

Resource: [Reference Framework MR-004](#)

Deliberation No. 2018-155 of 3 May 2018 approving the reference methodology for the processing of personal data implemented for the purposes of research not involving the human person, studies or evaluations in the field of health (MR-004)

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Title I: DEFINITIONS AND SCOPE OF APPLICATION

1.1. Definitions

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

- personal data: any information relating to an identified or identifiable natural person (hereinafter referred to as a “data subject”); an “identifiable natural person” is deemed to be a natural person 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 his or her physical, physiological, genetic, mental, economic, cultural or social identity;
- processing: any operation or set of operations which may or may not be performed using automated processes and applied to personal data or sets of personal data, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;
- data controller: the natural or legal person who, alone or jointly with others, is responsible for a research, study or evaluation not involving human persons, ensures its management,

verifies that its funding is secured and determines the purposes and means of the processing necessary for it;

- scientific officer or data processing manager: the person appointed by the data controller, acting under their responsibility, to ensure the quality, integrity and security of the information and processing thereof, as well as compliance with the purpose of the processing;
- subcontractor: a natural or legal person, public authority, service or other body that processes personal data on behalf of the data controller. Examples include the participating centre, a contracting research company or IT service provider, biological resource centres or health data hosts;
- research professional(s): the natural person(s) who collect(s) the data, lead(s) or supervise(s) the conduct of the research in a participating centre. This includes healthcare professionals, medical staff and qualified persons;
- participating centre: an organisation that holds, collects and/or transmits data and/or biological samples used in the context of research, studies or evaluations;
- genetic data: personal data relating to the inherited or acquired genetic characteristics of a natural person which provide 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;
- protocol: document specifying, in particular, the research methodology, the purpose of processing personal data, the categories of individuals concerned by the data processing, the origin, nature and list of personal data used and the list of the justification for their use, the duration and organisational methods of the research, study or evaluation, the data analysis method and, when required by the characteristics of the study, research or evaluation, the justification for the number of individuals to include and the chosen method of observation or investigation chosen;
- research: research not involving human subjects, study or evaluation in the field of health;
- child system: a system hosting or providing access to data directly extracted from the French central National Health Data System (SNDS) or from a source system or another child system; a child system is part of the “extended SNDS”;

1.2. Processing of personal data included in the scope of this methodology

Only the processing of personal data for the purpose of conducting research, studies or evaluations in the field of health that does not meet the definition of research involving the human person as defined in Article L. 1121-1 of the Public Health Code and is of the public interest may be the subject of a commitment to comply with this reference methodology. A research protocol must be drafted and scientifically approved by the data controller before data processing begins.

The following are not eligible for this reference methodology:

- research involving the human person, as defined in Articles L. 1121-1 and R. 1121-1 et seq. of the Public Health Code;
- genetic research whose primary or secondary purpose is the identification or re-identification of people by their genetic characteristics;

- research, studies or evaluations requiring the processing of data from medico-administrative databases, in particular those of the SNDS and its components;
- research requiring the data controller to match existing data of the same individual from several participating centres;
- research for which, with regard to informing data subjects, the exception provided for in Article 14, Paragraph 5, point b) of the GDPR is applied;
- research for which the analysis of the impact of the processing operations envisaged on the protection of personal data (“data protection impact assessment”) indicates that the processing would, despite the measures taken pursuant to Article 35 of the GDPR to mitigate the risk, present a high residual risk to the rights and freedoms of the data subjects;
- research requiring the processing of the social security numbers recorded in the French National Social Security Register.

Title II: PROCESSING OF DATA RELATING TO INDIVIDUALS CONCERNED BY RESEARCH

2.1. Purpose of processing

The sole purpose of processing personal data of the data subjects is to carry out research not involving the human person, studies or evaluations of public interest described in Article 1.2 below.

2.2. Origin and nature of data

2.2.1. Necessity of using personal data

In databases containing personal health data collected for the purpose of carrying out research, the data subjects may only be identified by means of a sequence number or an alphanumeric code, established in accordance with Article 2.2.3, and to the exclusion of any personal data that could identify individuals directly.

