate guidelines on specific issues, concerning: transparency, regulation and accountability for HRs violations (para. 9.1); affirming expressly «the need for any machine, any robot or any artificial intelligence artefact to remain under human control» (para. 9.3), and «the recognition of new rights in terms of respect for private and family life, the ability to refuse to be subjected to profiling, to have one's location tracked…» (para. 9.4).

[38] See the Declaration.

[39] Rec(2020)1.

[40] Algorithmic systems «are understood as applications that, often using mathematical optimisation techniques, perform one or more tasks such as gathering, combining, cleaning, sorting, classifying and inferring data, as well as selection, prioritisation, the making of recommendations and decision making», see the *Guidelines on addressing the human rights impacts of algorithmic systems* (para. A.2).

from the proposal stage onward»[41]. One of the main concerns regards the possible errors that may occur in the form of false positives or false negatives, with the result that: «people who are affected by these errors and inbuilt bias, will also expand, triggering additional interferences with the exercise of human rights in multiple ways»[42].

With a specific focus on personal data protection, the Consultative Committee of the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data adopted the *Guidelines on artificial intelligence and data protection* on 25 January 2019[43]. The Guidelines are human rights oriented and adopt the privacy-by-design approach intended to « avoid any potential biases, including unintentional or hidden, and the risk of discrimination or other adverse impacts on the human rights and fundamental freedoms of data subjects» (para. II, 3)[44]. Importantly, the autonomy of human decision making is strongly affirmed in the *Guidelines*[45]. The same principles are expressed by the *High-Level Expert Group on Artificial Intelligence* set up by the European Commission in the *Ethics Guidelines for Trustworthy AI* of 8 April 2019, promoting a human-centric approach on AI[46].

The General Data Protection Regulation (GDPR) establishes a special protection to genetic data considering that genetic data are sensitive data. Especially Article 9 provides for the requirement of informed consent to process genetic data and allows Member States to adopt a more restrictive regulation with that purpose[47]. However, as scholars pointed out, the Regulation does not specifically address the AI challenge nor it provides for any solution on the delicate issue of access to genetic data (even not strictly related to medical research) by AI applications. Therefore, the protection appears «très fragile face au risque réel qui est celui de la captation des données génétiques par une intelligence artificielle apprenante»; consequently, where information systems are not sufficiently protected by specific regulation on the access of healthcare AI applications to genetic data, «les règlements sur la protection des données établis jusqu'ici ressemblent à autant de barrières de papier»[48].

Article 35 of the Regulation provides for a data protection impact assessment (DPIA) focusing on the «risk to the rights and freedoms of natural persons. In this respect, Article 29 Data Protection Working Party adopted the *Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679* [49]. The Guidelines explicitly address genetic data processing as the object of a

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[41] Para. A.4.
[42] Para. A. 5.
[43] T-PD(2019)01.
[44] Particularly, the Guidance for developers, manufacturers and service providers provides for innovative participation of all stakeholders in AI risk assessment: «Participatory forms of risk assessment, based on the active engagement of the individuals and groups potentially affected by AI applications, should be encouraged» (para. II, 7). In addition, the Guidance for legislators and policy makers is aimed at enhancing trust in AI products and services, through various instruments and means: «the principle of accountability, the adoption of risk assessment procedures and the application of other suitable measures, such as codes of conduct and certification mechanisms» (para. III, 1).
[45] «The role of human intervention in decision-making processes and the freedom of human decision -makers not to rely on the result of the recommendations provided using AI should therefore be preserved» (para. III, 4).
[46] See the Guidelines.
[47] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
[48] D. GRUSON, *op. cit.*, p. 565.
[49] The *Guidelines* have been adopted on 4 April 2017.

mandatory DPIA, for example related to "profiling or predicting" (e.g. a biotechnology company offering genetic tests directly to consumers in order to assess and predict the disease/health risks)[50], or a hospital processing its patient's genetics and health data where at least two criteria are met (e.g. sensitive data and data concerning vulnerable data subjects)[51].

