



EUROGLYCANET

Congenital Disorders of Glycosylation:
a European network for the advancement of research,
diagnosis and treatment of a growing group of rare
disorders.

INFORMATION AND CONSENT

Name of the patient: _____ Date: _____

Name of the relative: _____ Date: _____

EUROGLYCANET

Congenital Disorders of Glycosylation: a European network for the advancement of research, diagnosis and treatment of a growing group of rare disorders.

Description of the concept

We kindly ask your consent

- as a patient,
 to allow the patient of whom you are parent or guardian,
 as a relative to patient _____
(delete where appropriate)

to participate in a study. This study aims to learn more about the actual types of CDG (Congenital Disorder of Glycosylation) and, eventually, discovering new types of this deficiency.

The study is part of a European study incorporating as many CDG-patients as possible. This study is called EUROGLYCANET.

The study depends on both physical examinations, accomplished by the attending physician or specialist, and laboratory tests.

The results of the physical examination will be stored in the EUROGLYCANET database. The data will be controlled in the central computer of the project in Leuven and stored under a code number.

Blood- and tissue samples and cells are saved with a code number as well in order to guarantee the medical confidentiality. Only the attending centre and the database administrator (=study coordinator) know the name related to this code.

These stored samples can be forwarded to a group of scientists doing research for CDG. Each research performed with these samples will be performed after the permission of the appropriate ethical commission, e.g. the Ethical Commission at the Faculty of Medicine of the KATHOLIEKE UNIVERSITEIT Leuven.

It is the study coordinator who, in co-operation with the participating centres and the scientific committee of the project, decides to send samples to the different laboratories for further investigation. Serum samples, DNA samples and cells in culture (if available) are therefore distributed within the network. The movements of the samples are traceable in the database. There are no names or other identifiers, except a code, on these samples. The physician can always consult these centres through the study coordinator for any information about his patient or to add new information or can retrieve the data from his/her patient from the database. This access is personalised and password protected.

You will always retain the possibility to ask for information and to withdraw from the research at any time. You can ask at any time to have the blood-, tissue- or cell samples removed from the collector of samples. For this you can contact the attending physician.

The stored samples can be used later for new research projects, as the future can bring new findings and techniques.

All research data resort under medical confidentiality. If some important and relevant information will become available from the lab research, the attending physician will contact you.

Overview of the data, relevant for the study

1. Your attending physician, who will supply all the relevant data to a local referral centre or to the database administrator, will do the *physical examination*.
2. *Photographing* patients. The possibility exists that photos will be taken from patients in order to illustrate specific characteristics and the evolution in time. The original picture will be stored by the referring physician and copies will be electronically attached to the codified patient's file in the database. They will not contain any identification apart from the code number in case of publication. The patients will be unrecognizable. If the photos can be useful for scientific or medical publications, your consent will be needed before any distribution.
3. *Clinical database*: to guarantee the anonymity, all research data are sent to the central database in Leuven, for coding. A code number is automatically allocated after input in the central database. Only the study coordinator, assisted by the administrative officer, who is also the database administrator, has the complete list of names and corresponding codes at his/her disposal. This allows the study coordinator to inform the referring clinicians and hence, the patients, about clinically relevant results. It also allows the study coordinator to avoid duplications in the database.
4. *Samples*: all samples are collected in consultation with your attending physician and in accordance with the requirements of good medical practice.
5. *Biochemical and genetic analysis*: the samples will be stored in Leuven or in one of the reference centres, provided with a code number. The key to unlock the code is only known to the reference centres and by the study coordinator. The biochemical and genetic analysis can be done in one of the participating centres. It is possible that an abnormality or defect that explains the disease is found. The initial diagnosis can then be confirmed to the patient.

It is possible that other enzymes or genes, possibly of interest to the way the defect is manifesting, will be studied as well. These results are stored and not communicated to anyone without your explicit consent. You have the opportunity to be informed about eventual important results and to have them communicated to your attending physician.

