Official Title of the study:

A Multifaceted Assessment of Eating Behaviors, Anthropometric Measurements and Body Composition in Pediatric Patients With Drug-resistant Epilepsy on a Ketogenic Diet and Healthy Children

Date 08.07.2026

INFORMATION FOR THE PARENT OF A MEDICAL EXPERIMENT PARTICIPANT

Title of the medical experiment: " A Multifaceted Assessment of Eating Behaviours, Anthropometry Measurements and Body Composition in Paediatric Patients With Drug-resistant Epilepsy on a Ketogenic Diet and Healthy Children."

Name of the researcher: mgr Katarzyna Gołąbek

Dear Sir/Madam,

Your child has been asked to take part in the above-mentioned medical experiment. Before giving consent, please read this "Information Sheet" carefully and make sure you understand it. The researcher will clarify any doubts if needed. If you decide that your child will take part in the above-mentioned experiment, you will be asked to sign the "Informed Consent Form for participation in the study." You may also withdraw your child from participation at any time, without giving a reason and without any consequences.

I. Purpose of the study and full plan of the medical experiment

The purpose of the study is to compare the eating habits of healthy children with children suffering from epilepsy, including drug-resistant epilepsy treated with a ketogenic diet. The researchers want to determine whether the therapeutic diet, or the illness itself, may influence the occurrence or change of children's eating habits.

Study plan:

1. Assignment of a code and recording of your child's age. Performing painless measurements of weight (scale) and height (stadiometer).
2. Completion of 4 survey forms by you together with your child and a dietitian.
3. In healthy children, explanation of the procedure and performance of a resting metabolic rate measurement using a calorimeter.
4. A brief dietary consultation, and answers to any questions.

II. Course of the study, scope and duration of the procedures to be used, in particular any burdens and health risks for the participant associated with participation in the experiment

Completing the survey forms with your child and the dietitian will take approximately 15–20 minutes. The resting metabolic rate measurement takes about 10 minutes and applies only to healthy children. It involves lying down and breathing through a mask at an appropriate pace. It is performed using a Fitmate WM calorimeter (COSMED), with a mask fitted appropriately for the child's age. The test will be conducted in your presence. The study poses no health risks to the child. Breathing through the mask for 10 minutes may only be uncomfortable. However, to reduce discomfort during the

test, your child may listen to music or watch a screen. You may speak to/soothe your child during the test. The child must not move or talk during the measurement.

III. Risks associated with participation in the medical experiment

For healthy individuals, the study carries no risk; it may only be uncomfortable. The survey portion of the study carries no risk.

IV. Benefits of participation in the experiment

At the end of the study, you and your child will receive a free dietary consultation regarding eating habits. Additionally, parents of healthy children will learn their child's resting metabolic rate, which is important for correctly determining caloric requirements.

V. Arrangements for responding to adverse events, as well as participant questions and concerns

The study may be discontinued by you or your child at any point. Both the child and the parent may remove the mask independently without any harm to health. The measurement attempt may be repeated several times. Before the test begins, the child will be introduced to the mask and the measuring device, and will be able to practice breathing through it to become accustomed to it. You and your child may ask questions at any stage of the study process.

VI. Measures taken to ensure respect for the participant's private life and confidentiality of personal data

The data obtained will be anonymized and stored securely. The data obtained will be used only for scientific purposes. The study will be conducted only with your consent and your child's consent, expressed at every stage.

VII. Rules for access to information relevant to the participant, obtained during the course of this experiment, and to its general results

At the end of the study, you and your child will be informed of the results, so that you can obtain as much relevant information as possible about your child's health status and eating habits.

VIII. Any anticipated further use of the results of the medical experiment, data, and biological material collected during it, including use for commercial purposes

The data obtained will be statistically analyzed and used solely for the preparation of scientific publications.

IX. Rules for compensation in the event of harm

The study is covered by an insurance policy of the Wrocław Medical University (UMW). If necessary, please contact the researcher, mgr Katarzyna Gołąbek, at phone no. 697405863.

X. Sources of funding for the medical experiment

The study is funded by the Wrocław Medical University.

XI. Rules for access to experimental treatment after the end of participation in the therapeutic experiment, in the event that the experiment proves beneficial to the participant's health (applies to therapeutic experiments)

Not applicable.

XII. Possibilities and rules for access to another therapeutic experiment, if it may bring health benefits to the participant (applies to therapeutic experiments)

Not applicable.

This information is recorded in the experiment documentation.

Date and place information was provided:
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Researcher's name:
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Researcher's signature:
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I confirm that I have read and understood this information, that I had the opportunity to ask questions, and that I received satisfactory answers to all questions I asked.

Name of the study participant:
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Signature of the study participant / legal representative