Only the professionals and their partners involved in research at a centre are aware of the link between the coded identity of the individuals concerned by the research and their surname(s) and first name(s) (correspondence table stored securely).

Data subjects are identified by means of a sequence number or alphanumeric code to:

- certify that, for each data subject, the information collected successively in the course of the research concerns him or her;
- carry out validity and consistency checks to ensure that the data collected during the research matches the data in the source documents.

In the case of research involving the re-use of data:

- only those individuals initially authorised to access the personal data may have access to the correspondence;

- the sequence number assigned to the person for the study is different from the number identifying the patient in the initial database. Correspondence, if required, will be held by the person responsible for the initial database.

2.2.2. Origin of personal data

Data relating to data subjects must come exclusively from:

- the interested parties themselves and/or their legal representative(s);
- professionals involved in the research;
- databases and/or collections of biological samples, legally collected and having undergone the necessary formalities with the competent authorities.

2.2.3. Nature of personal data

Pursuant to Article 5, Paragraph 1, point c of the GDPR, the data processed must be relevant, adequate and limited to what is necessary for the purposes for which it is processed (data minimisation). In this respect, the data controller undertakes to only collect or process data that is strictly necessary and relevant to the research objectives. Consequently, each category of data may only be processed if its processing is scientifically justified in the research protocol.

Only the following categories of personal data relating to the individuals included in the research are processed:

- identification:
 - age or date of birth (month and year of birth, or day of birth if this is required for research involving people under the age of two), place of birth, gender, country and department of residence; sequence number or alphanumeric code excluding surname(s), first name(s) and social security number. When the alphanumeric code is made up of letters corresponding to the surname and first name of the individuals concerned by the research, it may correspond to the first two letters of the surname and the first letter of the first name. However, it is recommended that you restrict yourself to initials only, i.e. the first letter of your surname and the first letter of your first name. These initials may be supplemented by an inclusion number and/or a participating centre number;
 - in strict compliance with the conditions set out in Article 2.3.2. of this methodology: administrative data identifying the data subjects (surname, first name, postal, electronic and telephone contact details, bank details);
 - health: data strictly necessary for carrying out the research and relating to the health of the person in question (for example: weight, height, therapy followed as part of the research and simultaneously, results of examinations, results of analysis of biological samples, medical imaging, data relating to adverse effects and events, personal or family history, associated illnesses or events, data relating to a state of health likely to influence the results or make it impossible to participate for medical reasons) ;

- photographs and/or videos and/or voice recordings that do not allow the individuals concerned by the research to be identified (by masking the face, eyes and distinctive features for example) and collected under conditions that comply with the applicable provisions in terms of image and voice rights;
- dates concerned with conducting the research (in particular the date of inclusion and the dates of visits or data collection);
- ethnic origin;
- genetic data strictly necessary to meet the objectives or purposes of the research, which may under no circumstances be used to identify or re-identify individuals, and which is processed under the following conditions:
 - re-use of genetic data obtained as part of medical treatment or for previous research in accordance with the applicable legislative provisions in force at the time or,
 - carrying out an examination of genetic characteristics in accordance with the conditions set out in the first paragraph of Article L.1131-1-1 of the Public Health Code;
- family situation;
- level of education (for example, primary, secondary, higher education);
- socio-professional category (for example, INSEE categories);
- professional life (for example: current occupation, previous employment, unemployment, work-related travel and exposure);
- social security scheme (excluding social security number), supplementary health insurance (private insurance);
- participation in other research or studies, to ensure compliance with inclusion criteria;
- travel (for example, to the place of care or research (transport mode, duration, distance));
- consumption of tobacco, alcohol and drugs;
- lifestyle habits and behaviour, for example: dependency (alone, in an institution, independent, bed-bound), assistance (home help, family), physical exercise (intensity, frequency, duration), diet and eating habits, leisure activities;
- lifestyle, for example: urban, semi-urban, nomadic, sedentary; housing (private house or block of flats, floor, lift, etc.);
- sex life;
- vital status, when this information appears in the source document or is known to the professional involved in the research;
- reimbursement of expenses incurred by the data subject, in connection with the research;
- level of quality of life or other information about the person's quality of life.

