

**PATIENT CASE CONSENT FORM
CASE DATABASE FOR INHERITED METABOLIC DISEASES (CDB-IMD)**

To [---] / the legal representatives of:

Name:

Date of birth:

Sex:

Dear Madam / Sir [---],

You / your child has been diagnosed with a rare Inherited Metabolic Disease (IMD). Doctors are often not well trained about rare diseases and so it may be difficult for them to recognize the symptoms of a rare disease. This is unfortunate since early recognition of a disease is optimal for patients / families to learn about the cause of medical issues, to find out if family members may be at risk for getting sick, and when possible, to access effective therapies.

We want to educate doctors to more quickly recognize rare diseases, like the one in you / your child. That is why we want to include a description of your illness/your child's illness in an international digital database of rare IMD cases that will be available to health care providers and trainees in the field.

We hope that by reviewing you / your child's medical history, other physicians will recognize the same symptoms in another patient in a more timely fashion.

In this letter, we are asking your permission to include information about your / your child's medical history in the database. Personal information, such as name, date of birth, place of residence, will not be shared. However, your / your child's IMD may contain certain information that is unique to you / your child, and it is possible that a user of the database will recognize your / your child's case based on this information.

If you consent to share your / your child's medical history, we kindly ask that you review and sign the consent form attached to this letter and return it to your physician.

After having signed the consent form, if you decide that you wish to withdraw your / your child's case from the Case Database, you may do so at any time and without providing a reason; please notify your physician to have this done. Your decision to participate or not to participate in this initiative, or to remove your / your child's case from the database will have no bearing on your / your child's care.

If you have any questions or concerns about this letter or about the attached consent form, please ask your doctor. Your doctor can be reached via: [enter telephone number and / or e-mail address].

Thank you in advance for your cooperation,

Dr. Irene Körver-Keularts, laboratory specialist clinical chemistry EMZ, MUMC+

Dr. Klary Niezen-Koning, laboratory specialist in clinical genetics, UMCG

On behalf of the CDB-IMD Committee

.....

your treating doctor (name of doctor)

DISCLAIMER

This form is intended as a basic text in which you inform the patient and / or his legal representative (s) about the submission of the medical history of the congenital metabolic disease in question to the international database, as well as about the structure of the database, the way in which the data is used and the possibility that a given consent can be withdrawn and the medical data will then be removed from the database. The concept of the information letter to which this form is attached can serve as a starting point, but sending / handing it over to the patient is insufficient to guarantee an informed consent.

Please share the information about the processing of the data in the database as factually as possible and in the simplest possible language. Based on this information, a prospective participant can make an informed and formal decision regarding disclosing his / her medical history to the database available only to physicians. For additional support and customization, please contact Dr. Irene Körver-Keularts (06-30702855) or Klary Niezen-Koning (06-25650024).

The information letter and this informed consent have been drawn up under Dutch law. If the patient in question falls under a different jurisdiction, it is important that the care provider in question guarantees that the informed consent complies with the laws and regulations that apply to the treatment relationship.

* Remove this disclaimer block from your informed consent form

*INFORMED CONSENT FORMULIER

Name database	CDB-IMD Database
Goal database	<p>By including a large variety and number of cases of inherited metabolic diseases in the Case Database, the CDB-IMD founders hope that users of the database will recognize and identify these conditions in undiagnosed patients more efficiently and in a more timely fashion.</p> <p>Only doctors and their trainees affiliated with a (medical) institution that has access to the database will be able to consult the aforementioned medical information.</p> <p>* See an illustration of the database on the last page of this form</p>
Confidentiality of data	<p>Your personal data will remain protected. Apart from the age, no personal data relating to your or your child will be included. In this way, the case is de-identified. No information will be shared with any other commercial or other interest.</p>
Potential inconvenience	<p>We cannot rule out the possibility that a user of the Case Database will recognize the unique features of your / your child's case and trace the information back to you / your child.</p>
Financial compensation	<p>You will not receive any compensation for making your / your child's medical information available to the database.</p>

Voluntariness	Participation in the Case Database project by sharing the information about your / your child's inherited metabolic disease is entirely voluntary. You can refuse to participate, and even after providing consent to participate, you can then remove that consent and have the case removed, if you wish and without providing a reason. Your decision to participate or not to participate in this initiative, or to remove your / your child's case from the database, will have no bearing on your / your child's care.	
Consent statement	By signing this form. you indicate that you are a patient with an inherited metabolic disease, and / or that you are the legal representative (s) of a minor child with such a disease; that you are well informed about the purpose of the database and the way in which the data are to be collected and used; that you are aware of the possible inconvenience you / your child may incur by giving permission and; that you and / or your child are giving permission to the Case Database to include your / your child's medical information. You will receive a copy of the signed form on request.	
<u>Patient data</u>		Signature
Name patient	[fill out patient name]
Name of legal representative(s) underage patient Consent of patient and legal representatives required if patient is between 12 and 16 years old.	[name of legal representative 1] NOTE: Parents with authority are the legal representative of the minor patient. If parents do not have authority, then the guardian must sign and only one parent has the authority to sign / consent only!
	name of legal representative 2
Date en place	[please fill out]	
Name medical doctor/medical professional	[name]
Date and place	[Invullen]	