



HEALTH
DATA HUB



Toolkit for users

Accessing health data in France

User toolkit - Accessing health data in France

In France, access to health data is submitted to regulations. Procedures, rules and timeframes to access the data may vary based on which conditions you meet and whether the requested data has already been collected or not.



The purpose of this toolkit is to help you **characterise the type of research you are considering** to then help you **identify the applicable procedure and how to implement it**.

You are not in the scope of this toolkit, if :

- ❖ you are using **data** for your project that is perfectly **anonymised** : data protection principles do not apply in this case.
- ❖ you are using individual-level data that is not health data

For more information about anonymisation, please visit the [CNIL website](#).

To learn more about the definition of health data, consultez le [CNIL website](#).

Toolkit - Accessing health data in France

Two main types of research requiring the use of health data exist in France and involve different procedures for their implementation: research involving human subjects and research not involving human subjects. Traditionally, whenever you wish to re-use personal data, there is a need to be in conformity with a simplified procedure, or at least, to obtain authorisation from the National Data Protection Agency (CNIL).

In order to identify the right regulatory process for your project, the two following questions need to be raised:

- ❖ **Question n°1:** Does my research project involve human subjects ?
- ❖ **Question n°2:** Is my research project eligible to a data access procedure exempted from a CNIL authorization ?

This toolkit provides you with assessment criteria to help you answer these questions.

Question n°1

I characterize my research project :

Question n°1: Does my research project involve human subjects ?

Research project Involving Human Subjects (RIPH)

To qualify as RIPH, the research project must meet two cumulative conditions :

- 1 **Be carried out using the human body** : meaning that additional data collection is necessary for the research, i.e. beyond the data already collected as part of the healthcare procedures relating to the person.
- 2 **Lead to the development of biological and medical knowledge** :
 - ❖ **Biological** knowledge refers to the functioning of the human organism in a broad sense (development, physiology, behaviour, reactions to the environment)
 - ❖ **Medical** knowledge refers to prevention, diagnosis or treatment of diseases or disabilities.

Research project Involving Human Subjects (RIPH)

There are **three categories of RIPH**, depending on whether or not the research involves a procedure/ intervention and on the risks incurred by the person who undergoes it:

Category 1

The research project entails a procedure that is not justified by his or her usual care and is not without risks for the person.

A clinical trial involving a drug or an innovative surgical procedure.

Category 2*

The research project entails a procedure with minimal risks and constraints for the person.

Low-risk blood sampling, non-invasive imaging

Category 3**

The research does not entail a procedure and does not bring any risks.

Safe and non-invasive sampling, medical imaging without radiation or contrast injection



Determining the category of RIPH is important in order to identify the appropriate procedure to follow.

Research project Not Involving Human Subjects (RNIPH)

Research projects not involving human subjects (RNIPH) is defined as opposed to RIPH: if one or none of the conditions for qualifying the research as RNIPH are not met, then the research is RNIPH.

In other words, a RNIPH is a research that

- ❖ is based on data already collected in the context of care or during a previous research (retrospective data)
- ❖ and/or is based on data collected in the course of care or specifically collected for research without satisfying to biological or medical knowledge (prospective data)



An example of retrospective data study : Thesis on data from medical records or from research requiring access only to SNIIRAM (French healthcare claims database) data.

An example of prospective data study : Satisfaction survey of effectiveness of the nurse assistance of patients with Alzheimer's disease.

Question n°2

Is my research project eligible to a data access procedure which would not require an authorization from the CNIL ?

Prerequisite: I know whether my research project involves human subjects or not.

Various modalities of data access

1 Three ways of accessing health data for research purposes in France:

- ❖ **Internal research** not involving any formality with the CNIL
- ❖ **Simplified procedures** that do not require authorization from the CNIL: these can be used as soon as the planned research meets a certain number of conditions set out in the legislation
- ❖ The **standard procedure**, if none of the two previous methods is applicable: the CNIL's authorization must then be obtained after receiving the opinion of the competent expert committee*.

In all cases, the project coordinator relating to the definition of data controller**:

- ## 2
- ❖ Determines the procedure applicable to the research project;
 - ❖ Carry out an impact assessment regarding the data protection, if need be;
 - ❖ Maintain the security of the system at the state of the art;
 - ❖ Document the conformity of the treatment to the proceedings;
 - ❖ Must respect the framework set by the internal research, the simplified procedure or the authorization throughout the duration of data processing;
 - ❖ Records each processing operation into the register of processing activities.

