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The Protection of Human Genetic Information in the EU: Ethical, Constitutional and Criminal Law Aspects

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Abstract

The European Union has achieved a significant milestone through the widespread implementation of genomic and postgenomic technologies in diverse fields including personalized and regenerative medicine, immunology, nutrition practices, sports medicine, and the wellness industry. This article revolves around the practical application of genomics and EU bioethics, with a specific emphasis on investigating the cutting-edge legal methodologies referred to as Lex Genetica and Legal Biotech.

The European Union market for genomic research is presently experiencing significant and swift expansion, coupled with ongoing progress and effective integration of genetic technologies. Consequently, there exists a pressing necessity to strengthen legal protections and guarantees, specifically concerning the privacy of human genomic information, within the domain of EU criminal legislation.

Within the framework of Horizon Europe, a funding program dedicated to research and innovation, the European Union (EU) prioritizes three pillars, with one specifically focused on tackling global challenges and augmenting the competitiveness of European industries. The "health" cluster within this pillar underscores the significance of advancing healthcare technologies, reducing health hazards, protecting communities, and fostering the welfare of individuals. Genomic research harbors immense possibilities in achieving these aims and has emerged as one of the most pioneering and groundbreaking fields in recent years. This paper aims to complement prior publications by offering an updated analysis of selected topics since 2018.

The urgency of legal regulations for all the accompanying processes becomes evident within the global roll-out of postgenomic technologies and the pan-European tendency to move from fundamental exploratory research to the practical application of omics technologies in the EU (the study of genome, proteome, and metabolome).

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Numerous jurisdictions in the EU provide for gene-related offenses, including cloning, modifying the human germ line, and dispersing GMOs without appropriate authorizations. However, the specific offenses vary in the EU countries to a large degree.

Keywords: European legislation, genetic privacy, genomic research, bioethics, genetic big data, somatic rights

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Защита генетической информации человека в ЕС: этические, конституционные и уголовно-правовые аспекты

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Аннотация

Европейский союз достиг значительных успехов в персонализированной и регенеративной медицине, иммунологии, практиках питания, спортивной медицине и индустрии здоровья благодаря широкому внедрению геномных и постгеномных технологий в этих областях. В этой статье анализируется практическое применение геномики и биоэтики ЕС с особым упором на исследование передовых юридических методологий, таких как Lex Genetica и Legal Biotech.

Рынок геномных исследований ЕС быстро расширяется наряду с постоянным прогрессом и эффективной интеграцией генетических технологий. Следовательно, существует острая необходимость усилить правовую защиту и гарантии в сфере уголовного законодательства ЕС, особенно в отношении конфиденциальности геномной информации человека.

Актуальность правового регулирования всех сопутствующих процессов стала очевидной в условиях глобального внедрения постгеномных технологий и общеевропейской тенденции перехода от фундаментальных поисковых исследований к практическому применению «омик»-технологий в ЕС (т.е. изучение генома, протеома и метаболитов).

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Во многих юрисдикциях ЕС предусмотрены преступления, связанные с генетическими технологиями, включая клонирование, изменение зародышевой линии человека и распространение ГМО без соответствующих разрешений. Однако конкретные правонарушения в странах ЕС в значительной степени различаются.

Ключевые слова: европейское законодательство, генетическая конфиденциальность, геномные исследования, биоэтика, большие генетические данные, соматические права

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The new ethical dilemma of genomics and biopolitics in the EU

Currently, the EU countries are implementing projects aimed at collecting, researching, storing, and transmitting human genetic information with the subsequent application of the acquired data in everyday life. New technologies and developments in the field of the human genome have been widely introduced in such areas as medicine, pharmaceuticals, industrial biotechnologies, agriculture, and forensics. The development of omics sciences, e.g. genomics, has led to the accumulation of large arrays of complex data (Big Data). This leads to a closer interaction of legal protection mechanisms with bioinformatics and biostatistics.

The application of genomic sequencing technology in a number of contexts is continuing to grow: ranging from the detection of crime to the identification of the causes of disease. In this regard, there is increasing interest around the use of CRISPR-Cas9 DNA editing technologies, enabling precise cutting and pasting of DNA by specialized proteins (Angers et al., 2018).

While genomic technologies and genetic engineering are developing, EU countries are looking for new ways and methods to ensure the biosafety of both individuals and society as a whole. The European community is becoming more aware of the need to effectively protect constitutional and civil human rights against the backdrop of scientific studies and their subsequent application.

The legal regulation goes hand in hand with the patenting procedure. For example, the EU has approved the MammaPrint test developed by the Agendia, Inc. (Netherlands). The test analyzes 70 genes associated with breast cancer using the patient's tumor tissue and a DNA microarray. In this regard, there is a need to develop uniform EU rules on the registration, validation, and examination of the safety, quality, and efficiency of such testing methods, as well as to evaluate their potential risks. This raises the ethical question of whether it is acceptable to allow the patenting of genes in the EU. The prob-

lem is that a scientific product is usually patented when it becomes a commodity.

In addition to the legal issues, genomic studies deal with a number of social, ethical, and moral conflicts. After all, the undeniable advantages of such studies are often associated with potential risks for human health, society, and the environment. Nowadays, the bioethical aspects and moral dilemmas of genetic screening include: data privacy protection or disclosure of information for the sake of biosafety; personal choice or coercion of citizens; voluntary or mandatory screening; discrimination and stigmatization based on genetic characteristics. Effective ethical and legal ways need to be developed, in order to resolve the problems arising from the introduction of genetic data-based personalized medicine technologies into medical practices. The bioethical principle of justice together with the classical 'do-no-harm' principle also needs to be observed, since knowing too much about a person's genome can be harmful (Furrow, Greaney, Johnson, Jost, & Schwartz, 2013).

