Physiological Reactivity and Psychosocial Functioning in Pediatric Patients with Gastrointestinal Disease

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You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 56 children (and 1 parent) who are being studied, at Emory and elsewhere.

Why is this study being done?
This study is being done to answer the question: Do youth with inflammatory bowel disease (IBD), a chronic gastrointestinal illness, benefit from a coping skills training program that incorporates biofeedback? You and your child are being asked to be in this research study because your child has been diagnosed with IBD.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your or your child's access to medical care for your child's condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for up to 7-months (up to 4 assessments and 6 treatment sessions). The researchers will ask you to do the following: Complete questionnaires about your child's emotional and behavioral functioning. Researchers will assess how your child's body responds to stress in a painless assessment. Your child will be asked to participate in a 6-visit group treatment to learn coping skills for managing gastrointestinal illness, administered virtually. All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, your child may learn strategies that help manage stress associated with having a gastrointestinal diagnosis.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include emotional distress resulting from completing questionnaires, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You will not have to pay for any of the study procedures.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study psychologist or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University and Children's Healthcare of Atlanta
Consent to be a Research Subject / HIPAA Authorization

Title: Physiological Reactivity and Psychosocial Functioning in Pediatric Patients with Gastrointestinal Disease

Principal Investigator: [redacted], PhD

Study-Supporter: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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 Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?
The purpose of this study is to test a coping skills treatment protocol for youth diagnosed with chronic gastrointestinal disorders, inflammatory bowel disease (IBD). Your child is being asked to participate because he/she has been diagnosed with IBD. This treatment will be administered in a group format and virtually. Treatment will target psychological problems like anxiety and depression that affect some youth with gastrointestinal conditions. Past research has shown that how a person's body reacts to stress can be associated with psychological functioning. In this treatment study, we will teach patients new strategies for managing stress and their body's reaction to stress.

What will I be asked to do?
Individuals who are enrolled in the study will participate for a total of 7-months. During this period, your child will receive a 6-session, group-based coping skills treatment protocol delivered virtually. The other tasks involved in this study involve you and your child completing online surveys regarding your child's emotional and physical well-being, and your child will be asked to participate in a painless assessment of how his/her body responds to stress. Answering the survey questions will take about 30-40 minutes at each time-point. You will be asked to take surveys at enrollment, before the treatment starts (baseline), upon completing the 6-week treatment program, and 2-months after completing the treatment program. The assessment of how your child's body responds to stress will occur immediately before and after the 6-week treatment. The study as a whole should take about 18 months to complete, and the results should be known in about two years' time.

If you decide to participate, then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin or pulling a name out of a hat). There is no way to predict which group you will be assigned to. You will have a 50% chance of being placed in either group. Neither you, the research staff, nor the researcher can choose which group you will be in.

What are the two groups in this study?

We will be comparing two groups of patients. The first is the immediate treatment group, which will do the coping skills treatment protocol immediately after enrollment. The second is the waitlist control group, who will be in a 2-month waiting period and will do the same coping skills treatment protocol after 2 months. There will be no group interaction between members of either group.

What will I and my child do should I decide to participate in this study?

If you choose to participate in the research you will be expected to:

- Agree to be randomly assigned to the immediate intervention group or the waitlist control group (like the flip of a coin). You don't get to choose which group you get; we assign you.
- Complete the assessments and activities involved in this study as described in Table 1:

Study Activity	Time (weeks/months)	Description of study activity	Study Group	
			Immediate Group	Waitlist Group
Survey 1	Month 0	Answer online surveys	✓	✓
Stress Assessment 1	Month 0	Participate in assessment of how child's body responds to stress	✓	
Treatment Protocol	Month 1	Participate in treatment protocol	✓	
Waiting	Months 1 and 2	Be in waiting period		✓
Survey 2	Week 7	Answer online surveys after completing treatment protocol or after waiting period of 6-7 weeks	✓	✓
Stress Assessment 2	Week 7	Participate in assessment of how child's body responds to stress after completing treatment protocol or after waiting period of 6-7 weeks	✓	✓
Survey 3	Month 4	Answer online surveys 2 months after completing treatment protocol or after waiting period of 3 months	✓	✓
Treatment Protocol	Month 4	Participate in treatment protocol		✓
Survey 4 (Waitlist group)	Month 5	Answer online surveys after completing treatment protocol		✓
Stress Assessment 3	Month 5	Participate in assessment of how child's body responds to stress after completing treatment protocol		✓
Survey 5 (Waitlist group)	Month 7	Answer online surveys 2 months after completing treatment protocol		✓