2.3. Recipients of the personal data processed

Under the responsibility of the data controller or in application of specific legal or regulatory provisions, the categories of individuals described below have access to the data processed, within the limits of their authorisations depending on their roles and under conditions that comply with the regulations.

These categories of individuals are subject to professional secrecy under the conditions defined by Articles 226-13 and 226-14 of the French Criminal Code.

2.3.1. Recipients of indirectly identifying data

The following recipients may receive indirectly identifying data relating to the individuals concerned by the research:

- the data controller and their subcontractors;
- the research scientist;
- professionals involved in research and staff acting under their responsibility or authority;
- staff of companies in the group to which the data controller belongs and who are involved in collecting and analysing data as part of the research;
- those responsible for data collection, quality control, processing and analysis;
- those responsible for regulatory affairs and for registering the research with the competent authorities;
- staff of healthcare authorities and public control authorities who are legally authorised, as part of a specific mission or the exercise of a right of communication;
- authorised personnel acting under the responsibility of the insurance body company that guarantees the civil liability of the data controller;
- independent experts responsible for re-analysing the data to verify the results of the research, in strict compliance with the conditions mentioned in Paragraph 2.4 of this methodology.

2.3.2. Recipients of directly identifying data

The following recipients may receive directly identifying data relating to the individuals concerned by the research:

- professionals involved in research and staff acting under their responsibility or authority, with regard to the persons under their care;
- those responsible for quality control and quality assurance, during the visit or inspection at the investigating centres responsible for controlling and evaluating the quality and authenticity of the data collected, in particular by comparing the recorded data with the content of the source documents. Under the responsibility of the data controller, these individuals also ensure compliance with provisions relating to integrity and the protection of individuals. Thus, controls carried out to ensure the quality of research (for example, access to patients' medical records for clinical research associates and clinical study technicians) must comply with the following confidentiality rules:
 - they must be carried out under the guidance and supervision of a professional involved in the research;
 - the recipients of data must be appointed and authorised by the data controller;
 - the data subject is informed in advance and does not object to the control being carried out;
 - the person in charge of quality control only has access to the specific data required for this control;
 - the data consulted is used to check the authenticity and consistency of the information collected and, if necessary, to correct or supplement it, provided that confidentiality rules

are respected;

- the data controller's data protection officer, as provided for in Article 37 of the GDPR, only if the data subject voluntarily gets in contact with them;
- staff of healthcare authorities and public control authorities who are legally authorised, as part of a specific mission or the exercise of a right of communication;
- authorised personnel acting under the responsibility of the insurance company guaranteeing the developer's civil liability.

Subcontractors acting on behalf of the data controller, and not having the status of participating centre, may be recipients of the administrative data identifying the persons concerned by the research (surname, first name, postal, electronic and telephone contact details and bank details) in strict compliance with the following cumulative conditions:

- access to personal data is intended to enable:
- reimbursement of transport expenses for the individuals in question or;
- follow-up of data subjects as specified in the research protocol (e.g. sending a text message (SMS) to fill in an online questionnaire, activation of an IT account to use a connected application);
- the subcontractor does not have access to health data relating to the persons concerned by the research. With the exception of the identity of the data controller, the research reference provided to the organisation does not reveal any pathology or state of health of the data subjects;
- the data subjects involved in the research have been informed in advance of the identity of the subcontractor, the categories of personal data concerning them to which they will have access and the tasks entrusted to them by the data controller;
- the data is kept by the subcontractor for no longer than is necessary for the performance of their tasks;
- a correspondence table specific to these tasks is drawn up and kept by the subcontractor using secure means.

2.4. Publication of results

In accordance with the provisions of the Data Protection Act, the presentation of the data processing results will under no circumstances allow direct or indirect identification of the individuals concerned by the research.

