

Ethical approach to the genetic, biometric and health data protection and processing in the new EU General Data Protection Regulation (2018)

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Abstract

Purpose: The main purpose of the present paper is to analyze the rules for processing of special categories of personal data (genetic data, including biological samples, biometric and health data) in the light of the new General Data Protection Regulation (GDPR), thus contributing to overview the health status and the biomedical state of the data subject. **Background:** Over the last two decades, debating the European Union's (EU) major legislation with regard to personal data and patients' rights became relevant for the scientific research. The paper assesses the basic legal provisions with regard to the genetic, biometric and data concerning health considered as "sensitive data", while safeguarding the ethical standards of the scientific research. The present article investigates the ethical and legal approaches to processing personal data in the understanding of the new regulatory guidelines regarding the data protection, here including the health status and the rights of a data subject. **Conclusions:** The protection of natural persons with regard to the processing of genetic, biometric and health data and the free movement of such data are reinforced in the new GDPR entered into force in May 2016 and applied from 25 May 2018. The new legal context elucidates: the special categories of personal data ("sensitive data"), the "consent" and the research exemption by explicitly recognizing the "pseudonymised" data. Although the new guidelines revisit the EU data protection reform, it also grants the EU Member States the right to maintain or introduce further limitations to the processing of such data.

Keywords: research ethics, genetic data, health data, data protection, European Union, GDPR.

Introduction

The ethical use of the personal data and the enhancement of the personal data privacy present many challenges considering the accelerated nature of the interdisciplinary research and, especially, the rapid pace of the medical research [1]. The ethical dilemmas in the medical research and practice address a wide range of topics, such as: the medical communication, communicating sensitive information, the patients' rights, communicating results [2], using animals [3], etc. In addition, considering the importance of the health data for the medical research

[4], as well as the new European Union (EU) legal provisions, the article relates the impact of the General Data Protection Regulation's (hereinafter GDPR) implementation for the scientific research in the field of the data subject's consent and the purposes for the medical research [5]. Therefore, the GDPR replaces the Data Protection Directive 95/46/EC (DPD) following the vote of the European Parliament for a draft version on 12 March 2014 [6, 7].

The timeline of evolution of GDPR could be show in Figure 1.



Figure 1 – Timeline of evolution of data protection.

In the light of the new EU Regulation, the genetic, biometric and health data are considered "sensitive data" drawing on their use and processing in the medical research. Hence, an ethical approach to the protection and processing of personal data is required in the view of the new EU data protection reform here including:

the lawful basis of the processing activities; the scientific research purposes; the research exemption; the new legal definitions of "data concerning health"; "genetic data"; "biometric data"; "pseudonymisation"; "anonymisation"; the mean and the legal basis of "consent" for the use of special categories of personal data in relation with the

human fundamental rights and freedoms of the data subject. The GDPR current data protection reform specifically states: (1) the right of the data subject to access the data collected concerning him or her “at reasonable intervals”; (2) the right to exercise the access to the collected personal data in order to verify “the lawfulness of the processing” here including the data concerning the health status, the data regarding the medical records of the data subject referring to: “diagnoses, examination results, assessments by treating physicians and any treatment or interventions provided” (Recital 63 of the GDPR).

The GDPR also contributes to the establishment of the rights and obligations both for data controllers and processors by maximizing “the use of personal data to ensure quality and reliability in scientific research” and data processing in the healthcare sector [8] and by providing an “ethico-legal framework compatible” for all Member States [9]. Consequently, there are specific implications of the GDPR on the personal data balancing the fundamental rule for “harmonized conditions” and the governing processing activities of special categories of personal data “concerning health, in respect of specific needs, in particular where the processing of such data is carried out for certain health-related purposes by persons subject to a legal obligation of professional secrecy” (Recital 53 of the GDPR).

