CHILDREN'S NATIONAL MEDICAL CENTER
Division of Psychology
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Consent/Parental Permission to Participate in a Clinical Research Study

STUDY TITLE:	Testing a Behavioral Intervention in Pediatric Celiac Disease
PRINCIPAL INVESTIGATOR:	Shayna Coburn, PhD, Assistant Professor and Attending Psychologist, Division of Gastroenterology

SUMMARY AND KEY INFORMATION

We are inviting you to be part of a research study at Children's National Medical Center (Children's National). **Taking part in this study is your choice.** You can choose to take part, or you can choose not to take part in this study. You also can change your mind about participating at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To help you decide if you would like to participate, we want you to know why we are doing the study, what you will be expected to do, and the possible risks and benefits of being in the study. This form has information to help you make your choice about whether or not to participate.

The purpose of this research study is to improve and test a program called the GROW Project. "GROW" stands for Gluten-free Resilience and Overall Wellness. It was designed to help teens and their parents cope with celiac disease and its challenges. This study consists of different phases, and you will be invited to participate in just one phase of the study. The three phases are:

Phase 1: Feedback sessions in individual meetings or focus groups of about five people per group to look at the GROW Project materials and talk with the research team about how it could be improved. You can participate in one feedback session, or more if you choose.

Phase 2: A pilot test of the GROW Project for one group of teens and one group of parents. The GROW Project will be delivered using the internet for six weeks, with live weekly group meetings and educational information about living with celiac disease.

Phase 3: A larger test of the GROW Project called a randomized controlled trial (RCT). If you participate in this phase, you will be randomly selected to either participate in one of three possible groups: Care as Usual, the GROW Project, or the GROW+ Project.

There are no known risks to completing any part of this study. If you participate in the GROW Project, you and/or your teen may learn from the educational experience of participating in a scientific study and enjoy the opportunity to communicate your experiences to others or understand more about yourself and your teen by participating in interviews, gluten immunogenic peptide testing, and surveys.

If you are interested in learning more about this study, please continue reading below. The rest of this form gives you more important information you need to know about the study before you decide if you want to participate. The study doctor or a member of the research team will talk to you about the study and answer all of your questions. We encourage you to discuss this study with your family and anyone else you trust before making your decision. It's important that you have as much information as you need and that all your questions are answered.

Your participation in this research is voluntary.

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to be in the study or withdraw from the study later. This means that:

- You do not have to join the study.
- You may change your mind and stop being in the study at any time.
- We will tell you if we make any important changes to the study or if there are any important new findings so that you can decide if you still want to be in the study.

Why is this research study being done?

You are being asked to be in the study because your child has celiac disease. We want to see if the GROW Project helps teens with celiac disease and their parents feel better about the diagnosis and follow the gluten-free diet successfully. In other groups of people with conditions like diabetes, and in adults with celiac disease, people have felt better after participating in group programs that teach people how to live with their condition. The GROW Project is based on a program made for adults with celiac disease, which has been changed to be helpful for teens and their parents. Dr. Shayna Coburn is the person responsible for this research study at Children's National. She is called the Principal Investigator.

How many people will be in the study?

The study will involve up to a total of 128 families of teens and their parents who will be called "participants" (256 total participants). Participants can be teens with celiac

disease or parents/legal guardians of teens with celiac disease. All participants will be recruited from the Children's National Health System.

What will happen in this research study?

If you decide to participate in the research study, here is what will happen. First, we will tell you which phase we are inviting you to participate in.

If you participate in Phase 1, you will participate in a feedback session. The study team will show you some of the information in the program and will ask you to tell them what you like or don't like about it. They will ask for your honest opinions of how to make the program better for teens and their parents. We expect to have a total of three feedback sessions as we work on improving the GROW Project. Focus groups will have about 5-8 people and will be about 1 hour long. You can participate in one feedback session, or more if you choose.

If you participate in Phase 2, you will participate in a first test of the GROW Project. This is called a trial. The GROW Project is described in the next section below.

If you participate in Phase 3, we will run a computer program to randomly pick whether you and your teen will participate in Care as Usual, the GROW Project, or GROW+ Project. Parents and their teens will be assigned to the same study group. This is called a randomized controlled trial (RCT). Here is a description of what will happen for each group:

<u>"Care as Usual" Group (Phase 3):</u>
You will be asked to complete your baseline visit (V0), which includes a 1-hour interview, urine samples (for teens), and surveys.

