

TITLE:

Assessment of symptom patterns in Celiac disease: A prospective longitudinal survey (AG#033926)

PROTOCOL NO.:

TAK-101-5001

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SPONSOR:

Takeda Development Center Americas, Inc (TDCA)

INVESTIGATOR:

Lisa Meckley, PhD

650 E Kendall St

Cambridge, Massachusetts 02142

United States

PDF version of the Adolescent Assent Form is available at: <https://celiac.org/vcss-adolescent-consent-forms/>

Adolescent Assent Form

Virtual Celiac Symptoms Study: A study to find out more about what it is like to live with celiac disease.

We are asking if you want to join a study. Please read this information carefully, or, if you want to, get someone else to read it for you. This form tells you what you will have to do and what happens during the study. It is good to talk about it with your family and ask them about any questions you have.

What is a study?

A study is a very careful plan to find out the answer to an important question so that people can be helped.

Why have I been asked to take part in this study?

Because you have celiac disease, your parent(s) or guardian(s) thought you might want to take part.

What is celiac disease?

Celiac disease is an autoimmune condition that makes you sick when you eat things like bread, pasta, crackers, and cake. That's because those foods have gluten, which is a tiny protein in wheat, barley, and rye. When you have celiac disease, gluten hurts your body, making it harder for you to get the vitamins and nutrients you need to grow strong and healthy.

Why is this study being done?

This study is being done to learn more about the symptoms that people with celiac disease experience and how these symptoms affect their daily lives.

Is anyone else taking part in the study?

About 400 people living with celiac disease in the United States are taking part in this study.

What is informed assent?

This is when someone, like you, is **under the legal age to consent** to participate in a study in their given state or country. When assenting, you must:

- Understand as much as possible about the study—this includes what it is, possible benefits (good things) and possible risks.
- Make the decision yourself without any pressure from anyone.
- Get consent from your parent(s) or guardian(s)—but only if they agree to your participation in the study and they sign a consent form.

If, after reading this assent form, you want to take part in the study, you can select “**Yes**, I agree to participate” at the bottom of the form from your phone.

- If you turn 18 during the study, you will receive an email letting you know that you will need to provide your informed consent to continue to participate in this study. The informed consent form will be available through the uMotif app, and the email will provide instructions.

Do I have to take part in the study?

No! Taking part is completely up to you (voluntary). It is OK to say you don’t want to take part. Nobody will be upset with you if you say “no”.

- You can stop taking part any time **before or after** the study has started.
- You don’t have to give a reason; nobody will mind.
- Just tell your parent(s) or guardian(s) **any time** if you want to stop or email the Celiac Disease Foundation (CDF) at virtualstudy@celiac.org.

What happens if I don’t take part in the study?

Nothing. Nobody will mind.

What happens if I join the study?

The study will last for three months. Every day, you will be asked to answer a set of questions through an app on your phone. These questions will ask about your health and how you are feeling:

- On the first day, you will be asked to answer a set of questions that will take about 1.5 hours to complete.
- After the first day, it will take you about 5-10 minutes a day to answer the set of questions.
- Once a week, you will be asked to answer another set of questions that may take about 4-5 minutes to complete.
- Once a month, you will be asked to answer another set of questions that may take 30-45 minutes to complete.

There are no blood draws, medications, medical procedures, or visits with a doctor that are part of this study.

During the study, you will be sent reminders to answer the questions. These will be sent to your email address and, if you want, through the app. No one will call you on your phone.

Who is in charge of the study?

Takeda is the pharmaceutical company who runs this study. They make medicines.

Other companies are also working with Takeda on this study:

- Analysis Group is helping to run the study.
- CDF is helping to find people to join the study and to organize payments.
- Greenphire will help organize payments.
- uMotif has developed the app that you will use to answer the study questions.

What technology is used in the study?

Takeda is working with a company called uMotif to create an app that you will use to answer the study questions on your phone. The app will be used to:

- Provide you with questions and collect your answers.
- Help us pay you during the study.
- Give you an easy way to provide your assent to join the study.