An interesting tool to carrying out the risk assessment outlined by the Regulation may be provided by the proposed human rights, social and ethical impact assessment (HRESIA)[52] aimed at analysing not only privacy related issues but also non-discrimination and human rights in the development of AI[53].

The scope is to shift the focus from «the traditional sphere of data quality and security to fundamental rights and freedoms… to address the collective dimension of data processing»[54]. The proposal is intended to help data controllers with a tool that aims at «suggesting a broader range of safeguarded interests and affecting individuals as a group»[55]. It can be observed that this broader range of safeguarded interest is already considered in the experience of national data controllers with regards to genetic data[56].

3. *Genetics, AI and the right to healthcare in International Law*

For a long time, biomedical research and applications have offered new opportunities for both diagnosis and treatment of some grave diseases, thus giving further instruments to protecting the right to healthcare.[57] It is sufficient to consider the possible benefits of gene therapy and stem cell research or the utility of genetic testing in medical settings. In this context, converging technologies (genetics, nanotechnologies, robotics) may also play a significant role as they can improve human performances[58].

Therefore, it does not come as a surprise that researchers using algorithms have discovered significant gene mutations in autism, strongly contributing to healthcare progress for many patients suffering from that condition[59]. The use of an algorithm for the quick diagnosis of COVID-19 in a University Hospital in Italy is another example of AI

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[50] Para. III, B), a), 1.

[51] Para. III, B), a), 9.

[52] See A. MANTELERO, *AI and Big Data: a Blueprint for a Human Rights, Social and Ethical Impact Assessment*, in *Computer Law & Security Review*, Vol. 34, Issue 4, 2018, pp. 754- 772.

[53] See Article 35 of the General Data Protection Regulation (GDPR).

[54] See A. MANTELERO, *cit.*, p. 17.

[55] *Ivi.*

[56] On the practice of genetic data protection in Italy see D. MARRANI, *Investigación biomédica y consentimiento informado para el tratamiento de datos genéticos*, in R. ANDORNO, V. IVONE (edited by) *Casos de Bioética y Derecho*, Torino-Valencia, 2015, pp. 111- 120.

[57] The relationship between emerging technologies, including genetics, and human rights may to some extent be ambivalent: «While human rights tend to protect the intrinsic value of the individual, biomedicine increases the medical (or, instrumental) value of human body and body parts». See H. BOUSSARD, *cit.* p. 246.

[58] A wide debate has developed, for example, on the legitimacy of therapeutic human enhancement as opposed to non-therapeutic human enhancement. On this issue, see the reports of *Ethics in Public Making: the Case of Human Enhancement* (EPOCH) project funded by the European Commission's Seventh Framework Program – Science in Society, at *www.epochproject.com.*

[59] *La Repubblica*, 27th May 2019, *L'intelligenza artificiale scopre nuove mutazioni dell'autismo*, https://www.repubblica.it/salute/medicina-e-ricerca/2019/05/27/news/l_intelligenza_artificiale_scopre_nuove_mutazioni_dell_autismo-227347019/

performance[60]. As recognized by the European Parliament in its resolution on *a comprehensive European industrial policy on artificial intelligence and robotics* of 12 February 2019 there is a broad catalogue of possible applications of AI and robotics in medical care[61].

The importance of genetic research to improve health (or the right to access to health care) is recognised at the international level. The UNESCO Declaration affirms: «The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole»[62]. Similar international statements are reiterated and seem unequivocal. Firstly, health is an interest of the International Community as whole, thus it is protected by States. Secondly, the individual right to healthcare (with specific regards to genetic health practices) and even genetic confidentiality may find some limits in other individual or collective interests. The Oviedo Convention on Human Rights and Biomedicine and the additional Protocol concerning genetic testing for health purposes provide general principles and rules applying in this field[63].

Until recently, the individual was perceived as the vulnerable subject in biomedical research; thus, human rights in this field were considered as freedom-rights[64], protecting the individual's privacy and physical integrity and right to non-discrimination in medical health care[65]. More recently, the individual began to be considered as a partner in both scientific research and medical practice. In addition to freedom-rights, the claim-right to enjoy the benefits of science was invoked increasingly to access treatments and medicines[66].

