'Big data analytics' and processing of health data for scientific research purposes : The french legal framework

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1. Overview of the legal framework

First, we would like to get an overview of the current and upcoming legal framework applying to the processing of health data for research purposes in your country.

a. Which laws regulate the processing of health data for research purposes (the current regime, in force till 25 May 2018)

What are the relevant applicable provisions governing the processing of health data in your country? Please provide online references (also to an English version, if available), a brief description and any specific relevant information.

Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés: Act n°78-17 of 6 January 1978 On Information Technology, Data Files and Civil Liberties

This Act governs the collection and the processing of personal data. The Act was adopted in 1978, and has been amended often since then, in particular in 2004 to transpose Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.[1] The Act was also amended twice in 2016, due to the modernisation of our [the French] health care system Act[2] and the Digital Republic Act.[3] It will undergo further changes with the implementation of the GDPR.

The Act is complemented by an implementation decree[4] from 2005. The Act and the decree will soon be revised to implement the GDPR in France.

This Act was amended by the Data protection Act of 20 June 2018, to reflect the changes introduced by the GDPR.

- Le Code de la Santé Publique: Public Health Code

The Public Health Code governs the provision of health services. This voluminous document contains provisions on the rights of patients, illness prevention, but also on the administration of health establishments. This Code also contains specific provisions relevant to data processing, in particular provisions concerning: medical research, the authorisation procedures by the Data Protection Authorities, and the provision of health data by the Système National des Données de Santé (the National System of Health Data).

This system, which was created in 2016 and was implemented in spring 2017, brings together the major public health data bases. "The National System of Health Data (SNDS) combines health insurance data (SNIIRAM), data from health

[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

[2] LOI n° 2016-41 du 26 janvier 2016 de modernisation de notre système de santé .

[3] LOI n° 2016-1321 du 7 octobre 2016 pour une République numérique.

[4] Décret n°2005-1390 du 20 octobre 2005 pris pour l'application de la loi n°78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés.

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care institutions (PMSI), the medical causes of death, data on disability (NCSA data from departmental homes for disabled persons), and a sample of supplementary health insurance reimbursement data."[5]

Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research.

The patient's (electronic) medical file: Dossier medical partagé (DMP)

In France, there is an electronic patient medical file that is shared amongst the medical team treating the patient.[6] However, it can only be used for medical treatment purposes, to ensure the coordination of treatment(s). Indeed, under Article L. 1110-4 (II) of the Public Health Code, "A professional may exchange information with one or more identified professionals concerning the same person receiving treatment, provided that they all participate in the care of this same person and that this information is strictly necessary for the coordination or continuity of care, prevention or medico-social and social follow-up."

Moreover, "In compliance with the professional (deontological) rules applying to them and Articles L. 1110-4, L. 1110-4-1 and L. 1111-2, each health professional, regardless of his or her mode and place of practice, shall enter in the shared medical file, at the time of each act or consultation, the diagnostic and therapeutic elements necessary to coordinate the care of the person receiving treatment. Whenever a covered person stays in a healthcare establishment, the authorised health professionals of the healthcare establishments shall enter in the shared medical file, in compliance with the obligations defined by the High Authority for Health, a summary of the main elements relating to this stay"[7].

Finally, the data contained in the shared medical file is protected by professional secrecy, any breach of which may be penalised under Article 226-13 of the Criminal code.

Based on this information, it follows that the shared medical file may only be shared among health professionals when following the treatment prescribed to patients.

- Le Code de la Recherche: the Research Code

The Research Code governs scientific research in France. It defines the rules governing the establishment of research policy, and research entities. This code also governs research activities such as medical and biomedical research, and, in particular, the processing of personal data.

Indeed, the Research Code[8] provides that the processing of personal data for scientific research purposes is governed by Chapter IX of the Act. Any breach of the obligations relating to the processing of personal data for scientific research purposes is penalised under the provisions set out in the Criminal Code.

[5] Rapport du groupe CSF mesure 1-5, « Promouvoir une démarche active visant à faciliter l'accès aux données de santé à des fins de santé publique, de recherche et de développement industriel », 29 mars 2017, Fiche 3 : Le Système National des Données de Santé, p. 10.

[6] Décret n° 2016-1545 du 16 novembre 2016 autorisant la création d'un traitement de données à caractère personnel dénommé « dossier médical partagé » .

[7] Article L. 1111-15 Code de la Santé Publique.

[8] Article L 225-1 and L 225-2 Research Code.

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- Le Code du Patrimoine: the Heritage Code

The Heritage Code brings together provisions governing heritage and cultural services. This is relevant for data protection and data processing due to the provisions concerning archives. Those provisions can be found in Book II of the legislative part of the Code, and as such apply to data and personal data. Archives can be public or private. The relevant provisions describe the modalities for transferring personal data to archives, in particular the selection of the data to be archived. This selection is made by common agreement between the data-holding body and the administration. Once this agreement has been made, the data is transferred to the competent public archives services.

The personal data kept in the archive under the provisions of the Heritage Code may be used for research in the field of health purposes. In such an instance, the information obligation rests upon the controller under Article 57 (II) of the Act.[9]

- Le Code Pénal: the Criminal code

The Criminal code governs criminal responsibility and the associated penalties. Concerning personal data, any breach of the obligations laid down in the 1978 Act is punished under Article L.226-16 and following of the Criminal Code. Any offences constituting a breach of the rights of a person resulting from the archive system or any data processing are punished by a maximum fine of € 300,000 and five years' imprisonment. Moreover, breach of professional secrecy, as provided by Articles 8 (the processing of sensitive data), 20 (the CNIL agents' professional secrecy obligation), 54 (the processing authorisation for scientific research purposes) and 55 (the professional secrecy obligation for data processors) of the 1978 Act are punished by up to one year's imprisonment and a € 15,000 fine under Article L.226-13 of the Criminal Code.

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework introduced by the GDPR addressed in your country? What is the adopted legislative approach?

To ensure the French framework's compliance with the data protection package, the Act has been amended. In December 2017, the French government presented a Bill amending the 1978 Act to the National Assembly.[10]

The Bill was preceded by an extensive explanatory statement. This statement detailed the approach followed by the French government in proposing the Bill. It was also the opportunity to highlight the fact that, the Bill did not abrogate the 1978 Act. Indeed, the government considers the Act to have a symbolic value. Therefore, the Bill only amended some provisions and abrogated others. But the basic articles stating the main principles and values promoted by the 1978 Act remain. Incidentally, this particular approach made the result relatively unclear[11] and

[9] Article 57 of the Act n° 78-17.

[10] https://www.legifrance.gouv.fr/affichLoiPreparation.do;jsessionid=F4A991BA7EDE1988C4E10B6836C3258C.tplgfr36s_3?idDocument=JORFDOLE000036195293&type=general&typeLoi=proj&legislature=15.

[11] Conseil d'État, Avis sur un projet de loi d'adaptation au droit de l'Union Européenne de la loi n°78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés, NOR : JUSC1732261L, §9.

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both the Conseil d'État and the Commission National de l'Informatique et des Libertés (the CNIL) share this opinion. In its Opinion, CNIL considered the Bill misleading for the data subject regarding the scope of his or her rights and obligations. Indeed some of the Act's provisions are formally unchanged and still in force, but they no longer apply because they are replaced by GDPR provisions. Moreover, national law will not reflect certain new rights or obligations imposed by the Regulations.[12]

Given that the Regulation is directly applicable, the Bill only dealt with the provisions giving some leeway to the Member States. Nevertheless, the government had sometime chosen not to take up this option.

This Bill has been enacted the 20 June 2018. After having been assessed by the "Conseil Constitutionnel", and found partially non-compliant to the Constitution[13]. This Act on the protection of personal data amends the existing Act. The modified data protection Act shall be referred to as the New Data Protection Act (NDPA). This NDPA takes some of the opportunities given by the GDPR for leeway. However this text remains extremely unclear, in particular concerning the rights of data subjects[14]. But, according to Article 32 of the Act, the Act as a whole is to be rewritten by Ordinance[15] to ensure its clarity and coherence. This Ordinance is to be enacted within six months after the enactment of the Bill.

