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The regulatory framework applicable to the processing of personal data used for health research purposes

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- French Data Protection Authority = Supervisory Authority
- independent public authority responsible for monitoring the application of the GDPR
- created in 1978

The concept of « Data concerning Health »

GDPR : Article 4

« personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status »

The principle : prohibition to process

Prohibition of processing of data concerning health

- **GDPR : article 9-I**
- **French Data Protection Act (Loi « Informatique et Libertés ») : Articles 6-I and 44**

Prohibition shall not apply in specific cases (non exhaustive list) (refer to the GDPR article 9.2)

- the data subject has given explicit consent to the processing
- processing is necessary to protect the vital interests of the data subject or of another natural person
- preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional
- necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices
- scientific or historical research purposes or statistical purposes

Room for manoeuvre

Member States may maintain or introduce further conditions with regard to the processing of :

- data concerning health
- genetic data
- biometric data

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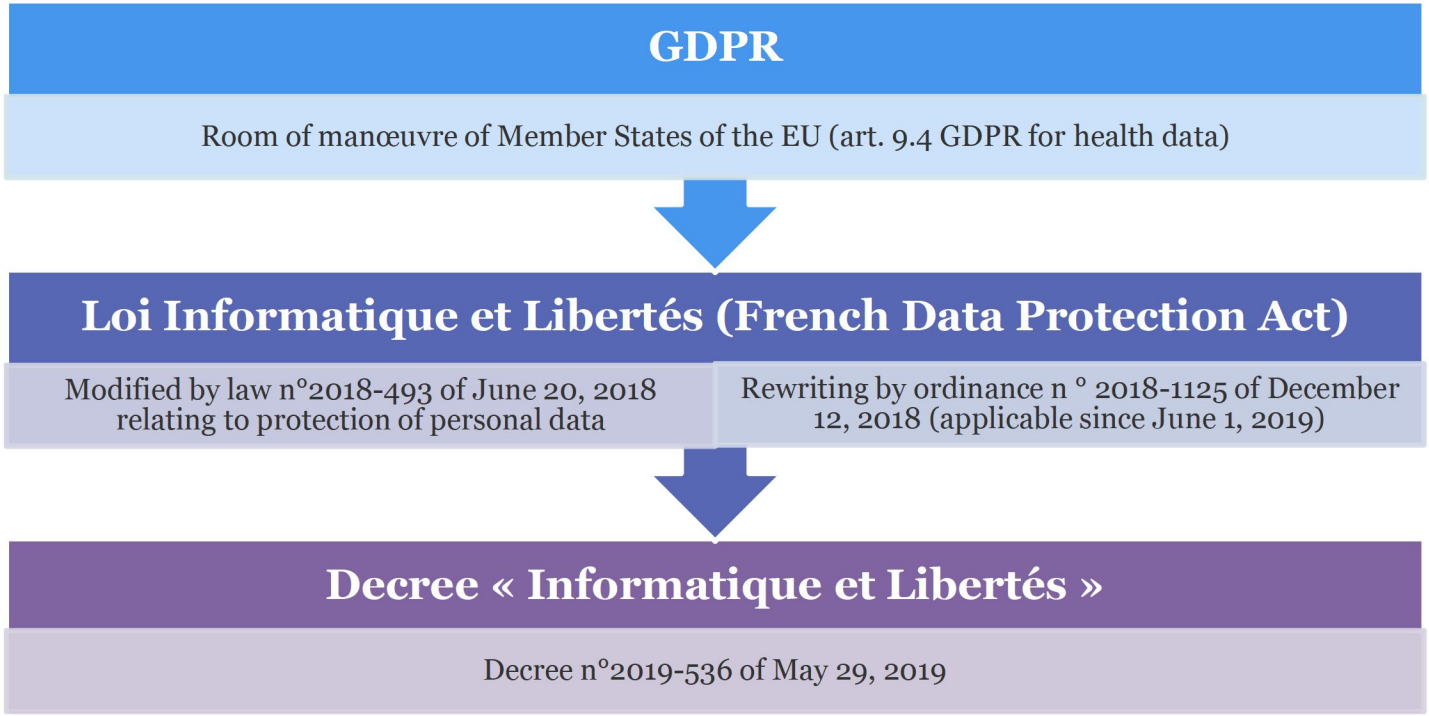
THE LEGAL FRAMEWORK IN FRANCE

