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## **TOOLKIT FOR USERS**

**Simplified reference  
framework MR-008**



Reference Methodology 008 (MR-008) is a simplified procedure\* allowing data to be processed **without having to obtain authorisation from the CNIL**. It concerns data from the main SNDS database for processing operations for the purposes of research, study or evaluation in the field of health for Research Not Involving the Human Person (RNIPH).

It allows data from the main SNDS database to be used for studies carried out by data controllers in accordance with **their legitimate interests\*\***.



The purpose of this toolkit is to present the **main requirements** of this methodology and, where appropriate, the procedures to follow in order to implement this simplified procedure\*\*\*.

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\*For more information on simplified procedures, we invite you to consult our [toolkit for users on access procedures](#).

\*\* For more information on legitimate interest, we invite you to consult this [page](#) on the CNIL website.

\*\*\* For a full assessment of your compliance with the MR-008, you can consult our checklist.

# MR-008 SCOPE OF APPLICATION

MR-008 applies to data controllers\* who can provide evidence that the processing of data from the main SNDS database for the purposes of **research, study or evaluation** is necessary for the pursuit of a **legitimate interest**. It expressly excludes insurance and mutual insurance providers.

Only processing involving data from the main SNDS database and carried out by a study office or contract research organization\*\* is concerned by MR-008, provided that it complies with all the conditions listed in the guidelines\*\*\*. These include the following :

- ✓ The data controller must obtain an **expressly favourable opinion (with or without recommendation)** from the CESREES;
- ✓ The data in the main SNDS database must come **exclusively and directly** from the CNAM.
- ✓ the data controller must never have access to individual data, as the data is made available to a **study office or contract research organization (LRBE)** that carries out the processing operations.

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\* This is the person, public authority, department or organisation that determines the purposes, objectives and means of the study. It assumes legal responsibility for the data processing.

\*\* The list of these study offices or contract research organizations is available on the [HDH website](#). If the data controller is a study office or contract research organization, it does not need to call upon the services of another study office or contract research organization.

\*\*\* A checklist is provided listing all the requirements of this reference methodology (MR)

# MR-008 SCOPE OF NON-APPLICATION

In particular, MR-008 does not apply to the following processing operations:

- ✗ Those hosted outside a **controlled environment** (conditions set out in slide 16);
- ✗ Those **requiring matching** of data from the main SNDS database with personal data from other sources (e.g. medical records);
- ✗ Those **requiring re-use** of data made available as part of a previous study or from a health data repository containing data from the main SNDS database.

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\* This is the person, public authority, department or organisation that determines the purposes, objectives and means of the study. It assumes legal responsibility for the data processing.

\*\* A checklist is provided listing all the requirements of this MR.

# DATA CONTROLLER'S COMMITMENTS (1/2)

The data made available under this simplified procedure is data from the **main SNDS database**.

When making a request, the data controller undertakes to **comply with all the legislative and regulatory provisions relating to the SNDS** and in particular the following requirements:

## Requirement 1

Carry out a processing operation that is justified by the public interest and not use the data for prohibited purposes\*.

## Requirement 2

- ✓ Use a study office or contract research organization that complies with the [security standard applicable to the SNDS](#) defined by article L1461-1 of the Public Health Code.
- ✓ Not have any connections with the study office or contract research organization and the purpose of the processing operation that might constitute a conflict of interest.

## Requirement 3

[Record the study](#) in the HDH's public directory prior to its launch, and at the end of the study, send the HDH the method, the results obtained and the means of assessing their validity with a view to their publication on the HDH [website](#).

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\* These purposes are the promotion of healthcare products to healthcare professionals or healthcare product establishments and the exclusion of cover from insurance contracts or the modification of insurance contributions or premiums for an individual or group of individuals.

# DATA CONTROLLER'S COMMITMENTS (2/2)

## Requirement 4

Do not seek access to personal data made available to study office or contract research organization.

## Requirement 5

Process data in a controlled environment once it has been approved (the approval decision must be valid), has been appraised by the CNIL for a processing operation (authorisation must be less than 3 years old) that complies with the [SNDS security standard](#) and is exclusively subject to the laws and jurisdictions of the European Union for data hosting\*.

## Requirement 6

Disseminate collective information to the research target audience, mentioning all the information required by article 14 of the GDPR. As a minimum requirement, this information must be shared on the data controller's website and, where applicable, the study office or contract research organization's website.

## Requirement 7

Issue a review every 3 years for the CNIL and CESREES reporting on the uses of the reference methodology, observed over that period.

