

DELIBERATION n°2019-030 of MARCH 14, 2019National Commission for Computing and LibertiesNature of the deliberation: AuthorizationLegal status: In force Date of publication on Légifrance: Tuesday, November 05, 2019Deliberation n° 2019-030 of March 14, 2019 on a single decision and authorizing the Champagne-Ardenne Perinatal Network to implement automated processing for research, study and evaluation purposes requiring access to national data from the program for the medicalization of information systems (PMSI) (Request No. 919052)The National Commission for Computing and Liberties,Registration by the Champagne-Ardenne Perinatal Network of a request for authorization of automated processing for research, study and evaluation purposes requiring access to the medicalization program information systems; Having regard to Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of personal data ;Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing the directive 95/46/EC; Having regard to the public health code, in particular its articles L. 6113-7 and L. 6113-8; Having regard to law n° 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms, in particular its articles 8-II-8°, 54, 61 and following; Considering the law n ° 2016-41 of January 26, 2016 of modernization of our health system, in particular its article 193; Considering the decree n ° 2005-1309 of October 20, 2005 amended taken for the application of law n ° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Considering the decree n ° 2016-1871 of December 26, 2016 relating to the processing of personal data called "National Health Data System"; Having regard to the decree of March 22, 2017 relating to the security reference system applicable to the National Health Data System; Having regard to instruction No. DGS/PF3/R3/DGS/MC1/2015/227 of July 3, 2015 relating to the updating and harmonization of the missions of perinatal health networks in a regional framework; Having regard to the opinion of the Expert Committee for research, studies and assessments in the field of health of December 18, 2018; On the proposal of Mrs Valérie PEUGEOT, commissioner, and after having heard the observations by Mrs. Nacima BELKACEM, Government Commissioner, Makes the following observations: Processing manager According to an instruction of July 3, 2015, perinatal health networks are responsible in particular for contributing to the implementation of both regional and national perinatal health policy and provide their expertise to regional health agencies. To do this, the networks collect, produce and analyze perinatal health indicators annually. As part of the management of the networks, a certain number of common tracer indicators, calculated by the Technical Agency for Information on Hospitalization (hereinafter "ATIH") based on data from the program for the medicalization of information

systems (hereinafter "PMSI") are monitored by the networks (multiple births, maternal age, prematurity, stillbirth, etc.). The Network perinatal Champagne-Ardenne is one of these networks. On the advisability of using the single decision The performance of the tasks of the data controller involves the implementation of numerous processing of PMSI data intended for the evaluation of health indicators perinatal treatment. The treatments described come under the treatment authorization scheme for research, study or evaluation purposes. e request, to authorize the implementation of this processing on the basis of the provisions of articles 54-IV and 61 and following of the law n ° 78-17 of January 6, 1978 modified (hereinafter law "data processing and freedoms"), within the framework of a single decision. On the application of the provisions related to the SNDS Since the PMSI data comes from one of the databases making up the National Health Data System (hereinafter "SNDS"), the Commission recalls that all the legislative and regulatory provisions relating to the SNDS are applicable in this case and in particular the prohibition on using this data for the purposes described in Article L. 1461-1 V of the Public Health Code. the legality of the processing The processing implemented by the data controller is intended to allow the evaluation of the perinatal health policy. The perinatal health networks contributing to the implementation of the perinatal health policy according to the aforementioned instruction , these treatments ts, carried out for the purposes of scientific research, are necessary for the performance of the mission of public interest with which the Champagne-Ardenne Perinatal Network is invested. They are, as such, lawful with regard to Articles 6, paragraph 1 point e) and 9, paragraph 2 point j) of the General Data Protection Regulation (hereinafter "GDPR"). On the purpose of the processing and its nature of public interest The processing requiring access to PMSI data is intended multi-year monitoring of the perinatal health policy through production as well as the analysis of indicators and perinatal care pathways. To do this, studies will be carried out aimed at monitoring perinatal health indicators, thanks to: analysis of the supply of care and hospital flows; a study of mother/child patient pathways; an evaluation of practices; implementation of indicators and the relevance of care; an evaluation of PMSI coding. The Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5 paragraph 1 point b) of the GDPR. Furthermore, it considers that the processing serves a purpose of public interest, in accordance with Article 54 I of the "Data Protection" law. On the categories of data processed The Commission recalls that the data controller must not process, for each of the processing operations implemented within the framework of this single decision, only the data strictly necessary and relevant with regard to the purposes of the processing operations. Provided that these files are distributed by ATIH, in addition to the specific file allowing all the data from the PMSI concerning the same patient ("ANO" file), the data