High-throughput genomic technologies consisting of whole-exome and whole-genome sequencing pose substantial challenges regarding clinical utility, interpretation of results, detection of variants of unknown clinical significance, and incidental findings, including a variety of ethical issues (Burton, Cole, & Lucassen, 2012).

Notable genome-related achievements and rapidly developing genetic engineering and genome editing technologies have been a source of continued concern to the international community (Kohn, Porteus, & Scharenberg, 2016). It should be noted that the outstanding scientists in this field have suspended their research work, in order to appeal to government agencies and specialized ethics organizations with a request to develop a set of legal, ethical, and technical standards for genomic studies in the EU (Soini et al., 2006).

In 1991, the European Group on Ethics in Science and New Technologies (EGE) was established within the framework of the European Commission. Its work is related to the issues of human genome editing, the use of artificial intelligence, and potential challenges to humanity (Commission Decision (EU) 2021/156)[1].

In May 2021, the EGE submitted a document (the Statement) entitled 'Values for the Future: the Role of Ethics in European and Global Governance' with the following concepts: 'design for values', 'value-sensitive design', and 'ethics by design'. These concepts are mentioned in the context of policy and regulation of 'privacy by design' in data protection and 'transparency and fairness by design' in AI governance. EGE experts believe that this approach needs to be an integral part of European education, production, monitoring, and governance of innovation and new technologies. 'The Statement highlights the role of moral values and proposes central and proactive involvement of ethics in governance in Europe and the world. It also brings to light the connections between ethics and fundamental rights, democracy, and the rule of law, concluding with a recommendation for the EU to maximize opportunities for public participation in policymaking' (European Commission, 2021). A very important factor in the legal regulation of the EU is the WHO instrument entitled

[1] EUR-Lex (2021). Commission Decision (EU) 2021/156 of 9 February 2021 renewing the mandate of the European Group on Ethics in Science and New Technologies. Available at: Available at: https://eur-lex.europa.eu/eli/dec/2021/156/oj

'Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services' which covers ethical issues of medical genetics (World Health Organization, 1997).

Taking into account the rapid progress in genomic developments, this sphere of legal regulation is subject to constant transformations (Travieso, Ferraro, Trikoz, & Gulyaeva, 2021). Thus, every year we see not only new trends in human genome research but also the expansion of legal regulation boundaries. Therefore, there is a need for legal research and the subsequent formation of a special regulatory environment, i.e. genome law (Yastrebova & Gulyaeva, 2021).

EU constitutional law on genome protection and genetic data privacy

The human rights theory is giving rise to a new fourth and fifth generations of human rights. The fourth generation of human rights started to develop at the end of the 20th century. According to Rudinskiy (2006), a prominent researcher of the issue of human rights and freedoms, these rights are designed to protect a person from threats associated with experiments in the field of genetic inheritance, i.e. these are human rights that are associated with cloning and other biological discoveries. When people violate divine, spiritual, and moral laws, as well as human rights of the fourth and fifth generations, such violations provoke universal crimes, although they are not fixed in national criminal legislation.

Some experts incorporate somatic rights, genetic rights, the right to access personal data, the right to be forgotten, the right not to know and not to be informed, the right to correct and clarify personal data, etc. in the fourth-generation human rights. The new achievements of the fourth industrial revolution in the field of medicine and genetic engineering (e.g. ZFN, CRISPR, Antisense, TALEN, etc.) provide a lot of benefits aimed at protecting human health. However, questions arise concerning the personal rights of each citizen, public health (Leenen, Pinet, & Prims, 1986), and the principles of humanity and genetic privacy (Clayton, Evans, Hazel, & Rothstein, 2019).

In this connection, SDG 3 'Good Health and Well-Being' is of most interest among the 17 UN Sustainable Development Goals (SDGs). This Goal deals with ensuring healthy lives and promoting well-being for all at all ages. One of the 13 targets within SDG 3 is ensuring universal access to sexual and reproductive health care services, including services for family planning.

According to WHO definitions, genetics is the study of heredity, functioning, and composition of the single gene, while genomics is the study of all genes, their interrelationships and functions, as well as related techniques in order to identify their combined influence on the growth and development of the organism.

According to the European Bioinformatics Institute, 'genomics is the study of whole genomes of organisms and incorporates elements from genetics and it differs from "classical genetics" in that it considers an organism's full complement of hereditary material, rather than one gene or one gene product at a time'.

In the EU, the fundamental right to preserve human life and health is interpreted as the right which includes legal protection of the genome (a set of all genes) of the person and the genome of his/her successors, in order to preserve the genetic health of the person and his/her descendants (Trikoz & Gulyaeva, 2018).

Moreover, the European Commission interprets the concept of 'genetic testing' quite

broadly. Genetic testing is understood as any test that yields genetic data or, in general, genetic information about heritable characteristics of individuals obtained by analysis of nucleic acids or any other material (McNally et al., 2004).

In March 2012, an interdisciplinary workshop was held, involving representatives of both professional societies: the European Society of Human Genetics and European Society of Human Reproduction and Embryology. The workshop also included experts from the European Union Eurogentest Coordination Action Project, to discuss developments at the interface between clinical genetics and assisted reproductive technology.

Framework for the human genome protection in the Council of Europe documents and the soft law

The Council of Europe 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 (ETS No. 164) was adopted by the participating States in Oviedo (Spain) on 4 April 1996, and came into force on 1 December 1999 (Council, 1997). Pursuant to this Convention, it is important to obtain and secure the person's consent for medical intervention and donorship as well as transplantation of human cells, tissues, organs, genetic studies of the brain, and the use of information technologies in this area, including in the processing of Big Data.

