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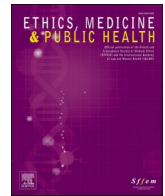
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Humanities in health

## The human body and the body elements—Conditions for their use in genetics under the French bioethics law and beyond

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## ABSTRACT

French legislation has strictly regulated genetic analysis since the adoption of the bioethics laws in 1994. Following a historical perspective, we discuss how French laws have provided a stable legal regime for access to and use of the human body and its elements until the recent revision of the laws. We present the main bioethical principles attached to the human body and their jurisprudential treatment. We balance this approach of stability by showing the strong evolution of the provisions regulating genetics in French laws. Initially based on and centred on the protection of the individual, we present and analyse the new possibilities for using genetic analysis in the name of solidarity with family members and with society as a whole, for research perspectives and for public health prevention.

### Introduction: the genealogy of the bioethics law(s) in France

As most of the European countries, France has engaged in framing bioethics for the purposes of care and of research. Since a long time, the French institutions have decided to strictly regulate the access to the human body and to its elements through binding rules adopted by law. This vision of a “regulatory bioethics” is almost unique in Europe since France adopted bioethics laws in 1994 [1].

These laws, at the time of their adoption, intended to first, update obsolete legislation (such as the one on organ donation), and second, to provide a legal framework for new medical techniques (i.e. in vitro fertilisation). When proposed, the legislator anticipated future issues that could appear regarding emerging technologies and thus enshrined in the laws the principle of their regular revision (after 5 years and recently after 7 years). Over time the laws were revised through one single instrument called the “Bioethics law” first in 2004 [2], then in 2011 [3] and lastly in August 2021 [4]. In 1994, the law on informatics and freedom was also revised which was an opportunity to align the provisions to protect privacy with patients’ rights and processing of health data for research purposes [5].

The two initial 1994 laws were pioneers in the “*bioéthique à la française*” (meaning bioethics built on legal roots) as the first one adopted the general legal status of the human body and the general principles underlying its use and the second one translated these principles for their use in human health. Therefore, the law on the human body status was implemented in the Civil Code (CC), which organises

personal relationships (contracts, marriage and divorce etc.) whereas the law on medical practices was implemented in the Public Health Code (PHC) to regulate medical interventions, medical professions, patients’ rights, research and the organisation of the health care system. In this regard, the main goal of the bioethics law was to cover emerging technologies applying to health interventions such as organ, tissues, gametes and cells donation, medically assisted reproduction and prenatal diagnosis. The initial law was also covering medical genetic testing and genetic research as well as research on embryos. Since these first laws were framing conditions to access to the human body and the finalities for which it can be used (the laws specified that in health only medical or research activities are acceptable finalities) including for genetics, they also stated the core fundamental rights of patients and research participants such as prior information on the intervention and consent. Thus, the initial philosophy, which has been maintained all along the revisions, was based on the need to promote the progress of science for the benefit of individuals while ensuring that the latter are able to express their autonomy and that their fundamental rights are respected. In this sense, the Bioethics Law has strong links with other provisions stated in the PHC related to the respect of patients’ rights.

Over time, the laws evolved to cope with the scientific and technological advances [6]. Thus, in 2004 the main changes occurred in the field of embryos where the ban of research, initially adopted in 1994, was confirmed, but where the law opened for the first time some exceptions to allow research activities. The ban of cloning was also stated. The 2004 law also created a unique agency (Agence de la Biomédecine)

