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 A PARTICIPANT IN A MEDICAL EXPERIMENT WHO HAS TURNED 13 YEARS OF AGE

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 Participant,

You have been asked to take part in the above-mentioned medical experiment. Before giving your consent, please read this "Information Sheet" carefully and make sure you understand it. You have been asked to read this information and give informed consent to participate in the experiment because you have already turned 13, and, in addition to the consent of your parent/legal guardian, you should also decide for yourself whether to take part in this experiment, and should carefully read and understand what your participation involves. You have the right to ask questions at any time and to receive clear and understandable answers. The researcher will clarify any doubts for you if needed. If you decide to take part in the above-mentioned experiment, you will be asked to sign the "Informed Consent Form for participation in the experiment." You may also withdraw 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 eating habits.

Study plan:

1. Assignment of a code and recording of your age on the form. Measurement of your weight and height (painless).
2. Completion of 4 survey forms together with your parent and a dietitian.
3. If you are healthy, at this stage the resting metabolic rate measurement will be explained to you and performed using a calorimeter.
4. A brief dietary consultation, and answers to your 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 forms together with your parent and the dietitian will take you approximately 15–20 minutes. The resting metabolic rate measurement takes about

10 minutes. 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 your age. The test will be conducted in the presence of your parents. The study poses no health risks. Breathing through the mask for 10 minutes may only be uncomfortable. However, during the test you may listen to music or watch a screen. Your parent may also talk to you or hold your hand. During the 10-minute test, you must not move or talk.

III. Risks associated with participation in the medical experiment

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

IV. **Benefits of participation in the experiment**

Taking part in the study will let you learn your resting metabolic rate, which determines your true caloric requirements. In addition, you will receive a free dietary consultation regarding your eating habits.

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

The study may be discontinued at any point. At any time, you may remove the mask on your own without any harm to your health. The measurement attempt may be repeated several times. Before the test begins, you will be introduced to the mask and the measuring device, and you will be able to practice breathing through it to become accustomed to it. You 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 the consent of the participant and the parents, 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, the participant will be informed of the results, so that they can obtain as much relevant information as possible about their health 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.

XI. [sic] 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 who has turned 13, together with date of birth:
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Signature of the study participant / legal representative