Alternatives

Not participating at the study has NO influence on the medical care offered to you at our department.

For those participating in the study, it is possible that researchers may contact you with information about the results of a study, if the study has significant implications to the health of your child.

Medical care for problems sustained from the study

If the patient suffers from physical injuries caused by the study, the related medical costs will not be charged.

CONSENT (ATTENDING PHYSICIAN)

I have explained to _____ what EUROGLYCANET stands for and what the purpose of this study is. I have given the best possible answers to all questions. I have given a copy of the Informed Consent form to the parent/guardian.

Date

Name and signature of **ATTENDING PHYSICIAN**

CONSENT (PARENT OR GUARDIAN)

I am informed properly about the study and the possible benefits and disadvantages. I hereby give my consent to have patient _____ participating in this study. I know that the coordinator can be reached on the number 00-32-16-34 6070 and that he will answer all my questions about the study. I know that I can cancel this consent and that I can withdraw the patient from the study at any moment. The medical care of the child will not suffer from this decision. I have a copy of this informed consent form.

I know that the blood, tissue or body fluid collected during this study will only be used for scientific research and that I will not receive money or other forms of compensation for the collection and the use of this. I am aware that new products might be developed and commercially sold as a result of the research done and that I will receive no economic benefit from this.

READ AND AGREED

Date

Signature of **ADOLESCENT or ADULT PATIENT**

Name of adolescent or adult patient _____

Address of adolescent or adult patient _____

READ AND AGREED

Date

Signature of **PARENT or GUARDIAN**

Name of parent or guardian _____

Address of parent or guardian _____

READ AND AGREED

Date

Signature of **WITNESS**

Name of witness: _____

Address of witness: _____

Communicating information resulting from blood tests or genetic tests.

Please mark if you prefer to be informed about the results of the blood tests or the genetic research that might be of any interest to the patient and his/her family.

- I prefer to be informed about the results of the blood tests or the genetic tests carried out on the blood or tissue of patient _____ and which can be important for the health or for genetic advice.
- I prefer not to be informed.

(Delete where appropriate)

READ AND AGREEED

Date

Signature of **ADOLESCENT or ADULT PATIENT**

Name of adolescent or adult patient

Address of adolescent or adult patient

READ AND AGREEED

Date

Signature of **PARENT or GUARDIAN**

Name of parent or guardian

Address of parent or guardian

READ AND AGREEED

Date

Signature of **WITNESS**

Name of witness:

Address of witness:

Form for donation of samples.

EUROGLYCANET

Name of patient _____

I voluntarily consent to donate blood, tissue or body fluid to the Centre for Human Genetics. I favour all rights on these samples to the researchers of the EUROGLYCANET project.

READ AND AGREEED

_____	_____
Date	Signature of ADOLESCENT or ADULT PATIENT
Name of adolescent or adult patient	_____
Address of adolescent or adult patient	_____

READ AND AGREEED

_____	_____
Date	Signature of PARENT or GUARDIAN
Name of parent or guardian	_____
Address of parent or guardian	_____

READ AND AGREEED

_____	_____
Date	Signature of WITNESS
Name of witness:	_____
Address of witness:	_____

Form for the use of pictures in the database and in publications.

EUROGLYCANET

Name of patient _____

I voluntarily consent that clinical pictures will be shared among the researchers and doctors involved in the study, for advice and discussion.

I consent with the publication of clinical pictures.

READ AND AGREED

_____ Signature of **ADOLESCENT or ADULT PATIENT**

Date _____
Name of adolescent or adult patient _____

Address of adolescent or adult patient _____

READ AND AGREED

_____ Signature of **PARENT or GUARDIAN**

Date _____
Name of parent or guardian _____

Address of parent or guardian _____

READ AND AGREED

_____ Signature of **WITNESS**

Date _____
Name of witness: _____

Address of witness: _____