This Convention is the only international legally binding instrument on the protection of human rights in the biomedical and genomic field. It is aimed at ensuring respect for human rights in the context of the technological revolution and securing the rights of patients by creating their updated code.

Today, only 17 EU Member States have fully ratified this Convention (Greece, Slovenia, and Slovakia in 1998, Spain and Denmark in 1999, Portugal, Romania, and the Czech Republic in 2001, Hungary, Cyprus, Lithuania, and Estonia in 2002, Bulgaria and Croatia in 2003, Finland in 2009, Latvia in 2010, and France in 2011). However, 5 Member States have not signed it (Austria, Belgium, Germany, Ireland, and Malta); and 5 States have signed but not ratified it (Italy, Luxembourg, the Netherlands, and Sweden in 1997, Poland in 1999).

The most innovative legal regulation of the human genome at the time when the Convention was adopted was enshrined in Chapter IV 'Human genome' (Articles 11-14). It deals specifically with daily medical practice, biomedical research, genetics, and transplantation of organs and tissues. Thus, Article 13 of the Convention 'Interventions on the human genome' addresses issues about genetic enhancement or germline genetic engineering by limiting the purposes of any intervention on the human genome, including research, prevention, diagnosis, or therapy. It prohibits any intervention aimed at introducing a modification in the genome of any descendants. This article was also guided by the greater possibility to intervene on and control genetic characteristics of human beings, raising concern about possible misuse and abuses.

In addition, the Committee of Ministers of the Council of Europe approved four Additional Protocols on specific subjects: on the Prohibition of Cloning Human Beings (CETS – No. 168) 1998, concerning Transplantation of Organs and Tissues of Human Origin (CETS – No. 186) 2002, concerning

Biomedical Research (CETS – No. 195) 2005, concerning Genetic Testing for Health Purposes (CETS – No. 203) 2008, the most innovative of which is about genetic testing. It was enforced quite recently (on July 1, 2018). The Protocol sets out principles relating to the quality of genetic services, prior information and consent, genetic counseling, and genetic screening. For the first time at the international level, this Protocol deals with directly accessible genetic tests, covering the protection of private life and the right to information collected through genetic testing. However, of all the EU Member States only Portugal, Slovenia, and the Czech Republic have ratified it.

In the light of the principles laid down in the Oviedo Convention (Committee on Bioethics, 2015), the Committee on Bioethics of the Council of Europe (DH-BIO) has agreed, as part of its mandate, to examine the ethical and legal challenges raised by these emerging genome editing technologies.

In accordance with its 'Statement on genome editing technologies' adopted in December 2015 and its Strategic Action Plan on Human Rights and Technologies in Biomedicine (2020–2025), the Committee on Bioethics examined Article 13 of the Oviedo Convention in the light of developments in human genome editing. Taking into account the technical and scientific aspects of these developments, as well as the ethical issues they raise, it concluded that the conditions were not met for a modification of the provisions of Article 13. However, the Committee agreed on the need to provide clarifications, in particular on the terms such as 'preventive, diagnostic and therapeutic' and to avoid misinterpretation of the applicability of this provision to research.

However, data derived from genetic sources should not be used in ways which disadvantage or discriminate unfairly against individuals, families, or groups in either clinical or non-clinical contexts, including employment, insurance, and access to social integration and opportunities for general well-being (European Commission, 2009).

Instruments adopted by the Committee of Ministers of the Council of Europe, but not legally binding for the EU countries, include the Recommendation on xenotransplantation, the Recommendation concerning the protection of human rights and dignity of persons with a mental disorder, the Recommendation on research on biological materials of human origin, and the Recommendation on genetic testing and screening for health care purposes.

In the EU, the doctrinal regulation of the genetic information flow is governed either by the various instruments adopted by the UN agencies (WHO, UNESCO, etc.) or by professional healthcare and bioethics organizations (the World Medical Association, the Council for International Organizations of Medical Sciences, the European Group on Ethics in Science and New Technologies, the European Bioinformatics Community, the European Bioinformatics Institute (EMBL-EBI), the European Society of Human Genetics, the European Society of Human Reproduction and Embryology, etc.).

At the national level, there are different depths of regulation relevant to genetics in certain jurisdictions of the EU Member States. Although Switzerland is not a member of the EU, the Swiss approach has the most comprehensive coverage of issues related to genetics and embryonic research (e.g. The Swiss Federal Act on Research

Involving Embryonic Stem Cells (2003)[2]; The Federal Act on Human Genetic Testing (2004[3]; The Federal Act on Research Involving Human Beings (2011)[4]). The Federal Constitution of the Swiss Confederation (1999)[5] has three Articles devoted to reproductive medicine and human genetic engineering (Articles 119, 119-A, and 120) (Zakharova, 2019). The Constitution states that all forms of cloning and interference with the genetic material of human reproductive cells and embryos are unlawful. Non-human reproductive and genetic material may neither be introduced into nor combined with human reproductive material. The procedures for medically assisted reproduction cannot be used exclusively, in order to conceive a child with specific characteristics or for further research. No more human egg cells may be developed into embryos outside a woman's body other than required for medically assisted reproduction. The genetic material of a person may be analyzed, registered, or made public, only with the consent of the person concerned or if the law so provides. At the same time, every person shall have access to data relating to their ancestry (Article 119 (2) a–g).

The Swiss Federal Human Research Act (2011)[6] contains basic legal definitions: 1) 'health-related personal data' which means information concerning the health or disease of a specific or identifiable person, including genetic data; 2) 'genetic data' described as information on a person's genes, obtained by genetic testing; 3) 'anonymized biological material and anonymized health-related data' summarized as biological material and health-related data which cannot (without disproportionate effort) be traced to a specific person. Further use may be made of biological material and genetic data in uncoded form for a research project, if informed consent has been given by the person concerned, or by the legal representative or next of kin. Biological material and genetic data may be anonymized for research purposes, if the person concerned or the legal representative or next of kin has been informed in advance and has not dissented to anonymization (Article 32).

