Information letter for participants

**Title of the study:** **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=1d35c03d-d342-4ae2-b542-789edfdb5ff0) ***OR***Hanne Elsen, [privacy@ugent.be](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=9f52ff71-daa0-4e62-b963-b40d1c7cd8f4)

# PARTICIPATING IN A STUDY

You are being informed of your participation in a retrospective study. A retrospective study is a study based on past data found in existing patient records, medical records, administrative records or files. The study does not collect new data from participants.

Please take sufficient time to read this information letter carefully and to ask questions if there are any uncertainties or if you would like additional information.

This document consists of 3 parts: 1) basic information about the study, 2) additional information and 3) a summary with important information.

# BASIC INFORMATION

We invite you to participate in a study xxx.

Processing personal data as part of retrospective research is part of public interest, with a purpose of improving public health. As a university institution, it is our legal mission to engage in research. Retrospective research is of essential value in this regard.

## Costs and compensation

Participation in this study involves no additional cost to you, but also offers no financial benefit.

# additional INFORMATION

This study was approved in advance by an independent Medical Ethics Committee affiliated with Ghent University Hospital and Ghent University or the Data Access Committee. The retrospective 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.

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

# *Advantages of participating in the study*

Participation in this study will probably bring no medical or other benefit to you. However, the results obtained may lead to new or more efficient methods for the treatment of xxx (vul hier in voor welke pathologie).

# *Protection of your personal data*

Participation in the study means that your personal data will be processed for the purpose of this retrospective 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[[1]](#footnote-2).

Your personal data[[2]](#footnote-3) 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[[3]](#footnote-4) ***OR*** UGhent[[4]](#footnote-5).

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.

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[[5]](#footnote-6).

# Summary

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| I have read and understood the document “Information letter for participants” page 1 to page xxx (enter here the page number of the end of the information letter) and I have received a copy. |
| I understand that processing my personal data as part of retrospective research is in the public interest, for the purpose of improving public health. As a university institution, it is a legal mission to engage in research. Retrospective research is of essential value in this regard. |
| I am aware that this retrospective study was approved by an independent Committee on Medical Ethics affiliated with Ghent University and Ghent University or the Data Access Committee and that this study will be conducted according to the guidelines for good clinical practice (ICH/GCP) and the Declaration of Helsinki, established to protect people participating in studies. |
| 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. If I wish my data not to be used for this study, I will contact the researcher (see contact information page 1). |

1. 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-2)
2. 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-3)
3. Go to: [https://www.uzgent.be/patient/gegevensbescherming/u-neemt-deel-aan-wetenschappelijk-onderzoek](https://zenya.uzgent.be/management/hyperlinkloader.aspx?hyperlinkid=af8ffbcf-7bbb-43f2-840b-15b6e53c9ebb) [↑](#footnote-ref-4)
4. Go to: https://www.ugent.be/en/ghentuniv/privacy/privacystatement.htm [↑](#footnote-ref-5)
5. 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=61ba40b3-810e-4a6e-98ff-37469ccb86bd) – website: www.dataprotectionauthority.be. [↑](#footnote-ref-6)