Moreover, the Bill also transposes into national law EU Directive 2016/680 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 by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data.

This analysis relies on the NDPA, the Bill's introductory statement, the Conseil d'État's Opinion[16] concerning the Bill, and CNIL's Opinion, as well as the government's Impact assessment of the Bill.[17]

c. The national data processing authority

Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current legal framework?

[12] Commission Nationale Informatique et Libertés, Délibération n° 2017-299 du 30 novembre 2017 portant avis sur un projet de loi d'adaptation au droit de l'Union européenne de la loi n°78-17 du janvier 1978, p. 4.

[13] Décision n°2018-765 DC du 12 juin 2018 ; http://www.conseil-constitutionnel.fr/conseil-constitutionnel/francais/les-decisions/acces-par-date/decisions-depuis-1959/2018/2018-765-dc/decision-n-2018-765-dc-du-12-juin-2018.151485.html

[14] https://www.cnil.fr/fr/loi-78-17-du-6-janvier-1978-modifiee

[15] In conformity with the Article 38 of the French Constitution (English version).

[16] Conseil d'État, Avis sur un Projet de Loi d'adaptation au droit de l'Union européenne de la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés, NOR: JUSC1732261L.

[17] Etude d'Impact, Projet de loi relatif à la protection des données personnelles, NOR : JUSC1732261L/Bleue-1, 12 décembre 2017.

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In France, the CNIL is an independent administrative authority, it is governed by the provisions of Article 11 and following of the 1978 Act. One of CNIL's functions is to authorise the processing of personal data for scientific research of public interest (Article 11, 2°, a, Article 25 (I) 1° and Article 8 (IV), as well as Article 54 (I)) (or Article 53).

Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?

Title I of the Bill deals with CNIL and its powers and obligations. CNIL is named as the French independent supervisory authority. Such authorities are governed by the provision of Chapter VI of the GDPR (Articles 51 to 59). Article 54 of the GDPR provides that each Member State must set in law the rules establishing the supervisory authority.

Accordingly, the NDPA modifies the articles of the Act regarding CNIL's powers. Additionally, regarding its obligations, CNIL must draw up and publish guidelines, recommendations or reference documents. They are intended to ease the compliance of data processing operations with the texts relating to the protection of personal data and help controllers and their processors carry out prior risk assessments. CNIL will encourage the drawing up of codes of conduct setting out the obligations incumbent on controllers and processors, taking into account the risk inherent in the processing of personal data for individuals' rights and freedoms. CNIL will acknowledge and publish the reference methodologies referred to in Article 54, II, to promote compliance with the processing of personal health data. Moreover CNIL will be consulted during the legislative process regarding the Bill dealing with the processing of personal data

The conditions of audits and investigation, in particular any visit of the controller's premises by CNIL's agents are amended. The NDPA also contains provisions regarding the relations and cooperation between CNIL and other European data protection authorities. Finally, Article 45 to 48 of the NDPA list the measures that CNIL can take to correct and punish the breach of the controller's obligation as set out by the Regulation or the Act.

2. Transposition of Article 8.4 of Directive 95/46

Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?

Art. 8.4 of Directive 95/46: "4. Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority."

a. Transposition of Article 8.4 of Directive 95/46

In France, data concerning health is a special category of personal data and as such its processing is prohibited by Article 8 (I) of the 1978 Act. However, the prohibition does not apply if, among other grounds, the data subject has given his/her express consent, or when the processing is done for medical purposes (Article 8 (II)(1°, 6°)).

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The exemptions, as taken up by the national legislator in applying Article 8.4 of the Directive, are laid down in (7°) data processing for statistical purposes carried out by the INSEE[18] or a ministry following a legal obligation, and (8°) data processing for research, studies and evaluations in the field of health. Moreover, CNIL may authorise some categories of the processing of personal data concerning health if the data has been subjected to an anonymisation protocol within a short time period and depending on the processing activity's purpose Article 8 (III). However, this authorisation is based upon CNIL's prior approval of the anonymisation protocol.[19] Once the anonymisation protocol has been approved, the provisions on the data processing for research in the field of health will no longer apply. Finally, the processing of sensitive data is possible if authorised by CNIL or the State's Council's Decree based upon CNIL's opinion and justified by the public interest.[20]

The most relevant to this study is the processing exemption for research, studies and evaluations in the field of health, following the procedures set in Chapter IX of the Act, governing research in the field of health.[21]

From these provisions we notice that the processing, for scientific research purposes, of sensitive data that was not anonymised is governed by a specific regime. This regime is defined in Chapter IX of the Act (see below).

b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes?

[18] Institut National de Statistiques et d'Etudes Economiques – The National Institute of Statistics and Economic Studies.

[19] Act n° 78-17, Article 8 (II) - *7° Statistical processing carried out by the National Institute of Statistics and Economic Studies or one of the ministerial statistical services in accordance with Act No. 51-711 of 7 June 1951 on the obligation, coordination and secrecy of statistics, after consulting the National Council for Statistical Information and under the conditions provided for in Article 25 of this Act;*

8° The treatments necessary for research, studies and evaluations in the health field in accordance with the procedures set out in Chapter IX.

III. If the personal data referred to in I is called upon to be subject to an anonymisation process at short notice, previously recognised in accordance with the provisions of this Act by the National Commission on Information Technology and Freedoms, the latter may authorise, taking into account their purpose, certain categories of processing operations in accordance with the procedures laid down in Article 25. The provisions of Chapter IX shall not apply.

[20] Act n° 78-17, Article 8- (*IV)- Similarly, processing operations, whether automated or not, justified by the public interest and either authorised under the conditions laid down in Article 25 (I) or Article 26 (II) or declared under the conditions laid down in Article 22 (V) shall not be subject to the prohibition laid down in (I).*

[21] Article 8 (II) 8°: *The treatments necessary for research, studies and evaluations in the health field in accordance with the procedures set out in Chapter IX.*

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Chapter IX, in its Article 54,[22] distinguishes between two main categories of research:[23] research involving the human person, and the research studies or evaluation not involving the human person.

Research involving the human person is defined by the Public Health Code. This refers to research that is organised and carried out on human beings with a view to the development of biological or medical knowledge. There are three types, depending on the level of patient involvement:

- Interventional research that involves an intervention upon the person that is not justified by his or her usual care;
- Interventional research involving only minimal risks and constraints, the list of which is fixed by order of the Minister for Health, after consulting the Director General of the National Agency for the Safety of Medicines and Health Products;
- Non-interventional research that involves no risk or coercion in which all acts are performed, and products are used in the usual manner.

The research may proceed once CNIL have given its authorisation. However, the CPP's (Person's Protection Committee) Opinion must be obtained prior to applying to the CNIL for its authorisation.

But CNIL's authorisation is not necessary if the research follows the referential methodologies detailed by CNIL, and that the controller has declared on CNIL's website that the research would be lead in conformity with that methodology.[24] This step considerably simplifies the procedure.

The second category includes research studies or evaluations not involving the human person. This is health research that does not belong to research involving the human person. In particular, it is research requiring only the re-use of covered personal health data (e. g. from medical records, existing cohorts, or the National System of Health Data). For this category of research, CNIL's authorisation is necessary too. But the Controller will have to obtain CEREES' opinion (the expert committee for research, studies and evaluations in the field of health) prior to applying CNIL for its authorisation. CNIL has yet to adopt methodologies of reference for research not involving the human person.

Although the processing of personal data for research purposes is subject to CNIL's authorisation, the application for such an authorisation is not addressed directly to CNIL but to the National Institute of Health Data. This institution guides the applicant during the authorisation procedure.