Six European countries have adopted bespoke genetic research laws which engage deeply with the issues of embryo research and genetic testing, prohibitions on germ-line alterations (Portugal, Hungary, Estonia, Latvia, Lithuania, and Norway) (Trikoz, Mustafina-Bredihina, & Gulyaeva, 2021). Amendment to the Constitution of the Portuguese Republic in 1997 mandated regulation of access to medically assisted procreation techniques 'in such a way as to safeguard the dignity of the human person' (para. 2(e) Article 67).

[2] Swiss Confederation (2003). Federal Act on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA) of 19 December 2003 (Status as of 1 July 2023). Available at: https://www.fedlex.admin.ch/eli/cc/2005/104/en

[3] Swiss Confederation (2004). Federal Act on Human Genetic Testing (HGTA) of 8 October 2004 (Status as of 1 January 2014). Available at: https://www.fedlex.admin.ch/eli/cc/2007/131/en

[4] Swiss Confederation (2011) Federal Act on Research involving Human Beings (Human Research Act, HRA) of 30 September 2011 (Status as of 1 January 2014). Available at: https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2013/617/20140101/en/pdf-a/fedlex-data-ad-min-ch-eli-cc-2013-617-20140101-en-pdf-a.pdf

[5] Swiss Confederation (1999). Federal Constitution of the Swiss Confederation of 18 April 1999 (Status as of 13 February 2022). Available at: https://www.fedlex.admin.ch/eli/cc/1999/404/en

[6] Swiss Confederation (2011). Federal Act on Research involving Human Beings (Human Research Act, HRA) of 30 September 2011 (Status as of 1 September 2023). Available at: https://www.fedlex.admin.ch/eli/cc/2013/617/en

Another six EU countries have only a few legislative instruments relating to genetics and they focus mainly on the environment and GMOs (Greece, Bulgaria, Ireland, Poland, Slovakia, and the Czech Republic) (Trikoz & Gulyaeva, 2021).

Genetic responsibility and confidentiality of genomic data in the EU

In the context of the fourth technological revolution, the importance of personal data protection in the field of human genome research in the regional and national jurisdictions of the EU Member States as well as in the European cyberspace (Danelyan & Gulyaeva, 2020) needs to be addressed.

Biological and medical research, together with developments in the field of biotechnologies, has led to impressive achievements in health care. However, these achievements have given rise to ethical issues which affect the protection of human rights and dignity in the field of genetics, transplantation of human organs, tissues, and embryos. This is also true for the creation of national and personalized biobanks, the use of modern technologies for building health databases, etc. This calls not only for positive legal regulation but also for public discussions of so-called 'genetic responsibility'.

The moral concept of 'genetic responsibility' (GR) is relatively new in the EU. It has been associated with a gradual responsibilization in health care (Leefmann, Schaper, & Schicktanz, 2017). The concept was formed within the discussion on genetic testing in the 1970s. The term 'genetic responsibility' was introduced by M. Lipkin and R. T. Rowley in favor of reproductive and positive eugenic considerations from a collective responsibility point of view, and to act 'responsibly' towards the next generations by avoiding the inheritance of diseases (Lipkin & Rowley, 1974).

The phenomenon of 'responsibility' has a broad range of conceptual and historical meanings in bioethics (Schicktanz & Schweda, 2012). In the 2000s, the concept of 'genetic responsibility' was closely linked to the concept of the biopolitical impact and 'genetic thought style' on conceptualizations of the self and its relation toward the sociopolitical realm (Lemke, 2006; Denisenko & Trikoz, 2020).

International instruments and current European regulations recognize that every person has the right to medical and genetic information about himself/herself, as well as the right not to know it. However, the medical professional community, employers, and ordinary people do not always agree on the issue of genetic responsibility.

Not so long ago, a comparative study was conducted among German and Israeli residents with the goal of studying their moral attitude to the issues of genetic responsibility. Three main aspects of this responsibility were considered, namely: 1) self-responsibility, 2) responsibility for kin, and 3) the responsibility of society towards its members. The ethnic and cultural differences in the responses of German and Israeli respondents showed serious discrepancies. A moral conflict was revealed between the right to confidentiality and the moral duty to inform relatives of genetic information (responsibility for kin). Also, there were disagreements on the more personal issue of the right not to know genetic information about oneself combined with the duty to know and make a responsible decision (self-responsibility). As a result, the study showed that the moral assessments of Israelis were more focused on public interests. German residents were

mostly concerned about individual rights and interests (Raz & Schicktanz, 2009).

In the European Union, general medical and genetic data is considered personal and confidential. This status was legally defined in the Regulation 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. The same meaning of genetic data is stated in the UN instruments. In particular, the WHO defines it as confidential personal information of a special socio-psychological and medical nature, important not only for the patient himself/herself but also for a wide range of his/her relatives (Wertz, Fletcher, & Berg, 2003).

According to the Guidelines for Quality Assurance in Molecular Genetic Testing of the OECD (2007), preimplantation genetic diagnosis and genetic screening should be reported by accredited laboratories or equivalent accreditation schemes to the International Standards Organization (ISO 15189, 2012)[7].

At the level of the Council of Europe, the relevant provisions of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms are interpreted by the European Court of Human Rights. The Court has repeatedly acknowledged that the protection of personal data, including medical and genetic information, is crucial to the implementation of the right to respect for private and family life. The requirement to respect the confidentiality of health data is a fundamental principle in all legal systems of the Parties to the Convention. It has also been observed that the disclosure of medical data can seriously affect a person's personal and family life, as well as his/her social position and reputation at work, exposing a person to the risk of ostracism (Trikoz & Gulyaeva, 2018).

