Date: September 30, 2026

PARENTAL INFORMED CONSENT FORM

Pediatric Clinical Research Consent Documentation • Appendix-3 (For Parents / Legal Guardians)

Dear Parent / Legal Guardian,

The scientific study in which your child is invited to participate is entitled **"Evaluation of the Effects of the Carbohydrate Counting Method on Glycemic Regulation, Quality of Life, Urinary Glc4 Levels, and Other Biomarkers in Children Diagnosed with Glycogen Storage Disease Type 1"**. This research protocol is conducted by Specialist Dietitian Şükrü Arman AKSOY as part of his doctoral dissertation within the Department of Nutrition and Dietetics at the Ankara Medipol University Graduate School of Health Sciences.

The primary objective of this investigation is to systematically examine the clinical outcomes of structured carbohydrate counting education on glycemic regulation, health-related quality of life, urinary Glucotetrasaccharide (Glc4) excretion levels, and secondary metabolic biomarkers in pediatric patients aged 2 to 18 years diagnosed with Glycogen Storage Disease Type Ia and Type Ib followed at the Outpatient Clinic of Pediatric Metabolic Diseases, Ankara Etlik City Hospital Children's Hospital. Prior to recruitment, eligible children and their parents or legal guardians will receive comprehensive written and verbal information via this Parental Informed Consent Form and the Pediatric Assent Form.

STUDY PROTOCOL & LONGITUDINAL PROCEDURES

Eligible children and their parents/legal guardians will complete a total of five assessment sessions conducted either in person or via telephone over a cumulative duration of 3.5 months. The second and fifth sessions will be performed face-to-face in the clinical setting, while the remaining three sessions will be conducted via structured telephone consultations. Data collection will encompass general demographic characteristics, clinical and medical status, nutritional practices, and standard anthropometric measurements (height [cm], body weight [kg], and Body Mass Index [kg/m²]).

Clinical Metrics & Surveys

- 24-hour dietary recall records
- Pediatric Quality of Life Inventory
- Carbohydrate Counting Knowledge Level Survey
- Survey duration: ~15–20 minutes

Biological Specimen & Records

- Retrospective review of clinical lab tests from patient records
- Analysis of standard physician-ordered urine specimens
- Collection of a 10 mL residual urine aliquot for external Glc4 quantification

A structured questionnaire requiring approximately 15–20 minutes to complete will serve as the principal survey instrument. Participants and guardians may complete the survey by selecting the designated options or writing answers to open-ended items. The protocol entails no anticipated physical health hazards or invasive therapeutic procedures. All research-related costs and laboratory expenses will be fully covered by the research team. Study monitoring personnel, institutional ethics review boards, and authorized regulatory health authorities may be granted direct access to the participant's relevant medical records for verification; complete data confidentiality will be strictly upheld at all times.

VOLUNTARY PARTICIPATION, CONFIDENTIALITY & ETHICAL PROTECTIONS

Participation in this study is entirely voluntary. Your child possesses the full right to decline participation or withdraw from the study at any time without punitive consequences, prejudice, or compromise of their standard clinical care and dietary consultations. Participation in this research does not involve financial compensation, nor will any costs or fees be levied upon you or your family. Strict confidentiality of all personal, medical, and demographic data will be maintained throughout all phases of the study. If new significant findings emerge during the course of the investigation that may influence your willingness to continue participation, you will be promptly notified.

For further inquiries, detailed clarification, or questions regarding research procedures and participant rights, you may consult the Principal Investigator, Spec. Dietitian Şükrü Arman AKSOY, at any time via telephone at **+90 505 638 54 42** or email at **dyt.armanaksoy@gmail.com**.

Parental / Guardian Consent Affirmation:
I confirm that I have thoroughly read (or have had read to me) the information contained within this Parental Informed Consent Form. The scope, scientific objective, procedural requirements, potential benefits, and voluntary nature of this research have been explained to me in detail, both in writing and verbally, by the investigator named below. I understand that our participation is completely voluntary and that I retain the right to withdraw my child from this study at any juncture without providing justification and without any adverse effect on our medical care. With full comprehension and free of any coercion, I hereby consent to my child's participation in this research study.

PARTICIPATING CHILD

Full Name: .....

Date of Birth: .....

PARENT / LEGAL GUARDIAN

Full Name: .....

Signature: .....

Date: .....

INVESTIGATOR ATTESTATION

I confirm that I have comprehensively explained the purpose, clinical protocol, risks, and procedures of this research to the participant and their legal representative, answered all questions satisfactorily, and obtained written voluntary informed consent.

Investigator: Spec. Dietitian Şükrü Arman AKSOY **Signature:** _____ **Date:** 30 / 09 / 2026

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