PARENT INFORMATION FORM

We are conducting a new research study to evaluate the effectiveness of probiotic treatments, which are considered supportive therapies, for addressing growth, nutrition, and constipation problems in children with cerebral palsy. The title of the study is:
"The Effect of Using Lactobacillus Reuteri and Prebiotic-Containing Lactobacillus Rhamnosus on Constipation and Weight Gain in Children with Cerebral Palsy: A Double-Blind Prospective Randomized Controlled Study."

We invite you and your child to participate in this study. However, participation is completely voluntary. You are free to decide whether or not to join. Before you make a decision, we would like to provide you with detailed information about the study. Please read this form carefully, and if you agree to participate after understanding the information, you may sign the form.

The reason we are conducting this research is that cerebral palsy (CP) is a permanent disorder characterized by impaired voluntary motor activity and sensory function caused by damage to the developing brain tissue, leading to movement and posture abnormalities. Gastrointestinal problems occur in more than 90% of these patients, and constipation is seen in about 75%. These problems include indigestion, feeding difficulties, bloating, gagging, vomiting, constipation, and fecal incontinence, which are related to intestinal motility disorders.

Studies have shown that disruption of the gut microbiota contributes to constipation. Some probiotic-based studies in children with cerebral palsy have demonstrated a reduction in constipation symptoms. *Lactobacillus reuteri* and *Lactobacillus rhamnosus* probiotics have been found beneficial and safe in current medical practice for various conditions such as infantile colic, functional constipation, obesity, necrotizing enterocolitis, and inflammatory bowel disease. In this study, we aim to investigate a supportive treatment that may help improve gastrointestinal, nutritional, and developmental problems in children with cerebral palsy.

The study is planned to include **66 patients** with cerebral palsy of similar functional levels. It will be conducted using three different probiotic formulations. The specific sample given to you will be determined randomly by **Dr. Aybegüm Kalyoncu Ayçenk**, and neither you nor other researchers will know which product your child receives.
This research will be carried out by the Departments of Pediatric Surgery, Pediatrics, and Pediatric Neurology of Ordu University Faculty of Medicine. Your participation is important for the success of the study.

If you agree to participate, you and your child will first be evaluated through a questionnaire and a physical examination performed by Dr. Aybegüm Kalyoncu Ayçenk or a member of her research team. If your doctor considers your child eligible, you will be included in the study. With your consent, you will be given a product sample to administer to your child **once daily for 28 days**. The product should be given every day at the same time. If product use cannot be maintained regularly, if any side effect occurs, or if hospitalization becomes necessary, your child will be withdrawn from the study.
At the beginning and end of the study, a stool sample will be collected from your child. These

samples will be analyzed by researchers at the Ordu University Biochemistry Laboratory and then disposed of safely according to standard waste procedures. For families who have difficulty traveling to the hospital for the final evaluation, the research team may conduct the last examination and sample collection at your home, or transportation to the hospital will be arranged.

Possible Side Effects of the Product: Probiotic products may rarely cause gas, bloating, diarrhea, or constipation. If any such symptoms occur, you should contact your study physician immediately.

Financial Information: You will not be charged any fees to participate in this study. No payment will be made to participants. The probiotic products used in this research will be provided free of charge, and no additional costs will be requested from you.

Confidentiality: All medical information related to you and your child will remain confidential. However, authorized monitors, ethics committees, or official authorities may access study data if required to ensure research quality.

Voluntary Participation: You are free to refuse participation. Taking part in this study is completely voluntary, and if you decline, there will be no change to your child's current treatment.
You may also withdraw your consent at any time without providing a reason.

Parent/Participant Statement

Dr. Aybegüm Kalyoncu Ayçenk and her research colleagues from the Departments of Pediatric Surgery, Pediatrics, and Pediatric Neurology at Ordu University Faculty of Medicine have informed me about this medical research project.
After receiving this information, I have been invited to participate as a "participant" in the study.

I understand that my personal information will remain confidential and handled with care and respect during this research. I have been assured that my personal data will be protected when the results are used for educational or scientific purposes.

I understand that I may withdraw from the study at any time without providing a reason (though I will notify the investigators beforehand when possible). I also understand that I may be excluded from the study by the investigators if medically necessary, without any harm to my child.

I will not bear any financial responsibility for study-related expenses, nor will I receive any payment for participation.

In case of any health problem directly or indirectly related to the study, I have been assured that all necessary medical interventions will be provided without cost to me.

If my child experiences any health issue during the study, I can contact **Dr. Aybegüm Kalyoncu Ayçenk** at **(0452) 225 03 78** or at the **Department of Pediatric Surgery, Ordu University Training and Research Hospital** at any time.

I understand that participation is voluntary and that my decision will not affect my child's ongoing medical care or our relationship with the medical team.
I have read and fully understood all explanations provided. After taking time to consider, I voluntarily agree for my child to participate in this research project with satisfaction and free will.

A signed copy of this form will be provided to me.

Mother:
Name/Surname:
Signature:
Date:

Father:
Name/Surname:
Signature:
Date:

Physician obtaining consent:
Name/Surname:
Signature:
Date: