Deliberation 2023-041 of April 27, 2023 National Commission for Computing and Liberties Nature of the deliberation: Other authorization Legal status: In force Date of publication on Légifrance: Friday May 05, 2023 Deliberation n° 2023-041 of April 27, 2023 authorizing the University Hospital Center of Poitiers and the company Clinityx to implement automated processing of personal data for the purpose of a study on the rate of reoperation for complication and the rate of reoperation for recurrence after implantation of suburethral strips during a surgery for stress urinary incontinence by distinguishing between the two approaches, entitled "Magellan Mesh" (Application for authorization no. 922274)

The National Commission for Computing and Liberties, Seizure by the University Hospital Center of Poitiers and by the company Clinityx of a request for authorization concerning the automated processing of personal data for the purpose of implementing a study on the rate of reoperation for complication and the rate of reoperation for recurrence after implantation of suburethral strips during surgery for stress urinary incontinence, distinguishing between the two approaches; Considering the 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/ CE (general regulations on data protection); Having regard to law n° 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 of the Ethics and Scientific Committee for research, studies and assessments in the field of health of November 17, 2022; Considering the file and its supplements; On the proposal of Mrs Valérie PEUGEOT, commissioner, and after having heard the observations of Mr Benjamin TOUZANNE, Government Commissioner, Makes the following observations: On the joint data controllers The two joint data controllers are: the University Hospital Center (CHU) of Poitiers; the company Clinityx, a design office which carries out research in the field of health, in particular from data from the National Health Data System (SNDS). In accordance with Article 26 of the General Data Protection Regulation (GDPR), joint controllers must define in a transparent manner their respective obligations. On the purpose of the processing and its nature in the public interest The purpose of the processing envisaged is the implementation of a study entitled "Magellan Mesh" intended to: the reoperation rate for recurrence after implantation of suburethral slings (USB) during stress urinary incontinence surgery, distinguishing between the two approaches; describe the reoperations according to their nature and according to the time which they occur; evaluate the prevalence of pain following the implantation of these strips; re-evaluate all the objectives according to different sub-groups (access route or according to the fact that the BSU is used alone or is associated with another surgical procedure); to assess

the representativeness of patients in the "VIGI-MESH" register of the Poitiers University Hospital. 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 in the public interest, in accordance with Article 66. I of Law No. 78-17 of 6 January 1978 as amended ("Data Protection" Law).On the lawfulness of processing and the conditions for processing data concerning health processing implemented jointly by the Poitiers University Hospital and Clinityx is necessary for the purposes of the legitimate interests they pursue. This processing is, as such, lawful under Article 6.1.f 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 and following of the amended law of January 6, 1978, which provide, in the absence of compliance with a reference methodology, that 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 reuse of data from an existing database The data reused in the context of this study will come from the health data warehouse called "Magellan" authorized by the CNIL (deliberation n° 2022-009 of January 27, 2022). This warehouse is fed by a determined and limited number of variables from the SNDS, over a data depth of five rolling years. During each data update, the oldest data is anonymized or deleted. The data from this health data warehouse feeds the "Magellan" tool intended to automatically calculate predetermined public health indicators relating to patient populations, the use of care and the use of health products. On the application of the provisions relating to the SNDSThe Commission recalls that all the legislative and regulatory provisions relating to the SNDS are applicable in this case, and in particular the ban on using this data for the purposes described in Article L. 1461-1 V of the Public Health Code (CSP). On the special categories of data processed The data processed, which will come exclusively from the "Magellan "composed exclusively of data from the SNDS, are described in the application file and will concern: the patients (taking analgesics, long-term condition, vital status, social disadvantage index, age, history of hysterectomy, region of residence, history of diabetes, history of surgery for prolapse or urinary incontinence), their hospitalizations (date, duration, main and associated diagnosis, procedures performed, type of establishment) and their care pathways (drug consumption, medical devices); the surgery performed (date, type of surgery and corresponding CCAM code, operative route, device implanted); the center (annual activity and geographical location, indicators from the PMSI); the complication (date of revision surgery, transfer to intensive care or death, type of reoperation).The Commission considers that the data whose processing is envisaged are adequate, relevant and limited to what is necessary in