Although the legislative framework of processing data and data-sharing is aimed to enhance and harmonize the EU framework [10], the ethical decision-making requires an in-depth analysis under the provisions of the Article 4 (“Definitions”), Article 5 (“Principles relating to processing of personal data”), Article 6 (“Lawfulness of processing”), Article 9 (“Processing of special categories of personal data”), Article 32 (“Security of processing”), Article 35 (“Data protection impact assessment”), Article 89 (“Safeguards and derogations relating to processing for achieving purposes in the public interest, scientific or historical research purposes or statistical purposes”) and further Recitals.

☞ **GDPR’s definitions with impact on using personal data in scientific research**

The main definitions of the GDPR with impact on using personal data in scientific research can be found in the Article 4 regarding “genetic data”, “biometric data” and “data concerning health” defined as “personal data”. Namely, Article 4(1) stipulates that “personal data” refers to “any information relating to an identified or identifiable natural person (“data subject”; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person”. Furthermore, the EU legislator individualizes new definitions for each special category of data. Also, it is important to develop a curriculum for the people who carry out medical research in the domain of data protection according to the new European regulation.



Figure 2 – Steps in the emergence of data protection professionals in medical research.

☞ **Genetic data**

The new EU data protection legislation defines in Article 4(13) “genetic data” as “personal data relating to the inherited or acquired genetic characteristics of a natural person”. This article elucidates the characteristics of the genetic data as personal data giving “unique information about the physiology or the health of that natural person”. The characteristics of the genetic data “result, in particular, from an analysis of a biological sample from the natural person in question” (Article 4(13) and Recital 34 of the GDPR). Additionally, Recital 34 sets out the circumstances of genetic data which “result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained”. Moreover, a part of the recent literature argues that these provisions challenge the limits of the new notion of genetic data by addressing extended legal justifications with this regard in a restrictive rather than extensive interpretation questioning the status of the genealogical data collected through questionnaires or the epigenetic data [8]. One of the major provisions of the Recital 34 refers to the genetic data as “personal data relating to the inherited or acquired genetic characteristics of a natural person”.

☞ **Biometric data**

The GDPR regulatory provision states that “biometric data” are personal data “resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person” (Article 4(14)). Moreover, the definition assesses the biometric data as personal data which “allow or confirm the unique identification of that natural person, such as facial images or dactyloscopic data”. This new legal provision on the biometric data imposes the terms of “the identification of the natural person” by enhancing two aspects: “the facial image” or the “dactyloscopic data”. Under the terms of the Article 4, genetic and biometric data are personal data regarding the “natural person” (an individualized “data subject”). It is therefore assumed to consider genetic and biometric data as “inherently identifying” imposing a general prohibition of “processing” such data unless

an “explicit consent” was given as they regard an individualized natural person [11]. The new legal provisions request explicit consent for data collection and further processing activities of genetic and biometric data. Article 9 suggests a factual analysis regarding the necessity to “avoid giving tissue donors a guarantee of absolute anonymity or privacy” [11].

☒ Data concerning health

The discussion about “data concerning health” and health research refers also to the new technical findings about the patient privacy, using the patients’ data, the health–IT relationship, informed consent required “for all data that is not anonymous” [12, 13] and new pathways of combining data sources and “re-usable data resources” [14]. Therefore, the new definition of the data concerning health is strongly enabled in the Article 4(15) considering the “personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status”. The same article offers a list of three categories of data “especially sensitive” (physical, mental and healthcare services) suggesting that “once genetic information is extracted from the sample, even if it is not whole genome/exome sequence data”, are considered to be “subject to data protection law” [11]. Moreover, given the EU law principles of subsidiarity and proportionality, both stated in the Article 5 of the Treaty of the European Union and the Protocol No. 2 on the Application of the Principles of Subsidiarity and Proportionality, Recital 35 regards the boundaries of personal data concerning the health status relating to the “past, current or future physical or mental health status of a data subject”. At any rate, this provision regards all information collected considering: (1) the registration status for health care services to the natural person according to the Directive 2011/24/EU of the European Parliament and of the Council [15]; (2) the identification for health purposes designing “a number, symbol or particular assigned to a natural person” with the aim to identify that unique natural person; (3) all “information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples” and (4) any information regarding: “a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an *in vitro* diagnostic test”.