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to be in charge of the follow up and of the control of activities in the fields covered by the law. The 2004 law was quite technical trying to answer to the challenges raised by the medical technologies in the practices. This “biologisation” of the law illustrated the limits to frame medical innovations and most of the required implemented decrees were not adopted in due time. As a result, a large number of the provisions did not come into force. In 2011, the revision addressed marginal issues and limited the revision to allow for the experimentation of new techniques (such as cross donation of organs) but the main originality came from the revision process. Indeed, French government experimented the “*Etats généraux de la bioéthique*” (general assembly of bioethics) where citizens were invited to contribute (through meetings and a dedicated website) to the debates organised prior to the revision begun at Parliament. The results were fruitful [7] and highlighted the needs for the society to be part of the process. However, by the end the law adopted in 2011 did not incorporate the proposals that were seen as societal demands rather than medical needs. By contrast, the revised law adopted in August 2021 improved the societal demand [8] addressed through the *Etats généraux de la bioéthique* that were then organised under the umbrella of the *Comité Consultatif National d’Ethique* (the national ethics committee). Indeed, the last revised law made assisted reproduction techniques available to women, opened possibilities to children to have access to their origins, adopted several provisions to facilitate research on embryos and human embryonic stem cells as well as on iPSCs cells and strongly modified the legal regime of genetic testing. In this paper, we will show, that, despite three rounds of revision, the core bioethics principles elaborating a legal status for the human body and its elements, which are applicable to genetic analyses, remain mostly the same but that they have been called into question mainly by the new rules on genetics.

### The core legal principles covering the human body and its elements: spirit and roots

As already mentioned, the main input from the 1994 law was to create a *de novo* legal status, inspired from the jurisprudence, for the human body and its parts. As the French legal system only recognises two legal categories, things and persons (*summa divisio*), the adoption of a dedicated legal status for the human body was needed and the legislator decided to embrace it under the regime of the persons. Before 1994, principles were already existing but in the Penal Code to protect individuals against infringement to their integrity. Several infractions, such as bodily harm, served as basis to judges for their rulings. Thus, the status of the human body was mainly framed by the jurisprudence occurring in the medical responsibility area (very few decisions have addressed harms in the research setting) with the main aim of protecting individuals against the medical power. The need for adopting a proper regulation for the human body emerged from the necessity to adopt binding rules in a context where new technologies were developing [6] and where ethical values were not seen as sufficiently protecting fundamental rights [9]. According to the previous decisions adopted by the judges, the legislator decided to implement in the CC in articles 16 and following the core legal conditions to allow access to the human body that must respect the human dignity principle.

The French Constitution (from 1958) does not refer to the dignity principle. However, the *Conseil Constitutionnel* (the supreme Court to control the laws’ conformity to the Constitution) ruled on the constitutionality of the first bioethics laws [10] and decided that “the safeguarding of the dignity of the human person against all forms of enslavement and degradation is a principle of constitutional value”. Thus, this decision has made this principle a core reference that must guide the legislator to frame the conditions for infringing the human body. As a result, the CC states in the first article dedicated to the protection of the human body that “the law ensures the primacy of the person, prohibits any violations of the person dignity and guarantees respect for the human being from the beginning of life”. In order to make

this principle effective for individuals three operational principles were indeed adopted in the CC: the respect of the human body, its inviolability and the ban of appropriation (CC, art. 16-1). These principles are considered of public order (CC, art. 16-9) which means that they cannot be limited by contract but only by law. The PHC also states several additional conditions to respect the use of the human body elements in these areas (PHC, art. L1211-2: consent, L1211-3: interdiction of the publicity, L1211-4: free donation, L1211-5: respect of anonymity in donation, L1211-6 and following: safety).