According with Article 12 of the Convention any predictive genetic test is prohibited unless it would be only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling. This provision seems crucial as the autonomy of an individual may be limited using pressure to force him to undergo a predictive genetic test for other reasons than health, such as the containment of public health spending

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60 A quick test to make a diagnosis of Covid-19 thanks to artificial intelligence and the analysis of a patient's CT. This system used by the Bio-Medical Campus in Rome, has been taken directly from China and was tested on thousands of patients in Wuhan. This is the first evaluation of prognosis without the aid of a swab and which will therefore allow to have diagnoses in no time and without any need to have the patient present on site.

61 For example: «managing medical records and data, performing repetitive jobs (analysing tests, X-rays, CT scans, data entry), treatment design, digital consultation (such as medical consultation based on personal medical history and common medical knowledge), virtual nurses, medication management, drug creation, precision medicine (as genetics and genomics look for mutations and links to disease from the information in DNA), health monitoring and healthcare system analysis, among other applications». See the EUROPEAN PARLIAMENT *Comprehensive European industrial policy on artificial intelligence and robotics* of 12 February 2019, 2018/2088(INI)

62 Article 12, b)

63 See, amongst others, F. COSTAMAGNA, *Test genetici e tutela dei diritti fondamentali in Europa*, in L.S. ROSSI (edited by), *La protezione dei diritti fondamentali. Carta dei diritti UE e standards internazionali.* XV Convegno, Bologna, 10-11 June 2010, Naples, 2011, pp. 187- 211; D. MARRANI, *Genetica, tutela della salute e diritti umani: il Protocollo addizionale alla Convenzione di Oviedo relativo ai test genetici a fini medici*, in *La Comunità internazionale*, 2012, pp. 303-329.

64 The traditional human rights theory aimed at protecting the individual from the State *ingérence* is illustrated in the literature. See, among others, C. ZANGHÌ, L. PANELLA, *La protezione internazionale dei diritti dell'uomo*, Giappichelli, Turin, 2019; B. CONFORTI, *Diritto internazionale*, Naples, 2018; U. LEANZA-I. CARACCIOLO, *Il diritto internazionale: diritto per gli Stati e diritto per gli individui. Parti speciali*, Turin, 2010.

65 See C. CAMPIGLIO, *Il principio di non discriminazione genetica nella recente prassi internazionale*, in Venturini, Bariatti (Eds.), *Diritti individuali e giustizia internazionale.* Liber Fausto Pocar, Milano, 2009, p. 51 ff.

66 *Ibidem*, p. 248.

or private interests (for example insurance or labor). Similarly, Article 2 of the Protocol limits the object of the agreement to tests "which are carried out for health purposes",[67] excluding different situations which seem problematic such as genetic tests carried out on the human embryo or fetus (therefore, preimplantation (PGD) and prenatal genetic diagnosis (PND) are not covered)[68] and genetic tests carried out for research purposes[69].

In line with the ethical guidance which considers unjustified a genetic test for a disease for which there is still no therapy[70], genetic counseling seems to support freedom and autonomy in the individual's (informed) health choices[71]. Therefore, genetic counseling is at core of a very complex process designed to provide appropriate assistance to the person in relation to any possible personal, psychological and family implication of a genetic test[72]. In particular, the Protocol states that "appropriate genetic counseling" shall be available for the following genetic tests: tests predictive of a monogenic disease; tests serving to detect a genetic predisposition or genetic susceptibility to a disease; tests serving to identify the subject as a healthy carrier of a gene responsible for a disease. At this regard, the Explanatory Report illustrates that: «the predictive nature of the information obtained with tests covered, the emotional impact for the person concerned of knowing about a genetic risk, the possible implications for family members and the important decisions with which the person concerned may be faced, including where appropriate in relation to procreation choices, explain the importance of an appropriate genetic counselling for those tests».