Teens will also be asked to complete brief weekly surveys to report any symptoms or gluten exposures for V1-V6. They will receive $5 each for completing each survey (up to $30 total).

Teens should participate in your usual celiac disease clinical care. You will NOT attend the GROW or GROW+ Project sessions.

Around 6 weeks after V0, we will ask you to complete your first follow-up visit (V7), which includes a 1-hour interview, surveys, and test your teen's urine using Gluten Detect.

Then 3 months after V7, we will ask you to complete another round of interviews (V8), surveys, and Gluten Detect urine test, to tell us how you are doing.

<u>The GROW Project (Phases 2 or 3, GROW or GROW+ Project Groups)</u>
First, we will ask you and your teen to participate in the first study visit. We will call this your "baseline visit" (V0). During the baseline visit, we will interview you and your teen

to ask about your life with celiac disease, ask teens to collect urine sample and test it for gluten using a kit called Gluten Detect, and have you both fill out surveys.

Next, you will be part of the Grow Project for 6 weeks (V1-V6). Teens will meet with study staff individually or in a group with 5-8 people, and you will meet separately individually or in a group with 5-8 other parents. Meetings will be held for about 1 hour once a week using Zoom for Telehealth, a secure computer program designed to protect the privacy of participants. All zoom sessions will be audio and video recorded. After each session, we will ask for feedback (phase 2) or new symptoms and potential exposures (phase 3). We may send you e-mails and text messages up to 3 times per week to share information, give reminders of skills and goals for the week and provide online support and guidance for individuals completing the Gluten Detect tests. Participants in the GROW+ group will also be sent up to three Gluten Detect urine sample collections per week and asked to report their results electronically. Each group meeting will introduce skills to help with managing celiac disease and coping with the challenges that come along with it. You will be encouraged to use your audio and video to participate in the conversation with the group leader and other members of the group. All interviews and telehealth groups will be recorded.

After the program is over (V7), we will ask you to complete another interview to tell us what you thought about the program, and to fill out surveys again and test your teen's urine using Gluten Detect.

Then 3 months after you finish the GROW Project (V8), we will ask you to complete another round of interviews, surveys, and Gluten Detect urine test, to tell us how you are doing.

Study Visit	Description	Study Visit	Description
V0	Baseline Visit (interview, Gluten Detect, and surveys)	V5	Program Session 5: Balancing life with your gluten-free diet Weekly survey Gluten Detect (GROW+)
V1	Program Session 1: Introduction; education about celiac disease and the gluten-free diet Weekly survey Gluten Detect (GROW+)	V6	Program Session 6: Bringing it all together Weekly survey Gluten Detect (GROW+)
V2	Program Session 2: Managing the challenges of the gluten-free diet Weekly survey Gluten Detect (GROW+)	V7	Post-Intervention Visit (interviews, Gluten Detect, and surveys)
V3	Program Session 3: Communication around the gluten-free diet Weekly survey Gluten Detect (GROW+)	V8	3-Month Follow-Up Visit (interviews, Gluten Detect, and surveys)
V4	Program Session 4: Thinking about the gluten-free diet Weekly survey Gluten Detect (GROW+)		

How long will my participation in the research study last?

If you participate in Phase 1 (feedback sessions): Your participation may only be a one-time, one-hour study visit held over Zoom. You can choose to return for more feedback sessions but are not required to.

If you participate in Phase 2 or Phase 3: You will be asked to participate in our study for about 6 months. We will ask you to participate in an interview and surveys for V0, V7, and V8. If you are selected to attend the GROW or GROW+ Project, you will also be asked to attend weekly, online, group program sessions for 6 weeks. Brief interviews after each weekly session will be approximately 5 minutes. These can all be done online using Zoom and electronic survey links.

You will be responsible for completing all data collection at each study visit (baseline "V0", post-intervention "V7", and 3 month-follow-up "V8") which adds up to about 3 hours (1 hour per visit). You and your teen should participate in your usual celiac disease clinical care.

You should tell us if you decide to stop being in the study.

We will ask you to drop out of the study if:

- You are bothered by participating in the study too much to continue.
- Your study doctor and/or the Sponsor of the study thinks it is in your best interest to stop.

What are the risks and possible discomforts from being in this research study?

