

Ghent University Hospital privacy statement for scientific research

Protection of the personal data of participants in scientific research

1 General

In addition to patient care and education and training, scientific research is one of the core tasks of Ghent University Hospital.

The main purpose of this privacy statement is to inform you why we process your personal data and what rights you can exercise.

We are responsible for your personal data and we extend this responsibility to everyone who comes into contact with it.

This policy has been drawn up in implementation of EU Regulation 2016/679 of 27 April 2016 on the protection of individuals with regard to the processing of personal data (hereinafter referred to as GDPR) and its implementing laws and decrees.

2 Who is the data controller of your personal data?

Ghent University Hospital, a public institution with its registered office at C. Heymanslaan 10, 9000 Ghent, Belgium and registered in the Crossroads Bank for Enterprises under number 0232.987.862 (hereinafter 'Ghent University Hospital', 'we' or 'us') is responsible for processing your personal data as a participant in scientific research as described in this privacy statement.

Ghent University Hospital is part of Ghent University, a public institution with legal status in accordance with the special decree of 26 June 1999, with its place of effective management at Sint-Pietersnieuwstraat 25, 9000 Ghent, Belgium and registered in the Crossroads Bank for Enterprises under number 0248.015.142.

3 Data Protection Officer

If you would like any further details, please do not hesitate to contact our Data Protection Officer at dpo@uzgent.be. Also, if you feel that the hospital is not or not sufficiently respecting your rights with regard to your personal data, you can always contact the Data Protection Officer to submit a complaint.

You also have the right to submit a complaint to the Belgian Data Protection Authority, Drukpersstraat 35, 1000 Brussels, Belgium and via e-mail to contact@apd-gba.be.

4 Basic principles and terms used in this privacy statement

We apply a number of basic principles when processing your personal data:

- The processing of personal data is always limited to the achievement of the intended objective.
- We strive to process the data accurately and correctly.
- We do not retain your data for any longer than necessary.
- The data will be used in pseudonymised form as far as possible.
- Scientific research can only be started at Ghent University Hospital after the Ethics Committee, which also watches over the protection of personal data and your related rights, confirms it does not object and grants positive advice for the execution of the specific study.
- Ghent University Hospital does not disclose your personal data to third parties, except to the academic sponsor of the research or to another academic research institute, university or university hospital that participates in the research if required, and then always in pseudonymised form.
- Ghent University Hospital also participates in commercial research. This is research in which a commercial company acts as the sponsor and Ghent University Hospital acts as a participating centre.
- In this case, the commercial company concerned will inform you of the use of your data in the context of such commercial research and of the rights you can exercise.

For the avoidance of doubt, a selection of terms used in the privacy policy are defined below:

Personal data: any form of information concerning an identified or identifiable natural person, such as a patient. An identifiable person is a natural person who can be identified, directly or indirectly, in particular by reference to an identification number (e.g. the National Registry Number), name and date of birth, location data, an online identifier (e.g. an e-mail address or an IP address) or one or more factors specific to his/her physical, physiological, genetic, mental, economic, cultural or social identity.

Data concerning health (or 'health data'): personal data that relates to the physical or mental health of a natural person, including data concerning health services provided that give information on the health condition of that person.

Anonymous data: all data that cannot (or can no longer) be linked to an identified or identifiable person and that therefore does not (or no longer) constitute personal data.

Pseudonymised personal data: personal data processed in such a way that it cannot be linked to specific natural persons without the use of additional data, provided that such additional data is stored separately and that technical and organisational measures are taken to ensure that the personal data is not linked to an identified or identifiable natural person. As a result, this is not anonymous data, given the natural person is identifiable after pseudonymisation.

Processing: any operation or set of operations that is performed on personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, protection, deletion or destruction of personal data;

Data controller: a natural or legal person, public institution, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data.

Processor: means a natural person or legal entity, public institution, agency or other body that processes personal data on behalf of the data controller, without being under the direct authority of the data controller.

Patient: the natural person admitted to or treated in hospital.

Patient consent: any freely given, specific, informed and unambiguous expression of will by which the patient or his/her legal representative, by means of a statement or an unambiguous active act, agrees to personal data concerning that patient being processed.

Personal data legislation: means (i) Regulation (EU) 2016/679 of 27 April 2016 on the protection of individuals with regard to the processing of Personal Data and on the free movement of such data and repealing Directive 95/46/EC as of 25 May 2018, (ii) the Belgian Act of 30 July 2018 on the protection of natural persons with regard to the processing of personal data and (iii) any other current or future applicable legislation that relates to or has an impact on privacy and the processing of personal data.

5 Your rights concerning the processing of your personal data

For the avoidance of any doubt, your rights with regard to your personal data are clarified in more detail below.

With regard to the right of access, the right to rectification and the right of deletion, the unrestricted exercise of these rights may be limited. This is because the unrestricted exercise of these rights may seriously impede the achievement of the objectives of the scientific research or render it impossible, create a danger for yourself and/or society or harm the public interest. For example, the right of access and the right of deletion could compromise the integrity and validity of the scientific research. As such, it will not be possible to exercise these rights absolutely if your data is processed in the context of scientific research.

5.1 Right to information

In addition to the privacy statement, researchers will always endeavour to inform you, no later than at the time your personal data is collected, about the purpose of the study, what participation entails for you, which procedures take place during the study, the expected benefits and the risks of participation.

You will receive an information letter and an informed consent form for participation in the study and/or you can find information via the patient portal.

5.2 Right of access and right to obtain a copy

You have the right to know, in accordance with the applicable legal provisions and legitimate exceptions as described above, which personal data we hold about you, what we do with it and why we do so. You also have the right to receive a copy of this information free of charge.