Please note that if the data controller, i.e. the person, public authority, department or organisation that determines the purposes, objectives and means of the research, **makes a commitment to comply with MR-008 without respecting its requirements**, they will incur legal liability. It is therefore important to **properly structure your project to avoid making any mistakes!**

# FOCUS ON THE REVIEW OF PROCESSING OPERATIONS

The data controller who has implemented one or more processing operations under MR-008 must send the CNIL and CESREES a **review in accordance** with the template available on the HDH [website](#).

The expected content must reflect as closely as possible the actual use of the reference methodology in question, if necessary with the help of statistics previously produced by the data controller, with the help of its subcontractor(s). This includes:

- ✓ The number of studies carried out;
- ✓ The type of objectives pursued;
- ✓ Concerning the data processed, the components of the main SNDS database that are most frequently called upon, the historical depth of the data consulted, the number of individuals concerned, etc.
- ✓ Collective information media used;
- ✓ The number and status of individuals authorised to access the data;
- ✓ The number of publications resulting from data processing;
- ✓ The benefits and scientific contributions of the studies carried out, observed and/or measured.

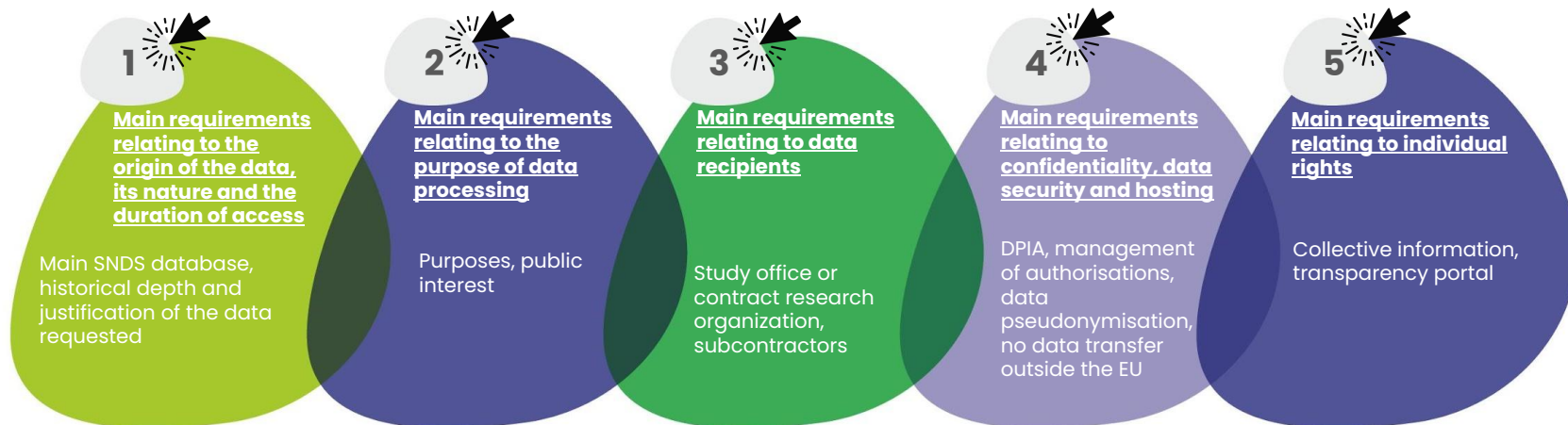
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# MAIN REQUIREMENTS OF MR-008

MR-008 **lays down numerous requirements** which must be checked one at a time by the data controller. To make this verification easier for you, the HDH provides a checklist and this toolkit to help you understand the requirements better.

The main requirements relating to the processing of health data of the individuals concerned\* by research have been grouped under the following objectives:



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# THE MAIN REQUIREMENTS RELATING TO THE ORIGIN OF THE DATA, ITS NATURE AND THE DURATION OF ACCESS (1/2)

The source of the data concerned by this access procedure is the main SNDS\* database as defined in article R. 1461-2 of the French Public Health Code.

This database features data that covers the entire population and is made up of the following components:

- ✓ **The SNIIRAM database including:**
  - data from the Inter-Scheme Healthcare Consumption Datamart, also known as “individual-level beneficiary database”
  - data from the Program of medicalization of the information systems (PMSI)
- ✓ **The PMSI database from healthcare institutions**
  - short-term hospital care data: medicine, surgery, obstetrics and odontology (MCO)
  - Follow-up and rehabilitation care (SSR)
  - Medical data collection for psychiatry (RIM-P) and home hospitalization (HAD)
- ✓ **The Medical Causes of Death database (Inserm's CépiDc database)**
- ✓ **Data on disability (CNSA data)**
- ✓ **Data from databases relating to the Covid 19 epidemic (Vaccin-covid and SI-DEP databases)**

# MAIN REQUIREMENTS RELATING TO THE ORIGIN OF THE DATA, ITS NATURE AND THE DURATION OF ACCESS (2/2)



1

The data processed from the main SNDS database must have a maximum historical depth of **9 years\*** (in addition to the current year).