We do not expect the GROW Project or data collection will cause you any harm. There are no known mental health risks to you filling out surveys, completing urine collection, or participating in interviews. However, the surveys, interview topics, and GROW Project topics may contain questions that could make you feel uncomfortable in that they ask about your physical and mental health. If any questions make you feel uncomfortable, you may skip or ignore these questions. There are also no known risks to recording video interviews. All recordings will be transcribed, and a different name ("pseudonym") will be used to replace any of your identifying information. All audio and/or video recorded information may be used for educational and research purposes. Finally, there are no known risks to urine collection for testing it for gluten. You and/or your teen may experience discomfort about following procedures which involve collecting urine. You and/or your teen will be given kits along with clear instructions, and a member of the study staff will be available by phone and e-mail for any questions or concerns about Gluten Detect testing. You and your teen may discontinue with specimen collection and testing if discomfort arises.

The main possible risk in this study is the risk of gathering sensitive social, behavioral, and medical information. Collecting data through the internet will be done using a secure application called REDCap, and videoconferencing will take place over a secure internet connection that meets the Children's National HIPAA requirements. Video and audio recordings will be stored on a secure server only accessible to study staff.

What are the possible benefits from being in this research study?

You may not directly benefit from participating in this research study. You or your teen may feel better from participating in the GROW Project. The things we learn from you taking part might help other people with celiac disease in the future by understanding the skills and support that make it easier to follow the gluten-free diet, cope with the condition, and designing additional treatment programs.

Will the information that I give you be shared with others? How will you protect my privacy?

We will be careful to protect and limit our use of your personal information, including research records, medical records, and Protected Health Information (PHI), to members of the study team who have permission to see it. Your identifiable personal information will not be given to anyone unless we get your permission in writing. We will make every effort to keep your information private, but no one's privacy can be totally guaranteed.

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all your identifiers, name, address, date of birth and phone number are removed.

Certificate of Confidentiality

Sometimes people tell us some very personal information about themselves when they participate in a study and it becomes part of their research record. To help us protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

- With this Certificate, the investigators cannot be forced (for example, by a court order or subpoena) to give information that may identify you in any federal, state or local civil or criminal court, or in any administrative, legislative, or other proceedings.
- It is important that you know that a Certificate of Confidentiality does not stop you or a member of your family from voluntarily giving information to others about yourself or your taking part in this research. You should also know that if an insurer or employer learns about your participation and you give them permission to receive research information about you, we cannot use the Certificate of

Confidentiality to keep your information private from them. This means that you must also actively protect your own privacy.

- Finally, it is important that you know that we are not prevented from taking steps to prevent serious harm to you or to others. If we learn that you or someone else is harming you or others around you, we may be required by law to report this to the police or a social services agency to get emergency help if it is needed.

What other choices do I have if I don't want to take part in the study?

If you do not want to participate in the study, there are no other choices except not to take part. If you choose not to participate, it will not be held against you.

Will it cost me anything to take part in the study?

There are no costs to you or to your insurance company for taking part in this study

Will I be paid for taking part in this study?

Phase 1: Each participant will receive a gift card worth $25 for each feedback session you complete. Teens and parents will be paid separately for their participation. If you participate in three feedback sessions, you will receive a total of $75.

In Phases 2 and 3, you will receive your study payments through a "ClinCard" debit card. ClinCard follows laws, like HIPAA, which protect your identifiable information. After each completed study visit for which you will be paid, the payment amount will automatically load onto your card within 3 business days. You can use your ClinCard at an ATM or bank to get cash, or at any store to make a purchase. There is a fee for using the card at an ATM machine and there may be other fees, like monthly fees.

The study team will give you a ClinCard and forms with more information about how to use it and about specific ClinCard user fees. The Internal Revenue Service requires that any monetary payments totaling $600 or more in a calendar year must be reported for tax purposes.

Phase 2: You and your teen will receive a prepaid and re-chargeable cash card called a ClinCard for your participation in this study. Teens and parents will be paid separately for their participation. You will receive $20 for completing the baseline visit (V0), $30 for completing the 6-week follow-up visit (V7), and $40 for completing the 3-month follow-up visit (V8). You will also have the option to complete brief feedback interviews immediately following each weekly telehealth group session and will receive $10 for each interview (up to 6 total per participant over the course of the intervention), for a possible total of $150 loaded onto your ClinCard.

