Information sheet for the participants

**Title of the study:** **Enter the official title as stated on the protocol**

Dear,

You are invited to participate in a study. Before you decide to participate in this study, take sufficient time to read this information sheet carefully and discuss this with the investigator/medical team or other people of your choice. Please take time to ask questions if there are any uncertainties or if you require additional information. This process is called "informed consent" for participation to a study. Once you have decided to participate in the study, you will be asked to sign the consent form at the end of this information sheet.

# description and purpose of the study

You will receive an xxx *(enter here the purpose of the normal contact with the patient where the patient will be asked to participate in the study, e.g. regular consultation with the doctor, examination, etc.)*.

The department xxx *(enter the name of the department here)* conducts an investigation to xxx *(enter the subject of the investigation here and why the study is being conducted)*.

We kindly ask you to take the time to complete a questionnaire for us. This will take approximately xxx *(insert the time it takes to carry out the study-specific interventions)* of your time.

This study was evaluated by the Ethics Committee of University Hospital Ghent and University Ghent. The study is conducted in accordance with the guidelines of good clinical practice (ICH/GCP) and the Helsinki Declaration, written to protect those involved in clinical studies.

The sponsor of this study is xxx. This collection of data is carried out under the supervision of Prof. Dr. xxx *(enter here the person responsible for the database, this person is also responsible for protecting the data that will be stored in the database)*. *Students from the department xxx will be part of the research team.*

# Consent AND REFUSAL

Your participation in this study is entirely voluntary. You can refuse to complete the questionnaires and you are free to withdraw from this study at any time, without having to justify your decision. This will not affect your treatment, medical follow-up, the quality of your subsequent care or the relationship with the investigator or the treating doctor.

# advantages

Participation in this study will probably not bring you any medical or other benefits. However, the results obtained can lead to new and more efficient methods for the treatment of xxx *(enter here for which pathology)*.

# COsts

Your participation in this study does not entail any additional costs for you, but it also offers no financial benefits.

# PROCESSING OF PERSONAL DATA

In accordance with the Belgian law of August 22, 2002, relating to the rights of the patient, the General Data Protection Regulation (or GDPR) (EU) 2016/679 of April 27, 2016 and the Belgian law of July 30 2018, on the protection of individuals related to the processing of personal data and on the free movement of such data your privacy will be respected and you will be able to access the data collected about you. Each error can be corrected at your request.

Your other rights (i.e. including the right to restrict the processing of your (personal) data, the right to have your (already collected) data erased in certain circumstances, and the right to lodge a complaint) are also safeguarded.

For more information on the rights you have and how to exercise them, please visit the website of UZ Ghent or UGhent.

Your participation in the study means that your data will be processed for the purpose of the clinical study. This processing of data is necessary for the performance of a task carried out in the public interest, as mentioned in article 6, paragraph 1 (e) and is necessary for the purpose of scientific research in accordance with Article 9, paragraph 2 (j) of the General Data Protection Regulation.

All information collected during this study will be pseudonymised (here your data can still be linked to your personal file by means of a code). The key to the codes assigned to you will only be accessible to the investigator/treating doctor or to his/her appointed replacement. In this study, data can also be collected via an electronic questionnaire. Therefore, you will be asked to provide a personal email address at which you wish to receive this questionnaire.

The pseudonymised data collected can be shared with other (future) researchers. This may lead to re-use of your pseudonymised data for future academic research projects and studies, exclusively in the context of the same or a similar disease/pathology or treatment. Such new studies and re-use of data always need to be submitted to and approved by the ethics committee. If you wish your data not to be used for future research, you can contact the DPO for this purpose (see contact details under chapter 5).

Only pseudonymised data will be used for analysis and in any type of documentation, reports or publications (in the medical scientific literature and/or at medical conferences) concerning this study. Therefore, confidentiality of the data will always be guaranteed.

Both personal data and data concerning your health will be processed and kept for at least 10 years after the end of the study and for safety reasons regarding the study conducted and its follow-up (if any).

The controller of the data is the institution of the principal investigator of the study, Dr. XXX (mention the PI of the study here) (UZ Ghent). His/her research team will gain access to your personal file.

In the context of data protection, the data will only be processed by personnel belonging to the research team and designated by and under the responsibility of the principal investigator, including internal employees with a non-healthcare profession.

Data from the patient file are processed in the context of improvement processes of the organization and health care in general.

In case your data has to be transferred to a country outside the European Economic Area (EEA), U(Z) Ghent will ascertain whether the country of destination offers an adequate level of protection. If the country to which U(Z) Ghent wishes to transfer data does not offer adequate guarantees, U(Z) Ghent itself will enforce adequate guarantees by means of model agreements, made available by the European Commission, or other accepted measures.

