Deliberation 2021-033 of March 18, 2021 National Commission for Computing and Liberties Nature of the deliberation: Authorization Legal status: In force Date of publication on Légifrance: Wednesday August 25, 2021 Deliberation No. 2021-033 of March 18, 2021 authorizing the University Hospital Center of Nantes to implement automated processing of personal data for the purpose of a study on the frequency, consequences and determinants of suboptimal care in the initial management of physical abuse of children under six years of age in the West region

(Request for authorization no. 920232)

The National Commission for Computing and Liberties, Seizure by the University Hospital Center (CHU) of Nantes of a request for authorization concerning the automated processing of personal data for the purpose of a study relating to the frequency, the consequences and the determinants of suboptimal care in the initial management of physical abuse of children under six years of age in the West region; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 relating to the protection of individuals with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC; Having regard to Law No. 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms, in particular its articles 66, 72 and following; Having regard to the favorable opinion with the Ethics and Scientific Committee for research, studies and evaluations in the field of health dated April 2, 2020; Considering the file and its supplements; After having heard the report of Mrs Valérie PEUGEOT, Commissioner, and the observations of Mr Benjamin TOUZANNE, Government Commissioner, Makes the following observations: On the controller The controller treatment is the Nantes University Hospital. On the purpose of the treatment The Nantes University Hospital plans to carry out research not involving the human person on the frequency, consequences and determinants of suboptimal care in the initial management of physical abuse of children under the age of six, i.e. before the first medical diagnosis leading to an alert from the administrative or judicial authorities. This study, which requires the inclusion of 250 children, will be implemented in 17 centers located in Brittany and the Nantes region). The target population is all children under six presumed to be victims of serious physical abuse who died in a pre-hospital environment or who required hospital treatment in one of the departments participating in the study and who were the subject of a concerning information or a report. For reasons of feasibility, children will be included on the occasion of a one-off admission to paediatrics, emergencies, intensive care or during a consultation in a specialized unit for receiving children at risk. Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with the provisions of Article 5-1-b of the GDPR.On the lawfulness of the processing and the

conditions allowing the processing of data concerning healthThe processing implemented by the Nantes University Hospital aims to improve the initial management of the physical abuse of children and is necessary for the performance of a mission of public interest with which the data controller is invested. The processing envisaged is therefore lawful within the meaning of Article 6-1-e) of the GDPR. In addition, the Commission considers that this processing, necessary for scientific research purposes, fulfills the condition provided for in Article 9-2-j) of the GDPR allowing the processing of data concerning health. The Commission considers that there is it is necessary to apply the provisions of articles 44-3°, 66-III and 72 and following of the modified law of January 6, 1978, which submit to its authorization processing for the purposes of research, study or evaluation in the field of health and justified, as in this case, by the public interest. On the nature of the data processed The data whose processing is envisaged are those usually collected during the clinical evaluation of a child presumed victim of mistreatment by the team caring for the patient and its 12-month follow-up, carried out by general practitioners, private pediatricians, maternal and child protection services, as well as school medicine. The categories of data will be collected following, detailed in the study protocol: administrative data (age, postal code of residence, place of residence, type of childcare, schooling); data concerning the child's family environment; data relating to the history of the child; data concerning the lesion(s) which motivated inclusion; 12-month follow-up data. The Committee notes that the collection of directly identifying data (surname, first name and complete date of One-year patient follow-up data. It recalls that directly identifying data must be processed and transmitted separately from health data, be recorded in a separate database and not be kept once the collection of one-year follow-up data has been completed. In addition, only a strictly limited number of authorized persons subject to professional secrecy will be able to access directly identifying data. Finally, it recalls that the minimization of data collection requires, in a logic of data protection from the design stage (privacy by design ), certain functional measures in the parameterization of the treatment. In particular, it calls for excluding comment or notepad areas that may contain irrelevant data. When a multiple choice is necessary, it must be proposed by means of drop-down menus offering objective information and assessments. Subject to compliance with these recommendations, the Commission considers that the data processed is adequate, relevant and limited to what is necessary. with regard to the purposes of the processing, in accordance with the provisions of Article 5-1-c) of the GDPR. On the recipients of the data Will be able to access the data, within the strict limit of their need to know for the exercise of their missions : the biostatisticians (staff member of the Nantes University Hospital) appointed for the statistical analysis; the coordinating investigator (member of the Nantes University Hospital staff) for the interpretation of the data, the

