Information letter for participants to a clinical study

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

Official title: Enter the official title as stated in the research portal or on the protocol

Sponsor: Ghent University Hospital ***OR*** Ghent University

Investigator(s):

U(Z) Ghent: Name, address, telephone number

DPO U(Z) Ghent:

Katya Van Driessche, [dpo@uzgent.be](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=4d168455-8534-4591-850f-10eaa3701ce3) ***OR***Hanne Elsen, [privacy@ugent.be](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=e2c28b99-e7b8-4c46-a10b-e66304bf346f)

No fault insurance: Allianz Global Corporate & Specialty; Uitbreidingstraat 86, 2600 Berchem; Tel: +32 33 04 16 00

# PARTICIPATING IN A STUDY

You are invited to participate in a clinical study (further referred to as “study”). Before you decide to participate in this study, we ask you to read the following pages carefully so you can make an informed decision about it.

If you wish, you may discuss the study with the investigator or his/her representative, or other persons of your choice. Please take the time to ask questions if there are any uncertainties or if you would like additional information.

If you wish to participate in the study, we ask that you sign the enclosed participation form. The investigator (or his representative) will also sign this form, confirming that you have received the necessary information about this study. You will also receive a signed copy yourself.

This document consists of 3 parts: 1) basic information about the study, 2) additional information and 3) the participation form.

# BASIC INFORMATION

We invite you to participate in a study xxx.

## What does participation include and what interventions take place?

If you decide to participate in the study and meet all conditions for participation, a number of interventions will take place as part of this study.

Taking into account your medical situation, the following investigations/appointments will be part of your standard care in our hospital: xxx.

The following interventions take place specifically as part of the study: xxx.

Study questionnaires will be sent to your personal e-mail address.

A total of approximately xxx (enter here the total number of ml of blood that will be drawn additionally during the study, including for screening) ml of blood will be drawn for the study. The blood draws will take place at the following times xxx.

The following points are useful to know if you wish to participate xxx.

For the study to run correctly, it is important that you cooperate with the investigator and follow his/her instructions closely. The investigator will monitor your safety during the course of the study.

## What is the duration of this study and who will participate?

In total, this study will last xxx (enter here the expected number of days/weeks/months/years that the study will last for a participant) for a participant.

Participation in the study includes xxx additional visits to the hospital, in addition to standard visits if you were not participating.

A total of xxx (mention here the expected number of study participants) persons will participate in this study. Xxx participants will be included in Belgium.

## Collection of human samples

Participation in this study will not require an additional puncture, but an additional amount of blood will be drawn during a blood draw that would occur anyway according to standard care.

The human samples will be stored in the biobank (Name biobank; if multicentric study: name biobank from participating center). A biobank[[1]](#footnote-2)is a collection of human body material (such as blood, tissue, urine and DNA) that is stored together with additional health and other (personal) data over a long period of time. These samples and associated (personal) data are collected, processed and stored for scientific research. This is done according to strict rules. The biobank gives scientists access to a large collection of human body material and medical data. Among other things, they can use this for the development of new medicines and treatments.

The biobank will store the samples during the study. At the end of this period your samples will be destroyed. The person in charge of this biobank collection is Prof. Dr. xxx.

You can ask to remove the human samples and associated sample data from the biobank at any time. To do this, it is best to contact the investigator of the study or the biobank. Please know that this request does not affect your contact with the investigator, hospital or biobank. You do not have to tell the reason why you are asking to remove your samples and associated sample data. Results of scientific research prior to this removal request will be retained. All samples collected in this study will be pseudonymised[[2]](#footnote-3).

## Costs and compensation

Participation in this study involves no additional costs for you.

You will not receive any compensation for your participation in this study.

# additional INFORMATION

This study was approved in advance by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University. The study is conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki drawn up to protect people participating in studies. Under no circumstances should you consider approval by the Medical Ethics Committee as an incentive to participate in this study.

Students from the department xxx will be part of the study team.

# *Risks and advantages of participating in the study*

Participation in this study will probably bring no immediate therapeutic benefit to you. Your participation in the study may possibly help patients better in the future.

The chance that you will experience any harm as a result of participating in this study is extremely low.

It is possible that other risks or discomforts may occur that are unknown at this time. Therefore, it is very important to report any new health complaint to the investigator as soon as possible, whether or not you believe the complaint is related to the study.

You have the right to ask questions about the potential and/or known risks of this study at any time. If any information comes to light during the course of the study that may affect your participation, you will be informed. If you do experience any harm as a result of your participation in the study, you will receive appropriate treatment.

# *Your rights*

Participation in this study is entirely free and voluntary. You can refuse to participate in the study and you are free to withdraw from this study at any time, without having to give a reason. Ending your participation will not affect your treatment or continued relationship with the investigator. This will also not negatively affect your quality of care and your continued follow-up.