GDPR and national legal framework



Scope of the French Data Protection Act

Establishment criterion :
controller or processor located in France

or

If data subjects resident in France are concerned, and even if the controller is not established in France

> Specific provisions related to the health sector must be respected (section 3)

Complemented by specific rules concerning :

- Research activities
  - Code de la recherche (French Research Code)
- Health-related activities (including Health research)
  - Code de la santé publique (French Code of Public health) ;
  - Code pénal (French criminal code) about medical records secrecy ;
  - Code civil (French civil code) about genetic analysis.

Loi « informatique et libertés » (section 3)

Subsection 1 (« data warehouse »)	Subsection 2 (« research »)
Public Interest purpose	**Public Interest purpose** *Possible referral to PDS or CNIL*
Authorization (CNIL)	Authorization (CNIL) OR declaration of conformity to a baselin methodology (MR) + *ethics committee opinion (Circuit CPP or PDS/CESREES)*
Tacit authorization by the CNIL after a period of two months (renewable once)	Tacit authorization by the CNIL after a period of two months (renewable once) *If ethics committe opinions are expressly favourable*
Individual information of data subjects concerned	Individual information of data subjects concerned
	Specific consent for genetics

Types of research

Recherche impliquant la personne humaine (RIPH) – Research on human subjects

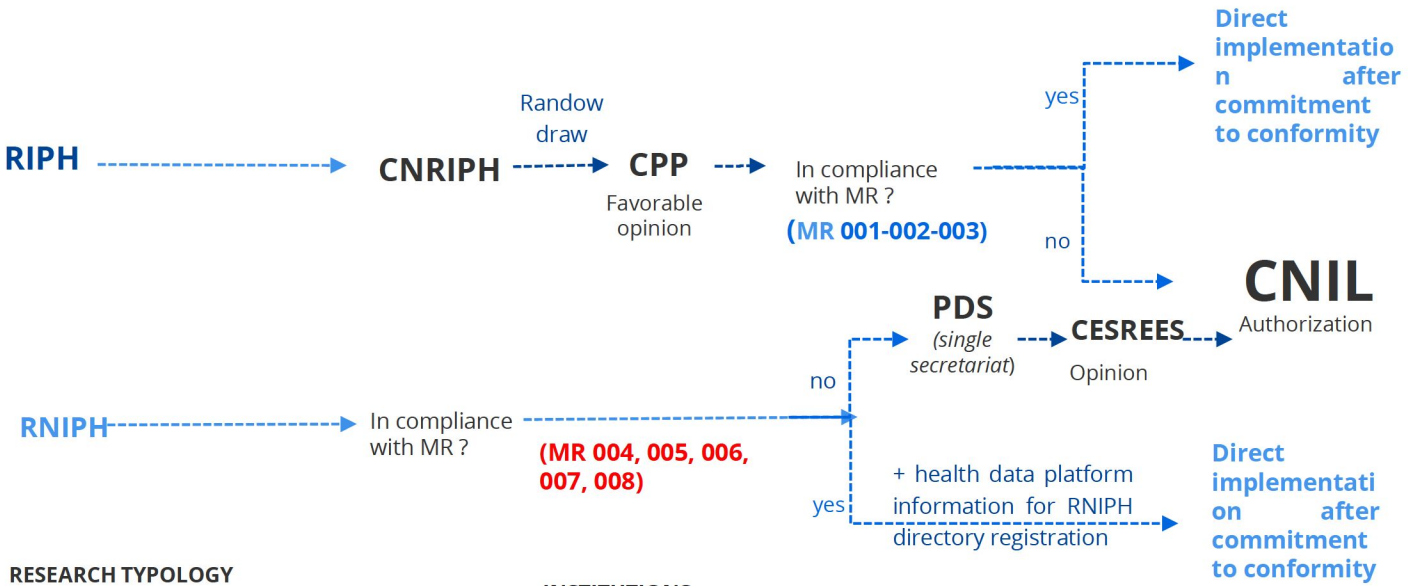
"Research organized and carried out on healthy or sick volunteers, with a view to developing biological or medical knowledge aimed at evaluating :
1° The functioning mechanisms of the human organism, normal or pathological ;
2° The efficacy and safety of procedures or the use or administration of products for the diagnosis, treatment or prevention of pathological conditions. (CSP, art. R.1121-1) "

