Deliberation 2020-003 of January 9, 2020 National Commission for Computing and Liberties Nature of the deliberation: Opinion Legal status: In force Date of publication on Légifrance: Saturday July 11, 2020 Deliberation n° 2020-003 of January 9, 2020 refusing to the Rafaël Institute the implementation of automated processing of personal data for the purpose of research aimed at determining the genetic frequencies of the French population, aggregated with multi-thematic online questionnaires, entitled “e-CohortE”. (Request for authorization no. 919335) The National Commission for Computing and Liberties, Seizure by the Rafaël Institute of a request for authorization concerning the automated processing of personal data for the purpose of research aimed at determining the genetic frequencies of the French population, aggregated with online multi-thematic questionnaires, entitled e-CohortE; Having regard to Convention No. 108 of the Council of Europe for the protection of individuals with regard to 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 individuals with regard to the processing of personal data and on the free movement of such data, and repealing the directive 95/46/EC; Having regard to law n° 78-17 of 6 January 1978 as amended relating to data processing, files and freedoms, in particular its articles 66 and following; Having regard to decree n° 2019-536 of 29 May 2 019 taken for the application of law n ° 78-17 of January 6, 1978 relating to data processing, files and freedoms; Having regard to the civil code, in particular its articles 16-10 and 16-11; Having regard to the code of public health, in particular its articles L. 1131-1 and following; Considering the penal code, in particular its articles 226-26 and 226-28-1; After having heard Mrs Valérie PEUGEOT, commissioner, in her report, and Mrs Nacima BELKACEM , Government Commissioner, in his observations, Makes the following observations: The Commission was seized of the request for authorization on the basis of Articles 72 et seq. of the amended Data Protection Act, applicable to processing for research purposes, study or evaluation in the field of health. The processing has been qualified by the applicant as research involving the human person, and more specifically as interventional research with minimal risks and constraints. A favorable opinion from the Committee for the Protection of Persons (CPP) was issued on May 15, 2019. The project is presented as a cohort of voluntary persons whose complete genome sequencing would be carried out and who would be invited to answer multi-thematic questionnaires. This cohort would originally be made up of 5,000 people recruited by five investigation centres. In the long term, it is envisaged that other centers could contribute to the project by accessing the genomes thus collected and by enriching the database with the contribution of the genomes of new volunteers recruited by them. Blood and/or saliva samples are envisaged in order to to carry out the analysis of genetic characteristics. As a preliminary point, the Commission

recalls that genetic data is considered, pursuant to the provisions of Article 9 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (EU) 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 (hereinafter GDPR), such as sensitive data. Article 9.4 of the GDPR also leaves Member States the possibility of introducing limitations with regard to the processing of such data. In this respect, the Commission recalls that the legislator has maintained specific legislative and regulatory provisions for carrying out examinations of genetic characteristics, which are provided for, in addition to the Data Protection Act, in the Civil Code, the Health Code (CSP) and the Penal Code.On the legal basis of the processing and the exception allowing to process sensitive dataThe transmitted DPIA indicates that the basis which makes the processing lawful, in accordance with Article 6 of the GDPR, is the consent granted by the participants in the project. The data controller also mentions the collection of consent to legitimize its processing of health data. The Commission infers from this that it wishes to rely on Article 9.2.a of the GDPR to lift the prohibition on processing this data. In this respect, it recalls that, in accordance with Article 4 (11) of the GDPR, consent is defined as any free, specific, informed and unequivocal manifestation of will by which the data subject accepts, by a statement or by a clear positive act, that personal data concerning him or her be processed . However, she notes that the consent form includes about ten elements to which the participant must consent and that consent to data, including genetic data, is diluted in this list. In addition, it notes that a tick box would allow the participant to agree to participate in the study. It recalls in this respect that consent to participate in research must be differentiated from consent to data processing, as recalled by the European Data Protection Board (Opinion 3/2019 concerning questions and answers on the interaction between the Clinical Trials Regulation and the General Data Protection Regulation (GDPR)) as well as the European Data Protection Supervisor (A Preliminary Opinion on data protection and scientific research , January 2020). The Commission therefore notes that the methods for obtaining consent, in particular the absence of a separate checkbox for the processing of health data, do not allow it to be considered as a specific and unequivocal consent. concludes that the proposed consent does not meet the criteria required by Articles 4 (11) and 7 of the GDPR and that the data controller cannot retain it as a legal basis for processing or as an exception allowing the processing of health data. the purpose of the processingThe file mentions that the Rafaël Institute plans to set up a cohort of volunteers for whom the complete sequencing of the genome would be carried out and who would also answer online questionnaires. The objective is to study, from a blood and/or saliva sample taken specifically for the project, the link between the phenotypes of each person in relation to their