The Council of Europe has established stricter rules for the processing of personal information related to human genes. In particular, the issue is covered in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of January 28, 1981[8]. The Convention contains requirements for the principles of proportionality, transparency, minimization, and legality of the collection, processing, and storage of personal data, as well as privacy by design and data protection during data processing, among other things for reasons of national security. Exceptions and restrictions are possible in accordance with the provisions of the Convention under independent control and supervision. This instrument also introduces a new category of sensitive data. This is genetic data, biometric data, and data on the ethnic origin of a person. Under Convention Article 7 'Data security, appropriate security measures shall be taken for the protection of personal data stored in automated data files against accidental or unauthorized destruction or accidental loss, as well as against unauthorized access, alteration, or dissemination. In addition, the Convention introduces the obligation for personal data operators to notify the authorized superviso-

[7] International Organization for Standardization (2022). ISO 15189:2022. Medical laboratories — Requirements for quality and competence. Available at: https://www.iso.org/standard/76677.html

[8] Council of Europe (1981). Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data. Available at: https://rm.coe.int/1680078b37

ry authority about data leaks, and establishes clear legal procedures for cross-border data flows, as well as the obligation for authorities to report data violations.

Through the Amendments (ETS No. 108) approved by the Committee of Ministers in Strasbourg on June 15, 1999, the Convention was updated to meet the challenges of the new time and ensure more effective protection of new human rights (FRA and Council of Europe, 2018).

The Protocol to the Convention provides a reliable, flexible, and multilateral legal framework to facilitate cross-border data flow with effective personal data guarantees. The document serves as a 'bridge' between various legal systems in the world, including the new legislation of the European Union.

The EU also has to comply with Regulation 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). Under Article 4 of the Regulation, 'processing' means any operation or set of operations performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Previously enforced Directive 2006/24/EC[9] of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks (Data Retention Directive) has been revoked. On 8 April 2014, the Court of Justice of the European Union in its Judgments C-293/12 and C-594/12 declared the Directive invalid, since its provisions contradicted the important principle of European law, proclaiming proportionality of limits on the exercise of fundamental rights (Dupan et al., 2016).

The EU pays special attention to the legal regulation of metadata processing as a tool for classifying, organizing, and characterizing data or content (so-called 'data about data') (Nadkarni, 2011). This includes traffic data, and location-based data, etc. According to interstate standard DIN ISO/IEC 17788-2014[10], 'data about data' is classified as 'cloud service derived data' managed by a cloud computing service provider and received by the consumer of the cloud computing service through interaction with the cloud computing service. Cloud service derived data includes an event log with the information about who used the service, at what time, what functions and data types were involved, etc. There is also information

[9] EUR-Lex (2006). Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells. Available at: https://eur-lex.europa.eu/eli/dir/2006/17/2012-12-17

[10] European Standards (2016). DIN ISO/IEC 17788-2014. Information technology – Cloud computing – Overview and vocabulary. Available at: https://www.en-standard.eu/din-iso-iec-17788-information-technology-cloud-computing-overview-and-vocabulary-iso-iec-17788-2014/

about the number of authorized users and their IDs.

When assessing the appropriate protection of personal data of third countries within the European Union Regulation 2016/679, the assessors take into account the country's participation in the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, as well as participation in multilateral or regional systems for the protection of personal data and compliance with international obligations. The information comes from paragraph 105 of the General Data Protection Regulation (GDPR) Preamble.

Under Articles 28 (3) and 28 (9) of the GDPR, a contract for the use of a cloud computing service (concluded in writing or electronically) must set out the subject-matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller in order to ensure data protection.

Chapter V entitled 'Transfer of personal data to third countries or international organizations' of the GDPR defines the procedure for cross-border transfer of personal data outside the European Union. For example, under Article 45 of the GDPR, cross-border transfer may take place in cases where the Commission has decided that the third country, a territory, or one or more specified sectors within that third country, or the international organization in question ensures an adequate level of protection. Moreover, such a transfer does not require any specific authorization.

Other directives of the European Union include: the EU Directive 98/79/EC33[11] on in vitro diagnostic medical devices, the EU Tissue and Cells Directive 2004/23/EC[12], and the supplementing technical EU Directives 2006/17/EC and 2006/86/EC, which have led to new safety and quality standards for clinical and laboratory procedures performed within in vitro fertilization. Most European countries already transposed them into their respective national legislations about testing, processing, storage, distribution, and import/export of reproductive cells and tissues (Harper et al., 2014). Certain national gene technology acts in EU-countries are based on EU Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and on Directive 2009/41/EC on the contained use of genetically modified micro-organisms (the former Directive 90/219/EEC).

A number of EU jurisdictions provide for specific DNA databases used in criminal justice systems. These are usually designed to store DNA profiles for the identification of suspects and convicts in criminal investigations and proceedings. For example, the Portuguese Law on the DNA Profile Database – Civil and Criminal Identification (2008) establishes a DNA profile database for both criminal and civil litigation (Angers et al.,

[11] EUR-Lex (1998). Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31998L0079

[12] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Available at: https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX-%3A32004L0023

2018). In Spain, the Law on Assisted Human Reproduction Techniques (2006)[13] and the Law on Biomedical Research (2007)[14] set out that the donation of gametes and pre-embryos for the purposes authorized by this act is non-remunerative, formal, confidential, and with mutual agreement between the donor and the authorized center. The donation has to be anonymous, and gamete banks must guarantee the confident donor's identity. Individuals born as a result of assisted reproduction have the right to obtain general information about donors, but not their identities.