writing of the articles; a pediatrician experienced in the accompaniment of child victims of physical abuse and a general practitioner appraising pseudonymised files and identifying elements of suboptimality in the course of care (staff external to the Nantes University Hospital) for the exploitation and analysis of the data; if necessary, the opinion of the child protection referent doctor of the Loire-Atlantique department may also be sought; clinical study technicians (TECs) and investigators from each center (one to three people per center) for the data entry in the electronic observation book (eCRF) and access to data from their center; the coordination team of the women-child-adolescent clinical investigation center (CIC FEA) of the Nantes University Hospital (a coordinator , a research child nurse and a TEC) for data quality assurance; the coordination team of the CIC FEA of the Nantes University Hospital (a coordinator, a research child nurse and a TEC) for monitoring the study; coordinating doctor, two epidemiologists, the investigator for the biostatistical analyses; a technical data manager (data manager) designated by the Nantes University Hospital's research and innovation department for data management; the logistics committee that, made up of the coordination team of the Women-Child-Adolescent Clinical Investigation Center (CIC FEA) of the Nantes University Hospital (a coordinator, a research child nurse and a TEC), who alone will know the identity of the patients in order to establish the link with the various centers and the data controllers. of the persons authorized to access this data, their respective access profiles and the procedures for granting, managing and controlling authorizations. Only persons thus authorized by the data controller may have access to the data. The qualification of authorized persons and their access rights must be regularly reassessed. These categories of persons are subject to professional secrecy under the conditions defined by Articles 226-13 and 226-14 of the Criminal Code. concerning the people included in the study: In accordance with article 69 of the law, the people from whom personal data are collected or about whom such data are transmitted must be recipients of individual information. , with regard to the participation of minors in a study, article 70 of the law specifies that the holders of the exercise of parental authority are recipients of the information and exercise the rights of the person concerned by the treatment .However, pursuant to Article 69 of the Law and Article 14-5-b) of the GDPR, the obligation to provide individual information to the data subject may be subject to exceptions, in particular in the event that the provision of such information would seriously compromise the achievement of the objectives of the processing. In such cases, the controller takes appropriate measures to protect the rights and freedoms, as well as the legitimate interests of the data subject, including by making the information publicly available. In this case, the controller specifies that the issuing individual information to each of the holders of parental authority would very likely have the effect of weakening the bond of trust between

caregivers and parents, which is essential to guarantee the quality of patient care, at the risk of cause its termination. Also, with regard to the elements developed by the data controller and taking into consideration the purpose of the processing envisaged, the objective of which is to improve the management of mistreatment, an exception will be made to the principle of individual person information. Appropriate measures will however be implemented, in particular by distributing an information note relating to the research project by posting in the waiting rooms of all the sites concerned and on the Nantes University Hospital website. . This information note must include all the information provided for by the GDPR.As regards the professionals involved:Information relating to the processing of data will be provided to them during a meeting to launch the study.The Commission considers that these information methods are satisfactory with regard to the provisions of the GDPR and the Data Protection Act. On the rights of persons The persons concerned may exercise their rights with the service that carried out the medical treatment or with the representative of the establishment. .Professionals involved in the research project will be able to exercise their rights with the Data Protection Officer of the Nantes University Hospital or with the coordinating doctor of the study.The Commission considers that these procedures for exercising their rights are satisfactory with regard to the provisions of the GDPR and the Data Protection Act. On the retention period of the data The data directly identifying They will be kept on an active basis for eighteen months, in order to collect data from the data subjects. At the end of this period, the data will be deleted. Indirectly identifying data will be kept in an active database for thirty months and then archived for a period of ten years. The Commission considers that this period does not exceed the period necessary with regard to the purpose for which they are collected and processed, in accordance with the provisions of Article 5, paragraph 1, point e) of the GDPR. On data security and traceability of actions The Commission recommends that access permissions be assigned for a determined and limited duration, after hierarchical validation, that they are deleted as soon as a user is no longer authorized and that a global review of the authorizations granted is carried out regularly. In view of the sensitivity of the data whose processing is envisaged , the Commission requests that health professionals be authenticated using a CPS or an equivalent device approved by ASIP Santé. It recommends that the creation of user accounts, the configuration of the channel used for the transmission of single-use codes and the renewal of the password are also secured by the aforementioned means. Subject to the consideration of the aforementioned recommendations, the measures described by the data controller comply with the security requirement provided for in Articles 5-1-f) and 32 of the GDPR. The Commission recalls, however, that this obligation requires the regular updating of security measures, the impact analysis relating to privacy as well as the

security accreditation with regard to the regular reassessment of the risks. Under these conditions, the Commission authorizes the CENTER HOSPITALIER UNIVERSITAIRE DE NANTES to implement automated data processing of a personal nature, the purpose of which is to carry out a study on the frequency, consequences and determinants of suboptimal care in the management of e n initial responsibility for the physical abuse of children under the age of six in the West region. President Marie-Laure DENIS