#### *Respect for the human body*

According to art.16-1 CC “everyone has the right to respect for their body”. This principle recalls that the human body is part of the individual and as such, it should be treated with the same considerations as the person is. The law adopted it rather in a form of a statement than as an operational principle. Its effectiveness is indeed enforced through the inviolability and non-patrimoniaity principles. One major evolution occurred after the second revision of the bioethics laws regarding the principle of respect of the human body after death [11] to rule on the legal status of the body after death and on the ashes of the deceased (cremation increased a lot in the 2000’s). To this end a law related to funeral legislation was adopted in 2008 [12] in order to protect the human body after the death, remains of the deceased and ashes. It introduces the following principle: “Respect for the human body does not cease with death. The remains of the deceased, including the ashes of those whose bodies have been cremated, shall be treated with respect, dignity and decency” (CC, art. 16-1-1). This modification by law was needed as the principle of respect for the human body was initially conceived to protect bodies of live humans in the Bioethics laws of 1994/2004. In fact, the principle of respect for the human body was originally attached to the person who, when deceased, is no longer considered as a subject of rights and cannot claim them [13]. In the context of health [14], the application of this principle recalls that the human body cannot be treated as a thing and that several conditions must be met to infringe it notably regarding individuals’ autonomy. It is of particular importance when the individual is deceased and cannot express any consent. In that case, the respect of the human body imposes that the body is not disposable and cannot be freely accessed for organs taking or research. Therefore, the law organises the conditions for individuals when alive to express their will on what should or should not be done after death [15].

#### *The inviolability of the human body*

The CC (art. 16-1 al.2) states, “the human body is inviolable”. From a fundamental rights perspective this means that all individuals have a subjective right to protect their body against third party infringement. Therefore, informed consent is the core guaranty of this principle but cannot be considered as the only one. Indeed, in addition to the necessary prior informed consent, activities that are conducted on the human body must not be contrary to the dignity principle and to the Public order (i.e., tattoos, piercing etc. are lawful since they are conducted in respect of these conditions).

When it comes to health and research on humans, the inviolability principle has been enforced by law through the respect of the integrity of the human body and under two necessary conditions (CC, art. 16-3). First, the human body “may only be violated in cases of medical necessity for the individual or exceptionally in the therapeutic interest of others”. This condition was stricter at the time of the adoption of the Bioethics law in 1994 where “the “therapeutic condition of the person” was the only exception to infringe the human body. Considered as too restrictive, a law adopted in 1999 [16] changed “therapeutic” for “medical” condition, which embrace more situations and in particular those that are aiming to improve diagnosis. The revision law of 2004 also added “the therapeutic interest of others” to cope with

transplantation activities. Second, “the consent of the person concerned must be obtained beforehand, except in cases where his or her condition makes necessary a therapeutic intervention to which he or she is not able to consent”. This recalls, that in health law, prior information and informed consent are pillars for accessing to the human body and that, there are only few situations where the medical professionals can intervene without asking for them.

The integrity principle is also stated regarding the protection of the specie (CC, art.16-4 al.2 and 3) which will be discussed in the genetic part.

#### *The non-patrimoniaity of the human body*

To ensure that the human body is strictly respected under personality rights, making a clear position on its status (and the one of the human body elements) regarding ownership was needed [17]. In the name of the sanctity of the human body, it was necessary to recall that it cannot be legally treated as a thing and that it was out of the market. Indeed, article 16-4 al.3 (CC) states, “the human body, its parts and products cannot be the subject of a patrimoniality right”. This principle, then, prevents individuals from selling or renting parts of their body and from taking profits. The CC provides additional safeguards in this regard as “agreements which have the effect of conferring a property value on the human body, its parts or its products are void” (art.16-5), “no remuneration may be paid to a person who lends himself to an experiment on his person, to the removal of parts of his body or to the collection of its products” (art.16-6) and “any agreement concerning procreation or gestation for the benefit of others is void” (art.16-7).

In health, this has been particularly enforced in the area of transplantation (of organs, tissues and cells including gametes) where all of the chain, from the donor to the recipient, must be respectful of the principles of gratuity and of anonymity (only effective for post-mortem donation). These are guaranties for the respect of the human body and for the equal access to human body donation. However, by custom, several body parts are not covered by the non-patrimoniaity principle that are hair, nails and teeth (PHC, art. R.1211-49). Another exception remains also in the field of research on humans where there is still a possibility to offer compensation to participants (which is not considered as a salary) for the constraints of their contribution to a research protocol (PHC, L.1121-11). However, this possibility is limited in terms of amount (6000 euros per year) [18] and of persons to be compensated (vulnerable persons, such as minors or prisoners, cannot be compensated).