[22] Act n° 78-17, *Article 54 - (I) - Processing of personal data for the purposes of research, study or evaluation of public interest in the field of health shall be authorised by the National Commission on Information Technology and Freedoms, in accordance with the principles defined by this Act and according to the public interest that the research, study or evaluation presents.*

[23] https://www.cnil.fr/fr/recherches-dans-le-domaine-de-la-sante-le-nouveau-chapitre-ix-est-applicable.

[24] Act n° 78-17, Article 54 (IV): *IV - For the most common categories of automated processing of personal health data for research, study or evaluation purposes in the field of health, the National Commission on Informatics and Freedoms may approve and publish reference methodologies designed to simplify the examination procedure.*

These are established in consultation with the expertise committee and public and private bodies representing the stakeholders concerned.

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Indeed, the application is made to the "secretariat unique",[25] which is run by the National Institute of Health Data,[26] under Article L 1462-1 1° of the Public Health Code. Depending on the nature of the research, the single secretariat will direct the application to the competent committee for an opinion.

The competent CPP has 45 days to adopt an opinion on the data processing, and the CEREES[27] has a month. They both adopt opinions explaining their findings. If CEREES fails to adopt an opinion within a month, its opinion is considered to be favourable. The opinions of the Committee are communicated to the applicants. If the given opinion is favourable to the data processing, or if the applicant informs the single secretariat of its intention to seize CNIL, the single secretariat transfers without delay the application and the opinion, or the application notification in case of a tacit favourable opinion, to CNIL. Each committee is informed of the follow-up to its opinions.

Accordingly, when CNIL considers such an application, it must assess the processing protocol in the light of the principle protected by the Act and the public interest that the respective research, study or evaluation presents.

When assessing an application,[28] CNIL checks the controller's guarantees, and the conformity of controller's demands to the controller's missions and corporate purpose. If CNIL considers the guarantees offered to be insufficient, it can forbid the transmission of data to the applicant or allow only the processing of reduced data. Additionally, the commission rules on the duration of data conservation and measures taken to ensure its safety.

If the Commission deems it necessary,[29] the National Institute of Health Data[30] can be consulted on the public interest of the research project for which the processing authorisation is required. The National Institute of Health Data can also provide an opinion on the public interest of the research project on its own initiative, under the conditions set out in Article 24 of the implementation decree. The National Institute of Health Data has one month to give an opinion on the public interest character of such a research project.

CNIL may through a single decision give to the same controller a processing authorisation for the same purpose about identical data categories having identical recipient categories.[31]

[25] Article 54 (II) Paragraph 5.

[26] This National Institute of Health Data (INDS: Institut National des données de santé) is a public interest group comprised of the State, associations representing patients, users of the health system, health data producers and public and private users of health data, including medical research organisations. This institute is primarily tasked with ensuring the quality of health data, and the condition of this data's availability to the public, in the context of the Act's provisions.

The Institute is also the single secretariat set out in Article 54 of the Act. The Institute provides its opinion on the public interest of a research project, as provided by the same article. Moreover, the Institute facilitates the provision of sets of aggregated data as approved by CNIL, following Article 54(V) of the Act. The opinion of the committee is explained and given within 45 days.

[27] Act n° 78-17, Article 54 (II) Paragraph 2.

[28] Act n° 78-17, Article 54 (III).

[29] Act n° 78-17, Article 54 (II) Paragraph 4.

[30] The National Institute of Health Data – Institut National des Données de Santé has its legal basis in Article L1462-1 of the Public Health Code.

[31] Act n° 78-17, *Article 54 - (VI) The Commission may, by a single decision, issue an authorisation to the same applicant for processing operations for the same purpose, involving identical categories of data and having identical categories of recipients.*

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In France, Chapter IX of the Act governs data processing for scientific research, studies or evaluation in the field of health purposes. Such processing is governed by a specific authorisation regime and its scope is defined by Article 53 of this Act.

However, the processing of data for medical and therapeutic purposes is not subject to a specific authorisation regime, nor are the processing enabling studies carried out on the basis of the data collected for medical and therapeutic purposes when carried out by the staff performing the monitoring, which is intended for their exclusive (internal) use. Those processing operations fall under the general authorisation regime set by Article 25 of the Act.

Specifically, Chapter IX applies to two categories of research involving data processing: the first is research involving the human person, such as clinical trials; the second concerns research or studies not involving the human person, such as, in particular, research and studies requiring only the re-use of personal data concerning health.

From which generally applicable data protection provisions are researchers exempted and under what conditions?

In France, Chapter IX sets out the regime applying to scientific research; thus the general regime does not apply, and the data controller's obligations can differ from the general regime.

According to Article 53 paragraph 1, Articles 23, 24, 25 (I), 26, 32 and 38 do not apply to the processing of personal data for research in the field of health purposes. Articles 23 and 24 respectively provide the obligation to declare a processing operation to CNIL, and a simplified declaration procedure. Article 25(I) indicates the instances in which CNIL's authorisation is required prior to the processing operation. Article 26 lists the instances in which the authorisation to process personal data is given by a competent minister, following CNIL's opinion. Article 32 sets out an obligation to inform the data subject or the person from whom the data has been collected. Article 38[32] gives the data subject a right to object to the processing for legitimate reasons.

Accordingly, researchers are not subject to the general regime's default notification to the CNIL. Instead a specific regime, tailored for scientific research in the field of health, apply to them as stated in Article 53 paragraph 1. However, this does not imply that such a data subject's right and controller's obligation do not exist. They are simply provided by different provisions laid down in Articles 56 and 57.

[32] Act n° 78-17, *Article 38 - Any natural person has the right to object, for legitimate reasons, to the processing of personal data concerning them.*

They shall have the right to object, free of charge, to data relating to them being used for the purposes of prospecting, in particular for commercial purposes, by the current controller or that of further processing.

The provisions of the first subparagraph shall not apply where the processing complies with a legal obligation or where the application of those provisions has been excluded by an express provision in the act authorising the processing.

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c. Are there additional specific conditions governing the processing of data for scientific research purposes?

What are the suitable safeguards applied to the exemption foreseen by Article 8.4 of the Directive in your country?

The text of Article 8 (4) of the Directive requires that the processing of sensitive data, when authorised by the Member States for reasons of significant public interest, are subject to suitable safeguards. In the French legal framework, processing for scientific research in the field of health is an exemption to the Directive's prohibition. However, these processing operations are governed by the provisions of Chapter IX of the Act, which, apart from requiring an authorisation from CNIL, sets out other requirements.

Are there any specific provisions concerning: (i) professional secrecy, (ii) express consent for specific data, or specific provisions for (iii) deceased data subjects, or (iv) specific provisions for minors or persons subject to guardianship?

Personal data concerning health is protected by professional secrecy.[33] However, according to Article 55, health care professional may transmit such data, with special care, in the context of studies and research falling within the scope of Article 53. But, as set out earlier, the recipient of the data is subject to professional secrecy obligations too. The protection afforded by professional secrecy to health data is thus considerably diluted[34] because the scope of the secrecy regarding the personnel to whom it applies is extended.

However, Article 56 provides the right for anyone to oppose the lifting of professional secrecy on health-related data concerning them, which would be made necessary by any processing permitted by Article 53. For example, if research requires biological samples identifying data subjects and their processing, then those data subjects must give their explicit and informed consent beforehand. The data concerning a deceased person may be processed unless they explicitly objected in writing while they were alive.

Article 58 of the Act concerns the data of minors, or persons under guardianship. The information provided under Articles 56 and 57, and the rights provided by the same articles are exercised by the legal representative of minors and persons under guardianship. However, for the processing of data for research stated in Article L1121-1, §1, 2° and 3° of the Public Health Code, or when the medical research has a public interest aim and includes minors, only one legal representative (the holder of parental authority) must be informed, if the other one cannot be found in a time frame compatible with the study's methodology. However, this situation does not mean that both holders of the parental authority cannot use their rights of access, information and objection later on. For the same category of processing, a minor that is 15 years old or older can object to the accessing of his/her personal data that has been collected during the medical study by the holder of the parental authority. In such a case, the minors receive the information as provided by Article 56 and 57 of the 1978 Act, and exercises his/her rights alone. Any minor that is

[33] Article L. 1110-4 du code de la santé publique.