The results of a genetic test undergone by an individual may be of some interest for genetic relatives, family members and the "genetic group"[73]. Such interests, however, may conflict with the right to know and the right not to know in genetic testing which are presented as a natural extension of individual autonomy (Art. 16 of the Protocol: «Everyone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test. The wish of a person not to be informed shall be respected»)[74].

It should be considered also that a genetic test may only be carried out after the person concerned has given free and informed consent to it (Article 9). However, the Protocol provides some exceptions to this general rule, for example to pursue the benefit of family

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[67] The Explanatory Report specifies that: "The Protocol covers any genetic test carried out for health purposes on a person whether living or dead (in the interests of the latter's family members), or on biological material of human origin. This includes diagnostic, predictive or healthy carrier tests as well as pharmacogenetic tests. Genetic tests offered in the framework of a genetic screening programme are also covered by the Protocol."

[68] On this issue, which is being examined at the Council of Europe's CDBI, see the *Background document on preimplantation and prenatal genetic testing*, CDBI/INF (2010) 6.

[69] However, Article 12 of the Convention also applies to predictive tests for health research purposes, and states that such tests may only be carried out subject to appropriate genetic counselling.

[70] See the Opinion of the Italian National Bioethics Committee, *Test genetici di suscettibilità e medicina personalizzata,* Rome, 12th July 2010.

[71] In this respect, genetic counselling is a valid tool to comply with the need of human supervision on AI processing of genetic data as well.

[72] See L. PALAZZANI-L. NEPI, *Gen-Ius. Consulenza genetica e normative europee*, Studium, Roma, 2012.

[73] A duty of the individual to inform relatives may be provided by certain European legal systems (for example the French system places the duty to initiate the family information process directly on the individual; see art. 1131 *Code de la santé publique*). On the other hand, a duty of the physician to warn relatives may derive from jurisprudence, as emerged in the US case law wherein the courts have recognized a duty to warn family members in the case of deceased persons where there was no explicit opposition before death (see, for example, *Safer v. Pack*, 677 A.2d 1188, *Super. Court NJ* 1996).

[74] On this issue, see further considerations developed at para. 2.

member(s), allowing a genetic test to be carried out on a person who does not have the capacity to consent, under specific conditions[75].

The discipline of the Protocol is aimed at protecting human rights when genetic testing is undergone for healthcare purposes, and applies also when AI is used to process genetic data for the same purposes. It can be argued that genetic counselling should be mandatory on healthcare decisions based on genetic testing, especially where automated decision is the result of aggregated data processing (healthcare information and lifestyle integrated with genetic data). This solution is consistent with an evolutive interpretation of the Protocol that considers the technological progress[76]. The same conclusion aimed at applying the Oviedo Convention and the Protocol to new technological challenges was raised by the Council of Europe with regards to the so-called genome editing technologies (such as CRISPR-Cas9)[77].

In addition, the risk of sorting patient into groups, with the result to make an algorithm decide on possible (and sometimes innovative) therapies and on the management of ongoing medical care may prove discriminatory without providing a specific human supervision. As scholars pointed out, there is a need to regulate this field, setting forth the principles at the global and European level and providing a "garant humain" operating in the main steps of the process, thus «permettant d'éviter que notre génome soit réduit à l'état d'une matière première pour algorithmes»[78].

This is the purpose of the European Commission's *Ethics Guidelines for Trustworthy AI* on the development of a lawful (complying with all laws and regulations), ethical (ensuring adherence to ethical principles and values) and robust (both from technical and social perspective, since AI systems, even with good intentions, can cause unintentional harm) AI. Importantly, the *Guidelines* recognize that general principles and rules should adapt to sector-specific AI (e.g. healthcare applications which are different from AI applications in other fields).