* This may be the CPP - Committee for personal protection - ethics committee for RIPH or Ethics and Scientific Committee (CESREES) for RNIPH.

** It is the person, public authority, service or organisation that determines the aims, objectives and means of the study and assuming legal responsibility for the processing.

Panorama des procédures existantes pour la réalisation d'une recherche en santé

I am considering carrying out an RIPH

I am considering carrying out an RNIPH

I need to identify the category of my research project

Category
1

Category
2

Category
3

I need to identify the procedure for data access applicable to my research project

MR001

MR003

OU

Standard procedure

Internal
research

OU

MR004

MR005

MR006

OU

EGB

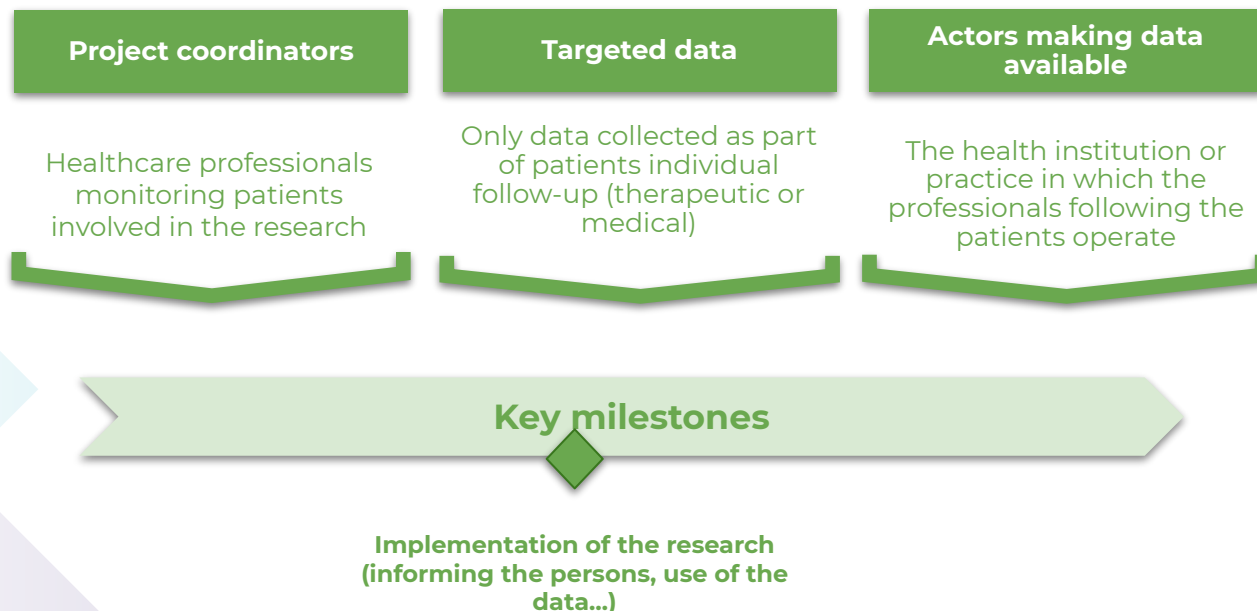
OU

Décision
unique

OU

Standard procedure

Internal research



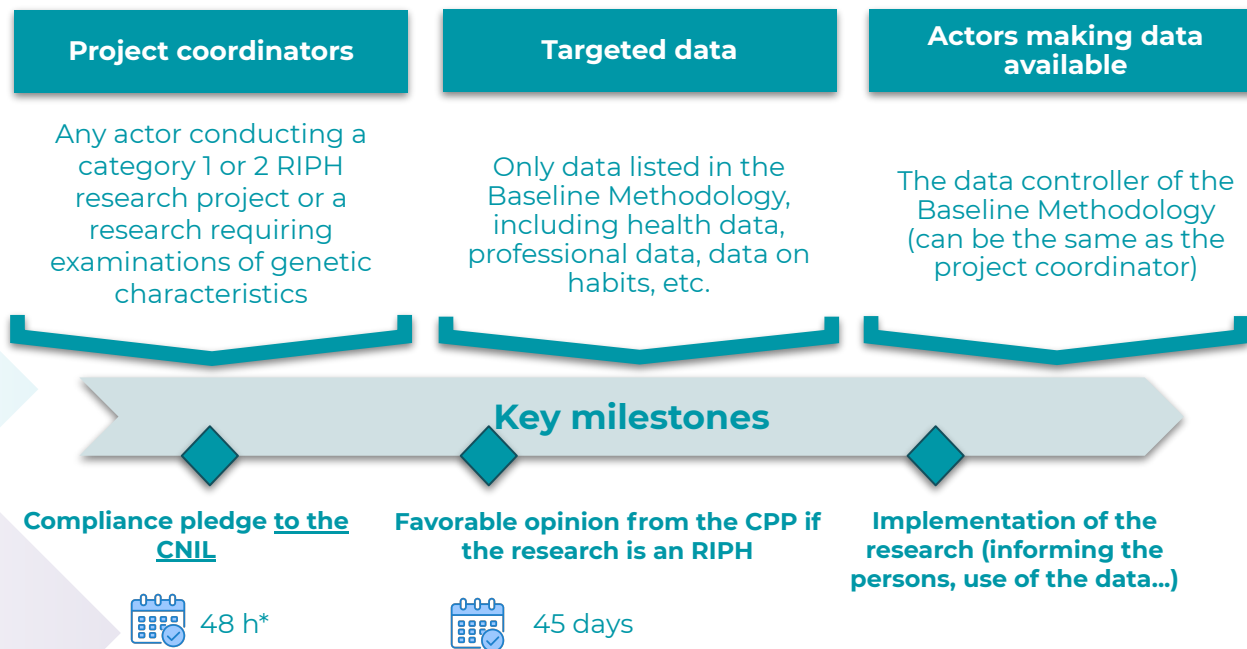
Critical points

The research must be conducted for the exclusive use of professionals involved in the follow-up of the patients concerned



Example of a study: study carried out by a midwife on pregnant women she has followed in her practice over the last five years to obtain indicators to improve their care.

Méthodologie de référence 001



Critical points

- (1) The express consent of individuals must be obtained**
- (2) Data from the SNDS cannot be used (except in the case of a daughter system)
- (3) The collection of NIR is not allowed