If the results of the research are published in a scientific medium, access to the data by an independent expert, specifically appointed by a scientific publisher, may only be provided via the interface made available or determined by the data controller for the consultation and manipulation of the data, and for the sole purpose of re-analysing the results.

Data controllers or persons acting on their behalf must ensure:

- that a technical solution is implemented or that a unified technical solution is used so that the data can be made available without those accessing it being able to extract it. Such a

solution must ensure the security of the data stored, in particular:

- by issuing authorisations that grant differentiated access to the data;
- through reliable user authentication;
- by using encrypted communication channels to authenticate the source and recipient;
- by using state-of-the-art encryption algorithms and trade secret management procedures;
- by implementing data access traceability measures.
- where applicable, that remote access to data complies with the provisions relating to the transfer of data outside the European Union described in this reference methodology;
- that data subjects are informed of these potential recipients;
- that the data is strictly necessary to reproduce the published statistics;
- that the data does not contain any directly identifying data and that the principle of data minimisation is respected. As part of this process, the following measures must be implemented:
 - information that could explicitly identify a research site (name of centre, alphabetical code of centre) is removed;
 - initials of participants and investigators are removed;
 - date of birth (month/year) is replaced by age or by age range;
 - all dates are replaced by deadlines in relation to a key date in the study (inclusion, randomisation, etc.);
 - data transmitted is limited to that used in the publication.

2.5. Information and rights of individuals concerned by the research

2.5.1. Informing individuals

In application of the provisions of the Data Protection Act, general information on the possibility that personal data may be used for research purposes must be provided in any establishment or centre providing services related to prevention, diagnoses and healthcare.

In addition, the individuals concerned by the research and/or their legal representatives are informed in advance and individually when their personal data is processed for the purpose of research covered by this methodology. The information provided complies with the provisions of Article 13 of the General Data Protection Regulation, when data is collected from data subjects. The information provided complies with the provisions of Article 14 of the GDPR, where the data is not collected from the data subjects or was collected beforehand.

In the case of an examination of genetic characteristics carried out in accordance with Article L. 1131-1-1 of the Public Health Code, the individuals concerned are also informed of the research project in accordance with the provisions of this article.

The individuals concerned by the research and/or their legal representatives are also informed in advance that their participation is optional, when the data is collected from the individuals concerned, and of the procedures for exercising their rights.

If information is collected by means of a questionnaire given to the individual concerned by the research and/or their legal representatives, the information is mentioned on the questionnaire, the attached letter or the information note relating to the research.

Where personal data is collected orally, the professional involved in the research shall provide or send a document containing this information to the individuals concerned by the

research and/or their legal representatives beforehand.

Data and/or biological samples collected but not specifically for research purposes may be re-used without further informing data subjects individually:

- when the data subject already has the information provided for in Articles 13 or 14 of the GDPR;
- or when the information provided when the data and/or biological samples were collected includes the possibility of re-using the data and/or samples, and refers to a specific information system to which data subjects may refer prior to the implementation of each new data processing operation.

With regard to the processing of data of deceased individuals, provided that the professional involved in the research is aware of the vital status of the data subject and that they did not object to it during their lifetime in writing, their personal data may be processed for research purposes.

This reference methodology shall not apply where, with regard to the information of data subjects, the exception provided for in Article 14, Paragraph 5, point b) of the GDPR is applied.

2.5.2. Procedures for exercising the rights of individuals concerned by the research

The right of access, provided for in Article 15 of the GDPR, may be exercised by the data subject at any time to the professional involved in the research, either directly or through a doctor designated for this purpose by the data subject.

In accordance with the provisions of Article 16 of the RGPD, the data subject has the right to obtain from the data controller, as soon as possible, the rectification of inaccurate personal data and the right to have incomplete personal data completed, including the provision of a supplementary declaration.

Any person who wishes to object to the processing of their personal data for health research purposes may, at any time and without having to justify their decision, express their objection by any means to either the person in charge of the research, the participating centre or the professional holding the data, in accordance with the Data Protection Act.