Criminal responsibility in cases concerning the protection of genetic data and genomic manipulation in the EU

The European Union and individual Member States are currently introducing criminal law regulations for the protection of personal genetic data from illegal use or forgery, from making changes to the human genome, modifying the progeny genome (the germ line), or the use of potentially harmful somatic gene therapies, in particular, through the use of CRISPR technologies.

Member States are required to refer to the Oviedo Convention, the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, the MEDICRIME Convention, and the Convention on Cybercrime. In addition, the European Charter of Patients' Rights (ECPR) represents the basic rights of patients in the field of health care.

In many jurisdictions of the EU countries, violation of a prohibition on the genetic modification of the human germ line can entail prosecution. Some States do not prohibit such gene changes but they are limited only for prevention, diagnosis, or treatment provided that the goal of this genetic modification is not to change the human germ line. The criminal law prohibitions extant in certain jurisdictions of the European Union should be considered in this context.

In Germany, the section 5 of the Embryo Protection Act (1990) strictly prohibits the alteration of the human germ line any breaches of the provision are punishable by a custodial sentence of up to 5 years. Anyone who attempts to fertilize a human egg cell artificially with a sperm cell selected for the sex chromosome contained in it, will be punished with up to one years' imprisonment or a fine. This does not apply when the selection of a sperm cell is made by a doctor, in order to preserve the child from falling ill with Duchenne-type muscular dystrophy or a similarly severe sex-linked genetic illness (sec. 3). Anyone who causes a human embryo artificially to develop with the same genetic information as another embryo, fetus, human being, or deceased person, or likewise anyone transfers into a woman such embryo, or any attempt to undertake cloning will be punished with a custodial sentence of up to five years or a fine (sec. 6) (Bundestag, 1990). The German Code of Criminal Procedure (1987)[15] lim-

[13] Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida [Law No. 14/2006 of May 26 'On Assisted Human Reproduction Techniques']. (2006). Revista de derecho y genoma humano = Law and the human genome review, (24), 221–249. Available at: https://pubmed.ncbi.nlm.nih.gov/17124978/

[14] Juan Carlos I, King of Spain (2007). Law 14/2007, of 3 July, on Biomedical Research. Available at: https://www.isciiies/QueHacemos/Financiacion/solicitudes/Documents/SpanishLawonBiomedicalResearchEnglish.pdf

its the scope of genetic analysis which can be performed on samples, provides for how DNA is to be used in the context of criminal investigations, specifies how DNA samples can be collected and when consent for collection is not necessary.

In Spain, the Criminal Code (1995)[16] creates several offenses relating to genetic information modification. It is prohibited to fertilize human eggs for any purpose other than for human reproduction and this provision carries a custodial sentence. So, according to sec. 159, genetic modification in humans is prohibited for all purposes except for those where the aim is to eliminate or reduce defects or serious disease (the sanction is imprisonment to six years and special barring from public employment and office, profession, or trade to ten years). The use of genetic engineering to produce biological weapons or to exterminate human beings is prohibited and punishable by imprisonment to seven years and special barring (para. 1 sec. 160). Anyone who fertilizes human ovules for any purpose other than human procreation and for the creation of identical human beings by cloning or other procedures aimed at racial selection are prohibited. Such actions are punishable by a custodial sentence of one to five years (para. 1 and 2 sec. 160). At least, the Penal Code also provides outlines the procedures for collecting, storing, and destroying DNA samples, which can be taken for suspects and convicts.

In Portugal, the Law on Medically Assisted Procreation (2006) considers MAR techniques as a subsidiary method of procreation, in the case of infertility or in order to treat a serious disease or prevent the risk of transmission of genetic, infectious, or other diseases (sec. 4). The following acts are prohibited in this Law: reproductive cloning; the use of MAR techniques for sex selection of embryos, except in the case of sex-linked genetic diseases; the use of MAR techniques to create chimeras or hybrids; and the use of preimplantation genetic diagnosis techniques in the case of multifactorial diseases where the predictive value of the genetic test is very low (sec. 7). The use of MAR techniques for the express purpose of creating embryos for research is prohibited (sec. 9) (Raposo, 2017). The Law on the DNA Profile Database – Civil and Criminal Identification (2008) regulates how the DNA data is to be stored and handled and what safety measures must be in place and for what purposes can DNA be collected.

In Switzerland, research involving humans is governed by the Human Research Act and its implementing ordinances. The Swiss Federal Human Research Act (2011) lays down key guidelines to safeguard the dignity, privacy, and health of people involved in research. Research projects designed to modify the properties of an embryo or fetus for non-disease-related reasons are prohibited (Article 25). Embryos and fetuses from spontaneous abortions including stillbirths may only be used for research purposes with the consent of the couple concerned and when death has been established (Article 40). The special Chapter 11 in the Federal Human Research Act is dedicated to criminal provisions and misdemeanors (Article 62):

[15] The German Code of Criminal Procedure. In the version published on 7 April 1987. Available at: https://policehumanrightsresources.org/content/uploads/2016/08/Criminal-Procedure-Code-Germany-1987.pdf?x49094

[16] Ministerio de Justicia (2011). Criminal Code. Available at: https://icj2.wpenginepowered.com/wp-content/uploads/2013/05/Spain-Criminal-Code-1995-eng.pdf

'Unless a more serious offense has been committed under the Criminal Code18, any person who willfully: (a) conducts a research project without the authorization of an ethics committee or deviating from an authorised protocol (Article 45) and thereby endangers the health of the participants; (b) conducts a research project as defined in Chapter 2, 3, 5 or 6 without obtaining the consent required under this Act; (c) offers, grants, demands or accepts payment or any other non-cash advantage in exchange for the human body or parts thereof as such; (cbis) uses the human body or parts thereof if they have been subject to a prohibited act as specified in letter c; (d) conducts a research project designed to modify properties of the embryo or fetus for non-disease-related reasons (Article 25); (e) uses embryos or fetuses from induced or spontaneous abortions for a research project before death has been determined (Article 39 § 3, Article 40 § 2), – shall be liable to a custodial sentence not exceeding three years or to a monetary penalty'.