genome and to attempt to map their entire genome. The collection of a great deal of information by means of questionnaires is also planned, without the list of questions being exhaustive, each center participating in the project being able to submit its own questionnaires. The project highlights the expected added value of this research aimed at collecting new data throughout the study, through questionnaires, in order to enrich knowledge of the genome. The legal framework for carrying out genetic examinations, in the field of health, must however be recalled .Article 16-10 of the Civil Code, to which article L. 1131-1 of the CSP refers, specifies that (…) the examination of the genetic characteristics of a person can only be undertaken for medical purposes or again scientific research. The person's express consent must be obtained in writing prior to carrying out the examination, after they have been duly informed of its nature and purpose. The consent mentions the purpose of the examination. It is revocable without form and at any time. With regard to medical purposes, Articles R. 1131-1 et seq. of the CSP specify the types of genetic analyzes that can be carried out and provide specific provisions relating to the examination of a person's genetic characteristics for such purposes. Specific methods for prescribing and reporting genetic results in the context of the medical care of a person are also detailed in these articles. It follows that the will of the legislator is to provide for a strict and protective mechanism in the delivery of this specific health information, in particular because of the complexity of their interpretation, the anxiety-provoking effect they are likely to cause in patients and, due to their multi-personal nature, their potential impact on the patient's family. medical purposes and taken pursuant to Article L. 1131-2 of the Public Health Code, specifies that: (…) Genetic tests should only be prescribed when they have clinical utility and are desired by the person. The mere fact that an examination is available and feasible does not justify either its prescription or its performance. With regard to scientific research, the Commission notes that the legislative and regulatory provisions applicable to the examination of genetic characteristics, even if they do not specify the conditions for carrying out such an examination, refer to the need for a defined research project , using the following terms the purpose of the examination in Article 16-10 of the Civil Code or this research project in Article L 1131-1-1 of the CSP. It follows from all of these provisions that the legislator intended to make the possibility of carrying out a research project based on the examination of genetic characteristics subject to the prior statement of a precise scientific objective. The Committee notes, moreover, that in practice it has always ruled on the treatments envisaged in the context of research projects meeting such an objective, in particular for the purposes of studying a particular pathology. However, it notes that no specific purpose has so far been defined for the processing in question, insofar as the project plans to collect the maximum amount of genetic data possible to map the human genome without associated methodology making it

possible to answer a specific scientific question , that the inclusion criteria are extremely broad (anyone over the age of 18 agreeing to participate in the study and affiliated with a health insurance scheme) and therefore aimed at the general population. It can therefore only question the scientific relevance of the planned research, particularly with regard to the scope and nature of the data likely to be collected (detailed below and including genetic data). Furthermore, the Commission notes that new questions may be asked by each researcher at a later date and that it is not currently aware of all the data likely to be collected. that the data controller does not clearly indicate whether he excludes any medical purpose in his project, insofar as he provides in particular for the transmission of genetic results which may reveal information relating to the health of the person concerned, with a medical opinion (see below). It also regrets that the Committee for the Protection of Individuals (CPP) did not provide in its opinion the necessary elements enabling the Commission to assess the relevance of the research, the satisfactory nature of the assessment of the benefits and risks expected as well as the methodology of the research, the need to resort to the collection and processing of personal data and the relevance of these in relation to the objective of the research, in accordance with the missions assigned to it by the Article L. 1123-7 of the Public Health Code. The Commission therefore considers that the purpose pursued by the processing is not sufficiently determined and explicit, as required by Article 5.1.b) of the GDPR. On the nature of the data processed The protocol transmitted in the file specifies that the participants would be recruited by a doctor from an investigating center (general practitioner, specialist, in town or at the hospital) during a consultation. on. During the recruitment visit of the person concerned, a blood and/or saliva sample would be taken in order to allow the genetic analysis of the biological sample. very diverse fields (health, behavior, physical appearance, sexology). In addition, new investigating centers could participate in this e-CohortE in order to ask specific questions related to their own medical specialty, which would require, according to the data controller, the filing of an amendment to the CPP. Data subjects could choose whether or not to answer each question asked.The collection of the following categories of data is envisaged:As regards data collected directly from data subjectsWhen recruiting data subjects by the investigation centres, the following data will be collected :identifying data: surnames, first names, e-mail address, date and place of birth, sex, height, weight, photo of the face (with grid of the front, back and the two profiles); health data, such as temperature, blood pressure, family history; ethnic origin as well as family genealogy. In addition, the protocol provides that the data subject may authorize access to certain health data from his shared medical file, applications or connected objects (these are cited in particular Middlecare software for managing patient files, the Santé La Poste application, medical analysis laboratory reports). After the

