

Deliberation 2019-010 of January 31, 2019 National Commission for Computing and Liberties Legal status: In force Date of publication on Légifrance: Wednesday March 27, 2019 Deliberation n° 2019-010 of January 31, 2019 issuing a single decision and authorizing the Calvados – Manche perinatal network – Orne 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. 918441)The National Commission for information technology and freedoms, Seizure by the Perinatal Network Calvados – Manche – Adorned with a request for authorization of automated processing for research, study and evaluation purposes requiring access to the medicalization program of the systems of 'information; 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 Directive 95/46/EC; Considering the public health code, in particular its articles L. 6113-7 and L. 6113-8; articles 8-II-8°, 54, 61 et seq.; Having regard to law n° 2016-41 of January 26, 2016 on the modernization of our health system, in particular its article 193; Having regard to Decree No. 2005-1309 of October 20, 2005 as amended, taken for the application of Law No. 78-17 of January 6, 1978 relating to data processing, files and freedoms; Having regard to Decree No. 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 within a regional framework; of the Expert Committee for research, studies and assessments in the field of health of December 18, 2018; On the proposal of Mrs Marie-France MAZARS, commissioner, and after hearing the observations of Mrs Nacima BELKACEM, commissioner of the Government, Makes the following observations: Data controller 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 for providing their expertise to regional health agencies. To do this, the networks collect, produce and analyze perinatal health indicators every year. 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") from data from the program for the medicalization of hospitalization systems information (hereinafter "PMSI") are monitored by the networks (multiple births, maternal age, prematurity, stillbirth, etc.) The

Perinatal Network Calvados - Manche - Orne is one of these networks. On the advisability of resorting to 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 perinatal health indicators. The processing described falls under the processing authorization regime for research, study or evaluation purposes. The Commission considered it appropriate, in view of the elements presented in the application file, to authorize the implementation of this processing on the basis of the provisions of Articles 54-IV and 61 et seq. of Law No. 78-17 of the January 6, 1978 amended (hereinafter the "Informatique et Libertés" law), within the framework of a single decision. On the application of the provisions related to the SNDS The PMSI data being taken from one of the bases making up the National System of health data (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. On the lawfulness of 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 perinatal health policy according to the aforementioned instruction, these treatments are necessary for the execution of the public interest mission with which the Calvados – Manche – Orne perinatal network is invested. of Article 6, paragraph 1 point e) of the General Data Protection Regulation (hereinafter "GDPR"). On the purpose of the processing and its nature of public interest The processing operations requiring access to PMSI data have the purpose of purpose the 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: an analysis of the supply of care and hospital flows; a study of the pathways of mother/child patients; an evaluation of practices; an implementation of indicators and the relevance of care; an evaluation of PMSI coding. mmission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with Article 5 paragraph 1 point b) of the GDPR. In addition, it considers that the processing has a purpose of public interest, in accordance with Article 54 I of the "IT and freedoms" law. On the categories of data processedThe Commission recalls that the data controller must only process, for each of the processing operations implemented within the framework of this single decision, the data that is strictly necessary and relevant with regard to the objectives of the processing. Provided that these files can be distributed by ATIH, in addition to the specific file allowing to link all the PMSI data concerning the same patient (file "ANO"), 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). unique relate to national PMSI data whose maximum historical depth is nine years plus the current year. The adequacy, relevance and limited 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 for each processing operation implemented within the framework of this decision. in the register of processing activities provided for in Article 30 of the GDPR. On the retention period of the data 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 platform must be limited to the duration necessary for the implementation of the processing. 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 several perinatal networks (Calvados – Manche – Orne and Eure – Seine Maritime), to the French Federation of Perinatal Health Networks, to health establishments involved in perinatal care, to user associations , learned societies and perinatal research organizations as well as the Normandy Regional Health Agency. On the categories of data recipients Only the controller and the persons authorized by him have access to the data in the context 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 authorisations. 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 procedure. of authorization established by the data controller. On information and the rights of persons The information of the persons concerned, as to the possible reuse of their data and the methods of exercising 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 controller, health insurance organizations and on media allowing it to be brought to the attention of persons , in particular posters in premises open to the public or documents given to them. The rights of access, rectification and opposition are exercised with the d Director of the organization 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 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 its 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 makes data available on a secure and approved platform within the meaning of the decree of March 22, 2017 relating to the security baseline applicable to the SNDS. It is based on a secure internet connection (HTTPS protocol) and strong authentication (one-time password generated by a token). 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 aggregated statistics in such a way that the direct or indirect identification 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 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 to account for 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 by the data controller or the person acting on his behalf, before the start of the processing, is accompanied by the transmission to the INDS of a file comprising: the protocol, including the justification of the interest public, 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 methods defined by the INDS. AUTHORIZES, in accordance with this deliberation, the Calvados – Manche – Orne perinatal network to implement the aforementioned treatments for a period of six years .For the President The Deputy Vice-President Marie-France MAZARS