Study example: Covid-19 vaccine immunogenicity study

Méthodologie de référence 003



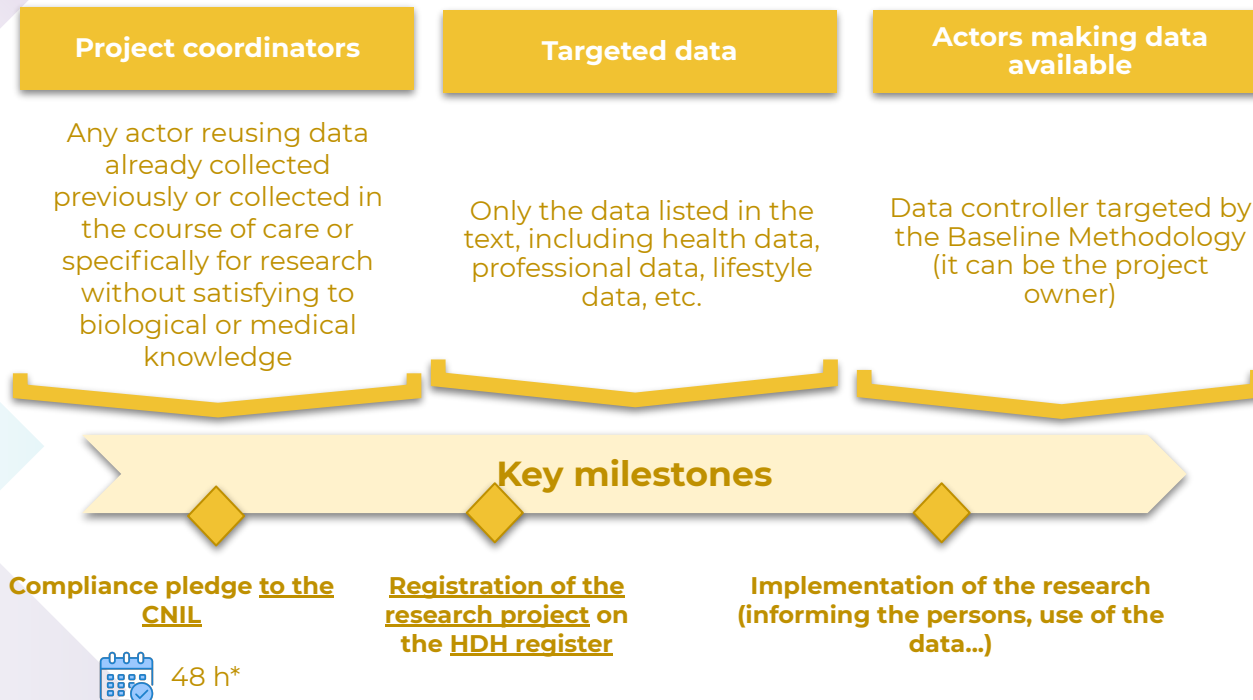
Points of attention

- (1) The persons concerned must not be set against the research participation
- (2) Data from the SNDS cannot be used (except in the case of a daughter system)
- (3) The collection of NIR (social security number) is not allowed



Study example: Study requiring the collection of an additional dose of blood to test for HIV not included in the initial care of patients

Méthodologie de référence 004



1125
projects in
2020

Critical points

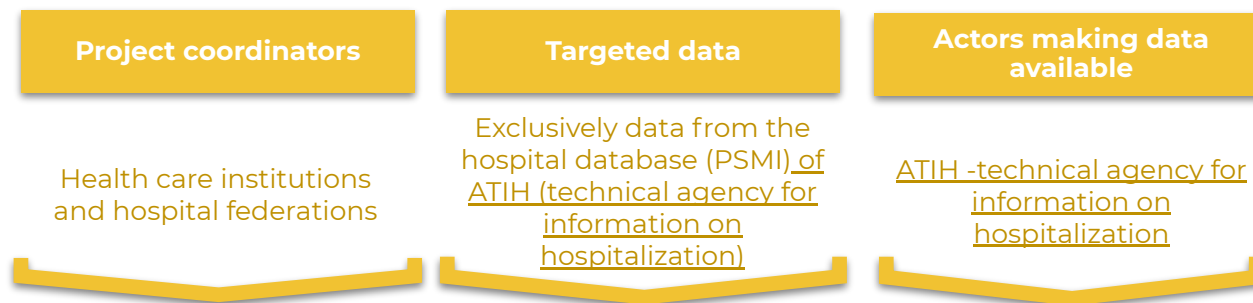
- (1) Data subjects must be individually informed
- (2) No data directly identifying the patient should be used (except for health professionals who have followed the patient)
- (3) Data from the SNDS may not be used (except in the case of a feeder system)



Example of a study: study of premature baby care based on the medical records of the university hospitals of the Occitania region

Méthodologie de référence 005

References :
National Gazette
Légifrance et CNIL



35
projects in
2020

Critical points

Data can only be processed on the ATIHI platform

Key milestones

Compliance pledge to the CNIL



48 h*

Registration of the research project on the HDH register

Implementation of the research (informing the persons, use of the data...)



Study example: study of the re-hospitalization rate following a stroke

Méthodologie de référence 006

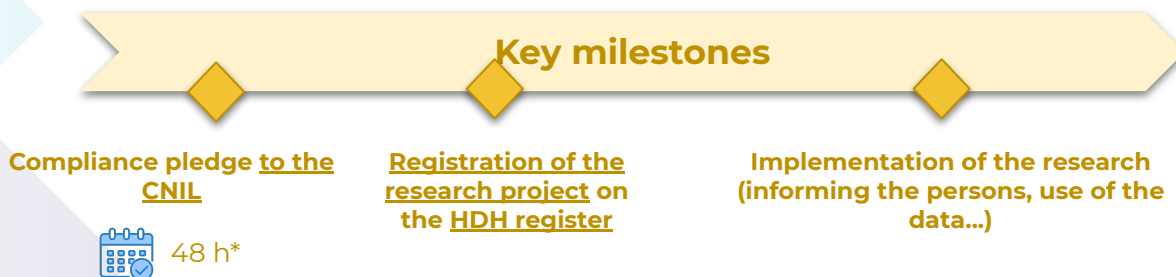
References :
National Gazette
Légifrance et CNIL