[34] Jean-Marc Sauvé, Vice-President du Conseil d'Etat (France), Septièmes entretiens du Conseil d'Etat en droit social, Santé et protection des données, Introduction, p. 7.

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15 years old or older may also object to the information of the holder of the parental authority, if the information would reveal any action of prevention, screening, diagnostic, treatment or intervention for which the minor explicitly objected to the information of the holder of the parental authority, or if the family ties have been broken and the minor is the beneficiary of his/her own health insurance.

Are there specific requirements about the data subject's information or about the person from whom the data was collected?

Chapter IX of the Act, in Article 53, exempts researchers from some of the general obligations laid down in the Act such as, to some extent, the obligation to inform the data subject. However, this exemption does not mean that the data subject is not informed altogether, because Article 57, which is part of Chapter IX on the processing of persona data for scientific research in the field of health, provides for a data subject's information. Indeed, Article 57 (I) provides that the data subject or the person from whom the data was collected are to be individually informed prior to the processing of: the nature of the information transmitted, the purpose of the processing, the natural or legal person to whom the data is addressed, their right of access and rectification, their right to object in specific cases, and the controller's obligation to obtain their consent in some instances.

Moreover, under Article 59, any establishments or centres having any prevention, diagnostic or caring activity that would cause the transmission of personal data for processing under Article 53 should provide information on Chapter IX of the 1978 Act.

Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

Article 60 provides[35] that any breach of the obligation set out in Chapter IX of the Act would cause the suspension or withdrawal of the authorisation given under Article 54. The same penalty applies in the case of a refusal to submit to the verifications set out in Article 11, 2° f) of the 1978 Act. Those verifications are carried out by CNIL staff upon a controller's processing activities. Those checks are carried out following the provision of Article 44 of the Act.

d. Formalities prior to processing: the general regime under the current framework

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail?

[35]Act n° 78-17, *Article 60 - The processing of data in breach of the conditions laid down in this Chapter shall entail the temporary or permanent withdrawal, by the National Commission for Information Technology and Civil Freedoms, of the authorisation granted under Article 54. The same shall apply in the event of refusal to submit to the verifications provided for in subparagraph f of 2° of Article 11.*

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In France the regime is set out by Chapter IV of the 1978 Act. In particular, it applies to the processing of sensitive data that is to be subject to an anonymisation protocol within a short time-period.

Under Article 22 (I): *"(…) automatic processing of personal data shall be declared to CNIL"*. Article 23 sets out the notification procedure. CNIL will deliver a receipt of the notification as soon as possible, and then the controller can start the processing.

Moreover, Article 22 (III) provide for the designation within the organisation – which is not mandatory - of a "correspondant informatique et libertés"[36]. This correspondent will ensure compliance with the law. The appointment of the correspondent is notified to CNIL and exempts the organisation from the declaration formalities set out in Articles 23 and 24 of the Act.

There is also a simplified declaration procedure for the most common processing activities. This procedure is set out in Article 24 of the Act.

However, there are some exceptions to this principle set out in Article 22 (II). Some processing activities simply do not have to be declared. While some others have to be authorised by CNIL

The authorisation procedure is set out in Article 25 (and the following). Article 25 exhaustively lists the processing operation requiring a CNIL authorisation. According to Article 25(III) of the Act, CNIL must decide on the authorisation within a two month timeframe running from the receipt of the application. The time period can be renewed once with an explained decision of the President of the Commission. However, if CNIL fails to authorise a processing, then the application is deemed to be rejected.

The processing of pseudonymised data or of identified patient data are both ruled by the same provisions. However, Article 8 (III) states that:

"*If the personal data referred to in (I) (that is sensitive data) is called upon to be subject to a process of anonymisation on short notice, which was previously recognised in accordance with the provisions of this Act by the CNIL, the latter may authorise, taking into account their purpose, certain categories of processing operations in accordance with the procedures laid down in Article 25. The provisions of Chapter IX shall not apply.*"

It follows that anonymised data may be processed after CNIL's prior authorisation following the general authorisation procedure set out in Article 25 of the Act.

3. Further processing of health data (for research purposes): the current regime

As seen above, the further use of personal data is particularly relevant for scientific research. Indeed, the second of the two main categories of scientific research in the field of health provided by Article 54 of the Act is scientific research not involving the human person. CNIL has interpreted this notably as research requiring further use of personal data (concerning health). This category of research use is governed by Chapter X of the Act regarding the processing of personal data concerning health for the evaluation or study of practice or the activity of care and

[36] Correspondant informatique et libertés : Informatics and Freedoms correspondent.

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prevention, which was abrogated by the Act on the reform of our [the French] health care system since January 2016.

How is the notion of further processing regulated in your national framework?

In the 1978 Act, the notion of 'further processing' (traitement ultérieur) is found in Article 6, 2° and 3° of the Act.[37]

To be lawful, further processing must be compatible with the purpose of the processing for which the data was collected. Indeed, data is collected for a determined purpose, and cannot be processed in a manner incompatible with this purpose.

However, further processing of data for statistical purposes or for scientific or historical research purposes shall be deemed compatible with the initial purpose of processing, if it is respectful of the principle and procedures set out in: Chapter IV, in particular in Section 1 of Chapter V (the obligation of the data controller), Article 32[38] (III) deals with the processing of personal data that has not been collected from the data subject, and at Chapter IX (processing for research in the field of health). These are the required conditions for it to be presumed to be compatible with the purpose of the initial processing.

Chapter IV[39] deals with formalities prior to processing, which are the notification of data processing, and the possible exemption and the authorisation given by CNIL. This means that the further processing of personal data is subject to the same conditions as the initial processing. It must be notified when necessary and approved when need be.

[37] Act n° 78-17, *Article 6 - Processing may only relate to personal data which satisfies the following conditions:*

1° The data is collected and processed fairly and lawfully;

2° It is collected for specific, explicit and legitimate purposes and is not further processed in a manner incompatible with those purposes. However, further processing of data for statistical purposes or for scientific or historical research purposes shall be considered compatible with the initial purposes of data collection if it is carried out in accordance with the principles and procedures laid down in this Chapter, Chapter IV and Section 1 of Chapter V and Chapter IX and if it is not used to take decisions in respect of the persons concerned;

3° It is adequate, relevant and not excessive in view of the purposes for which it is collected and its further processing;

4° It is accurate, complete and, where necessary, kept up-to-date; appropriate steps must be taken to ensure that data which is inaccurate or incomplete with regard to the purposes for which it was collected or processed is erased or rectified;

5° It shall be kept in a form which permits the identification of data subjects for no longer than is necessary for the purposes for which it is collected and processed.

[38] Act n° 78-17, Article 32 – (III) - Where personal data has not been obtained from the data subject, the controller or his/her representative must provide the data subject with the information listed in (I) as soon as the data has been recorded or, if a communication of the data to third parties is envisaged, at the latest when the data is first communicated. Where personal data was initially collected for another purpose, the provisions of the preceding paragraph shall not apply to the processing operations necessary for the preservation of such data for historical, statistical or scientific purposes, under the conditions laid down in Book II of the Heritage Code or for the reuse of such data for statistical purposes under Article 7a of Law n°. 51-711 of 7 June 1951 on the obligation, coordination and secrecy in relation to the protection of personal data. These provisions shall also not apply where the data subject is already informed or where his or her information proves impossible or requires efforts disproportionate to the interest of the measure.

[39] Article 22 to 31 of the Act n° 78-17.

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However according to Article 32 (IV),[40] when further processing shortly entails an anonymisation protocol, as approved by CNIL, the information delivered to the data subject can be limited to the data controller's identity and the purpose of the processing. Moreover, further processing must not be used to take a decision about the data subject.