2

The data processed must be **relevant, adequate and limited** to what is necessary for the purposes of the study.



3

The duration of access must be limited to **that strictly necessary** for the research. It may not exceed **5 years\*\***. Data cannot be archived.



4

The following must in particular **be justified in the protocol**: the categories of data processed, the targeting period, the components of the main SNDS database and the historical depth of the data requested, the duration of access, the geographical area and the number of data subjects.



5

The data must come exclusively and **directly** from the **CNAM** databases.



6

The data may not be re-used or matched with other sources.

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\* Provided it can be disseminated by the CNAM.

\*\* This period may exceptionally be extended for a maximum of 2 years, subject to another expressly favourable opinion from CESREES.

# MAIN REQUIREMENTS RELATING TO THE PURPOSE

The purpose of the project must **be clear and explicit in the protocol submitted** to the relevant HDH department with a view to its examination by the CESREES. It must be in the public interest and be conducted for one of the **6 following purposes**:

Comparative assessment of healthcare provision

Changes in care practices

Comparative analyses of healthcare activities

Feasibility studies for research involving or not involving the human person

Description and analysis of pathologies and patient care pathways

Epidemiological and/or medico-economic studies, including studies to prepare cases for discussions and meetings with the competent authorities and committees, or studies for monitoring purposes



The data controller must provide evidence in the scientific protocol submitted to the CESREES that one of these purposes applies to their research project.

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# A CLOSER LOOK AT THE CESREES EVALUATION (1/2)

Carrying out a research project under MR-008 requires an **expressly favourable opinion** with or without recommendations from the CESREES.



If the opinion obtained is accompanied by recommendations, the data controller undertakes to take them into account and if necessary, to amend their documents accordingly prior to beginning the processing operation.

The CESREES evaluates the methodological and scientific relevance of the project. More specifically, it issues an opinion on:

- ✓ the scientific quality of the project
- ✓ whether the project is in the public interest
- ✓ the clarity and relevance of the purpose of the project
- ✓ the clarity and consistency of the objectives with the purpose
- ✓ whether the chosen method is appropriate for the objectives pursued
- ✓ the need to use personal health data
- ✓ the need to use one of the potential credentials
- ✓ the relevance of the historical depth requested.



If the opinion obtained is accompanied by recommendations, the data controller undertakes to take them into account and if necessary, to amend their documents accordingly, prior to the application for agreement to make the data available. These adjustments must not involve any change to the expression of need attached to the protocol.

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# FOCUS ON THE CESREES EVALUATION (2/2)



## Your documents must include

- ✓ A scientific protocol\*
- ✓ An abstract\*
- ✓ An expression of needs for data from the main SNDS database to characterise the extraction of the desired data\*; **in the event of a discrepancy as to the nature of the data processed, the expression of needs shall prevail. The expression of needs may not be amended after the CESREES has issued its opinion, unless the CESREES expressly requests such modification.**
- ✓ A public declaration of interest from the data controller and the person responsible for implementing the declaration of interest from the study office or contract research organization\*.
- ✓ The list of funding partners for the study
- ✓ Receipt of commitment to comply with MR-008.

Most of these documents (marked with an asterisk\*) must conform to a template available on the HDH [website](#).

Documents are to be submitted via an online [platform](#). The entire procedure is paperless. Your application will only be processed if all necessary documents are submitted. You will be informed if you have submitted all the relevant documents and of the progress of my application through the various stages of the procedure (CESREES).

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# MAIN REQUIREMENTS RELATING TO DATA RECIPIENTS

If a subcontractor is responsible for processing individual data from the main SNDS database, they must:

1

Be declared compliant with the CNIL with the guidelines outlining the criteria related to confidentiality, expertise and independence for study office or contract research organization, as per [Decree of 17 July 2017](#).

2

Be exclusively subject to the laws and jurisdictions of the European Union, if the study office or contract research organization provides data hosting services.

3

If necessary, appoint a data protection officer in accordance with Article 37 of the GDPR.

4

Keep a register of the categories of processing operations carried out on behalf of the data controller, in accordance with Article 30 of the GDPR.

5

Respect the [security standard applicable to the SNDS](#)

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# MAIN REQUIREMENTS RELATING TO CONFIDENTIALITY, SECURITY AND DATA HOSTING (1/2)

For processing operations to comply with the standard, certain security measures must be respected. These measures come from two sources: the SNDS security standard and MR-008. In other words, the security measures set out in MR-008 are an extension of the principles featured in the SNDS security standard.

## These various measures include:

- ☑ Conducting a **Data Protection Impact Assessment** (DPIA)\*.
- ☑ Managing **authorisations and access**.
- ☑ Implementation of pseudonymisation operations.