5.3 Right to rectification and completion

If you believe that Ghent University Hospital is keeping incomplete or administrative incorrect data about you in the context of scientific research, you have the right to ask us to rectify or complete this data by simple request and free of charge. With regard to health data, rectification is only possible in consultation with the attending physician or the Chief Physician.

5.4 Right of deletion

If you are of the opinion that it is no longer necessary to keep your data, that there are no legitimate reasons to keep your data or that Ghent University Hospital is processing your data unlawfully, you may ask to have your data deleted. However, in order not to create false expectations, we would like to inform you that in practice, it will rarely be possible to grant a request for erasure.

For various reasons, Ghent University Hospital may be required to refuse your request for deletion. This may be the case, for example, when:

- The attending physician or Chief Physician believes that the retention of your data is reasonably important from a medical or ethical point of view, from the point of view of your life expectancy, from the point of view of defending your legitimate interests or those of your assignees or for reasons of public interest;
- The data is part of an archive kept for the purpose of scientific research and the deletion of your data threatens to make further research impossible;
- The data is necessary for the establishment, exercise or substantiation of a legal claim.

5.5 Right to withdraw your consent at any time

If the processing of personal data is based on your prior consent, you may withdraw this consent at any time. Withdrawing your consent implies that Ghent University Hospital is no longer allowed to process the data concerned.

5.6 Right to submit a complaint to the Data Protection Authority

If you believe you have a complaint regarding the protection of privacy, you may contact the Belgian Data Protection Authority (www.gegevensbeschermingsautoriteit.be) directly at Drukpersstraat 35, 1000 Brussels, Belgium, or via +32(0)2 274 48 00 or contact@apd-gba.be.

6 Which personal data does Ghent University Hospital process and for which purposes?

Below, you can find out which personal data we process for scientific research, on which grounds the processing is carried out, how we process it and who we might share it with.

You have rights that you may exercise in each of these situations.

6.1 Registering medical data for scientific purposes for which Ghent University Hospital is the sponsor

6.1.1 Legal grounds

In academic studies with Ghent University Hospital as the sponsor, the purpose of the study is described in the information letter. The processing of personal data for the purpose of academic research is in the public interest, i.e. to promote the organisation of healthcare with a view to improving public health and explicitly increasing knowledge in the interests of society.

In addition, as a university hospital, we have a legal obligation to carry out research.

The exact purposes for which you provide your informed consent will be defined as part of each scientific study or clinical trial. The request to sign an informed consent form will be in accordance with the applicable legislation and in accordance with the ethical principles applicable to clinical research.

Your consent will be sought for participation in the research, but your consent will rarely be sought for the processing of your personal data in the context of such research, as this processing is necessary to achieve the scientific research objectives.

However, you may exceptionally be asked to consent to the processing of personal data for research purposes. In such cases, you may always withdraw your consent, and you can speak to your doctor in order to do so.

Ghent University Hospital also uses data that is already available as a result of your treatment in hospital (**retrospective study**).

If new or additional information is needed for the conduct of the study, specific data will be collected on the basis of your participation in the clinical study (**prospective study**).

Which personal data?	How do we obtain this data?	How long do we retain your data?	Who do we share this data with?
Data on age, sex and origin	Retrospective: patient care	25 years after completion of the study,	Ghent University Hospital; another academic research institution; the research team; the researcher(s), research monitor and auditor; the Ethics Committee; Data Access Committee; national/international government agencies
Information about your health; medical conditions; medical history	Prospective: specific study data set	or at least 30 years and up to 50 years after last patient contact for data from your patient file	
Treatments and effect of treatments			
Your biological samples			
Your medical images			

6.1.2 What are your privacy rights?

- Right of access and the right to obtain a copy
- Right to alter/rectify your data

These rights apply unless, in case of the processing of data for scientific research purposes, they threaten to render impossible or seriously impede the attainment of specific objectives and derogations are necessary in order to attain the objectives, or they create a danger to yourself and/or to society, or they are detrimental to the public interest.

6.2 Processing of data required in the context of safety reporting by Ghent University Hospital

6.2.1 Legal grounds

Ghent University Hospital is subject to specific legal obligations that may require the processing of your data for the purpose of safety reporting. One example of this is the mandatory reporting of adverse reactions to a (potential) medicinal product to the supervisory authorities.

Which personal data?	How do we obtain this data?	How long do we retain your data?	Who do we share this data with?
Data on age, sex and origin	Retrospective: patient care	25 years after completion of the study,	Public supervisory authorities
Information about your health; medical conditions; medical history	Prospective: specific study data set	or at least 30 years and up to 50 years after last patient contact for data from your patient file	
Treatments and effect of treatments			

6.2.2 What are your privacy rights?

- Right of access and the right to obtain a copy
- Right to alter/rectify your data

These rights apply unless, in case of the processing of data for scientific research purposes, they threaten to render impossible or seriously impede the attainment of specific objectives and derogations are necessary in order to attain the objectives, or they create a danger to yourself and/or to society, or they are detrimental to the public interest.

7 Transfer of your data to a country outside the European Economic Area (EEA)

If your data needs to be transferred to a country outside of the EEA or to an international organisation, Ghent University Hospital will ascertain whether the country of destination offers an adequate level of protection. If the country to which Ghent University Hospital wishes to transfer data does not offer adequate guarantees, Ghent University Hospital will itself enforce adequate guarantees by means of template agreements made available by the European Commission or other accepted measures.

8 Entry into force and changes to the privacy statement

This privacy policy will enter into force on 28 August 2023.

Ghent University Hospital reserves the right to change its privacy policy at any time.

Such changes will be made by the Executive Committee of Ghent University Hospital and, insofar as they concern data relating to health, after the advice of the medical council.

The changes will be communicated on the website of Ghent University Hospital, and reference will be made to the relevant articles where such changes occur.