recruitment of the data subject, via questionnaires subsequently created by the researchers of the participating centers and of which the Commission was therefore unable to take cognizance, very varied information relating to a multitude of categories of data is likely to be collected. The categories of data presented by the data controller in the file are in particular the following: Medical data, Sexology data, Behavioral data, Physical appearance data, Psychological data, Lifestyle data, Anthropomorphic data, Images, Video, History of Participation in research or studies, Data relating to personal life, Consumption habits, Addictions, Assistance, Physical activities, Eating behavior, Lifestyle, Housing, Geolocation, Location, Socio-professional data Economic and financial data , Genetic Data With regard to data from DNA and RNA sequencing As part of the project, genetic data will be collected through the analysis of samples taken specifically for the project, an analysis which consists of a sequencing total of the genome. Thus, the Commission notes that the planned processing aims to collect a vo considerable amount of data in order to fulfill its main objective, namely the knowledge of the genome. In this respect, the data protection impact assessment (DPIA) and the study protocol do not provide any element to guarantee that the data collected will be limited to those which provide the knowledge necessary for the research. , the Commission points out that it does not currently have an exhaustive list of the data that can be collected, each future medical investigator having the freedom to ask the questions of his choice, with regard to his specialty. Conversely, some of the data from the draft questionnaires appearing in the appendix to the protocol, and for which no precise justification of their scientific relevance is provided in the file, are likely not to be used in any of the projects whose implementation is envisaged at a later date. Finally, the Commission notes that the draft questionnaire invites participants to scan their x-rays, enter their blood results and provide data from connected objects, if applicable. In this regard, the Commission notes that the data controller does not specify how the data from connected objects or applications will be collected and what the mechanisms for interconnection with these third-party systems will be. Thus, given the multiple categories data, most of which are sensitive, the collection of which is envisaged, in the absence of a specific study project to justify it, the Commission considers that the data are not relevant and limited to what is necessary with regard to the purpose for which their processing is envisaged, and that the requirement laid down in Article 5.1.c) of the GDPR is therefore not respected. On the return of genetic information directly to participants The Commission notes that the protocol mentions that the investigating doctors will be able to provide the persons concerned, from the genetic analyzes carried out, with certain individual results, whether or not related to the medical field. he Commission notes that no legislative or regulatory provision specifies the procedures for transmitting genetic results to people taking part in scientific research, unlike the results

of analyzes carried out in the context of therapeutic care, for which a particularly strict framework is described by the provisions of the CSP. It notes, however, that Article L. 1122-1 of the CSP, applicable to research involving the human person in general, provides that: The person whose participation is requested is informed of his right to have communication, during or at the end of the research, of information concerning his health, held by the investigator or, where applicable, the doctor or the qualified person representing him. This same article also provides that the person has the right to be informed of the overall results of the research. As regards information not strictly relating to health According to the project, predisposing factors linked to physical traits, tolerances (alcohol, caffeine) and results relating to ancestry (ethnic origin, percentage of Neanderthals) could potentially be passed on to people. The Commission considers that these results do not fall within the medical field and cannot a priori be prescribed in the context of traditional treatment of a patient. Article L. 1122-1 of the aforementioned CSP mentions the right for the person to obtain information on their health during the study, thus limiting the nature of the information which could be transmitted to the participants and thus excluding what is not related to health. purpose provided for in article 16-10 of the civil code and the provisions of article 226-26 of the penal code: the fact of diverting from their medical or scientific research purposes the information collected on a person by means of the examination genetic characteristics is punishable by one year's imprisonment and a fine of 15,000 euros. The Commission therefore considers that the transmission of information not expressly relating to the health of the persons concerned is not lawful. With regard to information relating to health The protocol also envisages the possibility for the investigating doctors to transmit to the participants information relating to predisposition factors to certain pathologies or tolerance to certain molecules, pursuant to Article L. 1122-1 of the CSP. First of all, the Commission notes that this provision does not specifically refer to the communication of information genetic data, and relates to the right for the person concerned, during or at the end of the research, to request the communication of information concerning his health, held by the investigator or, where applicable, the doctor or the qualified person who represents him. The Commission wonders, moreover, about the scope of the silence of the legislator and the regulatory power, which have not defined, in terms of research, precise methods of reporting the results. In any event, these provisions of article L. 1122-1 of the CSP could only be applied within the framework of the implementation of a precise scientific protocol, the person concerned thus being able to access the information relating to his medical condition collected and held by the healthcare professional for the purposes of the project. However, in the present case, in the absence of a determined and explicit purpose for the processing envisaged, the application of this provision could lead to the possible transmission of extremely varied and