It is common in the legal literature, to consider the non-patrimoniaity principle as part of the unavailability of the human body [19]. The latter has not been legally recognised as a core principle in the bioethics law but other principles contribute to it [20]. This principle has also been recognised as a principle of public order in a ruling of 1991 (Cass. Ass. Plén., 31/05/1991, n° 90-20.105: JurisData n° 1991-001378) related to a surrogacy contract and has never been implemented in law. For some of our parliamentarians, considering the advances in science and biomedicine, this absence of a legislative recognition, was creating insecurity regarding its respect, and there was a need to enforce it at the highest level [21]. This is the reason why some of them proposed, in 2013 [22], the inscription of this principle in the French Constitution. However, the Parliament during the vote session decided that it was not necessary to fully close the doors to future societal evolutions and that the principles already in place were providing strong safeguards against the commercialisation of the human body. Thus, this principle is still recognised at the jurisprudential level and can constitute the basis for further decisions protecting the human body.

The principles of protection of the human body are now well established and have only been submitted to very few modifications since their adoption in 1994. In comparison, the legal framework of one of the applications of the use of the human body, namely, genetics, has evolved a lot notably in the new bioethics law adopted in 2021.

### **The legal provisions for genetics in France: between protection of individuals and promotion of the circulation of the genetic information**

Since the adoption of the Bioethics laws in 1994, the legislator decided that genetics must be specially framed among the other medical procedures. Indeed, genetics is seen as particular in health law as it has something to do with the intimacy, privacy and the identity of individuals and can therefore be used for discriminatory purposes. Thus, it was decided that genetics and genetic information should be subject to strict rules in order to protect individuals from potential misuse and to ensure that they are fully consenting to genetic examination. However, even though the personal dimension of genetic information should be submitted to the highest legal standards, it also impacts relatives' health when the genes are at the origin of a heritable disease. Thus, the legislator has to balance principles that were contradictory, such as the respect for professional secrecy, and the need for family members to have access to information they could benefit from.

The global architecture for the legal framework of genetics is original in the French law as some of the provisions are stated in the CC and some others in the PHC. The 1994 law created a dedicated chapter for genetics in the CC (Examination of a person's genetic characteristics and identification of a person by genetic fingerprints, articles 16-10 to 16-13) to underline the importance of adopting binding rules in this regard. The PHC applies these rules in concrete situations namely in health care and in research. Since the adoption of the new bioethics law in 2021 [23] some of the core principles have been completed to incorporate the consequences of the development of new genetic technologies and genetic information is specifically addressed in the General Data Protection Regulation (GDPR). Off note, new provisions concerning the use of genetic tests in the fight against doping have been adopted [24] prior to the organisation of the Olympic Games in France, introducing a new article (L.232-12-2) into the Sport Code. According to this provision, in conjunction with article L.232-9-2 of the same code, athletes cannot refuse to undergo this genetic test (in other words, no consent is required) if the test is carried out under the conditions laid down by the law. However, the right to information must be respected and athletes must be specifically informed of the performance of this genetic test (Sport Code, art. L.232-12-2).

#### *The evolution of the general principles to perform genetic analysis in France*

The CC identifies three main lawful finalities to perform genetic analyses: the first relates to the use of genetics in health (according to the law “examination of a person's genetic characteristics”<sup>1</sup>), the second aims at the identification of an individual (for judicial procedures) and the third aiming at realising a constitutional genetic test as added by the 2023 law to fight against doping. In this paper, we will only focus on the first category. Thus, in health only two finalities are authorised under article 16-10 of the CC: health care and research. Therefore, performing genetic testing outside these finalities, for example direct-to-consumer genetic testing (DTC), is unlawful under the French law. Moreover, looking actively for genetic characteristics is punishable under criminal law (Penal Code art. 226-28-1) and publicity for DTC is, since the adoption of the bioethics law from 2021, also forbidden (CC, art.16-10 IV). The content of article 16-10 of the CC, which originally stated the core rules for genetic analyses, has strongly evolved in the last revision of the law. Where, in 1994 only the finalities and the need to seek informed consent in writing were mentioned as the conditions to perform the test, this article is now formed by 4 paragraphs detailing the information and consent process, as well as the legal regime for