61
projects in
2020

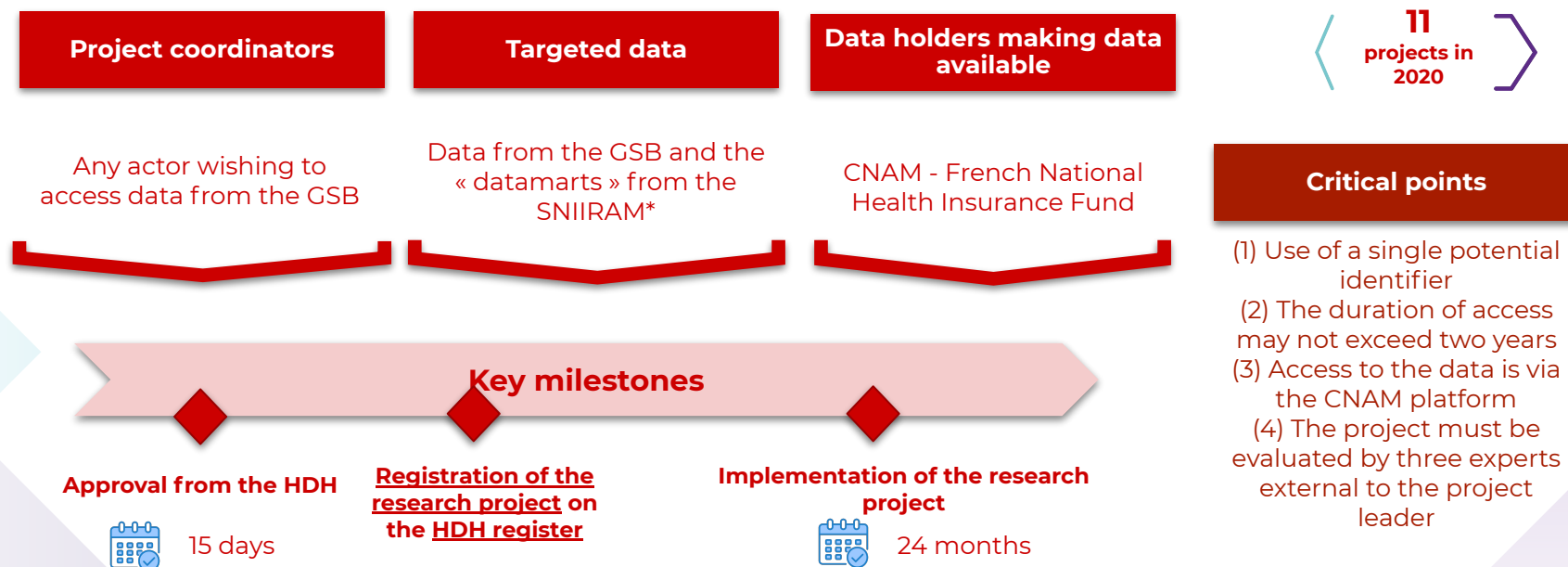
Critical points

- (1) The study must be carried out by a research laboratory or consultancy that has made a pledge of compliance to the CNIL
- (2) An audit on the objectives of the study and on the use of the results by the project leader.



