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French procedures on data protection

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Agenda

- Identify the different types of research
  - Research involving human participants
  - Research not involving human participants
  - → Allow to define the relevant rules
- 2 major aspects to consider:
  - Ethical aspects (by a dedicated committee)
  - Data protection (by the ***Commission Nationale de l'Informatique et des Libertés*** - **CNIL**)

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Context

- Legislative changes in the past few years
  - In Europe: **General Data Protection Regulation (GDPR)** since 25 May 2018
    - **With specific applications according to European countries** (French law published on June 20, 2018)
  - **Jardé Law** in France since November 17, 2016
    - changing the framework for French researches

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Jardé Law

- Research involving human participants
  - All researches performed on the human person **with the intent to generate new biological and medical knowledge**
  - 3 types, defined according to the risk for patients

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Research involving human participants

- Category n°1: Interventional studies → high risk
  - Clinical trials
- Category n°2: Intervention studies with minimal risks and constraints → low risk
  - Addition of one or more interventions to current practice (randomization, blood test, biopsies, physical activity assessment…)
- Category n°3: Observational studies/no intervention → low risk

  all procedures and drugs are used within the context of medical care without further proceedings
  - Questionnaire administration
  - Additional and minimal collection of elements or products of the human body carried out within the context of medical care

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Other types of research

- Not involving human participants:
  - Research on available data
    - Data collected within a medical care context
    - Data collected for a former research with a change of purpose
  - Research performed on humans but **not** contributing to **the development of biological and medical knowledge**
    - **Humanities and social sciences studies**

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GDPR

- Territory criteria → Rules apply:
  - For all data controller on French territory, whether or not the treatment takes place in France
  - The data subject resides in France; also includes studies where the data controller is not established in France
- Respect for information and human rights
- Integrity and confidentiality of data; obligation of security
- Explicit and legitimate specified purposes of studies
- Adequate and relevant data, limited to the necessity of the purpose
- Limited storage period (2 years after the last publication)

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GDPR main principles

- Obligation to nominate a Data Protection Officer (DPO)
- All data controllers must keep a register of all studies
  - The name and contact details of the data controller, the representative of the data controller and the DPO
  - Purposes of the treatment
  - A description of the categories of data subjects and categories of personal data
  - The categories of recipients to whom the personal data have been or will be disclosed, including recipients in third countries or international organisations
  - Time limits to delete the different categories of data
  - A general description of technical and organizational security measures

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CNIL

- Complements the requirements of the GDPR and reinforces some principles
- Compliance with CNIL standards → Standard methodologies
  - When the treatment complies with a standard methodology: implementation without authorization (after declaration of compliance)
  - Authorization becomes the exception
  - For each treatment, be able to demonstrate that compliance checking has been completed

  → *to facilitate administrative procedures*

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Standard methodologies

- MR 001 : studies requiring a consent from the participants
- MR 002 : medical devices studies
- MR 003 : studies not requiring a consent from the participants
- MR 004 : studies not involving human participants

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Standard methodologies

- Identification : code (no name or surname)
- Health: data strictly necessary for the conduct of the research and relating to the health of the person who is the subject of the research
- Age, birth (only month and year), gender, place of birth
- Images: photographs and/or video that do not allow for the identification of the persons who participate in the research
- Dates: enrolment, follow-up
- Ethnicity
- Genetic data strictly necessary to meet the objectives or purposes of the research, which do not by themselves permit direct or indirect identification of the person. Such data may under no circumstances be used for the purposes of identification or re-identification of persons
- Marital status
- Educational level, socio-professional category
- Occupational activity: current occupation, history, unemployment, commuting and business travel
- Social security affiliation scheme excluding the registration number in the national identification register
- Involvement in other research
- Travel (to the place of treatment: mode, duration, distance)
- Consumption of tobacco, alcohol, drugs; lifestyles and behaviours
- Dependency (alone, in an institution, autonomous, bedridden), assistance (domestic help, family), physical exercise (intensity, frequency, duration), diet and eating habits
- Sexual life
- Vital status
- Quality of life

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Studies in categories 001 and 002

- CNIL : standard procedure 001
  - Check collected data → conformity or specific authorization
- Institutional review board for ethical and methodological aspects: ***Comité de Protection de Personnes (CPP)***
- Specific insurance
- National drug safety agency authorization (for category 001 research only)

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Studies in category 003

- CNIL : standard procedure 003
  - Check collected data → conformity or specific authorization
- Institutional review board for ethical and methodological aspects: CPP

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Studies not involving human participants

- CNIL : standard procedure 004
  - Check collected data → conformity
  - Specific authorization to obtain from **CEREES** (dedicated board for studies not involving human participants)
- No ethics decision required
  - Frequently required to publish results
  - Encouraged
  - Local ethics committee

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In summary

Research involving human participants
To generate new biological and medical knowledge

Research not involving human participants

	Category #1 Clinical trials	Category #2 Intervention studies with minimal risks and constraints	Category #3 Observational studies	Research on available data	SHS studies
Ethics	CPP			Institutional ethics committee (encouraged)	
Data protection (CNIL)	MR-001 Specific authorization		MR-003 Specific authorization	MR-004 CEREES	

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