<sup>1</sup> For the needs of this paper, we will use indistinctly, examination of a person's genetic characteristics or genetic analysis or genetic testing.

incidental findings. Regarding the information and consent, the procedure was previously indicated in the regulatory part of the PHC. Since 2021, these principles have been updated and now are referred to in the law (CC). Indeed, article 16-10 requires that all individuals performing a genetic test revealing *constitutional information*<sup>2</sup> must receive prior information on : the nature of the examination, the indication of the examination or on the objective of the research protocol, the possible discovery of information unrelated to the initial indication (incidental findings) and the obligation to communicate this information to the relatives, their right to refuse the communication of the test's results and the potential consequences of this refusal on family members. Consent must then recall the indication of the medical procedure or the objective of the research and is revocable at any moment in any form. The article mentions one possibility for opt-out procedure to use genetic material in research when an informed consent in writing has been previously obtained for medical care. This option was already mentioned in the PHC in the previous version of the law and is now referred to as an exception of the main procedure for consent in genetics as stated in the CC. The practical conditions to seek consent and to inform family members have been completed in a decree adopted in December 2023 [25] which is referred to the use of a template for consent to be adopted in a governmental decision. Finally, the CC maintains the interdiction to use genetics characteristics for discriminatory purposes (art. 16-13).

The last bioethics law recognises, as previously demanded by professionals, two legal categories of genetic information that are submitted to two different procedures. The first category comprising constitutional information that could be of importance for family members as these characteristics can be transmitted. Thus, the legal regime is strict, supposes an informed consent in writing and identifies pathways for information of relatives. The second, covers somatic genetic information that is submitted to the general rules of medical follow-up and requires a consent delivered orally. The law also reflects new advances in genetics as it is expected that, due to the development of new generation of sequencing, more and more incidental findings will occur. It prepares for the management of information and on how the information will have to circulate between the patient/participant in research and relatives [26]. This solidarity in favour of family members is also at the heart of the new provisions implemented in the PHC for medical care and research. It has also been the main argument for adopting new possibilities to offer genetic analysis in the public health setting.

#### *Genetic analyses for medical care purposes*

The legal framework for performing genetic analyses in health care has been almost stable since 1994. The requirement to seek consent and to deliver an adequate information has been clarified (see above) and the main conditions are still required: the need to have a medical prescription to carry out a genetic test, the obligation that the results are given through genetic counselling and the right not-to-know. The main evolution came from the necessary recognition of family members to have access to genetic results and from the possibility to perform genetic tests from deceased individuals or individuals that are not able to consent (several new provisions of the Bioethics law are also tackling issues of performing genetic tests in the procreation area that we will not fully address in this paper. For more information, see Ref. Rial-Sebbag [23]). As for the transmission of genetic results to family members, the law of 2004 first recognised this right to the family members in the name of having access to information that could be useful for knowing their medical condition. Even though considered as a medical information covered by professional secrecy, the legislator decided that delivering this information was in the higher interest of the family member. However, the law was not followed by the implementation decrees and the procedure was only enforced in the 2011 law [26] where two