concerning the following activities are necessary to carry out these studies: medicine, surgery, obstetrics and odontology (MCO); follow-up and rehabilitation care (SSR); collection of medical information in psychiatry (RIM-P); home hospitalization (HAD). The treatments included in the framework of the single decision relate to data n national data of the PMSI, the maximum historical depth of which is nine years plus the current year. , the list of processing implemented in the context of this single decision. In addition, the adequacy, relevance and limited nature to what is necessary with regard to the purposes for which the data are processed, the geographical area concerned and the historical depth of the data consulted must be justified in this register for each processing implemented in the framework of this single decision. On the data retention period No export of personal data can be carried out within the framework of this single decision. The duration of access to data in the secure ATIH platform must be limited to the duration necessary for the implementation of the treatment. When the data controller justifies it, access to the data may be maintained at the end of the study, within the limit of two years from the last publication relating to the results. On the publication of the results The Commission recalls that, when the result of the data processing is made public, the direct or indirect identification of the persons concerned must be impossible, in accordance with article 56 of the law "Informatique et Libertés". The results of the studies carried out within the framework of this single decision may in particular be sent to members of the Champagne-Ardenne perinatal network, to the French Federation of perinatal health networks, to health establishments in the Grand-Est region involved in perinatal care, to user associations, to learned societies, to perinatal research organizations as well as to the Grand-Est Regional Health Agency. On the categories of data recipients Only the data controller ent and the persons authorized by it have access to the data within the framework of this single decision. The data controller keeps up-to-date documents indicating the competent person(s) within it to issue the authorization to access the data, the list of persons authorized to access this data, their respective access profiles and the procedures for allocation, management and control of authorizations. These categories of persons are subject to professional secrecy under the conditions defined by Articles 226-13 and 226-14 of the Criminal Code. The qualification of authorized persons and their access rights must be regularly reassessed, in accordance with the methods described in the authorization procedure established by the data controller. On the information and rights of the persons Informing the persons concerned, as to the possible reuse of their data and the methods of exercising of their rights, is ensured under the conditions provided for in Article R. 1461-9 of the Public Health Code, as well as by a statement appearing on the website of the data controller, health insurance organizations and on media allowing it to be brought to the attention of individuals, in particular posters in premises

open to the public or documents given to them. Access rights , rectification and opposition are exercised with the director of the body managing the compulsory health insurance scheme to which the person is attached, in accordance with the provisions of Article R. 1461-9 of the Public Health Code. On data security and traceability of actions The implementation of personal data processing occurring within the framework of the study is carried out under the responsibility of the data controller, including with third parties acting on his behalf, in compliance with the provisions of articles 24, 25, 28, 32 to 35 of the GDPR as well as the decree of March 22, 2017 relating to the security reference system applicable to the SNDS. ATIH provides the data on a secure and approved platform within the meaning of the decree of March 22, 2017 relating to the security reference system applicable to the SNDS. It is based on a secure internet connection (HTTPS protocol) and strong authentication (one-time password generated by a tokens). Access traceability is ensured and a computer monitoring mechanism records all actions performed by the user. A workspace on the platform is provided by ATIH so that users can consult the data. Only statistics aggregated in such a way that the identification, direct or indirect, of people is impossible, can be extracted from the platform. A copy of all data output is kept by ATIH, which reserves the right to make a report to the Commission if it becomes aware of information likely to reveal serious shortcomings. On the principle of transparency The provision of data from the SNDS and its components is designed in such a way as to render account of their use to civil society . To this end, Article L. 1461-3 of the CSP makes access to data from the SNDS and its components subject to the communication to the INDS of several elements by the data controller, before and after the studies. Thus, the data controller undertakes to register the studies carried out within the framework of this single decision with the public directory kept by the INDS. This registration, to be carried out before the start of processing by the data controller or the person acting on his behalf, is accompanied by the transmission to the INDS of a file comprising: the protocol, including the justification of the public interest , as well as a summary, according to the model made available by the INDS; the declaration of interests of the controller, in relation to the purpose of the processing. At the end of the studies, the method and the results obtained must be communicated to the INDS for publication. The recording of the treatments and the transmission of the results are carried out in accordance with the procedures defined by the INDS. AUTHORIZES, in accordance with this deliberation, the Champagne-Ardenne Perinatal Network to implement the aforementioned treatments for a period of six years. The President The Deputy Vice-President Sophie LAMBREMON