

# MR-003 annotated

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Reference methodology for the processing of personal data in the context of health research not requiring the data subject's consent to participate in the research

This document is a courtesy translation provided for convenience only. It has no official value and only the official French version of MR-001 shall prevail.

## I. Definitions

**For the purposes of this reference methodology, the following terms are defined as follows:**

- **Carer:** a person who assists, on a non-professional basis, in carrying out some or all of the acts or activities in the daily life of the research participant;
- **Ethics Committee:** a legally competent independent body authorized to examine the ethical aspects of the research and to issue opinions, in accordance with the relevant sectoral regulations. In France, it is the *comité de protection des personnes* (CPP);
- **Recipient:** as defined in Article 4 (9) of the GDPR [1]. Communication of the data may in particular take the form of transmission, dissemination, consultation by secure access or any other form of making available all or part of the data;
- **Personal data:** as defined in Article 4 (1) of the GDPR [2];
- **Genetic data:** as defined in Article 4 (13) of the GDPR [3];
- **GDPR information:** the information to be provided, pursuant to Articles 12 to 14 of the GDPR and Articles 69 to 71 of the Law on information technology and freedoms, to research participants, or to their legally designated representatives;

**[1] Corresponds** to a natural or legal person, public authority, agency or another body, to which the personal data are disclosed, whether a third party or not. However, public authorities which may receive personal data in the framework of a particular inquiry in accordance with Union or Member State law shall not be regarded as recipients; the processing of those data by those public authorities shall be in compliance with the applicable data protection rules according to the purposes of the processing.

**[2] Corresponds** to any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

**[3] Corresponds** to personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.

- **Research location:** place where the research is carried out in accordance with sectoral regulations, such as the service of a health institution or the patient's home;
- **Administrative tasks necessary to carry out the research:** activities carried out for the purpose of:
  - the defrayal or reimbursement of travel, accommodation or catering expenses for data subjects or the payment of allowances;
  - prior and/or ancillary activities [4] to the follow-up of data subjects as specified in the research protocol;
  - home delivery and collection of health products, equipment or samples necessary for carrying out the research;
- **Quality control:** the activity of verifying:
  - compliance with the applicable regulations and research protocol;
  - the completeness and authenticity of the data collected in the context of the research and transmitted by the professional involved in the research to the controller or its processors.

This task shall be carried out in accordance with the Quality Control Annex [5];

- **Information:** the activity of sending the GDPR information, including in a dematerialised manner;
- **Follow-up of the research participant:** activities carried out exclusively within a research location, corresponding to:
  - the collection of personal data in the context of direct interaction between the professional involved in the research and the research participant;
  - the transmission [6] of personal data between professionals involved in the research, for the activities necessary to the research participant's follow-up.

This follow-up may be carried out exclusively by professionals involved in the research.

This task includes searching for the vital status by consulting the record of deceased persons of the *Institut national de la statistique et des études économiques* (Insee) [7] [8];

**[4] Examples:** sending a reminder email to complete an online questionnaire, sending a text message (SMS) to activate an IT account to use a web application.

**[5] Watch point:** compliance with MR-003 implies compliance with all MR requirements, including with its annexes.

**[6] Examples:** transmission of biological samples or medical images (X-rays, etc.) for analysis, transmission of records of medical analyses

- **Research participant:** the data subject involved in a research in accordance with the applicable sectoral regulations and whose personal data is processed;
- **Professional involved in the research:** the natural person who collects the data, directs or monitors the conduct of the research. It includes:
  - the investigator and his or her collaborators acting under his or her responsibility and authority;
  - health professionals and their collaborators acting under their responsibility and authority;
  - psychologists or psychotherapists;
  - qualified persons within the meaning of the sectoral regulations [9];
- **Research:** research not requiring the collection of consent [10] for the data subject's participation.
- **Sectoral regulations:** the rules applicable to the research covered by the reference methodology. It includes:
  - Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use and Article L. 1124-1 of the Public Health Code;
  - Articles L. 1121-1 et seq. of the Public Health Code, as regards research involving the human person;

**[7] Watch point:** the Insee record of deceased persons should not be confused with the CépiDc; the Insee record includes information on the civil status of deceased persons (identity, date and place of death), allowing to find out whether a person has died (vital status) and is available in open data; conversely, CépiDc data is based on medical certificates in order to produce data on causes of death, is mainly used for epidemiological and public health purposes and is subject to restricted access, regulated by law.

**[8] See:** record made available by Insee on its website (<https://www.insee.fr/fr/information/4190491>) or on the French public data platform data.gouv.fr (<https://www.data.gouv.fr/datasets/fichier-des-personnes-decede>).

**[9] Example:** Article L. 1121-3 of the Public Health Code.

**[10] Watch point:** this consent is distinct from consent to processing personal data within the meaning of Articles 6 and 9 GDPR.

- sectoral regulations applicable in a third country or territory, where the controller is established in France;
- **Legally designated representative [11]**: the legal representative of the research participant and the persons entitled to authorize the research in accordance with the relevant sectoral regulations;
- **Controller**: as defined in Article 4 (7) of the GDPR [12].

This includes the sponsor [13] in accordance with the sectoral regulations;

- **Scientific Research Officer**: the person designated by the controller, acting under its responsibility, ensuring the quality, integrity and security of the data and of its processing, as well as compliance with the purpose of the processing. This may be the coordinating investigator;
- **Central SNDS**: as defined by the safety framework for the *Système National des Données de Santé* (SNDS);
- **Processor**: as defined in Article 4 (8) of the GDPR [14]. It is a separate legal entity from the controller, which must have legal personality. Thus, the various departments, services, divisions, *etc.* of the same legal person cannot be regarded as separate processors of each other;
- **SNDS wire system**: as defined by the safety framework applicable to the SNDS [15];
- **Processing**: as defined in Article 4 (2) of the GDPR [16].

**[11] Examples**: in the context of a research involving human person, the legally appointed representatives of a minor participant who is not emancipated are the holders of parental authority (Article L. 1122-2 of the Public Health Code).

