# PATIENT INFORMATION NOTE ON THE CREATION OF A REGISTRY

Registry title: [Official title in French]

Registry Manager: [Name and address of company, hospital, university or other organization]

Medical Ethics Committee: [Identification of the Ethics Committee that provided the single opinion on the registry and the local Ethics Committee that participated in the approval process].

Physician(s) responsible for data processing for the site [Name of hospital, centre, ...]: [Name, affiliation and contact details]

***Instructions for use (to be deleted from the final version):***

* *For use with national multicenter registries*
* *Delete the header (which only serves as a reference for the document on PaCo)*
* *Modify the footer that contains the reference for the PaCo document and indicate the version of your document and the date*
* *Follow the instructions to complete the parts [in red].*
* *This is an informational document that must be given to the patient whose data is going to be collected before you begin recording that data in the registry*
* *If the registry involves minors (under 18):*
	+ *Provide an information document (and assent form for them), appropriate to their age (see Procedure for Writing a Biomedical Research Participant Information Document, 013-AAHRPP-SOP-051).*
	+ *Adapt the text below to address BOTH parents: "Information to Parents", "Your Child is Invited to Participate", "Parental Informed Consent Form", "We, the undersigned, ...", "Last Name, First Name, Date and Signature of Parent 1", "Last Name, First Name, Date and Signature of Parent 2", ...)*

**DEFINITION OF A REGISTRY:** A systematic collection of [health] data of an epidemiological and/or scientific nature, in the form of an organized system of data collected on the basis of defined criteria relating to the field concerned, making it possible to characterize a population of persons in a longitudinal perspective.

The purpose of this registry is to prepare for subsequent research and analysis in an epidemiological and/or scientific context. The data of the registry may be used by duly authorized persons in order to facilitate recruitment in studies or to carry out retrospective studies with the following objectives: to understand or better treat the disease, to participate in the evolution of the quality of care, treatments, the cost of the management of the disease, etc... These studies must be submitted to the Ethics Committee.

INFORMATION TO PATIENT

Data involved, purpose and legal basis

Your data will be processed in accordance with the General Data Protection Regulation (GDPR, Ref. 3) and the Belgian Data Protection Act of 30 July 2018 (Ref. 4).

 We inform you that your clinical data will be collected by [indicate the name of the person identified in the above box as the data controller for the registry; this person must have a therapeutic link with the patient] in order to realize a database (registry) concerning [indicate the subject of the registry]. This data includes information about your health and illness, including your medical history, certain background information (e.g., your age, gender, and ethnicity), and the results of any tests required as part of the registry.

Only a health care staff member who has a therapeutic relationship with you and is identified as the data controller for this registry (see box above) is authorized to collect this data. The creation of this register has been accepted by one or more Belgian ethics committees.

In this registry, your data will be collected and aggregated with that of other patients who have [indicate the commonality between the subjects concerned]. This registry will eventually contain pseudonymized and confidential data collected in several [centers, hospitals, ...]. These data, which are of an epidemiological and/or scientific nature, may subsequently be used for retrospective clinical research purposes.

The day your data collected, coded and stored in this registry should be used for scientific research purposes in the framework of a clinical study, it will have to be approved by an approved Belgian ethics committee.

Thus, this collection is carried out by the registry manager as data controller, [select the appropriate proposal according to the type of registry and registry manager]

[ ]  On the basis of public interest missions

[ ]  On the basis of legitimate interest as a university hospital

[ ]  For the purpose of performing statistical analysis for the optimization of processes and quality of care, researching causes of pathology, analyzing the effect of medical treatments, improving medical and care practices and methods

[ ]  For the purpose of teaching medicine or nursing and paramedical sciences

[ ]  For the purpose of establishing registries in epidemiological research, risk groups, biomedical research, scientific care evaluation (dissemination of medical risks, morbidity, search for causes of pathology and causal patterns, analysis of the effect of medical treatments, analysis of the improvement of medical and care practices and methods, clinical trials,...)

This collection of health data is legitimate and complies with Article 9 of the GDPR, based on the fact that the processing is necessary for reasons of public interest in the field of public health (Art. 9 i), and/or for scientific or historical research purposes or for statistical purposes (Art. 9 j), while guaranteeing the safeguarding of the fundamental rights and interests of the data subject.