Further processing is also treated in Article 6, 3° of the Act, which incorporates the notion of data minimisation. This also implies that the possible further processing may already be acknowledged when the data is collected.

Are there specific conditions to the further processing for scientific research in the field of health purposes?

Chapter IX of the Act deals with processing of personal data for scientific research concerning health. It does contain specific provisions concerning further processing. Under Article 54 (V),[41] sets of aggregated data or samples of data from the processing of personal data related to health purpose and if they comply with the Act may be put at the disposal of controllers in settings previously agreed by CNIL, without the authorisation of Article 54 (I) being required.

This means that aggregated data and samples generated by prior processing activities, in conformity with the Act, may be made available, with CNIL's agreement. Such data and samples can then be used without requiring the authorisation set out in Article 54. However, the conditions upon which the data are made available must be agreed on by CNIL. Indeed, CNIL has 3 months to give its agreement, following the opinion of Committee that was consulted during the first authorisation procedure.[42]

What are the rights of the data subject when it comes to further processing?

Article 32, in its sections (I) and (II), sets out the data controller's obligation for processing and further processing. The controller must inform the data subject from whom the data is collected notably about: its identity, the purpose of the processing, the nature of the answers given (compulsory and optional), the identity of the recipient(s), of the data subject's rights to object, rectify, to be informed. The data subject must be notified about any intention to transfer his/her data outside the EU, and the duration for which the data will be stored.[43]

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[40] Act n° 78-17, Article 32 – (IV) - If the personal data collected is to be subject to a process of anonymisation which has been previously recognised under the provisions of this law by the National Commission for Information Technology and Freedoms, then the information provided by the data controller to the data subject may be limited to that stated in 1° and 2° of (I).

[41] Act n° 78-17, *Article 54 - V. - Aggregate datasets or samples derived from the processing of personal health data for purposes and under conditions recognised by the National Commission on Information Technology and Civil Freedoms as being in conformity with this law may be made available, under conditions previously approved by the commission, without the authorisation provided for in I of this article being required.*

[42] Decree n°2005-1390, *op. cit.*, Article 34-3

[43] Act n° 78-17, *Article 32 - I. -The person from whom personal data relating to him/her is collected shall be informed, unless he/she has been previously informed, by the controller or his/her representative:*

1° The identity of the controller and, where applicable, that of his/her representative;

2° The purpose of the processing for which the data is intended;

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Article 32 (III), described earlier, deals specifically with the rights of the data subject for further processing. In its first paragraph, this article obliges the controller to inform the data subject, if the data was not collected from him/her, about: its identity, the purpose of the processing, the nature of the answers given (compulsory and optional), the identity of the recipient(s), of the data subject's rights to object, rectify, to be informed. The data subject must be notified of any intention to transfer his/her data outside the EU, and the duration for which the data will be stored.

The second paragraph of Article 32 (III) provides that if the data was initially collected for a purpose different from that of the further processing then there are exceptions to the obligation to inform the data subject. These exceptions apply in two instances, when the data is processed for a public archived purpose, or when the data subject has already been informed or cannot be reached (through making a reasonable effort).

Moreover, under Article 38, a data subject may object without any costs to the further use of data concerning him/her by the controller. However, this right to object does not apply to further processing for scientific research purposes.

What about the data subject's rights and further processing for scientific research purposes?

The provisions[44] governing the obligation to inform the data subject are, as noted earlier, derogated to scientific research in the field of health by Article 53. However, the controller still has an obligation to inform the data subject when possible.

Article 57 of the 1978 Act provides for an obligation to individually inform the data subject or the person by whom the data was collected of: the nature of the transferred data, the purpose of the data processing, the identity of the recipient of the data, his/her right to access and/or rectify the data concerning him/her[45] and of his/her right to oppose the lifting of the professional secrecy on the data concerning him/her, and the obligation to obtain his/her consent for the processing of any identifying data collected by biological sample.

However, data cannot be delivered if the person concerned is not aware of its content, by ethical choice of the practitioner.[46]

3° The compulsory or optional nature of the answers;

4° Possible consequences, in his/her regard, of a failure to reply;

5° Recipients or categories of recipients of data;

6° The rights it derives from the provisions of section 2 of this chapter, including the right to define guidelines on the fate of personal data after death;

7° Where appropriate, the planned transfers of personal data to a non-member State of the European Community;

8° The length of time for which the categories of data processed are kept or, if impossible, the criteria used to determine this length of time.

Where such data is collected by means of questionnaires, they must indicate the requirements set out in 1°, 2°, 3° and 6°.

[44] Articles 32 and 38 of the Act n° 78-17.

[45] As provided by Article 39 and 40 of the Act n° 78-17.

[46] Act n° 78-17, Article 57 (I) paragraph 1.

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Moreover, Article 57 (II) provides that if the data was initially collected for a purpose other than medical research (secondary use) the obligation to inform may be derogated to under two conditions. First, when data is processed for the conservation of that data for historical, scientific or statistical purposes. In that case, the conservation protocol must conform with Book II of the Heritage Code. In particular, Article L212-3, under which a selection of the data destined to be preserved has administrative value or scientific, statistical or historical value. This selection happens when the time period necessary for the purpose for which the data is collected and processed comes to an end. Second, the obligation to inform the data subject can also be derogated when the concerned person cannot be found. But, in both instances, CNIL rules over the application for a derogation to the controller's obligation to inform data subjects.

Moreover, Article 57 (III) also provides a derogation to the data subject's right, described above, for the further processing of personal data stored in an institutionalised database. Indeed the modality of the information of the concerned person about the possible reuse if his/her data for medical research purposes, and the modality of the exercise of his/her rights are defined by a Conseil d'État decree. This decree was taken following CNIL's opinion. It applies when medical research, studies or evaluation relies on personal data collected on a mandatory basis that does not directly identify the person concerned and which was initially destined for the State, local authorities or social security organisations.[47]

4. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes). How is (or will be) Article 9(2)(j) implemented in your country?

Article 8 NDPA is the new provision on sensitive data, in which processing is in principle prohibited. The government has attempted to synchronise, including the processing, activities that are not within the scope of EU law. The definition of sensitive data is extended to included genetic and biometric data.

Article 9 aims to simplify the formalities prior to the processing of personal data. The NDPA abrogated most of the declaration regime, and most of the obligations of authorisation for processing.

Article 36 NDPA concerns processing for archiving purposes. this new article makes an explicit reference to the GDPR and to its possible derogations. Indeed, the Article 36 indicates possible derogations to Articles 15, 16, 18, 19, 20

[47] SNDS and other public databases, see Part VII of this study.

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and 21 of the Regulation to the extent that the right is likely to render impossible or seriously impair the achievement of the specific purpose of archiving.

Chapter IX of the Act applicable to the processing of personal data in the field of health has been redrafted. This chapter deals with the processing of personal data for research, study or evaluation purposes in the field of health.

b. Modification to the processing authorisation procedure applying to research in the field of health

Once the controller has made a data protection impact assessment, and the results indicate high risks in the absence of measures taken to limit such risks, then the controller will consult the competent supervisory authority.[48] The Authority can take action within an eight week time period. However, Article 36 (5) of the GDPR leaves the opportunity to the Member States to further regulate this issue for processing carried out in the public interest, in particular for social protection and public health. The French law takes up this opportunity.

How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change?

In France, the new procedure set in chapter IX not only applies to data processing for research purposes but also to health data processing in the scope of Article 53. The new Article 54 indicates that the processing falling under the scope of Chapter IX can be implemented only if the purpose of the processing exhibits sufficient public interest quality.[49]

The scope of Article 53 excludes the processing done with the explicit consent of the data subject, based on vital interest, based on the processing by non-profit organisation of religious, philosophical, political or trade union nature (under certain conditions), based on data made publicly available by the data subject, necessary to the establishment, exercise or defence of a legal claim, and processing necessary for medical purposes. Th chapter IX is also not applicable to studies carried out by the controller based on data collected for medical purpose (prevention, diagnoses…).[50]

The GDPR causes a change of logic in the French approach and the authorisation procedure would now be the exception. This change of logic is visible in the Bill, which adapts the procedure, and makes use of the existing mechanism. However, this new procedure still distinguishes the processing of personal data in the field of health from the processing of personal data for research, study and evaluation in the field of health.