**[12] Corresponds** to the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law.

**[13] Corresponds** to the natural or legal person who initiates, manages and organizes the financing of the research.

**[14] Corresponds** to the natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

**[15] See**: Article L. 1461-1 IV 3° of the Public Health Code and Order of 6 May 2024 on the safety framework applicable to the SNDS (<https://www.legifrance.gouv.fr/jorf/id/JORFTEXT00049516244>).

**[16] Corresponds** to any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation,

## II. Relevant controllers

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1. This reference methodology may be used by a controller who carries out data processing operations corresponding to those referred to in Part III.
2. In the case of joint controllership, the entities must define in a transparent manner their respective obligations [17], in accordance with Article 26 of the GDPR.

## III. Processing of personal data included in the scope of the methodology

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3. The methodology may be applied to researches for which the Law on information technology and freedoms shall apply, provided that one of the following criteria is met [18]:
  - the controller is established in France;
  - all or some of the data subjects concerned by the processing reside in France.
4. The processing operations concerned by the methodology must be justified and serve a public interest of research, study or evaluation in health sector [19].
5. The research that can benefit from the methodology is the research for which the sectoral regulations do not require [20] the consent of the research participant or their legally designated representatives to be obtained. These researches correspond to:

use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

[17] See: EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR ([https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-072020-concepts-controller-and-processor-gdpr\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-072020-concepts-controller-and-processor-gdpr_en)).

[18] See:

- Article 3 GDPR and Article 3 of the French data protection law;
- EDPB Guidelines 3/2018 on the territorial scope of the GDPR (Article 3) ([https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-32018-territorial-scope-gdpr-article-3-version\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-32018-territorial-scope-gdpr-article-3-version_en)).

[19] See: Health Data Hub guide on the public interest purpose (<https://www.health-data-hub.fr/intérêt-public>).

[20] Watch point: where the collection of consent results from a deliberate choice of the controller, without being required by the applicable sectoral regulations, the research falls within the scope of

- researches involving the human person as defined in Article L. 1121-1 2° of the Public Health Code, which characteristics and conditions are set out in Article L. 1122-1-4 of the Public Health Code;
  - research involving the human person as defined in Article L. 1121-1 3° of the Public Health Code [21] [22], i.e. non-interventional research involving no risk or constraint, in which all procedures are carried out and products used in the usual manner;
  - researches aimed at evaluating standard care subject to the provisions applicable prior to Law No. 2012-300 of 5 March 2012 on research involving human person;
  - clinical trials in which the data subject does not object to their participation, in accordance with the conditions laid down in Article 30 of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC (cluster clinical trials)
6. The methodology also applies to researches that meet the following cumulative criteria [23]:
- they are implemented by a controller established in France;
  - the data subjects do not reside in France;
  - sectoral regulations applicable in the territory or country [24] where the data subjects reside, other than those referred to in paragraph 5, do not require the consent of the research participant or of his or her legally designated representatives to be obtained prior to the participation in the research.
7. The following researches may not benefit from the methodology:

MR-003 and does not fall within the scope of MR-001 solely by virtue of that choice.

[21] See: Order of 12 April 2018 establishing the list of researches referred to in point 3 of Article L. 1121-1 of the Public Health Code (<https://www.legifrance.gouv.fr/loda/id/JORFTEXT000036805820/>).

[22] Watch point: MR-003 applies to all researches involving human persons of category 3, including those based solely on questionnaires or interviews and those not relating to healthcare products.

[23] Watch point: all the provisions of the MR (including its annexes) must be complied with, irrespective of the level of requirement laid down by the sectoral regulations applicable in the territory or third country (including if that level is lower than that of the other sectoral regulations covered by the MR); in the event of non-compliance with one or more provisions of the MR (including its annexes), the controller must apply for an authorization.

[24] Corresponds to other EU Member States or non-EU countries.

- research for which sector-specific regulations require the consent of the research participant to be obtained prior to their participation
- researches for which the Data Protection Impact Assessment (DPIA) indicates that the processing would, despite measures taken under Article 35 GDPR to mitigate the risk, present a high residual risk to the rights and freedoms of data subjects;
- researches requiring data to be matched with one or several databases created or governed by an act of a legislative or regulatory nature, and the central SNDS (main base and catalogue base) [25];
- researches requiring processing of the registration number in the *Répertoire national d'identification des personnes physiques* (NIR).

**[25] Examples:** central SNDS, its components and sources (e.g. SNIIRAM maintained by the CNAM, PMSI maintained by the ATIH), Vac-SI, SI-DEP, SI-VIC, RNIAM, Erasme database (Siam-Erasme), Insee EDP (*échantillon démographique permanent*), National Cancer Registry.

## IV. Objectives pursued by the processing (purposes)

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8. The processing of personal data:
  - relating to research participants is to carry out a research in the field of health. Such processing shall include the processing of data relating to research participants, with a view to enabling the collection, entry, verification of validity and consistency as well as analysis of the data collected in the course of the research;
  - relating to professionals involved in the research is to set up the research, carry it out and comply with the sectoral regulations.
9. The purpose of the processing may not be the identification or re-identification of the research participants by their genetic characteristics.

## V. Legal basis for the processing operation

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10. The processing of personal data for the above-mentioned purposes must meet one of the conditions laid down in Article 6 **[26]** of the GDPR.

The processing of sensitive data for the above-mentioned purposes must comply with one of the conditions laid down in Article 9 **[27]** of the GDPR.

**[26] Watch point:** the most appropriate legal basis is the performance of a task carried out in the public interest or the exercise of official authority vested in the controller (Article 6(1)(e) GDPR), where the controller is a sponsor entrusted by a text with a research task (e.g. a hospital, a research organization, etc.), and the legitimate interests pursued by the controller (Article 6(1)(f) GDPR), where the latter is a private sponsor (e.g. a pharmaceutical company, a manufacturer of medical devices, etc.).