The right to remove data provided for in Article 17 of the GDPR applies when the data subject exercises their right of opposition and also requests that their personal data that has already been collected, be removed. Subject to appropriate prior information by the data controller, certain data previously collected cannot be deleted because deletion is likely to render impossible or seriously compromise the achievement of the research objectives.

The right to restrict data processing provided for in Article 18 of the GDPR shall be exercised in accordance with the provisions of that Article.

In accordance with Article 12 of the GDPR, the data controller undertakes to implement procedures to ensure that such requests to exercise rights are responded to within a maximum period of one month from receipt of the request. This deadline may be extended

by two months, depending on the complexity and number of requests. This extension shall be notified to the individual concerned within one month of receipt of the request.

2.6. Storage duration

Personal data relating to individuals involved in research and processed for that purpose may only be stored in the information systems of the data controller, the participating centre or the professional involved in the research for a maximum duration of two years after the last publication of the results of the research or, if the results are not published, until the final report for the research is signed. It is then archived on paper or electronically for a maximum period of twenty years or for a period in accordance with current regulations.

The persons listed in Article 2.3 may, where necessary, access this data in order to carry out additional analyses or in the context of new applications for registration with the competent authorities of the medicinal products, devices and products, provided that the processing operations thus implemented are carried out for a purpose compatible with the initial purpose, in accordance with Article 5, Paragraph 1, point b) of the GDPR and are subject to separate prior formalities.

Title III: PROCESSING OF DATA RELATING TO PROFESSIONALS INVOLVED IN RESEARCH

3.1. Purpose of processing

The processing of data relating to professionals involved in research must be carried out solely for the purposes of setting up and conducting the research and complying with the legal obligations of the data controller.

The personal data of professionals involved in research may be used for other personal data processing operations carried out by the data controller in relation to human resources management and training.

3.2. Origin and nature of the data

3.2.1 Necessity of using personal data

Professionals involved in the research project may only carry out monitoring by using personal data containing directly identifying information.

3.2.2. Origin of data

The data relating to the professionals involved in the research comes from the interested parties themselves, from public lists or from any other list drawn up for this purpose in compliance with the applicable provisions.

3.2.3 Nature of data

Under Article 5, Paragraph 1, point c) of the GDPR, the data processed must be adequate, relevant and not excessive and limited to what is strictly necessary for the purposes of the processing. In this respect, the data controller undertakes to only collect or process data that is strictly necessary and relevant to the research objectives.

Only the following categories of personal data concerning the professionals involved in the research are processed:

- identity: surname, first name(s), gender, address, professional postal, electronic and telephone contact details, bank details;
- training - qualification(s);
- professional life (in particular, professional background, mode and type of practice, elements needed to evaluate the knowledge available to them to carry out the research);
- if applicable, shared directory of professionals working in the healthcare system (RPPS);
- amount of allowances and remuneration received;
- collaboration on other studies;
- history of access and connection to the medical data of individuals taking part in a research project.

3.3. Recipients of the personal data processed

Under the responsibility of the data controller or in application of specific legal or regulatory provisions, the categories of individuals described below have access to the data processed, within the limits of their authorisations depending on their roles and under conditions that comply with the regulations:

- the data controller and their subcontractors, including system administrators and information system security managers;
- the research scientist and their employees;
- professionals involved in the research project and staff acting under their supervision or authority;
- those responsible for regulatory affairs and for registering the research with the competent authorities acting on behalf of the data controller or belonging to the companies within their group;
- staff of companies in the group to which the data controller belongs;
- staff of healthcare authorities and public control authorities who are legally authorised, as part of a specific mission or the exercise of a right of communication;
- authorised personnel acting under the responsibility of the insurance body company that guarantees the civil liability of the data controller.

These categories of individuals, subject to professional secrecy under the conditions

defined by Articles 226-13 and 226-14 of the French Criminal Code, may come under the responsibility of the data controller, the centres involved in the research project or organisations acting on behalf of the data controller.

