DELIBERATION n°2018-300 of JULY 19, 2018National Commission for Computing and LibertiesNature of the deliberation: AuthorizationLegal status: In force Date of publication on Légifrance: Tuesday, October 23, 2018Deliberation n° 2018-300 of July 19, 2018 authorizing the modification of the treatment implemented by the National Institute of Health and Medical Research (INSERM) for the purpose of a study on the benefits and risks associated with the different methods of therapeutic management of hepatitis B and C (Application for authorization n° 918036) The National Commission for Computing and Liberties, Seizure by the National Institute of Health and Medical Research (INSERM) of a request for modification of the processing for the purpose of a study on the benefits and risks associated with the different methods of therapeutic management of hepatitis B and C; Having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2 016 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 (General Data Protection Regulation); public health, in particular its articles L. 1121-1 et seq.; Having regard to law n° 78-17 of January 6, 1978 as amended relating to data processing, files and freedoms, in particular its articles 22, 61 and following; application of law n° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Considering decision DR-2013-611 of January 10, 2014 authorizing the National Institute of Health and Research medicine – National Agency for Research on AIDS and Hepatitis (INSERM-ANRS) to implement data processing for the purpose of a study on the benefits and risks associated with the different methods of therapeutic management of hepatitis B and C (no. 912636); Having regard to the opinion of September 6, 2012 of the Advisory Committee on the processing of information in the field of health research relating to the ANRS CO22 HEPATHER study; Having regard to the successive opinions of the Committee protection of persons Ile de France III relating to study A NRS CO22 HEPATHER; Having regard to the opinion of January 18, 2018 of the Expert Committee for research, studies and assessments in the field of health (CEREES) relating to the matching of data from the HEPATHER cohort with the relevant data of the SNDS; After hearing Mrs. Valérie PEUGEOT, commissioner, in her report, and Mrs. Nacima BELKACEM, government commissioner, in her observations; Makes the following observations: INSERM is a public scientific and technological establishment, specializing in the medical research. As part of its mission, INSERM has implemented multicentre research involving the prospective collection of data and the constitution of a collection of human biological samples. This research, whose total estimated duration is 10 years, provides for the inclusion of patients with hepatitis B and/or C in a cohort. The main objective of the research is to improve knowledge of viral hepatitis and the management of patients suffering from these pathologies, in

particular to measure the benefits and risks associated with the different methods of therapeutic management of hepatitis B and C and to identify the individual, virological, environmental and social determinants involved in the response to therapeutic treatment. The cohort consists of 25,000 patients from 32 hepatology centers, including 15,000 infected with the hepatitis virus. C (HCV) and 10,000 infected with hepatitis B virus (HBV). These patients are the subject of active follow-up for 7 to 8 years following their date of inclusion. The constitution of this "HEPATHER" cohort was authorized by the Commission on January 10, 2014, on the basis of articles 54 and following of the amended law of January 6, 1978 (DR-2013-611, Authorization request no. 912636) , following a favorable opinion from the Advisory Committee on the Processing of Information in Health Research (CCTIRS). It was specified in the initial authorization application sent to the Commission that the collection of data relating to the health and access to care of voluntary patients with the health insurance was essential to improve the follow-up of these patients alive. real, and that it would give rise to a request for specific subsequent authorization from the Commission. INSERM now wishes to enrich the data from the "HEPATHER" cohort with data from the national health data system (SNDS), by bringing them together using the identification number in the national register of natural persons (NIR ) of the persons concerned. This processing, necessary for the performance of a task in the public interest, falls under Article 6-1-e of the General Data Protection Regulation (GDPR). INSERM submitted a request for authorization to the Commission on the basis of Articles 61 et seq. of the “Informatique et Libertés” law. On the purpose of the treatment: The main objective of the study carried out using the data from the cohort is to measure the benefits and risks associated with the different methods of therapeutic management of hepatitis B and C and to identify the determinants individual, virological, environmental and social intervening in the response to therapeutic treatment. The secondary objectives are grouped into four themes: therapeutic, virological, anatomo-pathological/physiopathological and public health. The study thus aims to enable national health authorities to base public health policies on a solid evaluation of the access, use, efficacy and safety of antivirals, the dispensing of which has been generalized at the national level for patients with hepatitis C since January 2017, and to promote the care strategies best suited to patient characteristics. The Committee considers that this final ity, which is of a public interest nature, is determined, explicit and legitimate within the meaning of Article 5-1-b of the General Data Protection Regulations. On the nature of the data processed: The proposed modification relates in particular to the nature of the data processed. Thus, INSERM wishes to reconcile data from the HEPATHER cohort with data from the SNDS. Such a reconciliation, which requires processing of the NIR, would make it possible to complete and validate the data already collected within the framework of the