Your participation in this study will be terminated if the investigator believes that it is to your best advantage. You may also be withdrawn from the study prematurely by the investigator if you do not properly respect the interventions or appointments to be followed.

The information collected during the study is pseudonymised[[3]](#footnote-4).

If you are withdrawn from the study or if you decide to terminate your participation, the pseudonymised data already collected (that is, identifiable only by a unique code) will remain in the database for analysis. No new data will be added in this case. If you leave the study early, you will be asked to come to the study center for a final evaluation.

# *Protection of your personal data*

Participation in the study means that your personal data will be processed for the purpose of this study. This processing of your personal data is necessary for the performance of a task carried out in the public interest and for the purpose of scientific research[[4]](#footnote-5).

Your personal data[[5]](#footnote-6) will be protected at all times. You may request access to the data collected about you. Any data can be corrected at your request. Your other rights (including the right to limit the processing of your (personal) data and the right to submit a complaint) will also be guarded.

For more information about your rights and how to use them, please visit the website of UZ Ghent[[6]](#footnote-7) ***OR*** UGhent[[7]](#footnote-8).

The pseudonymised data collected in this study may be shared with other researchers. Reuse of your pseudonymised data in future academic research can only occur when the research is compatible with the current study. This reuse of data must always be approved in advance by an ethics committee or Data Access Committee.

In case your data would be used for commercial purposes and partners in the context of future research, you must give your consent[[8]](#footnote-9) in the participation form.

In reports or publications about this study (such as in medical journals or conferences), the data will be processed in such a way that you are not directly identifiable as an individual. Also, when the datasets within this study are made public on an online platform, your personal data will not be made public. Your personal data will be protected appropriately.

Both your personal data and sensitive personal data (health data) will be processed and kept within this study for at least 10 years after the end of the study.

The data controller is the institution of the study's principal investigator, Dr. xxx (indicate the study's principal investigator here) (UZ Ghent ***OR*** UGhent). His/her study team will have access to your personal data. The data will be processed for data protection purposes by individuals within the study team, under the responsibility of the principal investigator. This team also includes employees with non-health care professions.

In case your data are transferred to a country outside the European Economic Area (EEA), U(Z) Ghent will verify whether the destination country provides an adequate level of data protection. If that country does not provide adequate guarantees, U(Z) Ghent will enforce adequate guarantees itself, for example, through model agreements. For this, your consent will be requested in the participation form.

When the procedures and or the data collected within the study need to be monitored by representatives of the sponsor, auditors, the Medical Ethics Committee or the appropriate authorities, these parties may have access to your files. These individuals will not violate confidentiality.

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

The Data Protection Officer can also provide you with more information about the protection of your personal data. In addition, you have the right to file a complaint with a supervising authority. In Belgium this is the Data Protection Authority[[9]](#footnote-10).

# *Incidental findings*

During the study, it may happen that we discover new information (“incidental findings”) about your health. If this information may be important to your health or others, the investigator will inform you and your treating doctor of the results and possible consequences. If necessary, the investigator and/or treating doctor will advise what you should do. If you do **NOT** agree to be informed about incidental findings you should tick the appropriate box in the participation form. The investigator/treating doctor will communicate this information in any case where not knowing about it may cause serious harm to your health or that of others.

# *Insurance*

The sponsor provides compensation and/or medical treatment in the event of damage and/or injury resulting from participation in this study. Therefore, insurance has been taken out with no-fault liability[[10]](#footnote-11). If the investigator believes that there is a possible connection to the study (there is no connection to the study in case of injury due to the natural course of the disease or due to known side effects of the standard treatment), he/she will initiate the declaration procedure with the insurance company. At that time, your data may be transmitted to the insurer. In case of disagreement with the investigator or with the expert appointed by the insurance company, you, or in case of death your beneficiaries, can sue the insurer directly in Belgium.

**PARTICIPATION FORM FOR PARTICIPANTS**

|  |  |
| --- | --- |
| Reference number of the participant |  |

|  |  |
| --- | --- |
| I have read and understood the document “Information letter for participants to a clinical study” 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. I have been informed about the nature of the study, its purpose, 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 ask questions about the study and I have had all my questions answered, including 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 or relationship with the investigator. | |
| I understand that representatives of the sponsor, auditors, the Medical Ethics Committee and the competent authorities may want to inspect my data in order to check the collected information. These parties will not violate confidentiality. | |
| I am aware that this study has been approved by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University and that this study will be conducted in accordance with the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, established to protect people participating in studies. This approval should under no circumstances be taken as an incentive to participate in this study. | |
| I have been informed that personal data, including health data, will be processed and kept for at least 10 years after the end of the study. I am informed that I have the right to access and correct this data. Since this data is processed for medical scientific purposes, I understand that access to my data may be delayed until after the study ends. If I want access to my data, I will contact the investigator who is responsible for the processing of the data. | |
| I am aware that my pseudonymised data will be used for the **current** study. | |
| I am aware that my pseudonymised data may be used for **future academic scientific research** compatible with the current study. Such new study should always be submitted and approved by an ethics committee or Data Access Committee. If I wish my data not to be used for future research, I will contact the investigator. | |
| I understand that my family doctor will be informed about my participation in this study. | |
| By signing the participation form, I agree to participate in the study that includes the following interventions:   * xxx * xxx |

