Deliberation 2023-028 of March 23, 2023 National Commission for Computing and Liberties Nature of the deliberation: Other authorization Legal status: In force Date of publication on Légifrance: Wednesday April 05, 2023 Deliberation n° 2023-028 of March 23, 2023 authorizing public assistance – Hôpitaux de Paris to implement automated processing of personal data for the purpose of a study on the epidemiology and care pathways of children with variations in genital development, entitled "VarGen" (Application for authorization no. ° 922276) The National Commission for Computing and Liberties, Seizure on November 30, 2022 by the Assistance Publique – Hôpitaux de Paris of a request for authorization concerning the automated processing of personal data for the purpose of a study relating to on the epidemiology and care pathways of children with variations in genital development, entitled "VarGen"; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons at with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC (general regulation on data protection); Having regard to Law No. 78-17 of January 6, 1978 amended relating to data processing, files and freedoms, in particular Articles 66, 72 and following; Having regard to the favorable opinion with recommendations of the Ethics and Scientific Committee for research, studies and evaluations in the field of health of the May 12, 2022; Having regard to the file and its supplements; On the proposal of Mrs Valérie PEUGEOT, commissioner, and after having heard the observations of Mr Damien MILIC, deputy government commissioner, Makes the following observations: On the controller The controller treatment of this study is the Assistance Publique – Hôpitaux de Paris (AP-HP). On subcontractors The Health Data Platform (PDS) will be involved in the implementation of this study. traces, the management of alerts and incidents as well as the management of anonymous data exports, must be formalized by an agreement between the two parties in accordance with Article 28 of the General Data Protection Regulation (GDPR). On the purpose of the processing and its nature in the public interest The purpose of the processing envisaged is to implement a study on the epidemiology and care pathways of children with variations in genital development, entitled "VarGen". The Commission notes that the implementation of this study aims to gather the elements necessary for the constitution of the report provided for by Article 30 of Law No. 2021-1017 of August 2, 2021 on bioethics. Pursuant to these provisions, the Government must submit to Parliament a report on the activity and operation of the competent reference centers for rare diseases concerning the care of people with variations in genital development in France, numbering medical acts carried out in connection with these variations, as well as compliance with international recommendations in terms of treatment protocols. It also notes that this report must be submitted within eighteen months

following the publication of the decree of 15 November 2022 setting the rules of good practice for the care of children with variations in genital development and be accompanied by figures regarding the number of people concerned as well as the nature of the medical acts performed each year. Subject to the exercise of the right of opposition, two cohorts will be formed within the framework of this study: a first cohort comprising the all of the children born between 2015 and 2023 followed in the rare disease expert network with an "orphanet" diagnosis of variation in genital development (the "BNDMR-VDG" cohort, made up of approximately 3,000 people); a second cohort formed from data from the National Health Data System (SNDS) including children born between 2012 and 2023 with a diagnostic code, procedure or treatment indicating a variation in genital development (the "SNDS-VDG" cohort, made up of 20 approximately 000 people). The purpose of the processing is determined, explicit and legitimate, in accordance with Article 5.1.b of the GDPR, and this processing has a purpose of public interest, in accordance with Article 66. I of Law No. 78-17 of the January 6, 1978 modified (law "computing and freedoms"). On the lawfulness of the processing and the conditions allowing the processing of data concerning health The processing implemented by the AP-HP of Paris is necessary for the execution of the mission of public interest with which it is invested. This processing is, as such, lawful under Article 6.1.e of the GDPR. In addition, this processing, necessary for scientific research purposes, also fulfills the condition provided for in Article 9.2.j of the GDPR allowing the processing of data concerning health. This research project is subject to the provisions of Articles 44.3°, 66. III and 72 et seq. of the "Informatique et Libertés" law, from which it follows that in the absence of compliance with a reference methodology, processing for the purposes of research, study or evaluation in the field of health can only be implemented after authorization from the Commission. On the points of non-compliance with the reference methodology concerned The application file mentions that the treatment envisaged complies with the provisions of the reference methodology MR- 004, with the exception of the nature of the data processed and the procedures for informing the persons concerned. Apart from these exceptions, this processing must comply with the framework provided for by the reference methodology MR-004. On the reuse of existing database data Data from the National Rare Diseases Data Bank (BNDMR) authorized by the CNIL (deliberation no. 2019-113 of September 5, 2019; authorization request no. 2211418) will be reused within the framework of this study. These data will be matched with data from the SNDS. The Commission notes that the data from the BNDMR are intended to integrate the database of the SNDS catalog pursuant to Article 3 of the decree of 12 May 2022 relating to the data feeding the main database and the SNDS catalog databases.Only data from children born between 2015 and 2023 monitored in the rare disease expert network with an