The Federal Act on Medically Assisted Reproduction of Switzerland (1998)[17] regulates how and when reproductive cells can be preserved: namely with the consent of the donor and for a maximum of 5 years. This Act contains the legal definition of prohibited 'chimera formation', which is legally encountered in the legislation of the EU countries. It means 'the fusion of totipotent cells from two or more genetically different embryos. Embryonic cells are totipotent if they are capable of developing into any type of specialized cell' (Art 2 § m). The RMA Act also prohibits ovum and embryo donation and surrogate motherhood (Article 4).

The Reproductive Medicine Act also creates certain corpus delicti of criminal offenses, the prosecution and adjudication of which are the responsibility of the Swiss cantons (Chapter 4 'Criminal Provisions' of the RMA Act). The following 9 offenses in this Act are noteworthy: Production of embryos for illegitimate purposes (Article 29); Development of embryos outside the woman's body (Article 30); Surrogate motherhood (Article 31); Misuse of reproductive material (Article 32); Impermissible selection of reproductive cells (Article 33); Acting without consent or a license (Article 34); Germ-line modifications (Article 35); Cloning, chimera and hybrid formation (Article 36); and Contraventions (Article 37). For example, any person who genetically modifies a germline cell or an embryonic cell shall be liable to a term of imprisonment. However, this paragraph does not apply if the modification of germline cells is an unavoidable concomitant effect of chemotherapy, radiotherapy, or other medical treatment. Any person who creates a clone, chimera or hybrid, or transfers a chimera or hybrid to a woman or animal shall be liable to a term of imprisonment. A person who in the course of a reproductive technique analyses the 15 genetic materials of reproductive cells or embryos in vitro and selects them according to their sex or according to other characteristics, without aiming to overcome infertility or avoid the transmission of the predisposition to a serious disease to the offspring shall be liable to a custodial sentence not exceeding three years or to a monetary penalty (Article 33).

[17] Lawbrary (2022). Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, RMA) of 18 December 1998 (Status as of 1 December 2022). Available at: https://lawbrary.ch/law/art/FMEDG-v2022.12-en-art-2/

The Swiss Federal Act on Research Involving Embryonic Stem Cells (2003) prohibits the following: (a) to create an embryo for research purposes (§ 1 Article 29 of the Reproductive Medicine Act of 18 December 1998), to derive stem cells from such an embryo, or to use such cells; (b) to modify the genetic material in a germ cell (§ 1 Article 35 of the Reproductive Medicine Act of 18 December 1998), to derive embryonic stem cells from an embryo that has undergone germ line modification, or to use such cells; (c) to create a clone, a chimera or a hybrid (§ 1 Article 36 of the Reproductive Medicine Act of 18 December 1998), to derive embryonic stem cells from such an organism, or to use such cells; (d) to develop a parthenote, to derive embryonic stem cells therefrom, or to use such cells; (e) to import or export an embryo of the kind specified under Item a or b, or a clone, chimera, hybrid or parthenote. This act also does not allow the following manipulations: (a) to use surplus embryos for any purpose other than the derivation of embryonic stem cells; (b) to import or export surplus embryos; (c) to derive stem cells from a surplus embryo after the seventh day of its development; (d) to place in a woman a surplus embryo used for stem cell derivation. Legal practice in the field of research of human genetic material should be based on a number of principles: informed written consent (Article 5); independence of participants (Article 6); licensing requirement for stem cell derivation, for research projects aimed at improving derivation methods and for the storage of surplus embryos (Art. 7–10); scientific and ethical requirements for research projects (Article 12).

A special section in the Swiss Stem Cell Research Act (2003) is dedicated to criminal provisions. The following willfully committed acts are attributed to criminally punishable misdemeanors: (a) deriving embryonic stem cells from an embryo created for research purposes or genetically modified, or from a clone, chimera, hybrid or parthenote, or using such embryonic stem cells, or importing or exporting such an embryo or a clone, chimera, hybrid or parthenote (Article 3 § 1); (b) using a surplus embryo for any purpose other than the derivation of embryonic stem cells, or importing or exporting such an embryo, or deriving stem cells from a surplus embryo after the seventh day of its development, or placing in a woman a surplus embryo used for stem cell derivation (Article 3 § 2). For any of these misdemeanors, a person shall be sentenced to imprisonment. Certain other criminal acts are punishable by imprisonment or a fine not exceeding 200 000 Swiss francs for willfully (a) acquiring or disposing of surplus embryos or embryonic stem cells in exchange for payment, or using surplus embryos or embryonic stem cells acquired in exchange for payment (Article 4), or (b) contravening the requirements concerning the consent of the couple concerned (Article 5); or (c) undertaking activities subject to licensing requirements without a license (Art. 7, 8, 10 and 15). However, if the offender acts negligently, the penalty shall be imprisonment for a term not exceeding six months or a fine not exceeding 100 000 Swiss francs (§ 4 Article 24).

In the Republic of Croatia, the Law on the Protection of Patient's Rights (2004) specifies that interventions directed at changing the human genome can only be undertaken for preventative or therapeutic purposes, and no interventions are allowed with the view to changing the patient's germ line (Karačić, Viđak, & Marušić, 2021). The Act on Assisted Reproduction (2012) prohibits the selection of the sex of a fetus, unless it is

to prevent a sex-linked condition. Research on embryos and their alteration is generally prohibited. Gender selection of embryos is only permitted in the eventuality of sex-linked diseases. Surrogacy and cloning are prohibited according to the Act on Medical Fertilization (1998)[18] (Korać, 1999).