In February 2020, the European Commission adopted a *White Paper on Artificial Intelligence – A European approach to excellence and trust*[79] that follows the Communication *Artificial Intelligence for Europe* of 25 April 2018[80]. The White Paper suggests that any regulatory intervention in order to be proportionate should define clear criteria to «differentiate between the different AI applications, in particular in relation to the question whether or not they are "high risk"»[81]. In particular, the Commission explained that a given AI application should be considered high-risk considering both the sector and the intended use from the viewpoint of

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[75] See Article 13. The conditions are based on the purpose to obtain a preventive, diagnostic or therapeutic benefit to the family member, after an evaluation of the benefit for that person and the risk and burden for the person who is undergoing the test.

[76] On the evolutive treaty interpretation, see P. TURRINI, *Teoria e prassi dell'interpretazione evolutiva nel diritto internazionale*, Naples, 2019; C. DJEFFAL, *Static and Evolutive Treaty Interpretation: A Functional Reconstruction*, Cambridge, 2015.

[77] See the Statement on Genome Editing Technologies of 2 December 2015, DH-BIO/INF (2015) 13 final. As recognized in the Statement: « There is strong support for the better understanding of the causes of diseases and for future treatment and these technologies have considerable potential for research in this field and to improve human health. However, the application of genome editing technologies to human gametes or embryos raises many ethical, social and safety issues, particularly from any modification of the human genome which could be passed on to future generations».

[78] See D. GRUSON, *op. cit.*, p. 565.

[79] EUROPEAN COMMISSION, *White paper on Artificial Intelligence - A European approach to excellence and trust* of 19 February 2020, COM(2020) 65 final.

[80] COM(2018)237 final.

[81] See para. 5 C, p. 17.

«protection of safety, consumer rights and fundamental rights».[82] To this end, the Commission required the application of two cumulative criteria (related first to the given characteristics of the activities typically undertaken where «significant risks can be expected to occur»; second to the AI application in the sector in question that shall be «used in such a manner that significant risk are likely to arise»). For example, AI applications in healthcare could be especially considered "high risk" where certain conditions are met[83]. In the light of the above, genetics healthcare applications would specifically be considered as high risk sector as well.

4. *Balancing conflicting rights: the role of the European Courts*

The need to balancing different human rights related to the collection and the use of genetic information may find a solution before the two European Courts (ECtHR and CJEU). The case law is not so developed at this moment but it seems that prospectively the European Court of Human Rights will need to balance rights that are equally protected by both the ECHR and the Oviedo Convention. The possible access to genetic testing and the use of their results, recently boosted by AI, brings into play some fundamental values that can be expressed in the triad of health-autonomy-dignity. A conflict between self-determination (or autonomy) of the individual (whose right to freely choose whether to undergo a genetic test or not and to refuse to know the results may not be violated), and the interests of the "significant others" (as they may be justified to be informed, for health purposes, certain genetic characteristics of their relatives) may arise.

The mentioned rights and interests may find adequate protection based on certain rules of the ECHR. In particular, Art. 8 on the right to respect private and family life, with reference to the information on the nature and consequences of a genetic test, or the right to know one's biological origins and in relation to the confidentiality of genetic data. In addition, Art. 2 (right to life), Art. 3 (prohibition of inhuman and degrading treatment), Art. 10 (freedom of expression) and Art. 14 (no discrimination) seem also relevant in this context. The application of the proportionality principle to which the national Constitutional Courts also refer in similar balancing of rights and the relevant practice of the Courts must be considered. The following judgments and decisions may illustrate, as leading cases, the Court's balancing of conflicting rights in the situations where individual and collective interests are at stake[84].

In the *Marper* case[85] the ECtHR held that holding DNA samples of individuals who are arrested but later acquitted or have the charges against them dropped, is a violation of the right to privacy under the European Convention on Human Rights. The Court recognized that the wide range of information contained in cellular and genetic samples of an individual may also be of some interest for other subjects (the relatives of the offender,

[82] *Ivi.*

[83] In this perspective, the creation of a Common European health data space is a new step that may prove problematic although essential in the new strategic vision. See the European Commission Communication on *A European strategy for data* of 19 February 2020, COM(2020)66 final.

[84] See the Report *Bioethics and the case-law of the Court*, Council of Europe/European Court of Human Rights, 2012, available for downloading at www.echr.coe.int (Case-law – Case-Law Analysis –Research Reports).