- The processing of personal data in the field of health is governed by general provisions, the main points are as follows:

[48] Article 35 and 36 GDPR.

[49] Article 54 (I) NDPA

[50] Article 53 NDPA

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In an effort to make the process flexible, CNIL will adopt, in consultation with the National Health Data Institute, guidelines and processing baseline.[51] These CNIL guidelines may contain recommendations about the safeguard measures to be adopted. Processing in conformity with those guidelines and baseline can be implemented after CNIL has been notified and sent a declaration of conformity.

The processing operations which are not in conformity with the CNIL guidelines[52] can be implemented only after CNIL has given its authorisation. CNIL or the competent Minister can request the Health Data National Institute to assess the public interest of the processing operation in question.

In such instances, CNIL must give or refuse an authorisation within two months,[53] otherwise the authorisation is deemed to be granted.

From this procedure, we can infer that the public interest quality required is relatively easy to demonstrate, and the National Health Data Institute's opinion about it is not necessary. However, this procedure has yet to be tried. The procedure of Article 54 (the current framework), which also gives a certain importance to the public interest quality of a processing has not yet led to any authorisation, due to its length and CNIL's work overload.

- Specificities of processing for scientific reasons are dealt with in the new Articles 61 to 64:

Section 2 of the new Chapter IX deals with personal data processing for research, study or evaluation in the field of health purposes. The Article 61 NDPA indicates that the general provisions set out in section 1 apply as long as there is no conflict with the provisions set section 2.

Those reservations are set out by the following articles. Under the Article 62 NDPA, CNIL will certify and publish baselines and reference methodologies. They are established in concert with the National Health Data Institute and public and private entities representing the organisations concerned. If the processing is in conformity with these methodologies, then CNIL's authorisation is not necessary. A simple declaration of conformity with the CNIL guideline[54] is required prior to the implementation. Otherwise, according to the Article 64, CNIL grants authorisation following the Article 54 procedure, following the opinions of the CPP and CEREES. The application is made to a secretariat unique, managed by the National Health Data Institute. In this respect the "old procedure" described earlier still applies; but it has now become the exception.

However, when the processing requires the examination of the genetic characteristics of the data subject, their explicit and informed consent is necessary[55], unless processing is done the data subject cannot be found. The person responsible for the research must ask for the opinion of a CPP.[56] This provision shows a higher degree of protection for genetic data.

[51] Article 54 (II) NDPA

[52] Article 54 (III) NDPA

[53] Article 54 (V) NDPA

[54] Article 62 NDPA

[55] Article 63 NDPA

[56] Article L. 1131-1-1 Code la Santé publique

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The new procedure does not have many differences compared to the previous one, other than the inversion between the principle and the exception to meet the new logic imposed by the Regulation. However, in the new procedure, as in the previous one, the notion of public interest is central.

What about the right of the data subject and the obligations of the controller?

Article 89 (2) GDPR provides the opportunity of derogations to: the right to access the data by the data subject, the right to rectify, the right to restrict the processing and the right to object. However, these derogations are only available if those rights would seriously impair or make impossible the scientific purpose of the processing.

In the NDPA however, only a simple reference to the obligation to individually inform the person for whom or about whom the data has been collected, under the GDPR's provision,[57] can be found in the new Article 58.

However, there is an exception when the patient does not wish to be informed of the state of his/her health, then such information about the patient's personal health may not be transmitted by the health professional caring for the patient.[58]

But article 36 § 3 provides that:

"A decree in the Council of State, issued after a reasoned opinion and published by the CNIL, shall determine under which conditions and subject to which guarantees all or part of the rights provided for in Articles 15, 16, 18 and 21 of the same Regulation may be waived with regard to the other processing operations referred to in the first paragraph of this Article".[59]

The Decree implementing the Data Protection Act was amended to reflect the GDPR. It indicates that Articles 15, 16, 18 and 21 of the GDOR may be derogated to for scientific research purposes if they would render impossible or seriously impair the realisation of the processing purposes and were such derogation are necessary to achieve said purposes.[60]

However to our knowledge such decree remains to be adopted.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing can be defined as "the processing of personal data for purposes other than those for which the personal data has been initially collected". Further processing is allowed only when its purpose is compatible with

[57] Articles 13 and 14 GDPR.

[58] New Article 58 § 2, Article 13 of the Bill.

[59] Article 36 § 3 NDPA

[60] Article 100-1, Décret n°2005-1309 du 20 octobre 2005 pris pour l'application de la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés, as amended by Décret n° 2018-687 du 1er août 2018 pris pour l'application de la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés, modifiée par la loi n° 2018-493 du 20 juin 2018 relative à la protection des données personnelles

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the purpose for which the data has been initially collected. Further processing for a compatible purpose of personal data is possible using the same legal basis as the one used for the initial processing. For example, if personal data is initially processed based on the data subject's consent, then further processing for a compatible purpose is possible on the same legal basis. It is, in other words, not required to contact the data subject again for a new consent authorising the further processing of the same data.

How to measure the compatibility of purpose of the further processing:

Further processing for a purpose other than that for which the personal data has been collected is governed by Article 6 (4) of the GDPR. In particular this article tries to address how to measure whether or not the purpose of the further processing is "compatible". This is particularly relevant to big data analytics. Article 6 (4) establishes a test to measure such compatibility.

Where this processing is not based on the data subject's consent, or EU or Member State law, but on another legal ground, the controller will ascertain the compatibility of the processing's purpose with the initial purpose stated during the data collection. To do so the controller will take several elements into account, in particular: any link between the initial purpose and the further processing purpose, the context of the collection and the relation between the data subject and the controller, the nature of the data, in particular if it is considered to be sensitive data under Article 9 of the GDPR. The controller will also consider the possible consequence of further processing for the data subject and the existence of appropriate safeguards. If the result of the test is positive for the controller and shows none of the elements have been significantly altered to make the further processing unfair or illicit, no further legal basis is necessary for the further processing. If this is not the case, then the further processing will have to rely on a separate legal basis.

If this test is successfully met, then the further processing is possible. However, it will be up to the data controller to demonstrate the compatibility of the purposes.

The particularities of scientific research: a presumption of purpose compatibility

However, the processing for scientific research purpose is an exception. Indeed, under Article 5 (1) (b) of the GDPR the compatibility of the processing purpose of further processing with the initial purpose of the collection is presumed under Article 89 (1). Here the GDPR establishes a presumption of compatibility of purposes for scientific research purposes. The reasoning behind this exception can be easily imagined. Scientific research is very often based on existing data, this is why allowing the processing of personal for different (if not incompatible) purposes is fundamental for scientific research.

This assumption made for the benefit of scientific research is linked to the derogation of the principle of data minimisation for scientific research purposes. However, this presumption is limited by some requirements, which are set out in Article 89(1) of the GDPR: the appropriate safeguards for the data subject's rights and freedoms, and ensured technical and organisational measures, such as pseudonymisation. Although a different scenario would require different technical and organisational measures to ensure the safeguards for the data subject's rights and freedoms. This is clearly indicated in recital 156 of the GDPR: "The further processing of personal data for (…) scientific (…) research purposes (…) is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which does not permit or no longer permits the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data)."

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Additionally, further processing of personal data is connected to the principle of storage limitation (Article 5(1)(e) of the GDPR), as it also constitutes a derogation to that principle, "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject".

Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

The rules set out by the GDPR will be directly applicable. However, the approach adopted by the French legislator is such that the former articles ruling over further processing continue to apply due to their symbolic value.