Tick by the participant if agreed

|  |  |
| --- | --- |
| I agree to participate in this study consisting of the following **mandatory items**: | |
| * This study requires a data transfer to a country outside the EEA. By checking this box, I give my consent for this. If I do *not* give permission for this transfer, I cannot participate in the study. |  |

I agree to participate in the following **optional items** in the study:

|  |  |
| --- | --- |
| * I agree that my samples will continue to be stored in a biobank after the end of the study for future scientific research compatible with the current study. |  |
| * I agree that my pseudonymised data can be used for commercial purposes. |  |

You will be notified by default of incidental findings. If you do not agree to this, please indicate this here:

|  |  |
| --- | --- |
| I do **NOT** want to be notified by the investigator (or treating doctor) when incidental findings come to light that may be of concern to my health or that of my relatives. |  |

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

2 copies should be completed. The investigator should keep an original for at least 10 years; the participant will also receive a copy.

\*By signing the participation form as investigator

* I certify that I have verbally given the necessary information about the study (the nature, purpose and foreseeable effects) and that the participant has received a copy of the information letter and participation form.
* I confirm that no pressure has been put on the participant to get him/her to participate in the study and show my willingness to answer any additional questions.

|  |  |  |
| --- | --- | --- |
| By signing the participation form as **legal representative**, I certify that I have been informed that I have been asked to make a decision about participation in the study by the person I represent. I am acting in his/her best interest and taking into account his/her possible wishes. My consent applies to all items included in the participation form.  I am also informed that as soon as the clinical situation allows, the person I represent will be informed of his/her participation in this study. He/she will be free at that time to consent to continued participation or to discontinue participation by signing or not signing this participation form. | | |
| Name, first name and relationship of the legal representative | Signature | Date |

|  |  |  |
| --- | --- | --- |
| By signing the participation form as a **witness/interpreter**, I certify that I was present during the entire information process and confirm that the information about the goals and interventions 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 |

1. More information about the biobank can be found at [https://www.uzgent.be/biobank](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=d6ccc14c-c11c-4751-bc17-c17068907b10). [↑](#footnote-ref-2)
2. Pseudonymisation is also called “coding”. This means that your data can be linked back to your personal file via a code. The key to the codes will only be accessible to the investigator or his/her designated representative. [↑](#footnote-ref-3)
3. Pseudonymisation is also called “coding”. This means that your data can be linked back to your personal file via a code. The key to the codes will only be accessible to the investigator or his/her designated representative. [↑](#footnote-ref-4)
4. According to Article 6, paragraph 1 (e) and Article 9, paragraph 2 (j) of the General Data Protection Regulation and the Coordinated Hospitals Act of July 10, 2008. [↑](#footnote-ref-5)
5. In accordance with the Belgian law of August 22, 2002 on patient rights, 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 natural persons with regard to the processing of personal data and on the free movement of such data. [↑](#footnote-ref-6)
6. Go to: [https://www.uzgent.be/patient/gegevensbescherming/u-neemt-deel-aan-wetenschappelijk-onderzoek](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=7af83607-da0b-41e2-b5f1-0ca971a9b83d) [↑](#footnote-ref-7)
7. Go to: https://www.ugent.be/en/ghentuniv/privacy/privacystatement.htm [↑](#footnote-ref-8)
8. This processing of your data is based on consent (as stated in GDPR, Article 6, paragraph 1(a)). [↑](#footnote-ref-9)
9. Contact Data Protection Authority: Drukpersstraat 35 – 1000 Brussels – Tel +32 2 274 48 00 – mail: [contact@apd-gba.be](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=067ba613-487b-4394-9470-037e231d1656) – website: www.dataprotectionauthority.be. [↑](#footnote-ref-10)
10. In accordance with the law on experiments on the human person of May 7, 2004, the Belgian law of May 7, 2017 on clinical trials of medicines for human use, the Belgian law of December 22, 2020 on medical devices and the Belgian law of June 15, 2022 on in vitro diagnostic medical devices (Allianz Global Corporate & Specialty – policy number sponsor UZ Gent BEL001889 – policy number sponsor UGent BEL000862). [↑](#footnote-ref-11)