3.4. Information and rights of professionals involved in the research project

3.4.1. Information for professionals involved in the research project

This information is provided by means of a notice on documents given to the individuals concerned or on agreements signed by the professionals involved in the research project. This information includes the details provided for in Article 13 of the General Data Protection Regulation.

3.4.2. Procedures for exercising the rights of professionals involved in the research project

The right to access, the right to rectify, the right to remove, the right to restrict processing, the right to data portability and the right to object may be exercised at any time with the data controller, in accordance with Articles 15, 16, 17, 18, 20 and 21 of the GDPR.

3.5. Storage duration

The personal data of professionals involved in the research may not be kept beyond a period of fifteen years after the end of the last research in which they participated. It is then archived on paper or electronically for a period in accordance with current regulations.

The persons listed in Article 2.3 may, where necessary, access this data in order to carry out additional analyses or in the context of new applications for registration with the competent authorities or to ask the individual to take part in another research project.

Title IV: IMPLEMENTATION AND SECURITY

The processing of personal data in the context of research is carried out under the responsibility of the data controller and/or third parties acting on their behalf, in accordance with the provisions of Articles 25, 32 to 35 of the General Data Protection Regulation. In particular, the data controller shall carry out a data protection impact assessment in accordance with the provisions of Article 35 of the GDPR, which must cover in particular the risks to the rights and freedoms of data subjects. The data controller implements appropriate technical and organisational measures to guarantee a level of security that is adapted to the risks identified. One single analysis may cover a set of similar processing operations presenting similar risks.

To provide a framework for the approach and justify its implementation, the data controller is invited to proceed as follows to:

- draw up a block diagram showing the flows of personal data and the media used;
- identify the security measures implemented;
- identify potential data breaches, specifying the level of impact on the data subjects and the likelihood of threats that make such breaches possible.

The data controller takes all necessary precautions to protect the security of the data processed, in particular its confidentiality, integrity and availability.

To this end, they define, implement and monitor the application of a security and confidentiality policy. In particular, they may describe the technical and organisational measures designed to reduce risks:

- physical security measures for equipment and premises and the measures taken to back up files;
- data access methods, in particular the management of authorisations, identification and authentication measures and procedures;
- measures for tracking access to medical information and the connection log file;
- security measures to be implemented for data transmissions.

Without prejudging the results of the process, the specific nature of the processing highlights the need for certain security measures:

- the data may be computerised or, where applicable, recorded on paper by the professionals involved in the research or under their responsibility. When data is entered, it is identified by a sequence number or an alphanumeric code, as defined in Article 2.2.3;
- all the data is entered either progressively during the course of the research project, or as a whole when the research project has been completed;
- data may also be input by healthcare professionals, medical biology analysis laboratories or other professionals involved in the research project who are required to process data as part of the tasks entrusted to them by the data controller or the person acting on their behalf. In particular, it may result from automatic recordings of parameters from additional examinations;
- research data must not be entered, even temporarily, outside the tools that are part of the processing;
- in the case of direct data input by the professionals involved in the research or by a subcontractor, the remote data input tool is secured in particular by user authentication and encryption of data flows;
- if paper observation documents are used, they will be delivered by any means that guarantees their security and confidentiality and whereby their receipt can be acknowledged by those authorised to input the data;
- in the case of digital observation documents installed on mobile devices (tablets, etc.), the data is encrypted on the device and protected by specific user authentication. It must be able to be transferred only to the processing operation, via a secure link using authentication and data flow encryption;

- all electronic exchanges of messages including personal data of the data subjects must be carried out securely (for example: sending an encrypted or password-protected file, secure messaging, dedicated platform applying specific access rights, etc.);
- the tools used to exploit the data collected must take account of the risk of individuals being re-identified by limiting the possibilities for targeted searches and detailed lists of results.

Once the automated data processing has been completed, the data is retrieved in the format defined by the department responsible for processing the research data and is stored temporarily, so that it can be archived, in a directory to which access is technically restricted to duly authorised and authenticated individuals.