**[27] Watch point:** the most appropriate exception is scientific research (Article 9(2)(j) GDPR).

## VI. Personal data (necessity, origin and nature)

11. In accordance with Article 5(1)(c) of the GDPR (minimisation principle [28]), the data processed must be relevant, adequate and limited to what is necessary in relation to the objectives of the research.

### A. With regard to the personal data relating to research participants

#### 1. Identification of the research participant

12. In the context of the research, it may be necessary to link data relating to the same person using unique identifiers associated with the data subject.

13. In such a case, the controller shall put in place measures to limit the risks of re-identification of data subjects, in particular by ensuring compliance with the general principles laid down in Part VII "*Recipients*".

14. The identification of the research participant shall be carried out by means of an identifier called a 'subject ID'. It shall be generated in accordance with requirements MR-CNS-01 to 04 of the Security Annex.

As an exception to requirements MR-CNS-01 to 03, the subject ID may contain the reference of the research, a reference corresponding to the organization qualified as a research location (study site number) and a number corresponding to an order for inclusion in the research (serial number) [29]. The subject ID shall also meet the following requirements:

- the subject ID does not reveal information about the research participant or pre-existing identifiers linked to that data subject, with the exception of the research reference, the study site number and the serial number;
- in particular, the subject ID does not contain information related to the identity traits of the data subjects (e.g. initials, date of birth), care (NIR, National Health Identifier (INS), Permanent Patient Identifier (IPP), episode of care identifier (EIP)), the data collection phase (tube number of a biological sample) or the identifier used in a source dataset.

[28] See: EDPB Guidelines 4/2019 on Article 25 Data Protection by Design and by Default (<https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-42019-article-25-data-protection-design-and-en>).

[29] **Watch point:** although this is accepted in the MR, it is preferable that the subject ID does not contain these elements.

- the subject ID is generated specifically for the dataset. Where certain data is taken from an existing database or collection of biological samples, the subject ID associated with the research participant is different from the identifier used in the source database. Correspondence, if necessary, is held by the person in charge of the source database.
15. By way of exception, the first letter of the first name and the first letter of the surname of the research participant may be temporarily added to the subject ID, provided that this concatenation is justified for carrying out certain specific steps of the research. The justification must be included in the protocol. This concatenation shall be carried out for no longer than is necessary to achieve the stated objective.
  16. Where applicable, the controller shall specifically document within the research-related DPIA the risks of re-identification of the research participant, induced by the presence of the initials, and shall put in place appropriate technical and organisational measures to limit those risks.
  17. For those stages of the research where the subject ID is not or no longer strictly necessary for carrying out the research or tracking the research participant, it shall be replaced by a non-meaningful code generated in accordance with requirements MR-CNS-01 to 04 of the Security Annex. More than one non-meaningful code can be generated for the different steps of the research or when data is shared with new recipients.
  18. The correspondence table linking the subject ID to the administrative data is kept by professionals involved in the research who carry out a follow-up task and who operate within a research location, with the exception of the patient's home. The information (correspondence table or secret key used) enabling a link to be made between a non-meaningful code, administrative data, subject ID or other identifiers relating to the research participant shall be kept in accordance with requirement MR-CNS-04 of the Security Annex.

## 2. Nature of the data

19. Only categories of personal data relating to the research participant may be processed:

- the collection of which, scientifically justified in the research protocol, has been considered relevant by an Ethics Committee and;
- which are included in the list below.

List of personal data that may be processed [30]:

20. *Identifiers:*

- subject ID, generated in accordance with the requirements specified in paragraphs 15 to 17;
- non-significant codes, generated in accordance with the specific requirements of the Security Annex (MR-CNS-01 to 04).

21. *Administrative data:*

- names, surnames [31];
- postal, electronic and telephone contact details [31];
- bank account details [31];
- full date of birth (day, month and year of birth) [31] if the latter is necessary for the search for vital status in the Insee record of deceased persons [32] in the context of a follow-up mission to the research participant or for the defrayal/reimbursement of expenses in the context of an administrative mission necessary for carrying out the research;
- social security regime (excluding the registration number in the *Répertoire national d'identification des personnes physiques*), supplementary insurance (mutual insurance, private insurance);
- reimbursement of costs incurred by the data subject in connection with the research;
- annual amount of allowances received.

Such data shall be processed in strict compliance with the conditions laid down in the methodology and in particular those specified in Part VII "*Recipients*".

**[30] Watch point:** only data that is adequate, relevant and limited to what is necessary for the purposes of the research may be collected; the fact that a data item is listed in the MR does not by default make it adequate and relevant.

**[31] Watch point:** as such data is particularly identifying, the GDPR information should explicitly refer to its collection.

**[32] Watch point:** the verification of the vital status must comply with the requirements of the MR relating to the data recipients, in particular if it is planned to use web browsers or tools made available by operators other than Insee (e.g. the MatchId tool (<https://deces.matchid.io/>)); in particular, the verification of vital status must not involve the transmission to third-party operators of data that may reveal the state of health of potential research participants.

## 22. Research data:

- age or date of birth (month and year of birth);
- day of birth if this is necessary to carry out a research involving data subjects under the age of two;
- place of birth and geographical origin [33];
- country, region or department of residence [34];
- references to sex and gender [35];
- any data relating to health [36];
- dates relating to the conduct of the research [37];
- ethnic origin [38];
- genetic data [39];
- family status;
- social determinants: educational attainment level [40], socio-professional category [41],

**[33] Example:** the place of birth of the parents.

**[34] Watch point:** geocoding of participants is excluded from the MR scope; geocoding involves assigning geographical coordinates (longitude/latitude) to a postal address (e.g. the IRIS (*Ilots Regroupés pour l'Information Statistique*) division of INSEE).

**[35] Corresponds** to both the sex and gender of birth of the participant and the sex and gender of the participant during the research.

