

Deliberation 2018-350 of November 27, 2018 National Commission for Computing and Liberties Nature of the deliberation:

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2018-350 of November 27, 2018 authorizing the University Hospital Center of Lille to implement a processing of personal data for the purpose of a register called "Epimad" of patients with Crohn's disease or ulcerative colitis

(Request for authorization no. 917089)

The National Commission for Computing and Liberties, Seizure by the University Hospital Center of Lille of a request for authorization concerning a register of patients suffering from Crohn's disease or ulcerative colitis; Having regard to convention n° 108 of the Council of Europe for the protection of individuals with regard to the 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 natural persons at the with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation); Having regard to Law No. 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms, in particular its articles 8-II-8° and 54; Considering the decree n° 2005-1309 of October 20, 2005 modified taken for the application of the law n° 78-17 of 6 January 1978 relating to data processing, files and freedoms; Having regard to the file and its supplements, and in particular the privacy impact assessment produced on October 2, 2018; On the proposal of Mr. Mrs. Valérie PEUGEOT, commissioner, and after having heard the observations of Mrs. Nacima BELKACEM, Government Commissioner, Makes the following observations: On the controller The University Hospital Center (CHU) of Lille. On the purpose Created in 1988, Epimad was the first French system for recording new cases of diseases inflammatory bowel disease (IBD) in the North-West region of France. Epimad was the subject of an opinion deemed favorable by the Commission on December 8, 1998. Epimad was qualified as a Registry by the National Registry Commission in 1992. This qualification was renewed in 1996, 2000, 2004, 2008 and 2012. The main objective of the Epimad registry is to know the incidence, that is to say the number of new cases per year and per 100,000 inhabitants, of Crohn's disease ( CM ) and

ulcerative colitis (UCH) in 4 departments of northern France: Nord, Pas-de-Calais, Somme and

Seine-Maritime (a total population of over 5.8 million). To date, 950 incident cases, on average, are recorded per year. .The Epimad register was renewed for 5 years by the register evaluation committee on December 1, 2016 with the aim of improving the data collection methodology and continuing to work on the completeness and quality of the data.In To this end, the Lille

University Hospital wished to present to the Commission the updated operation of the Epimad register, as part of an authorization request. The legal basis for the processing is the exercise of a mission in the public interest, meaning of Article 6-1-e of the European Data Protection Regulation (hereinafter, the GDPR). The Commission considers that the purpose of the processing is determined, explicit and legitimate, in accordance with the provisions of Article 5 -1-b GDPR. El the considers that it is necessary to apply the provisions of article 8-II 8° and 54 of the law of January 6, 1978 as amended, which subject to authorization processing involving data relating to health and justified, such as in this case, by the public interest. The Commission recalls that the processing of personal health data which will be implemented, for research purposes in the field of health, from the data contained are distinct processing operations which must be subject to specific formalities under Chapter IX of the Data Protection Act. On the data processed The main source of the data is constituted by all the adult and pediatric gastroenterologists of the departments concerned, regardless of their mode of exercise. The following data is collected: birth name; use name ; first name ; Date of Birth ; place of birth ; residential address at the time of diagnosis; data relating to all diagnostic criteria for IBD; colon damage; presence of a granuloma with epithelioid and giganto-cellular cells on biopsies or surgical specimens; clinical history of diarrhea and/or abdominal pain; existence of fistula and/or abscess related to the inflammatory digestive disease; small bowel lesions with or without colonic involvement; clinical history of diarrhea and/or rectal bleeding; macroscopically typical surgical or necroptic specimens of RCH etc. The names, first names, sex and date of birth of the patients included are collected in a notebook, associated with a file number. The files used to collect socio-demographic and medical information are identified by this file number. Two secondary sources of data are used: data from the PMSI and those from the anatomo-pathology laboratories (for the Somme department). with IBD. No medical information is associated with them. The usefulness of these lists is to make it possible to check the completeness of the register and to complete it if necessary with incident cases not detected by the main sources of data (gastroenterologists), by going back to consult the medical files of the patients. 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 the recipients the teams of researchers from the Epimad register of the Lille University Hospital Center; the teams of researchers from the Amiens Hospital Center; the teams of researchers from the Rouen Hospital Center. The Commission considers that the categories of recipient do not call for observation. information and the rights of individuals Among gastroenterologists practicing in private practice, information is delivered, in the waiting room,

by way of display. ro-enterologists practicing in public or private hospitals, an insert is inserted in the welcome booklet given to patients. The rights of the persons concerned are exercised with the doctors responsible for the register. are completed in order to contain all of the information provided for in Articles 13 and 14 of the GDPR. Subject to the modification of the information documents, the Commission considers that these methods of information and exercise of rights are satisfactory. security measuresThe Commission takes note of the fact that the data controller requires strong authentication of health professionals by using a health professional card (CPS) for any access to health data.The Commission takes note of the fact that the information is transmitted in an encrypted way using a state-of-the-art algorithm and for which the secrets are transmitted by a dissociated channel. all of the personal health data processed is hosted by an approved host under the conditions of decree no. 2006-6 of January 4, 2006. Access to processing is via the HTTPS protocol, which guarantees the confidentiality of data exchanged as well as the authentication of the data controller. Regarding the use of this protocol, the Commission recommends using the most up-to-date version of TLS possible. Finally, a sufficient level of traceability is implemented. The Commission considers that the security measures described by the data controller are 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 updating of security measures with regard to the regular reassessment of the risks. On the retention period of the dataA register aims, among other things, to study changes in the incidence of a disease. To do this, all the data recorded since the creation of the register is necessary. The register needs to have data over a long period, namely 30 years in the active database and 30 years in the archive database. The Commission considers that these durations of retention of data does not exceed the period 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 the Lille University Hospital Center, in accordance with this deliberation, to implement the aforementioned processing.For the President

Deputy Vice-President Marie-France MAZARS