In the French legal framework, as seen earlier, further processing is dealt with primarily in Article 6 of the Act. However, this article is not modified by the Bill and will remain unchanged in the NDPA. This solution has been heavily criticised by both CNIL and the Conseil d'État. However, this situation may be clarified in the future by the Ordinance that is expected to ensure the clarity and the coherence of this framework. Nonetheless, further processing for scientific purposes must be considered as falling within the scope of Chapter IX in its new formulation.

6. Health data sources for research purposes

c. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

In the current legal framework, Article 8 (III) states that CNIL may authorise certain processing activities of sensitive personal data that are subject to a process of anonymisation, as recognised by CNIL, within a short time period. In this instance, the provisions of Chapter IX do not apply.

In the revised legal framework, the new Article 8 (III) states that processing anonymised health data, according to an anonymisation protocol recognised by CNIL, is not prohibited.

In both instances the anonymisation protocol must be recognised by CNIL and the intervention must happen within a short time period, otherwise the processing authorisation procedure will not be that of the general regime.

What are the different sources of health data that can be used for research purposes?

- **DIRECT COLLECTION FROM PATIENTS:**

Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

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Health data or data concerning health is sensitive data and so in principle its processing is prohibited. However, this prohibition does not apply to processing for scientific research purposes under Article 8 (II), 8°. Such collection and processing must also comply with Article 57 (I) of the Act, which states that the data subject or the person from whom the data was collected are to be individually informed, prior to the processing, of: the nature of the information transmitted, the purpose of the processing, the natural or legal person to whom the data is addressed, his/her right of access and rectification, his/her right to object in specific cases ,and the controller's obligation to obtain his/her consent in some instances. Moreover, the provisions of the Public Health Code concerning research involving the human person also apply.

If data is collected by health professionals for medical and therapeutic purposes, and if such a person then uses the data collected for study and research purposes, for his/her exclusive use, then the provisions of Article IX of the Act does not apply. In this instance, the processing activities must be declared to CNIL under the Article 22 procedure of the Act.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

In the NDPA, all data processing activities in the field of health are governed by the provisions of the new Chapter IX. However, it follows from the Article 53 NDPA that "*Processing operations enabling studies to be carried out on the basis of data collected under Article 8, Article II, 6° where such studies are carried out by personnel following such monitoring and intended for their exclusive use*". Therefore, data processing of personal data for study and research purposes by health professionals, which they have gathered for medical purpose falls, under the data processing general regime set by the GDPR.

For the collection of personal data concerning health by researchers that are not also acting in the capacity of medical practitioners, in the NDPA Article 8 (II), 8° has been reworded as follows: "*Processing operations involving health data justified by the public interest and in accordance with the provisions of Chapter IX*." This means that the collection and processing of data comprising health data is allowed only if it is justified by the public interest and in compliance with the procedure summarised in (V) of this study. Moreover, the data subject would have to be informed under Article 13 and 14 of the GDPR.[61] Additionally, if the research requires an identifiable biological sample, then the data subject's informed and express consent is necessary and must be obtained prior to the processing.[62]

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS**

Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.

Collection by health professionals and health institutions for research purposes is possible under certain conditions.[63] Indeed, Article 55 of the Act states that health professionals may transfer the data held by them, but only for the processing activities authorised and governed by the provisions in Chapter IX on processing for research

[61] New Article 58 §1, Article 13 of the Bill.

[62] New article 57 §2, Article 13 of the Bill.

[63] https://www.cnil.fr/fr/communiquer-des-donnees-de-sante-0.

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in the field of health purposes.[64] Therefore, the processing activities must be authorised under the procedure set out in Article 54, as explained above. However, Article 55 also extends the processional secrecy requirements to the personnel who will carry out the processing activities.[65] However, the transmission of data by health professionals must be done in a manner guaranteeing the data's confidentiality.[66]

Data collection from health institutions can be active, or researcher can request access to the database of the PMSI (the Programme de médicalisation des systèmes d'information (PMSI) Information Systems Medicalisation Programme started in 1991).

The PMSI makes it possible to describe health establishments' medical activities in a summarised and standardised way. It is based on the recording of standardised medical-administrative data in a standard collection of information. It has 4 "fields":[67]

- "Medicine, Surgery, Obstetrics and Dentistry" (MCO)
- "Follow-up or rehabilitation care" (SSR)
- "Psychiatry" in the form of RIM-Psy (medical information in psychiatry)
- "Home hospitalisation" (HAD)

The PMSI aims to analyse the medical activity of public and private hospitals. Any stay in any hospital is subject to a systematic minimal collection of administrative and medical information. The information collected by the health care establishment is summarised and de-identified, so that it does not contain information enabling direct identification and is transmitted to the national level. Each summary contains coded medical information (such as about the diagnosis, the medical procedures performed, etc.) as well as administrative information (concerning the identification of the establishment, the length of stay, entry and exit methods including, possibly, death) and information about the patient (his/her gender, age, geographic code, based on his/her residential post code). In addition to this information, establishments must provide information about consultations and any external procedures carried out, as well as about the consumption of certain drugs and implantable medical devices (prosthetics, implants). This data, which is initially collected for financial and administrative purposes, may be used for research purposes. The technical agency for hospitalisation information (L'Agence Technique de l'Information sur l'Hospitalisation (ATIH)) is tasked with the PMSI's management.[68] Some of the data processed by the ATIH is available as open data. However, to access the databases, CNIL's authorisation is necessary. Moreover, the PMSI is part of the SNDS, and can be accessed through the access to the SNDS, as a public database.

Under the revised legal framework: o Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

[64] Act n° 78-17, Article 55 §1.

[65] Act n° 78-17, Article 55 § 5.

[66] Act n° 78-17, Article 55 §2.

[67] http://solidarites-sante.gouv.fr/professionnels/gerer-un-etablissement-de-sante-medico-social/financement/financement-des-etablissements-de-sante-10795/financement-des-etablissements-de-sante-glossaire/article/programme-de-medicalisation-des-systemes-d-information-pmsi.

[68] Rapport du groupe CSF mesure 1-5, *op. cit.*, p. 11.

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The NDPA does not substantially modify the conditions of access to data gathered by health professionals and health care establishments.

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

While creating a private database containing health data is not prohibited, its legal basis must be carefully applied. Indeed, while the processing of health data is in principle prohibited, it is possible to do so if the data subject has given his/her explicit consent.[69] Such a database must be notified to the data protection authority following the procedure set out above. However, if the database is used for scientific research purposes, then the provisions of Chapter IX apply.

Moreover, the hosting of health data is subject to an accreditation procedure described in Article L1111-8 of the Public Health Code and the decree on the hosting of personal health data.[70] The hosting of health data is the object of a contract between the host and the data controller.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The revised legal framework does not effectively change the conditions applying to the setting up of a private data base

- **PUBLIC DATABASES**

Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?

There are 250 public databases in the field of health in France.[71] Some have been built for administrative purposes, while others are the product of research. An overview of those databases can be found on Epidemiologie - France Portal | Health Databases. However, this website does not provide access to these databases. The access is organised depending on the features of each database; often CNIL's authorisation is necessary to access individual data. But if it is available, aggregated data may be openly accessible.

The most important public database concerning health is the Système National des Données de santé,[72] which was described earlier.

The Système national des données de santé (the National Health Data System) brings together health data from various sources: data from the study of the functioning of health establishments, data from the National health

[69] Act n° 78-17, Article 8 (II) 1°.

[70] Décret n°2006-6 du 4 janvier 2006 relatif à l'hébergement de données de santé à caractère personnel et modifiant le code de la santé publique.

[71] https://www.inserm.fr/information-en-sante/dossiers-information/big-data-en-sante.

[72] http://drees.solidarites-sante.gouv.fr/etudes-et-statistiques/acces-aux-donnees-de-sante/mise-en-oeuvre-du-systeme-national-des-donnees-de-sante-et-nouveau-cadre-d/article/mise-en-oeuvre-du-systeme-national-des-donnees-de-sante-et-nouveau-cadre-d.