☒ Pseudonymisation

“Pseudonymisation” is defined under the provisions of the Article 4(5) as “the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person”. Under the new prudent regime of pseudonymisation, the GDPR fulfills its initial dimension

by “reducing the risks to the data subjects and helping controllers and processors to meet their data-protection obligations” and leading to a win–win approach under the provisions of the Recital 28 in two directions, as follows: (i) the data controllers and processors and (ii) the data subjects’ rights [16].

Recital 29 grounds the means of pseudonymisation with the same controller and under the “technical and organizational measures” taken by the controller to safeguard the implementation of the Regulation. Recital 29 also presumes that the controller processing the personal data shall indicate “the authorized person within the same controller”. For this reason, the provision of the GDPR appreciates that the biomedical research on personal data has to be of “substantial public interest” in case consent has not been obtained [17]. As aforementioned, some experts argue that the GDPR’s provision is “too strict to be practically attainable” [18]. Moreover, Recital 26 states both aspects of pseudonymisation revealing first the personal data “which have undergone pseudonymisation” and, second, personal data “rendered anonymous”.

☒ Anonymous data

Therefore, Recital 26 claims that the personal data, which have undergone pseudonymisation, are considered to be “information on an identifiable person” under the condition that personal data “could be attributed to a natural person by the use of additional information”. Under these provisions, the definition for pseudonymised data as personal data differs essentially comparing to “anonymised data” which are “information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable” (Recital 26). Additional comments observe that pseudonymisation enables “the capability to reconstruct the processes of identity making” by permitting “re-identification” [19]. According to the provisions of the Recital 26, the data protection provisions do not apply to processing anonymous information, here including for statistical or research interests. After all, many comments and observations argued that the GDPR’s legal framework recognizes the difference between two main categories of data: personal data and anonymous data [13]. Furthermore, “complete anonymisation of data is no longer explicitly required” [20].

☒ Pseudonymised and anonymised data for scientific research

In fact, Article 89(1) states that pseudonymisation respecting the principle of “data minimisation” is a possible measure of processing for archiving purposes. In case the mentioned purposes can be fulfilled by other processing activities which “does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner”. The question of achievement these requirements enables Recital 26 to consider all factors, the period of time necessary for identification, the available technological advancements and advancements at the time of processing.

☒ Consent

The GDPR distinguishes the definition of “consent” using a new ethical and legal basis by individualizing the following patterns: free given, specific characters, informed and unambiguous determination of the data subject’s agreement on the processing of his or her personal data (Article 4(11)). With respect to the new law, Article 7 categorizes the conditions for consent: (1) the consent of the data subject demonstrated by the controller; (2) in case of written declaration, consent has to be provided in an “intelligible and easily accessible form, using clear and plain language”; (3) the data subject’s right to withdraw the given consent [20].

☒ Processing of personal data from patients

The GDPR provides in the Article 37(1b-c) clear provisions regarding the appointment of a DPO (“data protection officer”) when processing of personal data regards “a large scale”. Although the large-scale processing operations involves an appreciable amount of personal data and high risks, Recital 91 emphasizes the activities that “should not be considered to be on a large scale” as “the processing concerns personal data from patients or clients by an individual physician, other health care professional or lawyer”. The GDPR determines the processing of personal data at three levels: (1) regional level; (2) national level; (3) supranational level.

☒ GDPR’s ethical standards for scientific research

The concern to develop legal and ethical standards is not new, but the introduction of GDPR raises the level of current standards, regardless of the methodology in which the research is carried out, including the form for collecting the data or transmits it [21, 22].