Title V: SUBSYSTEMS INCLUDING DATA FROM THE SNDS

In the context of this methodology, only data from subsystems that comply with the provisions of Articles L. 1461-1 et seq. of the Public Health Code, as well as the security standard applicable to the SNDS as set out in the Order of 22 March 2017, may be used. The use of such data in the context of the research covered by this methodology is subject to the aforementioned provisions.

Title VI: DATA TRANSFERS OUTSIDE THE EUROPEAN UNION

Data that indirectly identifies the individuals involved in the research and data that directly or indirectly identifies the professionals involved in the research may be transferred outside the European Union when the transfer is strictly necessary for the implementation of the research or the exploitation of its results and under the conditions set out in Chapter V of the GDPR.

The transfer may be carried out as part of the commitment to comply with this reference methodology when one of the following conditions is met:

- data is transferred to a country or international organisation recognised by the European Commission as ensuring an adequate level of protection, in accordance with Article 45 of the GDPR (adequacy decision);
- the transfer is carried out subject to appropriate safeguards, listed in Article 46, Paragraph 2 of the GDPR (in particular: standard contractual clauses adopted by the European Commission, binding corporate rules, code of conduct, certification mechanism);
- in the absence of an adequacy decision or appropriate safeguards, the transfer may be based on one of the derogations provided for in Article 49 of the GDPR where such a transfer is not repetitive, in bulk or structured.

The data controller must have informed data subjects in advance of the transfer of their personal data to countries outside the European Union, of the existence or absence of an appropriate adequacy decision or safeguard, and finally of the means of obtaining a copy

in accordance with Article 13, Paragraph 1, point f) of the General Data Protection Regulation.

Title VII: SUBCONTRACTORS

Where the data controller uses one or more subcontractor(s), they shall ensure that the subcontractor(s) present(s) sufficient guarantees that appropriate technical and organisational measures have been implemented, to ensure that the processing complies with the requirements of the GDPR and the Data Protection Act, and guarantees the protection of the data subject's rights.

The data controller shall draw up a contract or other legal document with the subcontractor, specifying the obligations of each party and incorporating the provisions of Article 28 of the GDPR. In particular, the contract must stipulate that the subcontractor shall:

- only process data on the basis of documented instructions from the data controller and shall take all the necessary security measures;
- not subcontract without the written authorisation of the data controller
- assist the data controller in ensuring compliance with their various obligations (rights of individuals, security of data processing, breach notification, impact assessments, etc.);
- provide the data controller with all the information necessary to demonstrate compliance with their obligations and to enable audits to be carried out;
- immediately inform the data controller in the event of any case which, in their opinion, constitutes a breach of the GDPR or the Data Protection Act;

In addition, the subcontractor:

- must appoint, where necessary, a data protection officer in accordance with Article 37 of the GDPR;
- shall 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.

For any project started with a new subcontractor (who is not a participating centre), an audit is carried out. The audit covers, in particular, verification of the subcontractor's quality and security plans, the validation of IT systems and the existence of a data back up and recovery system, as well as measures to guarantee data confidentiality and integrity.

Title VIII: IMPLEMENTATION OF THE PRINCIPLE OF RESPONSIBILITY

Each data controller appoints a data protection officer in accordance with Article 37 of the GDPR. The data protection officer's main role will be to check the compliance of the processing carried out in accordance with this methodology.

Data controllers shall send the French Data Protection Authority a single commitment to

comply with this methodology for all the processing they carry out as long as it is carried out in accordance with all the provisions of the methodology. A request for an opinion from the CEREES is not required.

In accordance with Article 30 of the GDPR, the data controller shall keep an up-to-date list of the processing operations carried out under this methodology in the register of processing operations.

The data controller is required to register their data processing with the public directory made available by the French National Healthcare Data Institute.

Title IX: ENTRY INTO FORCE

This reference methodology enters into force upon its publication in the Official Journal.

The Chair,
I. Falque-Pierrotin