You will be asked to provide a username and your email to use the uMotif app. Only uMotif will have access to this information.

By providing your assent, you agree to use the uMotif app. If you choose not to use the uMotif app, you will not be able to join the study.

What are the risks if I take part?

There are no risks to your health or body if you decide to take part in this study. These questions are not tests, and there are no “right” or “wrong” answers. Some questions may ask you for personal information, which might make you feel uncomfortable. If you choose not to answer a question, please just move on to the next questionnaire.

What are the possible benefits (good things) if I take part?

There are no direct benefits of taking part in this study, but your answers are very important because they will help us understand what it is like to live with celiac disease.

Can I get paid for joining the study?

Yes. If you take part in the study and answer the questions, you could be paid as much as \$500 by the end of the study. Any payments will be provided to your parent/guardian. The amount paid depends on how many of the questionnaires you answer.

Are there any costs for taking part in the study?

No. There are no costs for you to take part in the study.

What information about me will be collected and who will see this information?

During the study, you will be asked to answer questions that give us information about you.

- Your parent(s) or guardian(s) will be asked to give us information that identifies you, including your name, email address, birth date, and home address. CDF and Greenphire will see this information and will use this information to enroll you in the study, remind you to answer the questions, and to pay you.
- Your email address will also be given to uMotif so that they can remind you to answer the study questions.
- When you answer the questions on the uMotif app, you will be providing other personal information, including information about your health. All of this information will be linked to a code number (a subject ID), without your name, address, or contact information. We call this “coded information,” and we use coded information so that none of your answers will be linked to your name. Only CDF will know which ID belongs to which person, and CDF will keep this information secure.
- Your coded information may be given to Takeda, and a few other trusted people who may be interested in the results of the study, but your name will not be included in this information.
- A description of this study will be available on <http://www.clinicaltrials.gov>. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- Information about the study may also be put on other public Web sites, including <http://www.clinicaltrials.takeda.com>, but you will not be personally identified on any of these Web sites.

How will my personal information and privacy be respected?

All of your information related to your participation in the study will be kept confidential. This means that only people with a right or need to see your information will be able to see it. All applicable laws that protect your privacy will also be followed.

Did anyone check if the research is OK to do?

An Independent Review Board (IRB) is a group of outside men and women that have approved this study. They have carefully read the research plan and said it was OK for the study to happen. Your project has been checked by the WCG IRB.

Can I stop taking part after the study has started?

Yes. The study is completely optional. Nobody will mind if you say no or change your mind before or after the study has started. **Just tell your parent(s) or guardian(s) or email CDF at virtualstudy@celiac.org if you want to stop at any time.** Once you've asked to stop being in the study, you can stop answering the questionnaires. Any answers or information that you have already given may continue to be used by Takeda.

What happens when the study stops?

You don't need to do anything more. You will stop answering questions.

Who do I contact for further information?

If there is a problem or if you want to know more about the study, please ask your parent(s) or guardian(s) first. If you are still not happy or would like more information:

- Please email celiacsymptoms@analysisgroup.com if you have questions about the study, including any comments, questions, or complaints about how your information is handled.
- Please email CDF at virtualstudy@celiac.org if you would like to stop participating in the study or have a question about payment.
- Please email virtualCeliac@uMotif.com if you have a question about the uMotif app.

Statement of Assent

Please read this language carefully and decide if you want to take part in the study.

If you have read the previous screens and completely understand the information and agree to take part in the study, please click the **Yes** button.

By clicking **Yes**, you are agreeing to the following:

- I have read (or had read to me) this assent form and have had plenty of time to ask as many questions as I need to and have understood the answers to the best of my ability.
- I understand that I can stop taking part in the study at any time without being affected in any way.
- I agree that my information from this study, without my name on it, may be given to Takeda so that Takeda and its business partners can analyze the results of the study.
- I agree that I can be contacted about participating in the study.
- I agree that I want to take part in this study.

If you do not want to take part in the study, click the **No** button.

- Yes**, I agree to participate.
- No**, I do not agree to participate.

I am between 12 and 17 years old.

Yes

No