Date: September 30, 2026

PEDIATRIC INFORMED ASSENT FORM

Investigational Protocol Assent Form for Pediatric Participants (Ages 2–18) • Appendix-2

Dear Participant,

My name is Specialist Dietitian Şükrü Arman AKSOY. We are conducting a clinical investigation involving pediatric patients aged 2 to 18 years diagnosed with Glycogen Storage Disease Type Ia and Type Ib who are currently followed at the Outpatient Clinic of Pediatric Metabolic Diseases, Ankara Etlik City Hospital Children's Hospital. This study incorporates a structured questionnaire designed to evaluate the clinical impact of carbohydrate counting education on glycemic regulation, health-related quality of life, urinary Glucotetrasaccharide (Glc4) excretion levels, and pertinent metabolic biomarkers. Consequently, pediatric volunteers diagnosed with Glycogen Storage Disease Type Ia and Type Ib who provide assent will be invited to participate. This research seeks to advance scientific knowledge and enhance metabolic management protocols; therefore, your participation is highly encouraged.

Upon granting assent to participate, you will be requested to complete a questionnaire requiring approximately 15–20 minutes. This survey protocol collects relevant data regarding demographic attributes, medical status, dietary and nutritional patterns, glycemic control, and overall quality of life. The study design involves no physical examinations and no venipuncture or blood sampling. Only a single 10 mL spot urine specimen will be required. Throughout the study period, comprehensive carbohydrate counting instruction will be administered. The resulting data will delineate the effects of targeted nutritional education on glycemic parameters, quality of life, urinary Glc4 biomarkers, and metabolic endpoints in this clinical cohort. All findings will be disseminated to the scientific community, and complete confidentiality of personal identifying data will be strictly maintained.

Protocol & Duration	Safety & Burden	Voluntary Autonomy
15–20 min survey, single 10 mL urine specimen, nutritional education.	Non-invasive study; no venipuncture or physical examination involved.	Participation is voluntary. You may withdraw at any time without prejudice.

Prior to making your determination, informed parental/guardian permission is required. Your parents or legal guardians will receive comprehensive disclosure regarding the protocol and must execute formal consent. Participation remains entirely voluntary. Even following provisional assent, you retain the full right to withdraw at any stage without prejudice to your ongoing medical and nutritional care. If you have any inquiries regarding the research protocol, you are encouraged to consult the investigator directly at any time using the contact details provided below.

If you agree to take part in this study, please complete the assent affirmation below and provide your signature. A signed duplicate copy of this document will be provided to your family.

PARTICIPANT (PEDIATRIC ASSENT)

Full Name: .....

Signature: .....

PARENT / LEGAL GUARDIAN (CONSENT)

Full Name: .....

Signature: .....

PRINCIPAL INVESTIGATOR / INTERVIEWER

Title & Name: Spec. Dietitian Şükrü Arman AKSOY **Signature:** _____ **Date:** 30 / 09 / 2026

Affiliation: Ankara Etlik City Hospital **Phone:** +90 505 638 54 42 **Email:** dyt.armanaksoy@gmail.com