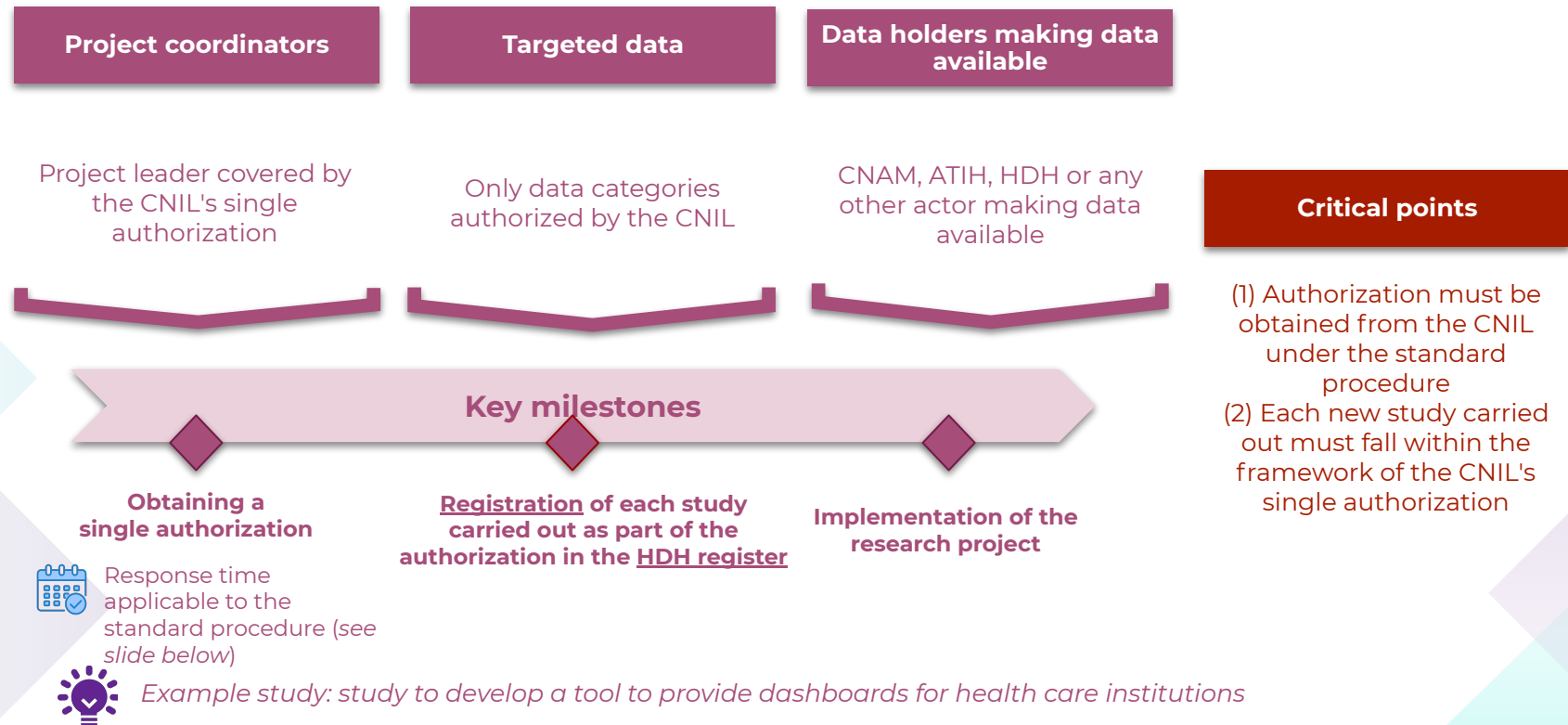
Example of a study: study of multiple sclerosis cost of care.

Generic/ Minimum Sample of Beneficiaries (EGB)



Example of a study: Study on the consumption of care by patients suffering from asthma in France

Single decision



The standard procedure implies prior authorization to access to the data

If none of the simplified procedures are applicable to your project, the standard procedure applies: it differs depending on whether the research envisaged is an RIPH or an RNIPH.

The research is a RIPH

The research is a RNIPH

398
projects in
2020

Key milestones

Key milestones

Opinion from the CPP



45 days

CNIL authorization



from 2 to 4 months

CESREES opinion



1 month

CNIL authorization



from 2 to 4 months

To learn more about how to submit a data access request to conduct a RIPH, contact the [CNRIPH](#) or go to [french Ministry of Health website](#)

To learn more about how to submit a data access request to conduct a RNIPH, go to the [HDH website](#).



Mixed research (RIPH and RNIPH): If the research planned is an RIPH and a match with existing data is desired, the RIPH procedure applies to the entire research. The opinion of the CPP alone is sufficient before submission to the CNIL.

Need help ?

If, after consulting this guide, you still have questions about the characterization of your research or the identification of the procedure applicable to it, you can

- ❖ [Consult our website](#);
- ❖ Consult the CNIL's thematic sheets on [formalities for thesis and dissertations](#) and on the [legal framework for medical research](#);
- ❖ [Ask your questions on the support forum](#);
- ❖ [Contact us](#). Do not hesitate to describe your project and your questions in detail so that we can provide you with the best possible answer.

List of acronyms

ATIH: Technical Agency for Information on Hospitalization

CESREES : French Scientific and Ethical Committee for Research, Studies and Evaluations in the Health Sector

CNAM: French National Health Insurance Fund

CNIL: French Data Protection Agency

CPP: Committee for the Protection of Individuals

EGB: Generic sample of beneficiaries

HDH: Health Data Hub

MR: Baseline Methodology

PMSI: Medicalisation of Information Systems Programme

RIPH: Research Involving the Human Person

RNIPH: Research Not Involving the Human Person

SNDS: French National Healthcare Data System