undifferentiated information, having a link, even very indirect, with the health of the person. Finally, the Commission also notes an inconsistency in the system for reporting the results between two documents in the file. Indeed, on the one hand, the protocol indicates that information relating to health would be subject to the expertise and prior validation of an approved geneticist and a multidisciplinary committee before being transmitted to the investigating doctor and then to the participant. during a consultation. On the other hand, the model information note provides: This is why, if you wish, we will send your request to the Committee for the protection of persons to ask them, within the framework of this protocol, to evaluate the reported such results on a cohort. Through this mechanism, we hope to perpetuate your trust so that you do not have to carry out these tests abroad without any medical advice and scientific or psychological support. (…) We will provide you with data relating to your genome (ancestry, health, predisposition factors) if you wish. If certain data is not returned, we will tell you the reason (CPP and/or CNIL decision, unscientific or not finalized). However, the Commission specifies that the tasks of the committees for the protection of persons as provided for by the Public Health Code do not include the evaluation of the individual reporting to the persons concerned of the results of analyzes carried out within the framework of research. In conclusion, the Commission considers that the envisaged methods of restitution do not meet the requirements of the texts mentioned above. On information and the methods of exercising the rights of individuals The consent form is accompanied by a note of information for the data subjects. As a preliminary point, the Commission considers that the approach envisaged, consisting in dynamically collecting the consent of the data subjects for each research project, makes it possible to guarantee them control of their data in accordance with the GDPR. The Commission notes, however, that the information note does not contain all the references to Article 13 of the GDPR and that there are inaccuracies. redundancies, inconsistencies or errors on the rights of individuals, as well as clumsiness in the formulations. The document also mentions the possibility of opening and feeding the shared medical file (DMP) of individuals with the most re. The document also mentions that despite his opposition to the research, the participant will be able to enjoy, unless expressly requested, his DMP. is intended to record medical information concerning the patient and that the latter has the option of opposing its opening at any time, in accordance with the provisions of the Public Health Code. Finally, the Commission notes that the analysis of impact on data protection does not specify the data to which individuals may have access. In addition, the measures provided for the application of the rights of individuals are not precisely indicated and do not allow the effectiveness of these rights to be assessed. In conclusion, the Commission considers that the information notice does not meet the requirements provided for by articles 12 and following of

the GDPR. Furthermore, since the procedures for exercising the rights of individuals are not sufficiently detailed in the request, the Commission is not in a position to assess their compliance. On data security and risk assessment The Commission notes that the AIPD does not describe the complete life cycle of the data. On the measures relating to data security The partitioning of the system is poorly delimited and the elements noted in the AIPD present contradictory aspects: the infrastructure would be placed on a strictly internal network but it will in fact have electronic data collection forms, numerous interoperabilities with external data sources as well as a remote administration interface; similarly, genetic data would be stored off-net but will be received through direct interoperability with sequencing platforms. are not sufficiently defined and are noted for improvement in the AIPD. Finally, the pseudonymization and anonymization mechanisms are not described, and the management of the correspondence tables is not compliant because they are not isolated from the data that 'they reference. On general security measures No information is present concerning the tool used for the data entry forms by the investigating or recruiting physicians; the same goes for the means to secure data transmissions. Then, many fundamental security measures are noted for improvement in the AIPD: traceability of actions and detection of intrusions on systems, restriction of access to premises, code audits , protection of backups, antivirus, etc. On organizational security measures No information is present on the means of monitoring and maintaining the information system in secure conditions - analysis of event logs, incident management, treatment vulnerabilities identified by intrusion tests, updating of the AIPD, decision-making on corrective actions, etc. On risk assessment Given the shortcomings of the AIPD concerning organizational and technical measures, general and specific to the processing, the level of attenuation of the likelihood of the risk of a loss of confidentiality is not demonstrated. threat are not operational because they are not specific to the means implemented within the framework of the processing. GDPR. Under these conditions, the Commission refuses to issue the authorization requested. President Marie-Laure DENIS