**[36] Examples:** weight, size, research and concomitant therapy, results of examinations, results of analysis of biological samples, medical imaging, data on adverse reactions and events occurring in the course of the research, personal or family history, diseases or associated events, data on a health status likely to influence the results or make participation impossible in application of medical contraindications.

**[37] Examples:** date of inclusion, dates of visits.

**[38] Watch point:** as such data is sensitive, the GDPR information should explicitly refer to its collection.

**[39] Watch point:** as such data is sensitive, the GDPR information should explicitly refer to its collection.

**[40] Examples:** primary school, high school, college.

**[41] Examples:** status (self-employed or employed), nature of employer (public or private), economic activity (agricultural, craft, industrial or tertiary), etc., as provided for in the nomenclature of socio-professional categories drawn up by Insee.

- working life [42], household income by categories/ranges, perceived social support scale [43] [44];
- participation in other researches, with a view to ensuring compliance with the inclusion criteria;
- tobacco, alcohol, drugs use;
- lifestyles and behavior [45], including travel [46] [47];
- lifestyle [48];
- sex life [49] [51], sexual orientation [50] [51];

**[42] Examples:** current occupation, employment history, unemployment, commuting and business travels, occupational exposure.

**[43] Corresponds** to the participant's self-assessment of the social resources at their disposal (e.g. a parent, spouse, child, colleague, friend, etc.) and the adequacy of those resources to their needs.

**[44] Examples:** categories of social resource the participant can rely on if they are ill, who can provide comfort if they are upset, from whom they can seek advice before making an important decision, with whom they can share pleasant moments to change ideas, etc.

**[45] Examples:** dependency (alone, in institutions, independent, grabs), assistance (home help, family), physical exercise (intensity, frequency, duration), diet and dietary behavior, recreation.

**[46] Examples:** travel to the place of care or research location, daily travel of the participant (mode, duration, distance).

**[47] Watch point:** geolocation of participants is excluded from the MR scope; geolocation is a set of location techniques to position the participant on a map or plane, using its geographical coordinates (e.g. latitude, longitude, altitude).

**[48] Examples:** urban, semi-urban or rural, sedentary, semi-nomadic or nomadic, collective habitat (including floor, whether or not there is a lift, etc.), individual, pavillary, etc.

**[49] Corresponds** to a set of practices and experiences related to sexuality, such as the frequency of sexual intercourse.

**[50] Corresponds** to long-term emotional and/or sexual attraction, e.g. heterosexuality, homosexuality, men who have sex with men (MSM), women who have sex with women (WSW), etc.

**[51] Watch point:** as such data is sensitive, the GDPR information should explicitly refer to its collection.

- vital status and date of death, where this information appears in the source document, is known to the professional involved in the research or is obtained after consultation of the Insee record of deceased persons;
- quality of life scale or other information on the data subject's quality of life;
- photographs, videos or voice recordings which do not permit the identification [52] of research participants and collected according to the applicable provisions [53] on image and voice rights.

These data shall be minimised and pseudonymised, in accordance with paragraphs 13 to 19 and measures MR-SEC-04 and MR-SEC-06 of the Security Annex.

[52] **Examples:** masking of face, eyes, distinctive signs.

[53] **See:**

- Article 9 of the Civil Code;
- Ministry of Economic Affairs website (<https://www.service-public.gouv.fr/particuliers/vosdroits/F32103>);
- Public Service website (<https://www.economie.gouv.fr/apie/droit-limage-des-personnes-et-des-biens>).

### 3. Origin of personal data

23. The data relating to the research participant shall come exclusively from:

- the data subjects themselves, their legally designated representatives and/or their carer, provided that the latter arrangement is expressly provided for in the protocol validated by the Ethics Committee;
- professionals involved in the research;
- databases or collections of biological samples, which have been legally constituted and have undergone the necessary formalities with the competent authorities.

24. For data from an existing database or collection of biological samples:

- only individuals initially authorised to access administrative data may hold the correspondence table;
- the subject ID is different from the identifier used in the source database. Correspondence, if necessary, will be held by the individual in charge of the source database.

## B. With regard to the personal data relating to the professionals involved in the research

### 1. Nature of personal data

25. Only the following categories of personal data relating to the professionals involved in the research may be processed:

- identity data: names, surnames, civil status, professional contact details (postal, electronic, telephone and bank account details), where applicable, identification number in the *répertoire partagé des professionnels de santé*;
- training, diplomas;
- professional life (in particular training, mode and type of exercise, information needed to assess the knowledge available to them to carry out the research);
- amount of allowances and remuneration received;
- collaboration within other researches;

- history of access to and modifications to the research participants' data.

## 2. Origin of personal data

26. Data relating to the professionals involved in the research come from:

- the interested parties themselves;
- public lists [54];
- any other list lawfully drawn up for that purpose.

## VII. Recipients

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27. The processing of personal data may require the communication of such data to recipients. This communication shall be made in accordance with:

- the general principles applicable to any recipient;
- derogations allowed with regard to the tasks carried out by certain recipients;
- as well as the specific conditions applicable to recipients wishing to combine the performance of several tasks entrusted by the controller.

28. The general principles and derogations described below do not preclude:

- the voluntary communication [55] by the individual of data relating to him or her for the exercise of his or her rights, in accordance with Part IX "*Data subjects' rights*";
- communication to the authorized staff acting under the authority of the insurance body guaranteeing the controller's civil liability, where applicable.

### A. General principles applicable to any recipient

29. Each recipient:

- is authorised under conditions which comply with the regulation;
- accesses the personal data that is strictly necessary for the performance of his or her duties in relation to the task entrusted to him or her [56];

### [54] Examples:

- *Annuaire Santé* (<https://annuaire.esante.gouv.fr>);
- ClinicalTrials.gov (<https://clinicaltrials.gov>).

[55] **Example:** information provided by the participant to the controller's DPO, when exercising their rights.

- is subject to professional secrecy, under the conditions laid down in Articles 226-13 and 226-14 of the Criminal Code or the sectoral regulations of the third country where the research is carried out;
- puts in place technical and organisational measures to ensure data security;
- keeps the personal data for no longer than is necessary for the performance of the assigned task.

