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 retrospective study which requires your explicit consent as data is transferred to a country outside the European Economic Area (EEA). A retrospective study is a study based on data from the past that are contained in existing patient records, medical records, administrative records or files and in which no new data relating to these participants are obtained by any means. Please take sufficient time to read this information letter carefully and to ask questions if there are any ambiguities or if you would like additional information. Once you have decided to participate in the study, you will be asked to sign the consent form at the back.

# description and purpose of the study

You are/were treated by us in the context of your disease xxx *(specify if possible)*.

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

We wish to inform you that we want to use data in your medical file for this scientific study. In particular, we are interested in the following information: xxx *(enter the information that will be collected here)*.

This study was evaluated by the Ethics Committee of University Hospital Ghent and University Ghent. The retrospective 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 retrospective study (for which your explicit consent is needed since data is transferred to a country outside the EEA) is entirely voluntary. You can refuse to participate and you can withdraw your consent for this data transfer 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 will be accessible only to the investigor/treating doctor or his/her appointed substitute.

Only pseudonymized 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.

Since your data has to be transferred to a country outside the European Economic Area (EEA) that does not offer an adequate level of protection, U(Z) Ghent itself will enforce adequate guarantees by means of model agreements, made available by the European Commission, or other accepted measures. The processing of your data is based on consent, as mentioned in GDPR article 6, paragraph 1(a).

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.

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

# Contact

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:

Name:

Address:

Telephone number:

**INFORMED CONSENT FORM FOR THE PARTICIPANTS**

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| 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 understand that participation in the retrospective study (for which my explicit consent is needed since data is transferred to a country outside the EEA) is voluntary and that I can withdraw my consent for this data transfer 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 retrospective 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. |

Tick by the participant if you agree

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| --- | --- |
| 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. |  |

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| --- | --- | --- |
| 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

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| --- | --- |
| 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. |  |

Aankruisen door de getuige/tolkindien akkoord

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| Ik was aanwezig tijdens het volledige informatieproces en ik bevestig dat de informatie over de doelen en procedures van de studie op de juiste manier werd gegeven, dat de deelnemer de studie begrepen heeft en dat toestemming voor deelname aan de studie vrijwillig is gegeven.  |
| Naam, voornaam en hoedanigheid van de getuige/tolk | Handtekening | Datum |