Patient’s right[[1]](#footnote-1)

You have the right to request from the data controller what data is collected about you and what purpose it serves in the registry. You have the right to inspect this data, the right to request the restriction of processing in the cases listed in Article 18 GDPR, the right to rectify it if it is incorrect and the right, at any time, to object to the use of your data.

With regard to the processing of your data, you have the right to lodge a complaint with the Belgian supervisory authority that ensures compliance with the fundamental principles of the protection of staff data: L'Autorité de Protection des Données (APD), Rue de la presse 35, 1000 Brussels

Tel: +32 2 274 48 00

e-mail: contact@apd-gba.be Website: <https://www.autoriteprotectiondonnees.be>

If you have any questions regarding the processing of your data or the exercise of your rights, you can contact your data controller (contact details at the beginning of this document). Your hospital's data protection officer is also available at the following address: [to be completed - for Saint-Luc: rgpd@saintluc.uclouvain.be ]

Data retention period

After the creation of the registry is completed, the encrypted data will be kept for at least [indicate the expected retention time of the data]. It will be stored in a secure environment providing adequate protection under the RGPD, i.e. [indicate where the data is stored, with which partner, ... Specify if it is within the European Union or not].

Obligation of the data controller

The physician responsible for processing the data on site is required by professional secret regarding the data collected. This means that he or she will never reveal your identity and will code the data (i.e., replace your identity with an identifying code and remove anything that might make you identifiable) before sending it to the registry manager. The database will not contain any combination of your initials, gender and full date of birth (dd/mm/yyyy).

Therefore, only the physician responsible for processing the data on site and the staff under his or her responsibility for data collection will be able to link your identity to the data transmitted.

The data transmitted to the registry manager will not allow the registry manager to identify you. The data controller is responsible for the collection of the data collected by all the data processors participating in the registry and for their protection in accordance with the requirements of the Belgian law on the protection of privacy.

 The physician responsible for on-site data processing and the registry manager may only use the coded staff data in a subsequent clinical study if this project is approved by an ethics committee. Only data collected, coded and stored in the registry prior to project approval may be used. If new data are collected as part of a clinical study, the investigator of that study will need to request your consent.

In addition, data collected, coded and stored in the registry cannot be transferred to outside researchers (who are not involved in the registry). In the event that an outside researcher wishes to use your data in a project other than the one described in this document, that project must be approved by an ethics committee. If your coded study data is sold, you will not benefit.

INFORM CONSENT FORM

1. I, (NAME, FIRST NAME(S)), ......................................................................................................... declare that I have read the above information and agree to the collection of my clinical data for the purpose of a database (registry) entitled [Title of Registry].
2. I have received a copy of this signed and dated informed consent form and the patient information note. I have received an explanation of the nature and purpose of the data collection and have been informed of what is expected of me. I have had the time and opportunity to ask questions about the registry; all my questions have been answered to my satisfaction.
3. I am aware that this registry has been submitted to and approved by the St. Luke's University Hospital Ethics Committee.
4. I am free to participate or not, as well as to stop my participation at any time without the need to justify my decision and without any disadvantage.
5. By signing this document, I authorize the use of my data in accordance with
* the Belgian law of 30 July 2018 on the protection of privacy ;
* the law of 22 August 2002 on the rights of the patient;
* the European (European General Data Protection Regulation [RGPD] of 25 May 2018) and Belgian regulations in force.
1. I have not been subjected to any undue physical or psychological pressure for my participation in this register.
2. I voluntarily consent to participate in this registry.

……………………………………………………………………        …...…/…..…./20…..…

Name, First Name and Signature                                                           Date (dd/mm/yyyy)

of the patient

I, the undersigned, Dr/Pr (NAME, First Name) ...................................................................................... confirm that I have explained the nature and purpose of this register to the patient named above.

……………………………………………………………………       …...…/…..…./20…..…

Signature of the Physician responsible Date (dd/mm/yyyy)

for the data processing for the site

[For the consent of the parents of a minor participant, provide the Names, First Names and signatures of BOTH parents exercising legal authority over the minor or, failing that, the Name, First Names and signature of the minor's guardian]

1. These rights are guaranteed to you by the General Data Protection Regulation (GDPR), by the Belgian legislation of July 30, 2018 on the protection of privacy with regard to the processing of staff data and by the law of August 22, 2002 on patients' rights. [↑](#footnote-ref-1)