"orphanet" code of variation in genital development will be processed.On the special categories of data processedAs regards the processing of SNDS data: Provided that it can be disseminated by the National Health Insurance Fund (CNAM), the data controller requests access to data from the national health insurance inter-scheme information system (SNIIRAM), the program for the medicalization of information systems (PMSI) and the medical causes of death (CépiDc) for the years 2012 to 2025. Only data that is strictly necessary and relevant to the objectives of the processing will be transmitted by the CNAM; in this respect, the filtering and matching of data will be carried out upstream of this transmission by the CNAM. As the data from SNIIRAM, PMSI and CépiDc come from the databases making up the SNDS, all the legislative provisions (articles L. 1461-1 to L. 1461-7 of the Public Health Code – CSP) and regulations relating to the SNDS are applicable in this case, in particular: the prohibition on using this data for the purposes described in Article L. 1461-1 V of the Public Health Code; compliance with the safety standards applicable to the SNDS provided for by the decree of March 22, 2017. Regarding the procedures for matching BNDMR data with SNDS data: Several procedures matching of BNDMR data with SNDS data is provided for in the application file: initially, the matching will be carried out in a deterministic manner using the registration number in the national identification directory of natural persons (NIR) of patients collected in the BaMaRa application (web application that allows professionals from rare disease reference and skills centers to collect and use their rare disease data themselves). The NIRs will be sent to the CNAM directly from the BaMaRa database, by the team in charge of this database, which is separate from that in charge of the BNDMR; for patients whose data will not have been matched thanks to the NIR due to fault of availability of the latter, a probabilistic matching will be carried out thanks to the date and place of care of the patient in the expert network, to his date of birth (month and year), to his place of residence (municipality and department) , gender and diagnosis; finally, for patients whose data could not have been matched using the two previous methods due to the lack of availability of the NIR and due to the low number of common variables between the two databases, BNDMR data can be matched with SNDS data thanks to the reconstitution of the NIR by the National Old Age Insurance Fund (CNAV): personal data, sex, full date of birth and place of birth participants will be extracted from the BaMaRa databases for the purpose of reconstitution of the NIR by the CNAV.As regards the first matching method (collection of the NIR from the BaMaRa application), the Commission draws the attention of the data controller on: the necessary effectiveness of the partitioning between the two teams working on the BNDMR and on BaMaRa, which it must ensure by organizational and technical measures adapted to the risks and by regular checks; the need for the "Operations" division, which operates BaMaRa and will perform the NIR

extraction, deletes the correspondence table [IDMR – IDacc] which is transmitted to it as a parameter of the extraction program; this deletion must take place at the end of the extraction procedure, the table being kept only by the BNDMR team; the need for each extraction request to use a different series of attachment numbers (IDacc), to limit the risks of cross-re-identification. The Commission considers that the data whose processing is envisaged are 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 information and the rights of individuals With regard to holders of the exercise of parental authority over children participating in the "BNDMR-VDG" cohort who received an individual information note when the BNDMR was set up providing for a specific information system to which they can refer prior to the implementation of each new study carried out using data from the warehouse: An information note relating to this study will be distributed before the start of the study on the website dedicated to the BNDMR. With regard to the other participants in the "BNDMR-VDG" cohort and those included in the "SNDS-VDG" cohort: Under Article 69 of the "Informatique et Libertés" 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 the event that the provision of such information proves impossible, would require efforts disproportionate or seriously impair the achievement of the objectives of the processing. In such cases, the controller shall take 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, an exception will be made to the principle of individual information of persons and appropriate measures will be implemented by the dissemination of collective information on the website of the data controller. This information will be brought to the attention of associations of intersex persons / with variation of genital development and disseminated in the OrphaNews review. This processing will also be recorded in the PDS transparency portal. With regard to the procedures for exercising rights:The persons concerned may exercise their rights with the data protection officer of the data controller throughout the duration of the study.These procedures for exercising rights are satisfactory with regard to of the provisions of the GDPR and the "IT and freedoms" law. On accessors and recipientsOnly the data controller and the persons authorized by him have access to the data within the framework of this authorization. The data controller keeps documents up to date indicating the competent person(s) within it to issue the authorization to access the data, the list of authorized persons, their respective access profiles and the methods of 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 security of the data and their hosting methods As a preliminary point, the Commission notes that the application file justifies the need to use the solution technique of the PDS, taking into account the characteristics as well as the specific methods of implementation of this study and in particular of: the urgency attached to its realization; the pooling of the data pre-processing process with that already used within the framework another AP-HP research project requiring data processing from the BNDMR and hosted by the PDS (the "Dromos" project already authorized by the CNIL). The data security of the project space dedicated to the "VarGen" project depends essentially on the technical solution of the PDS, which has been the subject of a global risk and privacy impact analysis, followed by an approval according to the SNDS security reference system. More specifically, an impact analysis relating to data protection has been sent to the CNIL concerning the technical solution of the PDS, which corresponds to an SNDS secure bubble and which will host the project "VarGen". The data controller has carried out and transmitted in support of the authorization request an impact analysis relating to data protection specific to the "VarGen" project and integrating the elements provided by the PDS for its technical solution.An approval of the project space was thus carried out by the data controller on October 27, 2022, for a period of three years, subject to the implementation of the action plan that it defined. This approval decision n is only valid until October 27, 2025 and must therefore be renewed before this date if the project is still in progress. The security measures implemented by the data controller appear proportionate to the risks presented by the processing. On transfers of data outside the European Union The provisions of article R. 1461-1 of the CSP provide that no transfer of personal data may be carried out outside the European Union, except in the case of occasional access to data by persons located outside the European Union, for a purpose falling under 1° of I of Article L. 1461-3 of the CSP. In this case, the application file mentions that, although that the service provider is not exclusively subject to the laws and jurisdictions of the European Union, no transfer outside the European Union of individual data from the SNDS is planned, no member of the research team being located in outside the European Union. On the retention period of the data The data necessary to carry out the deterministic matching (the NIR or the information allowing it to be reconstituted) will not be kept after the matching. The data of the "SNDS cohorts -VDG" and "BNDMR-VDG" will be made available for five years. These data retention periods do not exceed the periods necessary for the purposes for which they are collected and processed, in accordance with the provisions of Article 5.1.e of the GDPR. Authorizes, in accordance with this deliberation, the Assistance Publique – Hôpitaux de Paris to implement the aforementioned

processing. The President Marie -Laure DENIS