30. Apart from the cases provided for in Part B "*Derogations*", a recipient may not at the same time have access to or process:

- administrative and the research data;
- administrative data and the subject ID. Compliance with this principle may require the assignment of a non-meaningful code to the research participant.

## B. The derogations applicable with regard to the tasks carried out by the recipients of the research participant's data

### 1. Derogation for the research participant's follow-up

31. Recipients in charge of the research participant's follow-up may access the administrative data, identifiers and research data of the data subject being followed-up.

### 2. Derogation for administrative tasks

32. Recipients [57] entrusted with administrative tasks necessary for carrying out the research may access administrative data, non-significant codes and health data that is strictly necessary for the organisation of that task.

### 3. Derogation for information

33. Recipients in charge of data subjects' information may access the administrative data as well

**[56] Watch point:** as a matter of principle, the sponsor and controller of a research shall access participants' data in coded or pseudonymised form, in accordance with good clinical practice and the principle of minimisation; by way of exception, a sponsor and controller may access participants' administrative data, subject to compliance with the applicable sectoral regulations and the requirements of the MR, in particular paragraphs 19 (correspondence table) and 32 to 41 (recipients).

**[57] Examples:** coordinating nurse, vendor in charge of fees reimbursement, patient concierge services, vendor in charge of delivering/collecting medicines or samples to or from the participant's home, etc.; in the majority of cases, these recipients act as data processors.

as the elements included [58] in the GDPR information, which may reveal information on the health status of the data subject.

#### 4. Derogation for the quality control

34. Recipients in charge of quality control may access the data under conditions which comply with the Quality Control Annex [59].

#### C. Specific conditions applicable in case of multiple tasks

35. Subject to compliance with the general principles and derogations referred to above, natural or legal persons may combine several tasks in accordance with the conditions set out below.

##### 1. Professionals involved in the research working in a research location, excluding the patient's home

36. These professionals [60] can carry out follow-up tasks, information tasks, administrative tasks and contribute to the quality control. This cumulation is allowed only for the data subjects they take care of in the context of the research and, in the case of the information task, for the data subjects whose identity they knew before the start of the research [61].

[58] **Examples:** the title of the research, the inclusion criteria.

[59] **Watch point:** compliance with MR-001 implies compliance with all MR requirements, including with its annexes.

[60] **Corresponds** to professionals working within:

- an entity acting as processor on behalf of the sponsor (controller); and/or
- a health institution established in France, acting as sponsor and controller.

[61] **Watch point:** this includes data subjects whose identity is known to the professionals involved in the research prior to the first act of recruitment (e.g. prior to the first contact with a potential participant or prior to the publication of an advertisement for the research), data subjects already taken care of by the professional involved in the research, as well as data subjects who directly approach the professional involved in the research with a view to participating in the research.

## 2. Health institutions established in France [62], qualified as controllers, carrying out several tasks

37. When they act as sponsor, these institutions can carry out follow-up tasks, information tasks, administrative tasks and contribute to quality control.

38. Where several tasks are combined, they shall put in place measures to ensure physical and organisational separation between the individuals responsible for carrying out these various tasks (separate teams and access procedures) and segregation between the data processed in the context of each task (disjoined databases and applications, with different access rights).

They shall ensure that each individual responsible for carrying out a task shall have access only to the data necessary for the performance of his or her task [63].

## 3. Legal persons, qualified as processors [64] [65], performing several tasks

39. These legal persons may carry out follow-up tasks, information tasks, administrative tasks and quality control.

40. Where several tasks are combined, the processor shall put in place measures to ensure physical and organisational separation between the individuals responsible for carrying out the various tasks (separate teams and access procedures) and segregation between the data processed in the context of each task (disjoined databases and applications, with different access rights). It shall ensure that each individual

[62] **Corresponds** to the institutions referred to in Articles L. 6111-1 et seq. of the Public Health Code.

[63] **Example:** a hospital is a sponsor of a clinical trial and the reimbursement of participants' fees is handled by the invoicing department of that hospital; the personnel of the invoicing department can access administrative data relating to the research participants and a non-meaningful code (see paragraph 33 of MR); however, it is not allowed to access the subject ID or research data.

[64] **Watch point:** as a general remark, the EDPB considers that the mission of processor poses a risk of conflict of interest with the mission of external DPO and of representative within the meaning of Article 27 GDPR.

[65] **See:** EDPB Guidelines 3/2018 on the territorial scope of the GDPR (Article 3) ([https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-32018-territorial-scope-gdpr-article-3-version\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-32018-territorial-scope-gdpr-article-3-version_en)).

responsible for carrying out a task has access only to the data necessary for the performance of his or her task.

## VIII. Data subjects' information

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### A. With regard to the research participant

41. In accordance with Article 12 of the GDPR, the controller is required to inform [66] individually the research participant and/or his or her legally designated representatives of the existence of the processing of personal data relating to him or her or the data subject whom they represent.
42. The GDPR information must be concise, transparent, understandable, easily accessible and written in clear and plain language adapted to the ability of data subjects to understand.
43. This section is without prejudice to the information to be transmitted under the applicable sectoral regulations [67], which will in any case have to be complied with by the controller.

#### 1. Timeliness of information

44. As a matter of principle, the research participant and/or their legally designated representatives are informed, prior to inclusion in the research.
45. By way of exception, where the research participant is not in a position to receive the GDPR information prior to his or her inclusion, the information shall be provided, as soon as possible, to his or her legally designated representatives.
46. If the data subject's state of health so permits, he or she shall be provided with the GDPR information. The research participant or their legally designated representatives will be informed of the right to object to the use of data collected in the context of the research, in accordance with the sectoral regulation.

[66] See: Guidelines WP260 rev.01 on transparency ([https://www.edpb.europa.eu/our-work-tools/our-documents/article-29-working-party-guidelines-transparency-under-regulation\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/article-29-working-party-guidelines-transparency-under-regulation_en)).