pathways were identified for mandatory communication of relevant genetic information to family members. First, direct information by the patient him(her)self with the help of an information document provided by the medical professional or second, indirectly, if the patient does not want to communicate with his relatives, he provides the details of the relevant family members to the medical doctor who will be in charge of informing them about the existence of a genetic information that could be of medical relevance. This communication should be done while preserving the anonymity of the index subject. This scheme has been extended in the new Bioethics law to the discovery of a genetic defect in the context of medical assisted reproduction when affecting the donor of gametes or the child born after gamete donation. In that case, it is the responsibility of the director of the reproduction centre to communicate this information to the relevant medical doctor to provide this information to the relevant persons (PHC, art. L1131-1-1). Another extension has been adopted in the law for communicating genetic information in the case of birth given under the secret (PHC, art. L1131-1-2). The authority in charge of managing the procedure together with the medical doctors is the *Centre National pour l'accès aux origines personnelles* (National Centre for Access to Personal Origins). Lastly, it is now allowed under the new law, to perform genetic examination of deceased individuals when a genetic defect is assumed by the medical doctor to benefit family members (PHC, art. L1130-4). However, there are several conditions to be respected: the non-opposition of the person when she was alive, the access to the genetic material can only be done on previously collected samples or based on an autopsy.

#### *Genetic analyses in research*

As already seen for the medical care settings, the legislator has opened the uses of genetics in research in the last Bioethics law. Initially stated in the 1994 laws, consent in writing is still mandatory when a research protocol includes genetic analyses. The consent has to be specific and required for each protocol. The previous provisions of the law on research subjects adopted in 2012 [27] already made the rule more flexible when the genetic material was already stored for medical purposes, in that of reuse of biological samples an opt-out procedure was, and is still, lawful (PHC, art. L1130-5). When a research project includes genetics, the protocol must be prior submitted to the ethics evaluation of a Research Ethics Committee (*Comité de protection des personnes*, CPP). The CPP is in charge of assessing the information document, the consent (for primary genetic research) or the opt-out procedure (for reuse of the samples). In some cases, for material already stored, researchers may consider that it is not possible for them to carry out the information if the person cannot be found, is deceased (this point is clarified by the Décret n° 2023-1401 of 30 December 2023 *relatif aux modalités d'information des personnes concernées par l'examen de leurs caractéristiques génétiques réalisé à des fins de recherche scientifique prévu à l'article L. 1130-5 du code de la santé publique*) or is unable to express his or her wishes (art. 1130-5, PHC). In this case, the person in charge of the research can ask for the advice of a research ethics committee (CPP), which "assesses the reasons why it is not possible to inform the person and decides whether it is appropriate to study his or her genetic characteristics in the light of this situation and the ethical and scientific relevance of the research" (article 1130-5, PHC). While the CPP may or may not be asked to grant this waiver, if the individual information is impossible or requires a disproportionate effort, the data controller should provide a general information according to art. 14-5 of the GDPR [28].

Another issue has been solved in the new bioethics law regarding research using genome editing. The previous legal regime was unclear on the possibilities to perform research activities on embryos and gametes [29,30] as several provisions of the law were banning first to create transgenic embryos (previous art. L2151-2, PHC) and the modification of the integrity of the specie (CC, art. 16-4). Thus, these two articles have been modified to render lawful the modification of embryos and human embryonic stem cells in research while elaborating

<sup>2</sup> Constitutional information are those that are heritable.

corresponding safeguards: the research can only be performed on embryos already stored in the context of procreation that are no longer part of a parental project and under consent of the parents, the research must demonstrate its scientific interest, embryos cannot be re-implanted and the protocol must have obtained a prior positive opinion from the *Agence de la Biomédecine*.

### Genetic screening

For a long time, genetic and public health have ambiguous relations in France. Even though, prevention strategies were already in place for identified groups (notably in the context of procreation), the public policies were not deployed for the whole population for cultural reasons and regarding the eugenic risks. However, several patients' associations and geneticists were claiming for more openness of genetic testing for people that were not already identified at risk of having a genetic disease, in the name of the availability of new techniques allowing to better identify genetic defects. This argument was taken seriously by the legislators notably because of the deployment in France of a general program aiming at improving next generation sequencing techniques in clinical care [31]. The 2021 law supports this initiative through the adoption of a new provision allowing for the first time the possibility to propose to the whole population to have access to preventive genetic tests for neonatal screening. The new scheme proposes a complementary strategy to those already existing. To date in France neonatal screening is proposed for phenylketonuria, congenital hypothyroidism, sickle cell disease (for targeted populations), congenital adrenal hyperplasia and cystic fibrosis, and since the end of 2020, medium-chain fatty acid acyl-CoA dehydrogenase (MCAD) deficiency after a blot of a drop of blood on the child's heel (Guthrie test) which are not genetic testing. In the coming months, it will also be allowed to propose genetic analyses in first intention for selected diseases (the list is not yet adopted) to all parents on a voluntary basis and after their consent (PHC, art. L1411-6-1). This new practice is considered as an advance for the application of genetics in public health but will probably impact the practices on the feedback of results and on the information of relatives.