The legal provisions on the processing for scientific research are developed in Recital 33 of the GDPR. The new legal framework shall have a direct impact on the scientific research using personal data [20] by providing the possibility to not entirely identify at the initial moment of the data collection the purpose of processing personal data for scientific research. Furthermore, the Recital 33 identifies two moments during the coreactivities of processing personal data: (1) the time of the data collection and (2) the moment of giving consent “to certain areas of scientific research” with the respect of the ethical standards in scientific research.

Therefore, the use of personal data for biomedical research where consent has not been acquired “must be of substantial public interest” according to the new provisions (Recital 51) [9]. Recital 52 explicitly stipulates that the “public interest” derogation from the prohibition on processing special categories of personal data regards also health security and “the prevention or control of communicable diseases and other serious threats to health”. The derogation from the same prohibition mentioned by the Recital 52 regards: the health purposes, here including “public health and the management of health-care services” with the aim to safeguard “the quality and cost-effectiveness of the procedures used for settling claims

for benefits and services in the health insurance system, or for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes”.

Moreover, current researchers in medical health explore: (1) the concept of the “systemic oversight” towards the enhancement of the informed consent and the legal basis of the informational privacy and data-driven health research [23]; (2) the different legal provisions on research and audit in health-care sector such as the “primary use of health care data” under the provisions of the Recitals 52, 53 and 54 and the Article 9(2h-i) [9, 17].

Article 9(2h-i) clearly nominates: (1) the means of preventive or occupational medicine and the legal framework of “health or social care systems and services” as stipulated in Article 9(2h); (2) the processing for public interest in the field of the public health by guaranteeing the quality and safety of “health care, medicinal products, medical devices” according to the provisions of Article 9(2i).

☒ Processing of personal data

The general principles relating to processing are based in the Article 5 and the lawfulness of processing based in the Article 6 of the GDPR [24]. Article 5(b) explicitly states that the personal data collection regards “legitimate purposes” and further processing with the aim of archiving “in the public interest scientific or historical research purposes” is considered under the provisions of the Article 89(1). The condition provided by the same article regards the fact that the processing may not being compatible with the initial purposes (“purpose limitation”) [24].

Article 5 also overviews the necessary legal requirements for the lawfulness processing of personal data. Article 5(1e) reveals that the processing of personal data regards the “scientific or historical research purposes or statistical purposes” as long as the processing respects the provisions of the Article 89(1) subject to the establishment of the technical support and organizational means. Article 6(1a-f) implies the six conditions stating that processing is lawful (only if at least one of the six conditions occurs).

As Timmers *et al.* mentions: “*There is an inherent tension between critical care research and data protection*” [25]; however, in terms of data protection, medical research requires the application of European regulation rules including in telemedicine or in the development of research to improve medical devices or telemedicine [26, 27].

General Data Protection Regulation reform affect not only the European country, but also other country because processing of personal data could occur outside EU borders [28].

☒ Processing of genetic, biometric and data concerning health

The processing of this special category is “prohibited” under the provisions of the Article 9(1): “the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation shall be prohibited”. This prohibition shall not be applies if one of the following provisions applies:

(1) “explicit consent” of the data subject; (2) the specific purposes enabled by the rights and obligations of the controller or of the data subject in certain areas; (3) the necessity of protecting vital interests; (4) “legitimate activities” of a foundation, association, etc.; (5) processing of personal data publicly presented by the data subject; (6) the processing of the special categories of data is requested by the “substantial public interest” depending on the “aim pursued” and the legal basis of the EU legislation or the Member State Law; (7) the processing is needed for “reasons of public interests in the area of public health” (such as cross-border threats or safeguarding the “high standards of quality and safety of health care and of medicinal products or medical devices”); (8) for archiving means in the public interest, scientific or research purposes. Taking into account the importance of the medical information and the health, patients’ rights and medical research, the data protection enable a “directly applicable” framework in Europe [12].

