Information sheet for participants (≥18 years) to a clinical study

**Title of the study:** **Enter the simple title of the study here**

Official title: Enter the official title as stated on the protocol

EudraCT-number: Please complete the EudraCT-number of the trial

Sponsor of the study: Universitair Ziekenhuis Gent *OR* Universiteit Gent

Dear,

You are invited to participate in a clinical study to evaluate an experimental drug for the treatment of your disease. An experimental drug is a drug that is still under investigation to assess its efficacy, safety or mechanism of action. Before you decide to participate in this study, take sufficient time to read this information sheet carefully and discuss this with the 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 participating in a clinical 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.

# What is the purpose of this study?

We invite you to participate in a clinical study on study drug treatment.

This is a randomized/blind/open/crossed/study that compares the study drug with the current standard treatment/with a placebo.

The sponsor of this study is xxx. Students from the department xxx will be part of the research team.

# what does participation in the study includes for you?

As part of your participation in the study and taking into account your medical situation, part of the visits and examinations that we describe will be part of the standard care in our hospital while others are necessary for the study.

Give a description of the study and the treatment here.

Describe here the aspects of the study that are experimental.

# How many participants will be included in this study?

A total of xxx (state the expected number of participants in the study) children/young adults will participate in this study. Xxx participants will be included in Belgium.

# WHAT IS THE DURATION OF THIS STUDY?

The expected total duration of the study is xxx (describe here the expected number of days/weeks/months/years that the study will last for a participant).

Your participation in the study includes xxx extra visits compared to treatment without participation in the study.

# What is expected from you?

If you decide to participate in this study, we ask you to cooperate with the doctor-investigator and that you follow his/her instructions carefully. In particular, we ask you to respect the planned study appointments.

It is important that you respect the items mentioned below:

# WHICH procedures WILL be performed in the context of the study?

## Procedures:

Please describe the procedures, activities or examinations that will be conducted during the study (e.g. ECG, blood pressure measurement, blood test, questionnaires...). Also mention the procedures that will be performed during screening.

In total, approximately xxx (enter here the total amount of blood (in ml) that will be taken during the study, including for screening) ml of blood will be taken specifically for the study.

## Study progress:

If you decide to participate in the study and if all the conditions for participation are met, you will need to undergo the following tests and investigations:

Please give a schematic overview of the procedures that will be carried out during the study, including screening (per visit, per group...).

## Collection of biological samples:

Describe the path that the collected human body material will follow (storage, locations, destruction, dispatch to another center...).

If human body material is stored, include the following clause: Your samples collected and analyzed in the context of this study will be pseudonymized after collection. You remain the "owner" of your human body material. This means that you can always ask that your stored samples are destroyed by the biobank. In that case you should contact the responsible investigator of the study at UZ Ghent, who will then ensure that the stored body material is destroyed.

A result accidentally found during the study and on top of the objectives of this study is called an “accidental find”. If this result may be important for your health or that of your blood relatives, the sponsor will inform the investigator. The investigator will inform you and your treating doctor of the results and their possible consequences. If necessary, the investigator and/or your treating doctor will advise you on what to do. If you **do not wish to be informed** about this, you can tick this box on the consent form. However, your treating physician will always be informed about this.

# WHAT ARE YOUR RIGHTS WHEN PARTICIPATING IN THIS STUDY?

## Your rights when participating in the study

Participation in this study is entirely voluntary; there can be no coercion of any kind. You can refuse to participate in the study and you can withdraw from the study at any time without having to give a reason and without this affecting in any way your treatment or future relationship with the investigator or treating doctor. This will also not have a negative impact on the quality of care and your future follow-up.

Your participation in this study will be terminated if the doctor believes that this is in your interest. You may also be withdrawn prematurely from the study by the investigator if you don’t follow the procedures described in this information sheet properly or if you don’t respect the items described.

If you are withdrawn from the study, the pseudonymised data already collected will remain in the database for analysis, but no new data will be added. If you leave the study prematurely, you will be asked to come to the study center for a final evaluation.

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. Under no circumstances should you take the favorable opinion of the Ethics Committee as an incentive to participate in this study.

