Template No. 13: Informed consent (English)

INFORMATION LETTER FOR PARENTS

Patient Number: _____

Identification and treatment of gait disorders in children and adolescents with Dravet syndrome – Gait in Dravet

You are invited to voluntarily participate in a clinical research study about the evolution of gait pattern in Dravet syndrome. Before you agree to participate, it is important that you read this information.

This information and consent form explains the purpose of the study in which you are participating. The assessments, benefits, risks and discomforts from this study, as well as alternatives and your right to end your participation at any time are described below.
No promises can be made nor guaranteed about the results of this clinical research study. You have the right to ask questions about the study at any time.

Purpose and description of the study
This study is a clinical research study with the goal to come to optimal treatment of gait deviations in children and adolescents with Dravet syndrome based on thorough identification of gait deviations in this population.

This is mainly an observational study, meaning that no intervention will take place. We are observing the movements of your child. When, based on these results, the research team and physicians find that your child might benefit from assistive devices, they can be clinically recommended.

Sponsor of the clinical study
The study is sponsored by the *Faculty of Medicine and Health Sciences*, University of Antwerp.

Duration of the clinical study
You will be asked to participate *annually* until 2020, the year the study ends. Assessments take place in the gait laboratory of the University Hospital of Antwerp, M2OCEAN.

Investigations as part of the clinical study
If you decide to let your child participate and (s)he fits all inclusion criteria of the study, following assessments will be carried out.

First, you will be asked about the mobility of your child at home. We will also ask you to fill out a questionnaire on this topic (the MobQues28)

Second, some body measurements will be taken: Body weight, body height and leg length. Small reflective markers will be put on the skin (with adhesive skin friendly tape). Electrodes and probes will be put on specific muscle groups to measure muscle activity. Your child will be encouraged to walk forth and back on a walk way. To ensure a child friendly way of examination, the children will be given small tasks (i.e. collect building blocks). You can take place at the end of the walkway to encourage and support your child.

At last, a physiotherapeutic examination of 30-45 minutes will be carried out to map the movement possibilities of your child.

The total assessment has a duration between 2-3 hours, depending on the walking capacities and the need for breaks in between.

Voluntary participation

Your child's participation is completely voluntary and you have the right to refuse participation. Your decision to participate does not influence your right to stop your participation at any time during the study.

If you agree to participate, you will receive this information leaflet to keep and you will be asked to sign the adjacent consent form.

The study physician can end your participation at any time, even without your consent for following reasons:
- your child is not capable to sufficiently understand the instructions;
- further participation appears to be harmful for you or your child;
- it is later discovered that your child does not meet the inclusion criteria;
- the sponsor ends the study in general or in this specific centre due to other, at this moment unknown reasons.

You have the right to end your participation at any time, without stating a reason, even after signing the informed consent. Resigning your consent will have no influence or loss of benefits. Your decision will not influence the medical care of your child.

Risks and discomforts
The risks for you and your child are minimal. All members of the research team are well trained and experienced in gait analysis and working with children.

Benefits
The ultimate goal of the study is to elaborate an adequate, evidence based treatment to attenuate and if possible prevent gait deviations in children and adolescents with Dravet Syndrome. If, based on the results of your child's assessments your child might benefit from assistive devices, the treating physician will discuss this with you.

Insurance
If your child or entitled parties (family) experience damage as a result of this study, this damage will be refunded by the sponsor of this study according to 'Wet inzake experimenten op de menselijke persoon van 7 mei 2004'. You don't have to prove an error was made. The sponsor has a civil liability insurance that covers these risks and possible damage as a result of this study.

Refund
Travel expenses as a result of this study are only refunded if the assessments do not take place as part of a clinical consultation at 'Child Neurology'. Parking costs will be refunded, if you travel by car to UZA. Your child will be rewarded for his/her effort with a small gift from our surprise box.

Privacy
The identity and participation of you and your child in this study is treated strictly confidential. You or your child will not be recognizable by name or any other way in files, results or publications regarding this publication.

The information about your child will be electronically or manually processed and analysed to define the results of this study. A unique code will be administered so that your child can not be identified in the study. You have the right to ask the study leader which data are gathered concerning your child and to what purpose. You also have the right to see the personal information about your child and to correct if necessary. The protection of privacy is legally defined by 'de wet van 8 december 1992 betreffende de bescherming van de persoonlijke levenssfeer'.

If you agree to participate in this study, you also agree to the use of coded medical information about your child as described above for the purposes and to the persons or institutions above.

Videos that are made of your child are kept during the duration of the study. They will be scored by an investigator and this scoring will be coded. Video and gait reports will be handed to your treating physician and kept in your childes medical file for clinical use. They will not be stored by the investigators.

Ethical committee
This clinical research study is evaluated by an independent ethical committee, i.e. Committee for Medical Ethics UZA-UAntwerp (CME).

Contact in case of questions
If you think that you or your child suffered damage related to this study or if you have questions about the study or your rights as a participant, now or during participation, you can contact:

Research leader:

Prof. Dr. Berten Ceulemans
Universitair Ziekenhuis Antwerpen
Dienst Neurologie-kinderneurologie
Wilrijkstraat 10
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Gait analysis responsible:

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Informed consent

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Part for patient or legal guardian:

I, *(name and surname)*_____hereby confirm as parent or legal guardian of _____ *(name & surname)* born at _____ that I was informed and received the Patient information and written informed consent.

I have read the foregoing information, or it has been read to me. I was offered enough information concerning the requirements and the duration of the study, and the effects and side effects of the assessments. I was given enough time to consider the information and I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

- I understand that my child will be annually invited for the investigation
- I understand that my child is allowed to stop the participation in this study at any time after I informed my physician about it, without this doing any harm to my child.
- I give permission to those responsible for the sponsor (*Faculty of Medicine and Health Sciences, University of Antwerp)* and to the regulatory authorities to inspect the patient files of my child. Medical information will be kept strictly confidential.
- I am aware of the goals for which this information will be collected, processed and used in the context of this investigation
- I agree with the collection, processing and use of this medical information, as described in the information letter for parents.
- I agree with the use by the sponsor of this coded medical information for other research purposes.
- I consent voluntarily to let my child participate in this study and to cooperate in all requested assessments
- I am willing to provide information concerning the medical history of my child, the drug use and possible participation in other studies.
- I agree that my physician and other health care providers involved in my treatment can be notified of my participation in this study.

Date: _____

Signature patient or legal guardian:_____

Part for the research team:

I _____ (name of the investigator) hereby declare that I informed _____ _____ (name of the patient, parent or legal guardian) and that he/she gave permission to participate in the study.

Date: _____

Signature: _____