The genomic researcher are handling with a lot of data, including data storage on cloud, which could be also a problem approach in accordance with new EU regulation. According to Dove *et al.*: “Data location and transfer is a critical issue for researchers, given its intersections with data protection laws, ethical guidelines and consent forms that may (or may not) address data storage and sharing” [29].

☞ **Processing of special categories of personal data in the public health and the health research (research exemption under the GDPR)**

Another paragraph 9(2j) states the processing of the sensitive personal data when required for historical, statistical and scientific research purposes and, also, substantial public interest subject to the legal provisions of the Article 89(1) based on the EU law and Member State law “which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject”. However, this paragraph is interpreted differently by other authors. Pormeister argues that the research exemption stipulated by the Article 9(2i) may reveal many versions due to the Member States’ legislation [30]. Moreover, the same research exemption enabling the processing of sensitive data may be “directly applicable” due to the Article 288 of the Treaty on the Functioning of the European Union, “in the absence of other applicable EU and/or national laws at least when considering the definition of research” [30] as the EU regulation have general application in all EU Member States. Thus, Recital 159 enables a large and comprehensive definition of “research” including, for example, the “technological development and demonstration, the fundamental research, the applied research and privately funded research”. As to the sector of the public health, the same recital extends the scientific research purposes to the “area of public health” and admits a clear legal framework for the particular conditions of “processing personal data for scientific research purposes” stating the health sector where the results of the scientific

research may give reason for additional measures “in the interest of the data subject” (Recital 159).

Admittedly, Article 9(4) enables Member States to safeguard or introduce additional conditions “including limitations, with regard to the processing of genetic data, biometric data or data concerning health”. Other legal implications are enabled by the Article 89(2) that specifically determines the derogations from the rights revealed by the Article 15 (“right of access by the data subject”), Article 16 (“right to rectification”), Article 18 (“right to restriction of processing”) and Article 21 (“right to object”) in the case of the processing of personal data for scientific purposes in accordance with the legal provisions of the Article 89(1) “in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes”. The derogations are requested by “the fulfillment of those purposes” (Article 89(2)). However, the substantive legal clause on genetic data regards the legal framework for sensitive data processing (here including genetic data), while “restricting the data subjects’ suggests control over their personal data” [31]. Moreover, under the new provisions of the GDPR, the research exemption may enable the processing the sensitive personal data without the data subject’s consent for an undermined period of time for research purposes [30].

☞ **Conclusions**

The GDPR introduces new definitions and a new regulatory framework for the genetic, biometric and data concerning health and a research exemption with regard to the processing of sensitive data under the provisions of the Article 9 with the aim of harmonizing data protection and sharing across the EU [17].

According to Marelli & Testa: “The GDPR, which repeals previous European legislation on data protection (Directive 95/46/EC) (1), is bound to have major effects on biomedical research and digital health technologies, in Europe and beyond, given the global reach of EU-based research and the prominence of international research networks requiring interoperability of standards.” [32]

Moreover, the GDPR enables a new legal framework for the healthcare industry and a new interpretation of “research”. In the processing of the sensitive personal data, the GDPR enables the Member States to maintain or implement further measures “including limitations” when considering the processing of genetic data, biometric data and data concerning health. The second point regards the processing of special category of personal data (“sensitive data”) as the new legal context elucidates the practical implications of processing genetic data by explicitly assuming the effect that once the genetic data has been extracted, it is permitted to be further processed and stored for research purposes under the condition that the exemption is subject to purpose for which it was processed or “storage limitation” (in order to guarantee the rights and freedoms of the data subject). Although the GDPR’s legal guidelines conduct to a new regulatory framework for the data protection and processing, it also emphasizes the use of the “sensitive data” in scientific research.

Conflict of interests

The authors declare that there is no conflict of interests regarding the publication of this paper. All authors read and approved the final manuscript.

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