[85] *S. and Marper v. the United Kingdom* [GC] (App. 30562/04 and 30566/044) judgment of 4 December 2008, *Reports judgments and decisions* 2008.

for example) and has stronger potential of future use. This implies stronger conditions of protection of the personal privacy. Thus the ECtHR affirmed that the retention and storage of genetic data fall under the provision of Article 8 ECHR and need a strong justification to be considered "necessary in a democratic society" and a proportionality judicial assessment[86].

In the *Van deer Velden* case[87] the Court acknowledged that the compilation and retention of a DNA profile serves the legitimate aims of the prevention of crime and the protection of the rights and freedoms of others. Thus, the Court "does not consider it unreasonable for the obligation to undergo DNA testing to be imposed on all persons who have been convicted of offences of a certain seriousness." Consequently, the applicant complained that the impugned measure infringed Article 8 of the Convention, in that it constituted an unjustified interference with his right to respect for his private life was considered ill-founded and was rejected. Similarly, in the *W. v. the Netherlands* case[88] the Court ruled on the retention of cellular material from applicant (being a minor) following juvenile detention in order to determine his DNA profile. Considering that the DNA material is stored anonymously and encoded, and that the applicant will only be confronted with his stored DNA record if he has previously committed another criminal offence or commits one in the future, the Court saw no reason to diverge from its findings in *Van der Velden* on the account of the mere fact that the applicant was a minor. Therefore, the Court dismissed the applicant's objection. Furtherly, in the *Costa & Pavan* case[89] the Court concluded that the applicants' decision to resort to *in vitro* fertilization ("IVF") and preimplantation diagnosis (PID) to ensure that their baby would not suffer from cystic fibrosis was a form of expression of their private and family life protected by Article 8 (respect for private and family life)[90]. The Court's judgment has been criticized due to the low protection of embryo life and the violation of internationally agreed protection for persons with disabilities[91].

Importantly, the further developments of the Council of Europe work on preimplantation and prenatal genetic testing seem crucial for a European common standard on this delicate issue[92]. Because the Protocol does not discipline this topic and the European

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[86] See the *Marper case*, § 88.

[87] *Van deer Velden v. The Netherlands* (App. 29514/05), decision of 7 December 2006, *Reports of Judgments and Decisions*, 2006-XV.

[88] *W. v. the Netherlands* (App. 20689/08) decision of 20 January 2009.

[89] *Costa e Pavan v. Italy* (App. 54270/10), judgment of 28 August 2012.

[90] The applicants complained that under the current laws in Italy, the only possibility for them to ensure that their child would not have cystic fibrosis would be to start a pregnancy by natural means and medically terminate it if the fetus tests positive for the disease. This, they claimed, amounted to discrimination as they were treated differently from sterile couples and couples where the man carried a sexually transmitted disease. It should be remembered that PID is generally outlawed in Italy (by Law n. 40/2004) except for a one-off 2010 decision by an Italian court that allowed a non-sterile couple to use the PID procedure because they were carriers of muscular atrophy (see the judgment of the Tribunal of Salerno of 13 January 2010). Furthermore, IVF is outlawed in Italy except for sterile couples and couples in which the man has a sexually transmitted disease.

[91] See the Catholic University of the Sacred Hearth Bioethics Center press release at: http://centridiateneo.unicatt.it/centro_di_ateneo_di_bioetica. This complex and delicate issue can not be examined in this context. The legal and ethical implications of preimplantation diagnosis in the Italian jurisdiction are reported in the literature. See, among others, S. LAROSA, *La diagnosi genetica preimpianto: un problema aperto*, in *Famiglia e diritto*, 2011, fasc. 8/9, pp. 839-851; M. CASINI, *Novità delle nuove linee guida rispetto al divieto di diagnosi genetica preimpianto?*, in *Medicina e morale*, 2008, Vol. 58, fasc. 3, pp. 597-604; A. SANTOSUOSSO, *Ancora su fecondazione assistita e diagnosi preimpianto* [Nota a Trib. Cagliari 24 settembre 2007], in *Questione giustizia*, Fasc. 6, 2007, pp. 1231-1239.