relation to the purposes of the processing, in accordance with the provisions of Article 5.1.c of the GDPR. information and the rights of individualsAs regards the methods of information:The provisions of article 69 of the law "Informatique et Libertés" are applicable to all processing carried out using data from the SNDS. In accordance with the provisions of Article 14 of the GDPR, in the event that the provision of individual information proves impossible, requires disproportionate effort or seriously compromises the achievement of the processing objectives, appropriate measures must be implemented by data controllers in order 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 joint controllers in order to make the information publicly available concerning the performance of this study. The processing will be recorded within the transparency portal of the Health Data Platform. An information note will be made public on the Poitiers University Hospital website and on the transparency portal dedicated to the "Magellan" warehouse (via the "Semaphore" tool) set up by Clinityx. It must include all the information provided for in Article 14 of the GDPR.As regards the procedures for exercising rights:The persons concerned may exercise their rights concerning the "Magellan-Mesh" study with the data protection officer. data from the company Clinityx throughout the duration of the study. The Commission considers that these methods of information and exercise of rights are satisfactory with regard to the provisions of the GDPR and the law "Informatique et Libertés". accessors and recipientsOnly Clinityx and persons authorized by it have access to the data as part of the implementation of this processing. Clinityx maintains 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 methods of attribution. , 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 procedures described in the authorization procedure established by the company Clinityx.On data security and traceability of actionsThe technical infrastructure of the company Clinityx in charge of the implementation of the "Magellan" warehouse, used for hosting child systems of the SNDS has been analyzed by the Commission on various occasions, in particular in the context of previous applications for authorisation. Clinityx has carried out and transmitted in support of the application for authorization an analysis of impact relating to data protection specific to the "Magellan" warehouse and to the various project spaces containing studies related to this tool for producing indicators, as well

as a risk analysis on the security of information systems .An approval of the secure bubble was carried out by the approval authority on January 31, 2023, in accordance with the decree of March 22, 2017 relating to the security reference system applicable to the SNDS. This approval decision is only valid until December 31, 2024 and must therefore be renewed before this date if the project is still in progress. Technical and organizational measures have been planned by the company Clinityx in order to partition the different extractions of SNDS data that can be stored within its technical solution. Separate environments, based on software containerization solutions, are implemented in particular to prevent any data merger. The query tool, the data handled by this tool, as well as the project spaces containing the data used to produce the indicators will be partitioned between them thanks to the use of these solutions. The Commission notes that access to the query tool and the project spaces of this study will only be possible for specifically authorized persons who are part of the staff of the company Clinityx, to the exclusion of any other outside person. The Commission recalls that technical and organizational measures will have to be implemented in the technical solution in order to differentiate the personnel who can access the database from the "Magellan" warehouse containing the extraction of data from the SNDS on which the query tool and those that can only access the minimized data contained in the project spaces. The export of data out of the "Magellan" warehouse and the associated project spaces will consist exclusively of statistical reports including anonymous indicators that do not allow any re-identification of persons, and which will be transmitted exclusively to data controllers following requests made via the Magellan tool. To this end, a minimum threshold of eleven individuals will be retained for each aggregation. The Commission recalls that data controllers must carry out an analysis to demonstrate that their anonymization processes comply with the three criteria defined by Opinion No. 05/2014 on anonymization techniques adopted by the Article 29 group (G29) on April 10, 2014. If these three criteria cannot be met, an in-depth analysis of the identification risks must be carried out in order to demonstrate that the latter, with reasonable means, are non-existent. The security measures described meet the requirements provided for by Articles 5-1-f and 32 of the GDPR, taking into account the risks identified by the data controllers. It will be up to the latter to carry out a regular reassessment of the risks for the persons concerned and an update, if necessary, of these security measures. On data transfers outside the European Union No transfer of data outside the of the European Union will be carried out within the framework of this study. On the duration of data retention The data necessary for the realization of the requests will be kept in the workspace for the duration necessary for the production of the indicators and deleted in a maximum period of one month. The analyzes will be carried out annually for five years, via the query tool, in the project space of this study. The Commission

considers that this data retention period does 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 Poitiers University Hospital Center and the company Clinityx to implement the aforementioned processing.

President Marie-Laure DENIS