“HEPATHER” cohort thanks to the collection of data relating to the consumption of care. In this respect, INSERM indicates that the processing of SNDS data will allow the implementation of enhanced monitoring of the adverse effects of treatments, which is essential for the evaluation of health policy. The reconciliation of cohort data “ HEPATHER” with data from the SNDS, will concern the bases of the National Health Insurance Inter-scheme Information System (SNIIRAM), the Information Systems Medicalization Program (PMSI) and the Epidemiology Center on the causes death certificates (CépiDc) returned in the form of individual beneficiary data (DCIR). The data extracted relating to the voluntary participants in the cohort will concern a period extending from January 1 of the year of inclusion of the subjects in the cohort (January 1, 2012 for the first included) until December 31 of the year of the end of the research (2022, in the absence of extension of the cohort) for all other volunteer subjects. In addition to the data whose collection has already been authorized for the implementation of the research, the individual health and medical consumption data from the SNDS required are as follows: data relating to the consumption of care in health establishments: dates of care and date of reimbursement, medical reason for hospitalization, procedures performed, length of stay, mode of discharge and codes of the main pathologies and diagnosis, associated or related, technical procedures carried out by healthcare professionals including biological examinations or medical devices; data relating to the consumption of city care, medical procedures, biological procedures, medical devices and drugs; data relating to the social situation in relation to the methods of taking care of the disease, including: indication of social coverage and possible affiliation to universal health coverage; the possible diagnosis of long-term conditions; vital status and causes of death. identifying data (surname, first names, gender, date and place of birth) of patients in the cohort which will be sent to it by INSERM and whose collection was authorized under the previous Commission decision. However, in compliance with the principle of data minimization, the CNAM must not have access to these identity traits during this reconciliation process. Subject to this reservation, the Commission considers that these data are adequate, relevant and limited to what is necessary with regard to the purposes for which they will be processed, in accordance with the provisions of Article 5-1-c of the General Data Protection Regulation. data. On the data retention period: The end of the research is scheduled for 2022. INSERM has requested that the cohort data, including the passive follow-up data of people from the SNDS, be kept until 2025. The Commission also notes that the retention of the NIR by the trusted third party will be temporary and that the duration will therefore be limited to that necessary for the exercise of its missions. The Commission considers that these durations and methods of retention of data are proportional to the purposes pursued, in accordance with the provisions of Article 5-1-e of the

General Data Protection Regulation (GDPR). On the recipients of the data: The data is accessible to different recipients depending on their missions and their authorisations: ANRS CO22 – HEPATHER centers (hospital departments participating in the cohort): birth name and usual name; first names; municipality and department of birth; Date of Birth ; HEPATHER identifier; medical data (CRF); first three letters of the surname and first name (CRF). Developers team 2 – UMR-S 1136: date of birth; gender; HEPATHER identifier; medical data (CRF); first three letters of the surname and first name (CRF). Team 2 researchers - UMR-S 1136: date of birth; HEPATHER identifier; HEPATHER-SNDS identifier; medical data (CRF); SNDS data. Head of team 6 – UMR-S 1136: birth name and usual name; first names; gender; municipality and department of birth; Date of Birth ; HEPATHER identifier; HEPATHER-SNDS identifier; first three letters of the surname and first name (CRF). CNAVTS: birth and usual name, first names; municipality and department of birth; Date of Birth ; HEPATHER-SNDS identifier; NIR.CNAM: surname, first names, sex, date and place of birth; HEPATHER–SNDS identifier; NIR; data from the SNDS. As indicated above, in compliance with the principle of minimization of data, the CNAM must not have access to the identity traits during the reconciliation process. Subject to this reservation, the Commission considers that these recipients do not call observation. On the information of people and the procedures for exercising their rights: During the initial recruitment, the people concerned were individually informed by means of an information notice accompanied by a form for obtaining the consent of the volunteers given on the occasion of their inclusion in the study during a routine visit. This notice includes information relating to the identity of the data controller, the objectives and methods of implementing the survey and the conditions for exercising the rights of participants in the study. Individuals are clearly informed of the voluntary and optional nature of the study and the absence of consequences for refusing to participate. They are also informed of the possibility of ending their participation at any time. The information note specifies the procedures for exercising the rights and in particular the rights of access and rectification of the data. The Commission notes that a specific mention was already included at the time, concerning the reconciliation of individual data of the survey with those from the national inter-regime health insurance information system (SNIIRAM) managed by the National Health Insurance Fund (CNAM), in order to obtain information on the medical consumption of participants study. The Commission also notes that the consent form offered to people when they were included in the study enabled them to accept or refuse the processing of personal data concerning them, thanks to a system of checkboxes which includes a specific section relating to the collection of data concerning them from SNIIRAM, health registers and the RNIPP. The persons concerned therefore had the possibility of specifically refusing the transmission of