Representatives of the promoter, auditors, the Medical Ethics Committee and the competent authorities, all bound by professional secrecy, can have direct access to your medical records under the responsibility of the investigator (or one of his/her collaborators) in order to check the study procedures and/or the data, without violating its confidentiality. This is only possible within the limits of the relevant laws. By signing this consent form and having received the preliminary explanations, you consent to this access.

To obtain more substantive information about the study and to exercise your rights, please contact the study team.

The Data Protection Officer can also provide you with further information on the protection of your personal data if required. Contact details: Katya Van Driessche, dpo@uzgent.be ***OR*** Hanne Elsen, privacy@ugent.be.

The Belgian supervisory Data Protection Authority responsible for enforcing data protection legislation can be reached via the following contact details:

Data Protection Authority (DPA)

Rue de la Presse 35 – 1000 Brussels

Tel: +32 2 274 48 00

E-mail: contact@apd-gba.be

Website: www.dataprotectionauthority.be

# Insurance

The sponsor provides compensation and/or medical treatment in the event of damage and/or injury as a result of participation in this clinical study. For this purpose, insurance has been taken out with faultless liability in accordance with the Human Experiments Act of 7 May 2004, the Belgian Law of 7 May 2017 on clinical trials with medicines for human use and the Belgian Law of 22 December 2020 on medical devices (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00; policy number for UZ Ghent BEL001889 – policy number for UGhent BEL000862).

# Contact

If an injury occurs or if you would like to receive more information about this study or about your rights, you can contact the investigator or an employee of his/her team at any time during the course of the study:

Name:

Address:

Telephone number:

**INFORMED CONSENT FORM FOR THE PARTICIPANTS**

|  |
| --- |
| I have read and understood the document “Information sheet for the participants” page 1 to page xxx (enter here the page number of the end of the information letter, so the page before this page) and I have received a copy of this document. I have been informed about the nature of the study, its purpose, its duration and what is expected of me.  |
| I understand that participation in the study is voluntary and that I can withdraw from the study at any time without giving a reason for this decision and without this having any influence on my further treatment. |
| I am aware that this study has been approved by an independent Medical Ethics Committee at UZ Ghent and Ghent University and that this study will be conducted according to the guidelines for good clinical practice (ICH/GCP) and the declaration of Helsinki, designed to protect people participating in experiments. This approval should under no circumstances be taken as an incentive to participate in this study. |
| I have been informed that both personal data and data concerning my health are processed and stored for at least 10 years after the end of the study. I am aware that I am entitled to access and correct this information. As this data is processed for medical-scientific purposes, I understand that access to my data may be postponed until after the end of the study. If I want access to my data, I will address the doctor-investigator who is responsible for the processing of the data. |
| I am aware that my pseudonymised data will be used for **current** scientific research. |
| I am aware that my pseudonymised data may be used for **future** scientific academic research within the framework of the same / a similar research field. Such new study should always be submitted and approved by the ethics committee. If I wish my data not to be used for future research, I will contact the DPO (see contact details under section 5). |
| Optioneel toe te voegen indien van toepassing voor de studie:I understand that my GP will be informed about my participation in this clinical study. |

Tick by the participant if you agree

|  |  |
| --- | --- |
| I agree to participate in this study consisting of the following **mandatory interventions** as explained under section 1 of the information letter:* xxx
* xxx
* xxx
 |  |
| * Please note: This study requires data transfer to a country outside the EEA. By ticking this box, I give my explicit consent for this data transfer outside the EEA. If I do not give this consent, I cannot participate in the study.
 |  |

I agree to participate in the following **optional aspects** of the study :

|  |  |
| --- | --- |
| * XXX
 |  |

|  |  |  |
| --- | --- | --- |
| Name and first name of the participant | Signature | Date |
| Name and first name investigator\* | Signature | Date |

2 copies must be completed. The original is kept by the investigator in the hospital for a period of at least 10 years, the copy is given to the participant.

\* Tick by the investigator if you agree

|  |  |
| --- | --- |
| I declare that I have provided the necessary information regarding this study (the nature, the purpose, and the foreseeable effects) orally and a copy of the information document to the participant. |  |
| I confirm that no pressure has been exerted on the participant to allow him/her to participate in the study and I am prepared to answer any additional questions. |  |

Tick by the witness/interpreter if agreed

|  |  |
| --- | --- |
| I was present during the entire information process and I confirm that information about the aims and procedures of the study was given appropriately, that the participant understood the study and that consent to participate in the study was given voluntarily. |  |
| Name, first name and qualification of the witness/interpreter | Signature | Date |