[92] See the *Background document on preimplantation and prenatal genetic testing*, DH-BIO/INF (2015) 6.

States have different regulations on this matter, the ECtHR and national courts have also an important role to play.

Finally, in the *Parrillo v. Italy* case[93], the Court, was called upon for the first time to rule on the donation to scientific research of embryos obtained from an in vitro fertilization. The Court held that Article 8 was applicable in this case under its "private life" aspect, as the embryos in question contained the applicant's genetic material and accordingly represented a constituent part of her identity. However, the Court considered at the outset that Italy was to be given a wide margin of appreciation on this sensitive question, as confirmed by the lack of a European consensus and the international texts on this subject. Noting, lastly that there was no evidence that the applicant's deceased partner would have wished to donate the embryos to medical research, the Court concluded that the ban established under Italian Law "no. 40/2004" had been necessary in a democratic society. Consequently, the Court held that there had been no violation of Article 8.

This short analysis shall not conclude without mentioning the possible outcomes of the EU accession to the ECHR[94], which can pave the way for accession of the European Union to the Oviedo Convention and its Additional Protocols as well. Besides the problems of the ongoing accession process, scholars pointed out that the European Union already grants an effective human rights protection[95]. Importantly, the Charter on Fundamental Rights refers in the Preamble, in addition to the constitutional traditions common to the Member States and the ECHR, to international obligations common to the Member States and the European Courts case law. Indeed, it is ascertained that the Oviedo Convention and the additional Protocols principles and rules are frequently invoked by national courts[96]. Thus, the protection of human dignity, human health and other HR, balanced with the autonomy principle, in relation to genetic practices possibly combined with AI in the near future, are progressively creating a common framework and specific standards of protection.

The importance of an evolutive interpretation of the European Convention on Human Rights (ECHR) to address new societal phenomena, as well as the principle that there must be effective protection in national law against human right abuses[97], has been underlined in the High-Level Conference held in Finland on 26-27 February 2019[98]. As evidenced, the ECHR «creates a positive obligation to protect against the damage caused by AI, and this

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[93] App. 46470/11, judgment of 27 August 2015., *Reports of Judgments and Decisions*, 2015-V.

[94] After the European Court of Justice expressed a negative opinion on 18 December 2014 (based on the need to preserve the specific characteristics of the EU and the EU law) further efforts are being deployed by the EU institutions to overcome these problems. The different steps of the accession process are summarized at: https://www.europarl.europa.eu/legislative-train/theme-area-of-justice-and-fundamental-rights/file-completion-of-eu-accession-to-the-echr

[95] See G. TESAURO, *Manuale di diritto dell'Unione europea* (edited by P. DE PAQUALE, F. FERRARO), Naples, 2018, pp. 157- 158.

[96] On this topic, see A. TANCREDI, *Genetica ed altre biotecnologie nel diritto comunitario ed europeo*, in *Ordine internazionale e valori etici,* VIII Convegno Verona, 26-27 June 2003, edited by N. BOSCHIERO, Naples, 2004, pp. 381-411, espec. p. 408 ff.

[97] At this regard, see *Malone v. the United Kingdom* (App. no. 8691/79), judgement of 2 August 1984, and more recently *Big Brother Watch and others v. the United Kingdom* (App. nos. 58170/13, 62322/14 and 24960/15), judgement of 13 September 2018; this judgment has not become final as the parties referred to the Grand Chamber on 4 February 2019.

[98] COUNCIL OF EUROPE, *High-Level Conference Governing the Game Changer – Impacts of artificial intelligence development on human rights, democracy and the rule of law*, Helsinki, Finland, 26- 27 February 2019. See the *Conclusions* and *Conference Report*.

extends to damage caused by private actors»[99]. The challenge is, therefore, to provide adequate safeguards through national legislation that complies with international conventions on human rights and sector specific recommendations, further developing the debate according with a multi-stakeholder approach.