data from Health Insurance and nevertheless of participating in the study. health insurance, has received the approval of the CCTIRS and the Ile de France III CPP. without this choice affecting their participation in the study, in the processing of this data. It considers that the collection of such data remains fair and transparent with regard to the persons concerned. by Article 13 of the General Data Protection Regulation. However, INSERM justifies that the provision of such information would require disproportionate effort, in particular with regard to the number of people (25,000 people) already included in the cohort, in accordance with the provisions of Article 14-5-b of the General Regulations on data protection. The Commission notes that INSERM undertakes to provide additional information to the persons concerned. On the one hand by means of a specific information note which will be published on its website and, on the other hand, by distributing this updated information note to the 32 hepatology centers, so that it is provided to patients during follow-up visits to the centre. Concerning cured patients (1,500 to date), they are no longer the subject of a follow-up visit but of a follow-up telephone call. During this follow-up call, cured patients will be informed by the hepatology centers of the update of the information note on the INSERM website. The Committee considers that these methods of informing the persons concerned are satisfactory. The person concerned can exercise his rights with the doctor in charge of the study. The contact details of the principal investigator of the study appear on the consent form, a duplicate of which is given to the patient. The Committee considers that these procedures for exercising rights are satisfactory. On data security and traceability of actions: The Commission acknowledges that the data is exchanged between secure servers, in the form of files encrypted with algorithms and key management procedures in accordance with appendix B1 of the General Security Referential (RGS). The Committee notes that the processing requires the use of the CNAVTS as a trusted third party and the use of the CNAM to extract the data from the SNDS concerning the patients included in the HEPATHER cohort. Pending the final reconciliation of the cohort data and the SNDS data, the correspondence tables are kept encrypted by the manager of team 6 on a mobile medium, itself stored in a safe accessible only by an authorized person. They are destroyed once the reconciliation has been completed. In order to process the data from the SNDS, the Commission notes that INSERM has carried out an impact analysis relating to data protection as well as a plan for compliance with the security reference system applicable to the National Health System set by the order of 22 March 2017. Similarly, the Commission notes that regular audits of the information system are planned and carried out by an independent body. A computer station is dedicated to the simultaneous analysis of SNDS data and data of the cohort. Measures have been put in place to ensure the segregation of this position. Authorization profiles are provided to manage access to data as needed.

Authorized personnel are made aware and an IT charter is signed. In addition, access to the premises is restricted by means of locked doors controlled by electronic key. A security cable is provided to ensure the physical security of the equipment and the data is encrypted with state-of-the-art algorithms. Each user has their own identifier. Strong authentication is imposed by the use of a personal certificate. With regard to the procedures for storing words, the Commission recalls that this must comply with deliberation no. 2017-012 adopting a recommendation on passwords. Logging of consultation, creation and modification of the data is planned. The Commission recommends carrying out an automatic control of the traces in order to detect abnormal behaviour. Given the nature of the processing and the risks to the privacy of individuals in the event of misuse or breach of security of the processing, the Commission recommends that the traces of access to the data be kept for one year. previous observations, the security measures described by the controller comply with the security requirements of Articles 5-1-f and 32 of the General Data Protection Regulation. The Commission recalls, however, that this obligation requires the updating of security measures with regard to the regular reassessment of risks. Under these conditions, the Commission authorizes the National Institute for Health and Medical Research (INSERM) to modify the processing of personal data for the purpose of a study on the benefits and risks associated with the different treatment methods therapy for hepatitis B and C.The PresidentI.FALQUE-PIERROTIN