Recherche n'impliquant pas la personne humaine (RNIPH) – Research conducted only on health data

Collection of additional data for research purposes, without meeting the definition of RIPH (in particular the purpose).

Reuse (change of purpose) of data already acquired [for example, data from medico-administrative databases (e.g. SNDS) or from an approved register, data warehouse or medical records, without new information being collected from the persons concerned for research purposes].

A complex administrative set-up



RESEARCH TYPOLOGY

RIPH : Research on human subjects
RNIPH : Research conducted only on health data

INSTITUTIONS

CNRIPH : National Commission for Research Involving the Human Person
INDS : National Institute for Health Data
CEREES : Expert committee for health-related research, studies and assessments
CPP : Committee for the Protection of Individuals
CNIL : French Data Protection authority

SIMPLIFICATION

MR *Reference methodology*

Create a common framework of enforceable guidance

- Complex legal environment to monitor sensitive activities and data processing
  - Needs to be legally, scientifically, ethically irreproachable and to respect the main principles in order to guarantee the quality of research and its results
  - Need to create a common framework, adapted to sectoral practices in order to develop the main principles of the GDPR
  - A simplification tool (a single declaration of conformity)
  - Principle of accountability
  - Legal and technical compliance framework :
    - nature of data processed
    - data recipients (directly and indirectly identifying) ;
    - procedures for informing and exercising rights ;
    - technical and organizational measures;
    - data transfers outside the European Union;
    - etc.

Hélène GUIMIOT

French specificities in health research on data

- Discretionary opt-out right for health data processing
- Individual information
  - Layered approach : « transparency gate » : first an **individual information and future processing listed on the controller's website.**
- Consent for genetic analysis

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REGULATION ON THE EUROPEAN HEALTH DATA SPACE

European Health Data Space (EHDS)

1. PRIMARY USE OF HEALTH DATA

2. SECONDARY USE OF HEALTH DATA

- Essential for **structuring access and governance**
- Guaranteeing **strong protection of health data**

I. Primary use of health data

- **Access, maintain or restore the health** condition of the European resident ;
- **Ensuring confidentiality** and **respect for individual rights.**
- The information includes **essential elements** such as the **patient's medical summary, radiology and lab results, prescriptions, dispensations, and hospital discharge reports ;**
- Data shared through a **European infrastructure ;**
- **Ensuring privacy protection and data security** ;
    - Right to **object** ;
    - Right to **access** ;
    - Right to **insert information** ;
    - Right to **rectification** ;
    - Right to **data portability** ;
    - Right to **restrict access** and **to be informed of any access by caregivers**.

II. Secondary use of health data

To facilitate and widen the further processing of electronic health data initially collected for other purposes, in particular for :

- **public statistics** in the health and medico-social sector ;
- **activities of public interest** in the field of health, such as protection against cross-border threats or public health surveillance ;
- **scientific research** relating to the health sector ;
- activities relating to the **development and innovation of products or services** contributing to public health or healthcare safety, medicines or medical devices ;
- **educational activities** in the health sector.

National one-stop shop

Each Member State shall create or designate one or more Health data access body

- **Issue data request** and **data permits applications** (CNILs scope);
- **check the compliance of data users** and **data holders** with their respective obligations under the Regulation (CNILs scope) ;
- **make data available** through a **secure processing environment** ;
- **facilitate cross-border access to data** for **secondary use**.

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THANK YOU