Article 115 of the Croatian Criminal Code (1997) protects the right to health by incriminating refusal and limitation of health care. Criminal responsibility falls upon a physician who fails to implement measures for the patient's protection according to the rules of the medical profession, as well as in the case of damage caused by negligence. Article 241 of the Croatian Criminal Code states that any physician undertaking medical treatment without the patient's valid and informed consent would be sentenced to a fine or 6 months imprisonment, unless such medical treatment aims to avoid the aggravation of the patient's health or if the patient's life would be endangered without such medical treatment. The Criminal Procedure Code (2009) provides for how DNA is handled during and after criminal investigations and which persons have the authority to access the genetic data. It also covers when the data is to be destroyed and what consents are necessary from the subject of crime (Articles 187, 202, 211, 327). Therefore, personal data collected exclusively based on determining identity, physical examination or molecular-genetic analysis may, after criminal proceedings and according to regulations, be used only for the detection or prevention of a criminal offense (§ 4 Article 187).

The Penal Code of Finland provides that the cloning of a human, altering and generating human germ cells and animal genetic material and the generation of a human by combining embryos are punishable by imprisonment of up to 2 years. The Gene Technology Act (1995)[19] regulates the use of GMOs in Finland and prohibits the intentional spread of GMOs in violation of the Act and export GMOs without a license. Punishments for endangering health contrary to this Act or for gene technology offense contrary to this Act, or for damaging the environment are prescribed in the Penal Code of Finland (Chapter 48, sections 1 – 4).

Section 4 of the Act on Assisted Fertility Treatments[20] (2006) provides that genetically manipulated gametes and embryos, cloned embryos and gametes, and embryos, which have been used in research, cannot be implanted. The Act bans the production of embryos for research purposes (sec. 13) and prohibits 'research on embryos and gametes for the purpose of developing procedures for modifying hereditary properties… unless the research is for the purpose of curing or preventing a serious hereditary disease' (sec. 15). Also, the Coercive Measures Act of Finland (2011)[21] provides for situations when DNA can be collected from criminal suspects and specifies how the samples and

[18] Korac, A. (1999). Draft of the croatian act on medically assisted procreation – balancing procreative rights. Društvena istraživanja. Journal for General Social Issues, 8(2-3), 229-238. Available at: http://hrcak.srce.hr/file/31910

[19] UNEP-LEAP (1995). Genetic Engineering Act (No. 377 of 1995). Available at: https://leap.unep.org/countries/fi/national-legislation/gene-technology-act-no-377-1995

[20] Ministry of Justice, Finland (2006). Act on Assisted Fertility Treatments (1237/2006). Available at: https://www.finlex.fi/en/laki/kaannokset/2006/en20061237.pdf

any resulting data are to be handled, stored, and destroyed (section 32).

Lithuanian Law No. VIII-1679 of 17 September 2015 'On Ethics of Biomedical Research'[22], sets out that human biomedical studies which modify the human genome can be conducted only for diagnosis or treatment provided that the goal is not to predictably modify the human germ line. Biomedical studies are allowed, if the benefits are expected to outweigh the risks for the human embryo and human fetus. The Law on Artificial Fertilisation (2014) prohibits the use of IVF as a means of modifying the identity of the germ line of a person or their offspring. According to Article 308(1) 'Prohibited Biomedical Research Involving a Human Being or Human Embryo' of the Lithuanian Criminal Code (2000), a person who conducts prohibited biomedical research involving a human being or human embryo shall be punished by a fine or by restriction of liberty or by arrest or by a custodial sentence for a term of up to two years (Law No VIII-1968 of 26 September 2000 'On the Approval and Entry into Force of the Criminal Code')[23].

Conclusion

Within the framework of Horizon Europe, a funding program dedicated to research and innovation, the European Union (EU) prioritizes three pillars; one of which one specifically focuses on tackling global challenges and augmenting the competitiveness of European industries. The 'health' cluster within this pillar underscores the significance of advancing healthcare technologies, reducing health hazards, protecting communities, and fostering the welfare of individuals. Genomic research promises immense possibilities in achieving these aims and has emerged as one of the most pioneering and groundbreaking fields in recent years.

Most European countries have already transposed the European Union directives into their respective national legislations with regard to the testing, processing, storage, distribution, and import/export of reproductive cells and tissues.

A number of EU jurisdictions provide for specific DNA databases used in criminal justice systems which are usually designed to store DNA profiles for the identification of suspects and convicts in criminal investigations and proceedings.

Similarly, while a number of jurisdictions in the EU provide for gene-related offenses, including cloning, modifying the human germ line, and dispersing GMOs without appropriate authorizations, the specific offenses vary in the EU countries to a large degree.

The lack of legal harmonization and uneven access to infertility treatment and for genetic counseling and preimplantation genetic diagnosis provides fertile ground for the development of international biolaw.

[21] Ministry of Justice, Finland (2011). Coercive Measures Act (806/2011; entry into force on 1 January 2014) (amendments up to 1146/2013 included). Available at: https://www.finlex.fi/en/laki/kaannokset/2011/en20110806_20131146.pdf

[22] International Labour Organization (2015). Law No.VIII-1679 of 17 September 2015 "On Ethics of Biomedical Research". Available at: http://www.ilo.org/dyn/natlex/natlex4.detail?p_lang=en&p_isn=102253&p_count=96738

[23] Republic of Lithuania. Law on the approval and entry into force of the criminal code, 26 September 2000 No VIII-1968 (As last amended on 11 February 2010 – No XI-677). Vilnius. Available at: https://herloc.unodc.org/cld/uploads/res/document/ltu/criminal_code_of_lithuania_html/Lithuania_Criminal_Code_2000_as_amd_2010.pdf

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