[67] See: in particular, Articles L. 1122-1 et seq. of the Public Health Code, Article 16-10 of the Civil Code and Article L. 1130-5 of the Public Health Code, Article 30 of Regulation (EU) No 536/2014 on clinical trials on medicinal products and Article L. 1124-1 of the Public Health Code.

## 2. The arrangements for issuing the information

47. The GDPR information [68] [69] [70] may be:

- hand delivery during a consultation;
- sent by post;
- sent by electronic means.

48. Where it is sent by electronic means, the following cumulative conditions shall apply:

- the research participant and/or his or her legally designated representatives shall not object to this method of providing the information. In the event of an objection, the controller is required to provide the GDPR information in paper form;
- the research participant and/or his/her legally designated representatives have the necessary means to access the electronic medium through which the information will be provided;
- the GDPR information in electronic format [71] shall be made available [72] to the research participant and/or his or her legally designated representatives for the duration of the research;
- if the research participant and/or his or her legally designated representatives so request, they may at any time receive the GDPR information in paper format;
- the specific security measures for issuing information in electronic format provided for in the Security Annex shall be implemented (MR-INF-01 to 04).

49. In any event, the arrangements for the provision and access shall comply with the requirements laid down in Part VII "Recipients".

**[68] Watch point:** the information shall always be provided in writing, including when it is intended to collect the data orally; participant shall keep a copy of the GDPR information.

**[69] Examples:** the GDPR information is included in the informed consent form, is included on a questionnaire provided to the participant or is included in a specific document attached to the informed consent form or a questionnaire provided to the participant.

**[70] See:** in particular, Article L. 1122-1 of the Public Health Code and Article 30.2 of Regulation (EU) No 536/2014 on clinical trials on medicinal products.

**[71] Examples:** sent by email, made available on an online platform.

**[72] Example:** if the GDPR information is made available on an online platform, it shall be active and accessible for the duration of the research.

### 3. The recipients of the information

50. The data subject solicited to participate to the research and/or his or her legally designated representatives shall be individually informed of the data processing.
51. Minors and adults subject to a legal representation measure in the context of guardianship, family authorisation or a future protection mandate and/or their legally designated representatives shall be informed in accordance with Article 70 of the Law on information technology and freedoms.
52. For the researches referred to in paragraph 6 of the methodology, where the sectoral regulations so provide, and for the researches referred to in Article L. 1121-1 2° and 3° of the Public Health Code [73], where the second holder of parental responsibility cannot be consulted within a period compatible with the methodological requirements of the research, a GDPR information to the attention of the absent holder must be provided to the holder present at the time of inclusion.

### 4. The content of the GDPR information

53. The information provided shall contain all the elements [74] provided for by the GDPR, supplemented by the following:
  - the arrangements for the exercise of the data subjects' rights, in particular the contact points for the data subject exercising his or her rights and/or his or her legally designated representatives and, where appropriate, the information they shall provide for that purpose;
  - in case of reuse of databases and/or collections of biological samples legally constituted [75], the source from which the data originates and the categories of data in question;
  - registration in the national register of persons with no medical condition who are willing to search voluntarily in accordance with sectoral regulations [76];
  - where the controller entrusts a processor with one or more tasks requiring communication of or access to administrative data, the task(s) assigned and the categories of personal data it will have access to.

**[73] Watch point:** the derogation from the obligation to inform the second holder of parental authority is expressly provided for in Article 70 of the French data protection law. In the context of MR-003, this derogation is strictly limited to researches involving human persons of category 2 conducted according to Article L. 1122-1-4 of the Public Health Code and to researches involving human persons of category 3. Consequently, researches governed by other sectoral regulations cannot rely on such a derogation.

**[74] Watch point:** the information to be provided to data subjects varies slightly, depending on whether the data has been collected from the participant (cf. Article 13 GDPR) or from a third party (cf. Article 14 GDPR).

**[75] Example:** database resulting from a previous research in the field of health, which has undergone appropriate formalities (declaration of compliance with a MR or authorization) with the CNIL.

**[76] See:** Articles L. 1121-16 of the Public Health Code.

## B. With regard to professionals involved in the research

54. The GDPR information is provided through a note [77] included on documents provided to the professionals involved in the research or on the agreements signed by them. That information shall contain all the elements provided for by the GDPR.

## IX. Data subjects' rights

### A. General principles

55. In accordance with Article 12 of the GDPR, the controller shall implement procedures for handling data subjects' requests relating to their rights within a maximum period of one month from their receipt. That period may be extended by two months, considering the complexity and number of requests. Such extension shall be notified to the data subject exercising his or her rights and/or to his or her legally designated representatives within one month of receipt of the request.

56. Subject to the specific provisions described below and the legal basis chosen:

- the right of access [78] is exercised under the conditions laid down in Article 15 of the GDPR;
- the right to rectification is exercised under the conditions laid down in Article 16 of the GDPR;
- the right to restriction is exercised under the conditions laid down in Article 18 of the GDPR;
- the right to object is exercised under the conditions laid down in Article 21 of the GDPR;
- the right to portability [79] is exercised under the conditions laid down in Article 20 of the GDPR;
- the right to erasure is exercised under the conditions laid down in Article 17 of the GDPR.

**[77] Watch point:** the information to be provided to data subjects varies slightly, depending on whether the data has been collected from the data subject (cf. Article 13 GDPR) or from a third party (cf. Article 14 GDPR).

**[78] See:**

- EDPB Guidelines 01/2022 on data subject rights - Right of access ([https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-012022-data-subject-rights-right-access\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-012022-data-subject-rights-right-access_en));
- CNIL recommendation Computerized Patient File - Sheet 11: security measures related to information and the exercise of rights, that the controller may rely on as guidance.