Phase 3: You and your teen will receive one prepaid and re-chargeable card called a ClinCard for your participation in this study. Teens and parents will be paid separately for their participation. Participants will receive $20 for completing the baseline visit (V0), $30 for completing the 6-week follow-up visit (V7), and $40 for completing the 3-month follow-up visit (V8. Teens will also receive $5 for completing six weekly surveys (V1-V6), for a possible total of $120 for teens and $90 for parents loaded onto your ClinCard. You will receive the prepaid card even if you do not participate in the GROW Project or if you do not complete every group session, as long as you remain in the study and attend follow-up visits.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time, as required by U.S. law.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). Privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Dr. Coburn, and her research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

- Information that identifies you/your child such as name, address, telephone number, date of birth, and other details about you
- Information that relates to your child's health or medical condition from your medical records
- Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as medical information we learn from you/your child about your health history and family history, and information about your child's emotional, social, and behavioral functioning.
- Questionnaires or surveys you complete
- Interviews conducted with you by members of the research team

The Researchers may use and share my Protected Health Information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study
- Clinic staff responsible for scheduling and insurance reimbursement
- Government agencies that have the right to see or review your PHI including, but not limited to:
    - The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP)
- Children's National Medical Center Institutional Review Board
- Children's National Medical Center Institutional Quality Assurance Program
- Other staff in the Human Research Protections Program at Children's National Medical Center

In addition to the above people and organizations, the Researchers may also use and share my Protected Health Information with:

- The Patient Advocate or Research Ombudsman (person who watches out for your best interest)

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and revoke this Authorization.

- If you revoke the Authorization, you must send a written letter to the Principal Investigator to inform her of your decision.

  Dr. Shayna Coburn
  Children’s National Medical Center
  Division of Psychology
  111 Michigan Avenue, N.W.

Washington, DC 20010-2970

- If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study.

You will not be allowed to review the information collected for this research study until after the study is completed. If you are not allowed to review your information during participation in the study, when the study is over you will have the right to access the information.

This Authorization does not expire.

If you have not already received a Notice of Privacy Practices from Children's National Medical Center, you may request a copy and will be given one. If you have any questions or concerns about your privacy rights, you may contact the Children's Hospital Privacy Officer at 202-476-6464.

Whom can I call if I have questions about this research study?

We want you to ask questions about any part of this research study at any time.

- For questions about the study or the information in this informed consent/parental permission document, call the Principal Investigator, Dr. Shayna Coburn, at 202-476-4261 or e-mail: scoburn@childrennational.org.

Whom can I call if I have questions or concerns about my rights as a research study participant?

The Children’s National Office for the Protection of Human Subjects is available to talk with you about:

- Your rights as a research participant
- Your concerns about the research
- A complaint about the research

This is the administration office for the Institutional Review Board, which is a group of doctors, nurses, and non-medical people who review research studies for safety and the protection of people who participate in research. You can call the Office for the Protection of Human Subjects at 301-565-8447.

Children’s National has a research participant and family advocate. The advocate is here to answer your questions or concerns about taking part in this research. The advocate does not work for the doctors who are doing this research and is not paid by the researchers. The advocate is here only to help and protect you during any research.

You may contact the research advocate at any time. This can be done before you decide to take part in the research, during the study, or even after you finish the study. You can contact the research advocate at 202-476-5586 or by email at RSA@childrensnational.org. In urgent situations the research advocate and pediatric ethics program team can be reached at the pager number: 202-259-2082.

CONSENT/PARENTAL PERMISSION:

- I am the study participant or I am authorized to act on behalf of the participant.
- I have read this consent form or had it read to me.
- I have been invited to take part in a research study. I was told why the research is being done and how long my participation in the study is expected to last. I was told about what will happen in the study and if there are any procedures or drugs that are experimental.
- I was told that taking part in this research is voluntary. I also was told that I can decide not to take part or stop being in it at any time without any penalty to me or any change to the quality of care I receive at Children's National Hospital and Pediatric Specialists of Virginia.
- I was told about the risks and possible discomforts of taking part in this research study. I was also informed if there are any possible benefits to me if I am in this study.
- I have been given the chance to ask questions about the study, and my questions have been answered. If I have questions later, I can ask one of the people listed in this form.
- I agree to take part in this research study.
- I will receive a signed copy of this Informed Consent/Parental Permission form to keep.

Signature of Parent(s)/Guardian(s) for participant under the age of 18 years

Printed Name of Participant: _____

Printed Name of Parent/Guardian:_____

Signature of Parent/Guardian: _____

Date and Time: _____ a.m. / p.m. (circle one)

AFFIDAVIT OF PERSON OBTAINING CONSENT / PARENTAL PERMISSION:

I certify that I have explained to the above individual(s) the nature and purpose of the study, possible risks, and potential benefits associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Person Obtaining Consent: _____

Research Role: _____

Signature: _____

Date and Time: _____ a.m. / p.m. (circle one)