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\* One single analysis may cover a set of similar processing operations. Various tools are made available by the CNIL to carry out a DPIA: the [PIA software](#) and toolkits (description of the [approach](#), [templates](#) and [case study](#)).

# MAIN REQUIREMENTS RELATING TO CONFIDENTIALITY, SECURITY AND DATA HOSTING (2/2)

The data is made available in a secure processing environment of a **controlled environment\*** that meets the following conditions:

1



It must have been **issued an approval in accordance with the security standard applicable to the SNDS**. This approval, which **must not be expired**, is subject to regular monitoring and is regularly renewed within the time limits specified in the approval decision.

2



It must **have been appraised by the CNIL** as a data processing operation that has been issued express authorisation from the CNIL. This authorisation must date from **less than three years ago**.

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\* An agreement must be drawn up between the data controller and CNAM or the manager of the controlled environment, where applicable.

# MAIN REQUIREMENTS RELATING TO INDIVIDUAL RIGHTS

MR-008 allows the data controller to take advantage of an exception to individual information. In this case, **collective information\*** must be disseminated to the target audience to inform them of the upcoming research. This must include all the information provided for in Article 14 of the GDPR and must be shared in the following ways, **as a minimum requirement:**

1

Publication of the information note on the data controller's website and, where applicable, the study office or contract research organization's website.

2

Implementation of a transparency portal when the data controller carries out several studies using the main SNDS database. This portal must include general information on the main SNDS database and a specific information note for each study carried out.

Other collective information methods may also be used, depending on the characteristics of the studies carried out (social networks, patient associations, press releases, etc.).



With transparency in mind, the data controller must also record the study in the HDH [public directory](#).

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\*The information provided must comply with [Article 14 of the GDPR](#).

# MR-008 KEY MILESTONES

Completion of the MR-008 milestones (see below) requires a **verification of the compliance** of your project with MR-008 requirements. Data controllers can **easily check** this compliance using the MR-008 checklist. If your project meets the MR-008 requirements, the following steps must be completed:

## KEY MILESTONES

**CNIL**  
COMMISSION NATIONALE  
INFORMATIQUE & LIBERTÉS

Commitment to compliance **with the CNIL** \*

 48 hrs\*

**CESREES**  
Centre Français de Recherche pour les  
Techniques de Santé et de Surveillance  
en Santé

Submit documents to the CESREES and receive an expressly favourable opinion with or without a recommendation


**To be sent to the CESREES** 

- Scientific protocol
- Abstract
- Expression of needs
- Declaration of interest
- Receipt of commitment to comply

The data controller modifies the documents in accordance with the CESREES recommendations, if necessary.

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DATA HUB

**Record** the project in the **HDH public directory**, and disseminate information


**In order to respect individual rights** 

- Collective information note to data subjects

Carry out research (access data, data processing, etc.)

**HDH** HEALTH  
DATA HUB


Send study results and associated methodology to the HDH

**To be sent to the HDH** 

- Results and associated methodologies

**CNIL** **CESREES**  
COMMISSION NATIONALE  
INFORMATIQUE & LIBERTÉS Centre Français de Recherche pour les  
Techniques de Santé et de Surveillance  
en Santé

Send a review to the CNIL and/or CESREES every three years.

**To be sent to the CNIL and/or CESREES** 

- Review of processing operations.

# TO FIND OUT MORE

If, after reading this toolkit, you still have questions about whether your project complies with MR-008, you can:

- ✓ Consult the [ruling from the CNIL](#) adopting this procedure.
- ✓ Contact the CNIL during [switchboard opening hours](#) on Monday mornings (Tel.: +33 (0)1 53 73 22 22) or visit the [website](#).
- ✓ [Contact us](#). Please provide as much detail as possible about your project and any questions you may have, so that we can give you the best possible answer.
- ✓ Post your questions on the [support forum](#).

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# ACRONYMS

**DPIA:** Data Protection Impact Assessment

**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

**CNSA:** Independent-Living Support Fund

**DCIR:** Inter-Scheme Healthcare Consumption Datamart, also known as “individual-level beneficiary database”

**HAD:** Medical data collection for home hospitalization

**HDH:** Health Data Hub

**LRBE:** Study office or Contract research organization

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# ACRONYMS

**MCO:** Medicine, surgery, obstetrics and odontology

**MR:** Reference methodology

**PMSI:** Program of medicalization of the information systems

**SNDS:** National Health Data System

**SNIIRAM:** French National Health Insurance Inter-Schemes Information System

**GDPR:** General Data Protection Regulation

**RIM-P:** Medical data collection for psychiatry

**SSR:** Follow-up and rehabilitation care

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