## Rights in relation to the processing of your 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 7).

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 25 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

A description of the study will be available on https://www.clinicaltrialsregister.eu/ and/or https://www.Clinicaltrials.gov. You can visit this information at any time both during and after the study, using the official study title name given on the front page of this information sheet. The website will not include information that can identify you and a summary of the results will be included within 1 year after the end of the study.

# 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 – policy number for UZ Ghent BEL001889 – policy number for UGhent BEL000862). If the investigator believes that a link with the study is possible (the insurance does not cover the natural progression of the disease or the known side effects of the normal treatment), he/she will initiate the declaration procedure to the insurance company. At that moment, your details can be passed on to the insurer.

In the event of disagreement either with the investigator or with the expert appointed by the insurance company as well as whenever you deem it useful, you or – in the event of death – your dependents may bring proceedings against the insurer directly in Belgium (Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00).

# WHAT ARE THE RISKS AND EXPECTED BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study will probably not give an immediate therapeutic benefit for you. However, your participation in the study can serve to better help patients in the future.

What are the expected risks and benefits for the participant through participation in the study? If no benefit is expected, this must also be clearly mentioned.

It is also possible that other risks and side effects occur that are currently unknown. It is therefore of great importance to report every new health complaint to the doctor-investigator as soon as possible, regardless of whether you think the complaint relates to the study or not.

Which alternative procedures or treatments are available, and what are the important potential benefits and risks involved.

You have the right to ask questions at any time about the possible and/or known risks of this study. If information comes to light during the course of the study, that could affect your willingness to continue your participation in this study, you will be notified. If you do experience any disadvantage as a result of your participation in the study, you will receive an appropriate treatment.

# ARE COSTS ASSOCIATED WITH YOUR PARTICIPATION IN THIS STUDY?

There are no additional costs if you participate in this study.

Describe here the expected costs associated with participation in the study for the participant (if applicable).

# IS there A REIMBURSEMENT FOR PARTICIPATION IN THIS STUDY?

Mention here the reimbursement that is provided for participation in the study (e.g. voucher, expense...) (if applicable).

# TO WHOM you can turn IN CASE OF PROBLEMS OR IF YOU HAVE ANY QUESTIONS

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:

Hospital:

Address:

Telephone number:

**The emergency phone number, available 24/7, is XXXXX.**

If you would like more information about your rights, you can contact the **hospital mediator**:

XXX at the following telephone number: XXX or by email XXX.

**INFORMED CONSENT FORM FOR PARTICIPANTS (≥18 YEARS)TO A CLINICAL STUDY**

|  |  |
| --- | --- |
| Reference number of the participant for this study |  |

|  |
| --- |
| I have read and understood the document “Information sheet for participants (≥18 years) to a clinical trial” page 1 to 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, the foreseeable effects of the study and what is expected of me. I have been informed about the possible risks and benefits of the study. I have had the opportunity and sufficient time to think about it and to discuss it with a person of my choice. I have had the opportunity to ask any question that came to my mind and have obtained a satisfactory response to my questions, also on medical questions. |
| 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 understand that auditors, representatives of the sponsor, the Medical Ethics Committee and the competent authorities may want to inspect my data in order to check the collected information. My privacy will be respected at all times. |
| 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 25 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 academic scientific 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 7). |
| 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 agreed

|  |  |
| --- | --- |
| I agree to participate in this study consisting of the following **mandatory interventions** as explained under section 6 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 :

|  |  |
| --- | --- |
| * I agree that at the end of the study my samples will be transferred to a/will continue to be stored in the prospective research biobank for future scientific research solely in the context of my illness/pathology or treatment. Such a new study must always be submitted and approved by the Ethics Committee |  |

As part of the research on your human body material, you will always be notified of accidental findings. If you do not agree to this, please indicate this here:

|  |  |
| --- | --- |
| I do **NOT** want to be informed by the investigator (or my treating doctor) if my biological samples reveal accidental findings that may be of importance for my health or that of my relatives. |  |

|  |  |  |
| --- | --- | --- |
| 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 25 years, the copy is given to the participant.

\*Tick by the investigator if agreed

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