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database (SNIIRAM: Système national d'information interrégies de l'assurance maladie), data on the cause of death, and medico-social data from the common information system of departmental homes for disabled people. The Caisse nationale d'assurance maladie des travailleurs salariés (CNAMTS), the national organisation charged with the health insurance of employed workers is the processing controller for the data described above and organises the data.

The SNDS was created in 2016 and started its operation in April 2017, it is governed by Article L.1461-1 and following of the Public Health Code. One of the purposes of the National Health Data System is to provide data for scientific research concerning health purposes. Access to the SNDS is open to any person or organisation (whether or not it is: public or private, for-profit or not-for-profit) that has CNIL's authorisation to make a study or scientific research of public interest.[73]

The use or the further use of the SNDS's data is subject to limitations. No decision can be taken against an identified physical person on the basis of this data or its processing. The processing's controller, or the processor, is subject to professional secrecy, under Article L.226-13 of the Criminal Code. The data may only be accessed under conditions that ensure their confidentiality, integrity, and the traceability of that access and other processing. Data is kept for twenty years, without prejudice to the provisions of Article 36 of the Act, which provide that personal data may only be kept for the duration of the processing, after that time period it is to be archived, following the provision of the Heritage code.

Under Article L1461-2 of the Public Health Code, data from the National Health Data System that is made accessible to the public in the form of aggregated statistical or individual data that does not allow the data subject's direct or indirect identification. The use of this data does not cost anything. The further use of this data may not have the purpose or the effect of making possible the identification of the data subject.

Further conditions for accessing the National Health Data System are set out by a decree establishing the security baseline applicable to the National Health Data System. This decree requires, in particular, prior to the access to the data system, the performance of: a risk analysis, a Data Privacy Impact Assessment, the implementation of the measures addressing the risks, and an operational monitoring of the information system's safety. The access is subordinated to CNIL's authorisation, and conformity to the legal framework set out by: the GDPR, the Act and to various data safety policies.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Under the revised legal framework the rules applicable to the use of public databases do not effectively change.

d. Application of the national framework to the AEGLE cases

In the AEGLE project, the "research objective is to establish the use of Big data analysis in the prediction of outcomes in three working scenarios: Chronic Lymphocytic Leukaemia (CLL), Intensive Care Units and type 2 diabetes for the

[73] Article L 1460-1 Public Health Code.

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prediction of adverse outcomes. The research methodology is Big Data analysis to establish predictive values that may apply in three clinical scenarios and to see if this can be generalised to other healthcare disease models". [74]

To achieve its objective, the AEGLE project must base its approach on the study, and thus the processing, of data concerning health. This section aims to address each of the three proposed AEGLE cases, and to determine the requirements in general terms for access and the processes relevant to data under the Directive (the current framework) and the GDPR.

1. Type 2 diabetes

The AEGLE project uses, after pseudonymisation, existing databases with health data collected from patients who expressed their consent to their data being used for research purposes.

The operations realised in the AEGLE project qualify as processing for research in the field of health purposes, and this is why Chapter IX of the Act applies.

Once the data source has granted access to the database, before the start of any processing operation, a processing authorisation will have to be asked to CNIL, in application of Article 54 of the Act. The application will have to be submitted to the National Health Data Institute for CEREES' opinion (because this research does not involve human beings), and then CNIL will be consulted for its authorisation. But if the study led in the AEGLE project matches the Methodology of reference MR-003 set out by CNIL, then only a declaration of conformity with the methodology, made on CNIL's website, is necessary.

If the data has been collected by health professionals during their activities, then they may transfer the data to researchers, and the data recipient will be bound by professional secrecy for this data.

The data subjects will have to be informed of the further processing of the data as concerns them, in the application of Article 32 (II) of the Act. However, if the further processing entails an anonymisation protocol, in application of CNIL's standards, then only the identity of the controller and the purpose of the processing must be communicated.

Once the GDPR has been implemented:

In this case, the study requires pseudonymised or identifying data or sets of data. Once the DPIA is realised, then CNIL's authorisation is necessary. If the study fits a methodology of reference, then a simple declaration of conformity with the methodology of reference by the data controller on CNIL's website is necessary. If, however, the study does not fit into the methodology MR-003 elaborated by CNIL, then an application for CNIL's authorisation must be logged to the single secretariat of the National Health Data Institute, and it will require CEREES' opinion and then CNIL will decide on the authorisation of the processing. If the data used in the framework of the study is to be transmitted by a health professional, then the recipient is bound by professional secrecy. Moreover, the person concerned by the data can oppose the transfer. The data subject must be informed in conformity with the provisions set out in the GDPR.

[74] AEGLE Grant Agreement, Annex 1, p. 83.

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2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices without collecting the patient's consent (after pseudonymisation).

The operation realised in the AEGLE project qualifies as processing for research in the field of health purposes, and this is why the Chapter IX of the Act apply.

The data is collected by health professionals in ICU services when they are treating patients. The processing of such data for research in the field of health assumes a compatible purpose. This processing finds its legal grounds in Article 6, 2° of the Act. It is possible for health professionals to transfer the data they have collected to research, however, the recipient will be obliged to follow professional secrecy. Additionally, the data subjects will have to be informed about the transfer, and they may oppose it. The processing requires CNIL's authorisation. The data controller will submit the application of the processing to the single secretariat of the National Health Data Institute. The application is sent to CEREES for an opinion on the scientific methodology. The application and the opinion are afterwards sent to CNIL for its opinion. But if the study lead in the AEGLE project matches the Methodology of reference MR-003 elaborated by CNIL, then only a declaration of conformity to the methodology, made on CNIL's website, is necessary.

Once the GDPR has been implemented:

In this case, the compatibility between the purpose of the initial processing and the research project is presumed. But the research must conform with a methodology of reference elaborated by CNIL, in this case the Methodology MR-003, and it can be simply declared by the data controller as being in compliance on CNIL's website. However, if the research methodology does not match with the baseline, then a processing authorisation must be requested to CNIL. In this instance, the data controller applies for the authorisation to the single secretariat of the National Health Data Institute. Then, depending on the nature of the research, the opinion of the CPP for research involving the human person, or of the CERES for research not involving the human person, will be asked. The opinion, once given, is forwarded with the rest of the application to CNIL for its authorisation to process. In any case, the data subjects must be informed of the transfer of their data in conformity with the GDPR provisions.

3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In this instance, patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

The operation realised in the AEGLE project qualifies as processing for research in the field of health purposes, and this is why Chapter IX of the Act applies. Moreover, the purpose of AEGLE seeks to achieve is considered as compatible with the initial purpose, because the purpose is research in the field of health, and the processing will be completed in conformity with the principles set by the Act,[75] in particular its Chapter IX.

The further processing must be authorised by CNIL. The procedure is described in Article 54 of the Act. The application for authorisation must be made to the single secretariat of the National Health Data Institute, and CEREES' opinion will be sought. Once this opinion is given, the application will be transferred to CNIL for its

[75] Article 6, 2° of the Act.

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authorisation. If the research project fits into the reference methodology, MR-003 established by CNIL, then the authorisation procedure can be replaced by a declaration of conformity to the methodology on CNIL's website.

Once the GDPR has been implemented:

The research project must comply with an existing methodology of reference, the methodology MR-003 set out by CNIL. Then the controller will declare the conformity of the research project with the methodology on CNIL's website. If, however, the research does not fit into an existing methodology, an authorisation from CNIL will be necessary. In this case, the controller will have to apply to the single secretariat of the National Health Data Institute. Then the CEREES will give an opinion on the scientific methodology used. The opinion and the application are then forwarded to CNIL for its authorisation of processing. The personal data set may be subjected to additional conditions of use by the data source, moreover health data is protected by professional secrecy, and this obligation also applies to the recipient of the data.

If, however, in application of Article 54 (VI) of the Act, CNIL may deliver a single processing authorisation to the AEGLE project for all the processing operations with the same purpose concerning the same categories of data and having the same categories of recipients. This provision is mirrored by the new version of Article 54 (IV).

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