

## **ANNEX 1. Information letter for patient (de-identified)**

Dear Sir/Madam

Doctor MdU would like to invite you to take part in a research project on the autonomy of patients in chronic pain care.

Your participation in this research is entirely free and voluntary. You have the right not to participate in this research. In all cases, there will be no impact on your medical care, on the quality of the care and treatment you receive, or on your relationship with your doctor.

You are treated in our hospital for chronic pain.

### **What is the aim of this research?**

Etymologically, autonomy is the ability to "give oneself one's own laws".

In the medical field, autonomy can have several meanings (Diederich, 1998), as the Comité Consultatif National d'Ethique reminds us:

- Autonomy of action: the ability to perform the acts of daily life.
- Autonomy of thought: the power to reason and fully assume the consequences of one's actions.
- Autonomy of will: the ability to have preferences and make choices.

You have come to us for a consultation on chronic pain. The doctor who has seen you is proposing a treatment plan that he or she feels is best suited to your pain and its repercussions.

Our research consists in assessing whether you are perfectly autonomous in your decision to follow this program, which will enable you to play a full part in your own care and make the treatment as effective as possible.

### **Number of participants and duration of study**

This study is based on data from patients referred to your chronic pain service during the study period, *i.e.* 60 patients.

Your participation time is a few hours.

### **How does the research work?**

The study is proposed to you by a member of the chronic pain team, who gives you this written information form.

If you agree to take part in this research, after sufficient time for reflection and having asked all your questions, your free, informed and written consent is collected by the study's investigating physician, Dr. MdU.

As part of this research, you will be asked to complete a questionnaire with her (total duration 15 minutes): the MacCAT-T.

This questionnaire will be used to measure your autonomy in relation to the treatment plan proposed by your doctor.

Your participation in this research will not entail any additional costs for you over and above those involved in your usual treatment.

### **What are the expected benefits of this research?**

The research does not in itself provide any individual benefit for the people taking part, apart from contributing to the advancement of knowledge about chronic pain. Evaluating patient autonomy may help to improve the quality of support provided in chronic pain facilities. If you wish, the results of this assessment will be forwarded to your pain physician, who will be able to discuss them with you and review certain aspects likely to lead to changes in the various therapeutic proposals.

### **What are the foreseeable risks and constraints added by the research?**

The foreseeable constraints of this research are the completion of the MacCAT-T questionnaire, which lasts a total of 15 minutes. This is a data-driven study, so there are no risks involved.

### **What data is collected for the research?**

The medical data collected as part of this research corresponds to your demographic data (age, sex), your socio-demographic data, the type of pain for which you are consulting us, and the treatments you have undergone as part of your care during hospitalization. These data are collected directly from your medical file.

The evaluation of your autonomy will be carried out by asking you to fill in a standardized questionnaire, with the help of the doctor in charge of this research.

This data will be subject to computerized, pseudonymized and confidential processing in accordance with the regulations in force, Articles 6 and 9 of European Regulation No. 2016/679 (General Data Protection Regulation, RGPD) and Law No. 78-17 of January 6, 1978 relating to data processing, files and freedoms as amended, as well as the MR004 compliance commitment to which the Hospital has undertaken. No information bearing your name will be provided to anyone other than the doctor in charge of the study and authorized personnel.

The identification list (correspondence between your study code and your identity) will be kept strictly confidential within the Hospital.

All data collected will be kept confidential, coded and analyzed by the Clinical Research Department of the Hospital, the research promoter.

In accordance with current regulations (decree no. 2020-077 of June 18, 2020), data will be kept until the final research report is produced, or until 2 years after the last publication of results, and then archived for a maximum of 20 years.

The data controller is the promoter, the Hospital.

### **What are your rights?**

Your participation in this research is entirely free and voluntary. You have the right not to participate in this research.

This research is subject to European Regulation (EU) 2016/679 of April 27, 2016 on the protection of personal data (RGPD) and Law No. 78-17 of January 6, 1978 on data processing,

files and freedoms as amended. It is in line with the reference methodology MR004 issued by the Commission Nationale de l'Informatique et des Libertés - CNIL (French authority for the control of personal data, website: [www.cnil.fr](http://www.cnil.fr)) in May 2018, a methodology to which the Groupe hospitalier Paris Saint-Joseph, promoter of the research, has undertaken to comply relating to the processing of personal data in the context of research in the healthcare field. You may not be included in a research protocol not involving the human person without first being informed. Your doctor must provide you with all the necessary explanations concerning this research, in accordance with the provisions of Articles 13 and 14 of the General Data Protection Regulation (GDPR, Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016). Information to research is the subject of a written document.

You may stop your participation in the research at any time without justification in accordance with Article 21 of the RGPD. This will have no effect on the quality of care and treatment provided to you or on your relationship with your doctor. Data collected until you express your objection will be used unless you expressly request otherwise. Indeed, in accordance with Article 17 of the RGPD, you have the right to request the deletion of your data already collected. Your opposition and consent to the use or otherwise of your previously collected data will be traced in your medical record.

In accordance with the provisions of Articles 15 and 16 of Regulation (EU) 2016/679 of April 27, 2016 (General Data Protection Regulation) of Law No. 78-17 of January 6, 1978 relating to information technology, files and freedoms, amended by Law No. 2018-493 of June 20, 2018 (Decree No. 2018-687 of August 1, 2018), you have a right of access, rectification, portability, deletion thereof or a limitation of processing (see [cnil.fr](http://cnil.fr) for more information on your rights). You also have the right to object to the transmission of data covered by professional secrecy that may be used in this research and processed. Your request should be addressed to the Data Protection Officer of the Hospital.

You also have the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés - CNIL (French data protection authority, website: [www.cnil.fr](http://www.cnil.fr)).

Your medical file will remain confidential and may only be consulted under the responsibility of the doctor in charge of your treatment, by the health authorities and by persons duly authorized by the Hospital for research purposes and bound by professional secrecy.

If you wish, you may be kept informed of the overall results of this research once it has been completed. Dr MdU, principal investigator of this study, remains at your disposal to answer any questions you may have. He remains your privileged contact for this research.

If you receive this letter by post to your home address, and only if you object to the collection of data from your medical file, please inform us by e-mail, or by returning this dated and signed letter within one month (contact details in the box below),

Thank you very much for your participation,