5. *Concluding remarks*

The advent of AI has been defined as a "game changer" affecting the national and international legal order[100]. In this context, the multidisciplinary debate on AI development ongoing within the international organizations aims to modelling the discipline in accordance with the human rights protection. Managing the benefits and risks of AI in connection to genetics, not only is built on the former practice established in the field of genetics and human rights at the international level, as argued in this paper, but requires also to rely much on the role of the individual and groups in international law[101].

The Declaration recognizes the individual as depositary of the genetic heritage of the human species. In this respect, scholars referred to "collectivizing moments" whereby the individual "is protected as part of the whole"[102]. This construction goes beyond the traditional model where the "individualizing moments" are established through new forms of protection of human rights, namely genetic counseling for the protection of the right to know, and anonymization of data for the protection of the right to confidentiality. In "collectivizing moments" human rights are recognized with a trans-temporal approach. Thus, the protection is realized through "old" human rights tools (e.g. the principle of non-discrimination and the prohibition of practices contrary to human dignity).

In this context, the importance of general principles and values, especially within the European Union legal order where the Court of Justice can effectively recognize and promote the citizens' rights[103], may fill the gaps of the regulation that is being progressively adopted in the field of AI. The controversial debate around the principle of genetic non-discrimination is paradigmatic in this sense. The scholars' critics on the weakness of this right was supported by various legal arguments (one of the main critics concerns the fact that the EU Charter on fundamental rights, and thus art. 21, only applies to the EU Institutions and not to private actors in their relationships)[104], may be overcome where recognizing non-discrimination as a general principle of the EU law[105]. Consequently, such general principle

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[99] See the wording of former Judge at the European Court of Human Rights Paul Mahoney in the *Conference Report*, p. 13.

[100] See footnote 98.

[101] This aspect, along with the increasing relevance of different sources of soft regulation in the field of AI, such as international guidelines, ethical frameworks, private codes of conduct and other autoregulation tools are constructively modelling the international discipline on AI. On the ethical concerns, the "Rome Call for AI Ethics" (see footnote 6) aims to set forth ethical standards for the development of AI. With this purpose, the call lays out six main principles: transparency, inclusion, responsibility, impartiality, reliability, security and privacy. The call urges policymakers across the world to create new forms of regulation on "advanced technologies that have a higher risk of impacting human rights".

[102] See H. BOUSSARD, *cit.*, p. 271.

[103] A. TANCREDI, *cit.*, p. 409- 410.

[104] See above at para. 2.

[105] See F. COSTAMAGNA, *cit.*, p. 206- 207.

may be applied to the possible discriminatory practices affecting groups of individuals sorted by algorithm processing of personal/health/genetics data.

A new model of protection of individual and/or collective interests crossing over time and space may also be achieved through deliberative democracy, for example where citizens are asked to express their point of view on genetic screenings for hereditary genetic diseases[106]. The awareness on similar questions and the capacity to take responsible actions may avoid complex and delicate issues that could turn controversial.

The participatory model can make the most when considering the interplay between genetics and AI, particularly in the field of innovative diagnostics and/or therapy that may improve health. With regards to AI, the guidance for developers, manufacturers and service providers adopted by the Council of Europe encourages member States to adopt: «Participatory forms of risk assessment, based on the active engagement of the individuals and groups potentially affected by AI applications»[107]. Similarly, the guidance for legislators and policy makers suggests that: «Individuals, groups, and other stakeholders should be informed and actively involved in the debate on what role AI should play in shaping social dynamics, and in decision-making processes affecting them»[108].

The development of AI is still at its beginning and implies some degree of uncertainty, but the strong engagement of the international organisations, especially at the European level, will help to build a human-centered AI.

[106] See R. SATOLLI, *Una Giuria sui Test Genetici*, in *Corriere della Sera* of 20 May 2012.
[107] See footnote n. 44, especially *II. Guidance for developers, manufacturers and service providers*, para. 7
[108] *III. Guidance for legislators and policy makers*, para. 8.