

## **Join a Research Study to Evaluate a Patient Reported Outcomes Measure for use in Clinical Trials**

We are excited to tell you about a research opportunity we are actively recruiting for, your child may be eligible to participate if they are an adolescent within the ages of 12-18 with celiac disease, and has been on a gluten-free diet for at least 6 to 12 months but is still having symptoms.

### **What is this study about?**

The Celiac Disease Patient-Reported Outcome (CeD PRO) Measures study is a one-time, telephone interview study and the objective is to understand the signs and symptoms of celiac disease and to get feedback on a questionnaire related to these symptoms. This will allow researchers to better develop questionnaires to use in studies to evaluate potential future treatments for celiac disease.

### **Who is conducting this study?**

The interview will be conducted by a research group we are working with called Evidera, on behalf of Amgen, a pharmaceutical company, and will require approximately 60-90 minutes of your time. With your permission, this interview will be audio recorded and transcribed for research purposes only.

The interview will be scheduled at a time that is most convenient for you/your child, and this study does not involve the use of any drugs or medical interventions.

### **What would your child's participation look like?**

If you would like to join, a member of the Celiac Disease Program's research team will be in contact with you to review the details of the study and your child's eligibility. With your permission, your contact information will be provided to the Evidera team so that they may schedule the telephone interview, and review the details further. You and your child will be asked to sign a consent and assent form expressing your willingness to participate in this study.

This study is voluntary, and if you do not want to participate the care you receive at Boston Children's Hospital will not be impacted in any way. You can choose to withdraw your participation at any time.

If you decide to participate, you will be compensated for your time in the form of reloadable debit card given to you by Evidera. There are no benefits to you for participating in this study.

If you have questions about the Celiac Disease Patient-Reported Outcome (CeD PRO) Measures Study, please contact us at [CeliacResearch@childrens.harvard.edu](mailto:CeliacResearch@childrens.harvard.edu)

Sincerely,  
Jocelyn Silvester, MD PhD