**[79] Watch point:** the right to portability applies only where the processing is based on consent (Articles 6(1)(a) or 9(2)(a) GDPR) or on a contract (Article 6(1)(b) GDPR); this right therefore does not apply to researches carried out on the basis of the public interest task pursued by the controller (Article 6(1)(e) GDPR) or the legitimate interests of the controller (Article 6(1)(f) GDPR) and/or

57. The controller cannot rely on the provisions of Article 11 GDPR to restrict the exercise of data subjects' rights. Where sectoral regulations do not require the retention of administrative data or means of correspondence with the data subjects' identity, the controller remains able to handle data subjects' requests if they provide additional information allowing for their re-identification. To this end, the controller will have to put in place a mechanism to ensure that the information transmitted by the data subject exercising his or her rights corresponds to his or her personal data that is processed in the context of the research.

### A. Specific provisions for the rights of research participants

58. The research participant must be specifically informed of any restriction [80] of his or her rights prior to obtaining his or her consent to participate in the research.

59. The rights shall be exercised at all times, directly or through a professional appointed for that purpose by the research participant, with:

- the controller;
- the Scientific Research Officer;
- the professional involved in the research.

60. In accordance with the provisions of the Law on information technology and freedoms, the research participant may object at any time and without having to justify his or her decision [81] [82] to the processing of his or her personal data for research purposes.

the legal obligation to which the controller is subject (Article 6(1)(c) GDPR).

**[80] Example:** the participant cannot request the erasure of their personal data when it is processed for pharmacovigilance purposes (Article 17(3)(c) GDPR).

**[81] Watch point:** this refers to the discretionary right of any data subject to object to the processing of their data for research purposes, in particular any new data collection.

**[82] See:** Article 74 of the French data protection law.

## B. Specific provisions for the rights of the professionals involved in the research

61. The rights shall be exercised at all times with the controller.

### X. Storage duration

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62. According to Article 5 (1) (e) GDPR, personal data is processed for a period of time [83] not exceeding that necessary in relation to the purposes for which it is processed and to the needs of each processor to have access to it.

63. Personal data relating to research participants and professionals involved in the research may be kept in an active database until either:

- the marketing of the product under investigation in the research;
- two years after the last publication of the research results;
- in the event of no publication, two years after the signature of the final research report.

64. Data is then archived [84] in paper or electronic form for a duration complying with the applicable sectoral regulations.

### XI. Publication and results

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65. Where the results of the research are published in a scientific medium, access to the data by an independent expert, appointed in particular by a scientific publisher to consult and process the data solely for the purpose of re-analysing the results, may be granted only through the interface made available or defined by the controller.

66. In this regard, the controller must ensure that:

- the GDPR information refers to this category of recipients;
- the data is strictly necessary to reproduce the published statistics and does not contain the subject ID, other non-meaningful codes used in the research, or any

[83] See: CNIL website - Data retention periods (<https://www.cnil.fr/fr/passer-laction/les-durees-de-conservation-des-donnees>).

[84] See: in particular, Article 58 of Regulation (EU) No 536/2014 on clinical trials on medicinal products.

administrative data, according to the principle of minimization and the measure MR-PUB-01 of the Security Annex;

- the implementation of a technical solution or adherence to a shared technical solution complying with the specific measures for the publication of results provided for in the Security Annex (MR-PUB-02 and 03);
- where applicable, the compliance of the remote access to personal data with the provisions on the transfer of data outside the European Union (EU) described in Part XIV "*Transfer of data outside the European Union*".

67. In accordance with the provisions of the Law on information technology and freedoms, the presentation of the results of the research must under no circumstances allow for the direct or indirect identification of the research participants.

## XII. Security

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68. The processing of personal data shall be carried out in accordance with the provisions of Article 25 and Articles 32 to 35 of the GDPR.

69. The controller, as well as the processors acting on behalf of the controller, shall take all appropriate precautions with regard to the risks presented by the processing to safeguard the security of the personal data and to prevent their distortion, damage or access by unauthorised third parties.

70. In particular, it shall implement the general measures provided for in the Security Annex **[85]** (MR-SEC-01 to 30) as well as the specific measures (MR-INF-01 to 04, MR-PUB-01 to 03 and MR-CNS-01 to 04).

**[85] Watch point:** compliance with MR-001 implies compliance with all MR requirements, including with its annexes.

### XIII. Wire system including data from SNDS

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71. Data from SNDS wire systems which comply with the provisions of Articles L. 1461-1 et seq. of the Public Health Code and with the safety framework applicable to the SNDS provided for by Order [86] may be processed within the scope of this methodology.

### XIV. Transfer of data outside the European Union

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72. Data transfers outside the EU [87] [88] may be carried out in accordance with the methodology, when the conditions described below are met.

73. The data relating to professionals involved in the research as well as the identifiers and research data relating to research participants may be transferred outside the EU under the conditions laid down in Chapter V of the GDPR.

74. Administrative data of research participants may be transferred outside the EU:

[86] See: Article L. 1461-1 IV 3° of the Public Health Code and Order of 6 May 2024 on the safety framework applicable to the SNDS (<https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000049516244>).

[87] **Watch point:** in particular, any remote access (visualization) to data from outside the territory of the EU is considered to be a transfer.

[88] See:

- EDPB Guidelines 3/2018 on the territorial scope of the GDPR (Article 3) ([https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-32018-territorial-scope-gdpr-article-3-version\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-32018-territorial-scope-gdpr-article-3-version_en));
- EDPB Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data ([https://www.edpb.europa.eu/our-work-tools/our-documents/recommendations/recommendations-012020-measures-supplement-transfer\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/recommendations/recommendations-012020-measures-supplement-transfer_en));
- CNIL website - Transfer data outside the EU (<https://www.cnil.fr/fr/les-outils-de-la-conformite/transferer-des-donnees-hors-de-lue>).

- where the transfer is to an international organisation or a third country, a territory or one or more specified sectors within that third country that is recognized by the European Commission as ensuring an adequate level of protection, in accordance with Article 45 GDPR (adequacy decision); or
- in the specific case where the research is carried out in a third country by a controller established in France, where the transfer is carried out to that same third country, under the conditions laid down in Chapter V of the GDPR.

75. A transfer of data outside the EU may be carried out if it is strictly necessary for the implementation of the research or the exploitation of its results and if the provisions of Part VII "*Recipients*" are complied with.

76. Data subjects shall be informed in advance of the transfer of their data, of the country of destination, of the existence or absence of an appropriate adequacy or appropriate safeguards and of the means of obtaining a copy thereof.

## XV. Processor

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77. Where the controller relies on processor(s) [89], the controller shall ensure that the processor(s) and the sub-processors [90] provide sufficient guarantees to implement appropriate technical and organisational measures to meet the requirements of the GDPR and the Law on information technology and freedoms. The controller shall also carry out an audit [91] of each processor.

### [89] See:

- CNIL website - Working with a processor (<https://www.cnil.fr/fr/sous-traitant>);
- EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR ([https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-072020-concepts-controller-and-processor-gdpr\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-072020-concepts-controller-and-processor-gdpr_en)).

[90] See: EDPB Opinion 22/2024 on certain obligations following from the reliance on processor(s) or sub-processor(s) ([https://www.edpb.europa.eu/our-work-tools/our-documents/opinion-board-art-64/opinion-222024-certain-obligations-following\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/opinion-board-art-64/opinion-222024-certain-obligations-following_en)).

[91] Examples: desk audit, compliance review, inspection, *etc.* that can be carried out remotely or on-site.

78. Adherence by a processor to a code of conduct [92] approved by a supervisory authority may serve as evidence that it provides sufficient safeguards.
79. The controller shall establish a contract or other legal act with the processor specifying the obligations of each party and reflecting the requirements of Article 28 of the GDPR.
80. In addition, the processor shall:
- designate, where appropriate, a data protection officer in accordance with Article 37 of the GDPR;
  - keep a record of the categories of processing carried out on behalf of the controller, in accordance with Article 30 of the GDPR;
  - maintain and update information on its sub-processors.

## XVI. Implementation of the accountability principle

### A. Compliance documentation: data protection impact assessment (DPIA) and record of processing activities

81. The controller shall carry out a DPIA [93] in accordance with the provisions of Article 35 of the GDPR. This DPIA should cover in particular the risks to the rights and freedoms of data subjects.

A single DPIA [94] may cover a set of similar processing operations that present similar risks.

82. In accordance with Article 30 GDPR, the controller shall maintain, within the record of processing activities, the list of each of the processing operations implemented as part of the methodology.

[92] **Example:** EUCROF code (<https://www.cnil.fr/fr/recherche-clinique-la-cnil-approuve-le-code-de-conduite-europeen-de-la-federation-eucrof>).

[93] **See:**

- CNIL website - Data Protection Impact Assessment (DPIA) (<https://www.cnil.fr/fr/RGPD-analyse-impact-protection-des-donnees-aipd>);
- CNIL website - PIA tool (<https://www.cnil.fr/fr/outil-pia-téléchargez-et-installez-le-logiciel-de-la-cnil>).

[94] **Watch point:** the processing operations covered by one single DPIA must be similar with regards to the processing of personal data (same categories of data subjects, same categories of data processed, same categories of recipients, similar security measures, *etc.*); the fact that several researches fall under the same sectoral regulation is not sufficient to establish that they may be covered by the same DPIA.

## B. Appointment of a Data Protection Officer (DPO/DPO [95])

83. Under the conditions laid down in Article 37 of the GDPR, each controller appoints [96] a Data Protection Officer (DPO).

The DPO [97] will be responsible in particular for verifying the compliance of the processing operations carried out in accordance with the methodology.

## C. Formalities

84. The controller sends the CNIL a single declaration of compliance with the reference methodology for all the processing operations it implements in accordance with this standard.

85. In the case of joint controllership, each controller sends a declaration of compliance to the CNIL.

86. The declaration of compliance does not exempt the controller from taking the necessary steps provided for in the sectoral regulations, in particular with the competent authority [98] and/or an ethics committee.

## D. Principle of transparency:

87. Searches and their results are entered in the registers referred to in the sectoral regulations [99].

### [95] See:

- EDPB guidelines WP243 rev.01 on DPO ([https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/data-protection-officer\\_en](https://www.edpb.europa.eu/our-work-tools/our-documents/guidelines/data-protection-officer_en));
- CNIL guide - Data Protection Officer (<https://www.cnil.fr/fr/le-guide-du-delegue-la-protection-des-donnees>).

**[96] Watch point:** the MR does not require the appointment of a DPO by default; the controller *must* designate a DPO in the situations provided for in Article 37 (1) of the GDPR or if required by Union or Member State law, in accordance with Article 37 (4) of the GDPR and *may* designate a DPO in other cases.

**[97] Corresponds** to the DPO officially appointed with the CNIL or an individual working with the DPO (privacy champion, data protection contact point, etc.), in accordance with the data protection organisation in place within the controller.

**[98] Example:** the ANSM, in France.

**[99] See:** in particular, Article L. 1121-15 of the Public Health Code, Article 81 of Regulation (EU) No 536/2014 on clinical trials on medicinal products; at the date of adoption of the MR, some of the records covered by the sectoral regulations are not implemented.

## XVII. Entry into force

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88. The reference methodology shall enter into force on its publication in the Official Journal of the French Republic.
89. Data processing operations carried out pursuant to Decision No 2018-154 of 3 May 2018 approving a reference methodology for the processing of personal data in the context of research in the field of health not requiring the data subject's consent (MR-003) and repealing Decision No. 2016-263 of 21 July 2016 may continue in compliance with its provisions.
90. Controllers who have made a commitment or declaration of compliance with a previous version of MR-003 are not required to re-declare their compliance, provided that the researches implemented from the entry into force of this methodology comply with it.
91. Where a research previously authorised by the CNIL undergoes a substantial modification and complies with this methodology, it is not necessary to obtain a new authorisation from the CNIL.