There have been two other proposals that the legislators have not implemented in the area of genetics. First, during the consultation phase of the *Etats généraux de la bioéthique*, strong discussions occur regarding pre-conceptional genetic screening [32]. Citizens considered that offering knowledge on the future genetic status of the child was an opportunity for parents but they also underlined that some risks on the interpretation of the results and on the severity of the diseases were remaining. Therefore, this option has not been part of the law submitted to Parliament. Second, the Senators proposed to adopt a new article in the bioethics law to allow widespread access to genetic testing for people without signs of genetic disease. Again, this proposal has not been successful for almost the same reasons and because of the lack of demonstration of their utility in practice.

### Genetics and data protection

Lastly, considering genetics as a provider of a genetic information, there is a need to collect, store and use it according to the General Data Protection Regulation [28]. GDPR aims at protecting individual rights regarding the processing of their data (processing means "any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction", GDPR, art.4-2) and to organise the circulation and sharing of this information. The main input of GDPR regarding Genetic Data is to provide for a definition: 'genetic data' means personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or

the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question (GDPR, art. 4-13). Even identified in the GDPR (art. 9) and in the French Law (art. 6, Law on informatics) to be a special category of sensitive data, genetic data legal regime falls under the umbrella of health data. However, there is one specificity regarding genetic data where, according to art. 9-4 of the GDPR "Member States may maintain or introduce further conditions, including limitations, with regard to the (ir) processing". By principle this data cannot be processed unless it is falling under one of the exceptions provided for in art. 9-2 of the GDPR. Among these exceptions, genetic data can be processed either under consent (GDPR, art. 9-2(a)), for medical investigations (GDPR, art.9-2 (h)) or for research (GDPR, art. 9-2(j)). Several personal rights are attached to this processing: prior information, access, rectification, erasure, data portability, right to object (GDPR, Chapter III). GDPR allows also Members States to adopt restrictive measures for certain categories of data which is the case for genetic data processed in research (GDPR, art.89). Thus, in France, the law on Informatics and Freedoms [5] in coherence with the PHC and the CC requires in particular, which is not the case of GDPR, that the processing of genetic data for research purposes be based on written consent, except in the case of re-use, where only non-opposition is required (LIL, art.75).

### Conclusion

The bioethics law in France forms the basis for the use of genetics in medical care and in research. The law has strongly promoted patients/participants in research rights asserting that prior information and consent are the core roots for performing genetic analyses. Despite the willingness of the legislators to open the new bioethics law to new social demands (for example regarding reproductive technologies), it has not been reached for genetics as the only possibility to have access to a genetic test is within the health system and under strict conditions. The next challenges will probably arise from the genetic data management side. Despite the provisions of the GDPR and of the LIL, the new possibilities offered by next generation sequencing and whole genome/exome sequencing will provide for massive data and the need to interpret them thanks to artificial intelligence [33]. The use and reuse of genetic data will also be challenged by the new European proposal for a Regulation on the European Health Data Space [34]. This will be another story...

### Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

### Informed consent and patient details

The authors declare that the work described does not involve patients or volunteers.

### Generative AI

During the preparation of this work the author used DeepL Write in order to review and improve English. After using this tool/service, the author reviewed and edited the content as needed and takes full responsibility for the content of the publication. The manuscript has also been reviewed by an English native speaker before submission.

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## Conflict of interest

The author declares that she has no conflict of interest.

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