IQECAD STUDY

INFORMATION LETTER FOR PARENTS / GUARDIAN OF CHILDREN WITH DIABETES, WHO ARE MONITORED IN A RECOGNISED PAEDIATRIC DIABETES CENTRE.

Dear parents/guardian,

Dear Madam, Dear Sir,

Within the framework of the convention on re-education with regard to the self-management of diabetes mellitus in children and adolescents, the diabetes centre where your child receives treatment, is participating in a study for epidemiological purposes, in order to improve the quality of care.

This study is called **IQECAD**, which stands for "Initiative for quality improvement and epidemiology among children and adolescents with diabetes". Every diabetes centre recognised by the Belgian National Institute for Health and Disability Insurance "INAMI/RIZIV"[1] is participating in the IQECAD.

The **IQECAD** has existed since 2008, and collects medical information on patients who have diabetes (<18 years old) and who are being monitored by diabetes centres in Belgium recognised by the INAMI. It is being run by Sciensano, rue Juliette Wytsman 14, 1050 Brussels, which, with the RIZIV-INAMI, fulfil the role of data controller.

We need your authorisation (in accordance with Articles 6 and 7, 1° of the Law of 7 May 2004 on experiments on the human person) in order to record your child's data in the IQECAD and we ask that you read this document before you decide whether to participate.

Why are personal data collected?

The IQECAD is used to support medical research and to improve the quality of care and the treatment of patients. It has a range of objectives:

- To study the epidemiological aspects of the disease;

[1] The IQECAD is part of the convention on re-education with regard to the self-management of diabetes mellitus in children and adolescents (https://www.riziv.fgov.be/fr/themes/cout-remboursement/maladies/endocriniennes-metaboliques/Pages/diabete-intervention-couts-suivi-enfants-adolescents-centre-specialise.aspx#.XVE0XOgzbyQ) agreed between INAMI/RIZIV and the diabetes centres.

- To use the data to improve the quality of care for young patients with diabetes in Belgium;
- To share information concerning the health status and expectations regarding the health of young patients with diabetes in Belgium;
- To make a scientific database available to doctors and researchers who are studying and treating the disease;
- To issue advice to the official health authorities in Belgium.

The collection and processing of data will be done in accordance with Article 9.2.j of the General Data Protection Regulation (GDPR), which provides that the processing of sensitive data, including health-related data, is authorized when this is necessary for scientific research purposes.

How do we work?

The majority of this data comes from your child's medical file and are recorded by their doctor and the care team in the centre where your child is monitored. Data regarding your child well-being come from your child his/herself or you (his/her parents/guardian) via the HD4Patient web application (online questionnaire). During the consultation, the physician can invite your child to fill out the well-being questionnaire through a QR code (on the study information flyer). Data regarding your child well-being will be collected every two years during a period of 7 months. Your child can complete the questionnaire several times. Your child's name will never be communicated within the IQECAD. It is replaced by a code.

Your child's data will be stored for scientific research purposes. This necessitates long-term storage, according to the length of time for which the IQECAD exists. In the event of death, the data will be stored in pseudonymised form for a period of thirty years from the date of death and will then be stored in anonymous form after this thirty-year period.

This applies to the following data:

- The month and year of birth;
- The year of diagnosis;
- Gender;
- Ethnicity;
- Family structure;

- Communication difficulties (language);
- Psycho-social factors;
- Insulin treatment methods;
- The treatment of other diseases, such as coeliac (gluten intolerance) and thyroid conditions;
- Clinical data such as bodyweight, height, blood pressure, HbA1c (= an indicator of the long-term control of blood-glucose levels);
- Screening for nephropathy, coeliac disease or thyroid conditions, eye test, the number of times your child consulted the diabetes centre in the past year.
- Data on child well-being such as psychosocial stress via online questionnaire (5 min to complete).

The child's demographic data (year and month of birth, sex, etc.) can be extracted from the National Register.

Protection of the database

The data recorded is pseudonymised[2] and transferred in an entirely secure manner to the Healthdata.be platform at Sciensano, where they are stored. (For more information go to: https://healthdata.wiv-isp.be/fr/home), rue J. Wytsman 14 at 1050 Brussels. The data is only accessible to people who have been given authorisation. A strict user access management has been implement via procedural and technical measures.

Who has access to the data and how will the data be used?

The Group of Experts, represented by the doctors in the diabetes centres, the scientific collaborators from Sciensano and members of INAMI/RIZIV's college of doctor-directors and representatives of the patients' association always ensure they only collect essential data that could improve the care and health condition of young patients with diabetes. The use of data for a scientific project or another project always requires approval from this Group of Experts and from the data safety committee for Social Security and health information.

[2] Pseudonymisation: the processing of personal data in such a way that they can no longer be attributed to the specific person concerned without the use of additional information, provided that this additional information is stored separately and is subject to technical and organisational measures to guarantee that the personal data are not attributed to an identified or identifiable natural person.

The people or organisations that have access to the data are as follows:

- In the centre where your child is monitored, the doctors and care staff who assist them, have access to all of the data entered into the IQECAD for the patients in their centre.
- The researchers who work for the IQECAD at Sciensano have access to pseudonymised data.
- Researchers working on scientific projects in Belgium or abroad have access to the pseudonymised data (after approval by the Group of Experts and authorisation by the Committee on Information Security Social Security and Health).
- Pharmaceutical companies and health authorities have access to aggregated (grouped) and pseudonymised data (after approval by the Group of Experts and authorisation by the Committee on Information Security Social Security and Health).

Risks

We take every precaution to protect your child's data, but there is always a risk to personal data protection, however minimal that may be. Those responsible for the register, Sciensano rue Juliette Wytsman 14, 1050 Brussels, have therefore taken out a no-fault insurance policy with Ethias SA/NV, with policy number: 04/053 - 45.444.114.

What do we do with this information?

A general report that includes all of the results is published after every (biennial) data collection and this is available on Sciensano's website: https://www.sciensano.be/en/projects/initiative-quality-improvement-and-epidemiology-children-and-adolescents-diabetes

This report contains results from which is it not possible to identify the patients.

Doctors and employees in the diabetes centres also receive an individual report with analyses that enable them to compare their centre's results with those of the other centres with a view to improving the quality of care for patients.

Why is your consent important?

With your consent, we can use your child's data and we will be able to gain an overall picture of the quality of care for children and adolescents with diabetes in

Belgium. That way, any potential lack in the quality of care can be researched and improvements can be made.

Since this study is organised in several diabetes centres in Belgium, it has been approved by the ethics committee of each participating centre. The UZ Ghent's [Ghent University Hospital] ethics committee is the central ethics committee. However, you should not consider the ethics committee's approval as encouragement to participate in the study.

Participation and Rights

There will be no costs associated with participation in the IQECAD for you and your child. Participation in the IQECAD is entirely voluntary. The decision to take part in the IQECAD or not, will not affect the medical care your child receives. If you would like to view or correct your child's data, you can speak to the doctor responsible at the diabetes centre where your child receives treatment.

Nonetheless, this does not prevent you from ending your child's participation in the IQECAD in the future. In that case, no new data will be collected.

The continuity of the IQECAD and the storage of the data it contains are essential to support medical research and to improve the quality of care as well as the treatment of young patients with diabetes. To achieve the set aims of the scientific research, the rights usually provided to those affected by data processing have been waived. Thus, in accordance with the GDPR[3], the Belgian law of 30 July 2018, and the special regime it provides for[4], the following rights cannot be granted to you: the right to erasure, the right to restrict processing and the right to object.

For additional information concerning the protection of your child's personal data, you can consult Sciensano's data protection officer.

Contact details: dpo@sciensano.be

[3] Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016, concerning the protection of natural persons with regard to processing personal data and the free circulation of such data, and repealing Directive 95/46/CE, art. 17, § 3, d), 18, 21 and 89, § 3.

[4] The Act of 30 July 2018, on the protection of natural persons with regard to the processing of their personal data, *M.B.*, 5 Sept. 2018, p. 68616 and s., title 4 (art. 186 and following).

You can also contact or submit a complaint to the Data Protection Authority: Rue de la presse, 35 à 1000 Brussels, contact@apd-gba.be.

The social security and health chamber of the Security of Information Committee has determined, through its deliberation no. 13/093 on 22 October 2013, that the exchange of personal data related to health, within the framework of the IQECAD fulfils the legal and regulatory provisions regarding the protection of privacy. Any use or communication of data recorded in the IQECAD other than those authorised in said deliberation must be submitted again for approval from the sectoral committee.

Validity of Consent

This form that you are signing is valid up to your child's 18th birthday. Once your child turns 18, your doctor will ask him/her to sign a new informed consent form individually.

If the IQECAD project undergoes any important changes, you will always be informed and we may ask you to sign a new consent form.

For more information

You can find information about the IQECAD on Sciensano's website:

https://www.sciensano.be/en/projects/initiative-quality-improvement-and-epidemiology-children-and-adolescents-diabetes.

Should you have any further questions regarding the IQECAD? You can ask your child's care team or contact the Sciensano collaborators (contact person Suchsia Chao, tel: + 32 (0)2 642 50 24 or iqecad@sciensano.be).

Thank you for the attention you are giving to this study and for your and your child's participation.

Prof. Herman Van Oyen

Head of the Epidemiology Section of Sciensano

INFORMED CONSENT FORM - IQECAD STUDY

For patients aged under 12 years old, it is necessary to have authorisation from both parents, from the parent who has legal custody or from your legal guardians. **From age 12 onwards**, it is also necessary to have authorisation from the patients themselves.

Section to be filled out by the person registered and/or their legal representative.

Name of the person registered: _____

(In block capitals, please)

First name: _____

(In block capitals, please)

Date of birth: _____/_____/_____ (day/month/year)

Sex ☐ female

☐ male

Address: _____

_____

I, the undersigned _____, certify that I have been informed adequately, clearly and precisely concerning the objectives of the IQECAD, namely the collection of medical data concerning diabetes and the processing of this data within the context of the objectives stated in the information document. I give my consent for the automated processing of my child's data, collected within this context, on the condition that they are used solely for these purposes. I consent to participate in the:

□ data collection via hospital and national registry

□ data collection via the HD4Patient web application

The General Data Protection Regulation (GDPR) and the Act of 30 July 2018, on the protection of natural persons with regard to the processing of their personal data applies.

Signature of the person registered (if > 12 years old)

Date _____/_____/_____ (day/month/year) .....

Parents' / legal representative's signature (essential if the person registered is under 18 years old)

Surname and first name of parent/legal representative:
.....

Date _____/_____/_____ (day/month/year)

.....

Surname and first name of parent:
.....

Date _____/_____/_____ (day/month/year)

.....

Section to be filled out by the treating doctor

Date _____/_____/_____ (day/month/year)

Surname and first name of doctor:

Doctor's signature
.....