- You and your child will answer survey questions online at each assessment point, which will take about 30-40 minutes. The online surveys will ask about your child's psychological and physical well-being and will include questions about anxiety, depression, stress, and gastrointestinal symptoms.
- Your child will participate in a painless assessment of his/her breathing and heart rate before and after treatment. We will mail you a sensor to complete this assessment and guide your child in the process which will be completed from your home.
- You do not need to answer any question(s) that you or your child does not feel comfortable with. You will be a part of this study regardless of your responses to the questionnaires.
- When your treatment begins, you will be guided to download Zoom to your computer, tablet, or phone that your child can use for the duration of treatment. All treatment sessions will be conducted using an Emory zoom account.
- Your child will be asked to log into zoom for approximately 1 hour per week to participate in the 6-week coping skills treatment protocol. The day and time of the meeting will be determined once a treatment group of 7-8 participants is determined, based on best availability.
- Your child will be asked to complete assignments for homework between each of the 6 treatment sessions. Homework will be less than 15 minutes per day when assigned.

Who owns my study information and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may still be used for this study unless you request that study information be destroyed.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are: Time spent completing the questionnaires and participating in study procedures and treatment (approximately 30-40 minutes expected for questionnaires at each time point; about 30 minutes for each assessment of breathing and heart rate).

The less common risks and discomforts expected in this study are: Emotional distress resulting from completing questionnaires of emotional and behavioral functioning. If you or your child experience emotional distress, researchers and study staff will be able to provide referrals for psychological or emotional counseling. If your child expresses thoughts of harming himself/herself or others, follow-up psychological intervention will be provided in a timely manner and may result in referral for hospitalization if deemed medically necessary for safety.

There is a slight risk that you or your child may be identified after participating in this study. However, every effort will be made to protect your identity. All surveys will be completed via RedCap, a secure, web-based, HIPAA-compliant, data collection platform.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

Your child may learn helpful new strategies for managing stress and coping with a gastrointestinal condition through the treatment protocol. Your child's gastrointestinal condition may improve while you and your child are in this study, but it may not, and it may even get worse. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will get a $50 gift card at enrollment and a $15 gift card for each of the 6 treatment sessions, to compensate you for your time and effort. You will get an additional $30 gift card for completing each additional assessment session. If you do not finish the study, we will compensate you for the visits you have completed. You will get up to $230 total in gift cards if you complete all study visits.

What are my other options?

If you decide not to enter this study, there will be no consequences for your child's healthcare. This study is voluntary.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data to other researchers. If we do, we will not include any information that could identify you. If your data are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Medical Record

If you have been an Emory and Children's Healthcare of Atlanta patient before, then you already have an Emory and Children's Healthcare of Atlanta medical record. If you have never been an Emory and Children's Healthcare of Atlanta patient, you do not have one. Please note that an Emory or Children's Healthcare medical record will **not** be created for you just because you are in this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Children's Healthcare of Atlanta medical record you have now or any time during the study.

Emory and Children's Healthcare of Atlanta may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Children's Healthcare of Atlanta medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: Responses to psychological questionnaires and results from assessments of your child's physiological reactivity.

Tests and procedures done at non-Emory and Children's Healthcare of Atlanta places may not become part of your Emory and Children's Healthcare of Atlanta medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. [redacted] at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory and Children's Healthcare of Atlanta will help you to get medical treatment. Neither Emory, Children's Healthcare of Atlanta nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory, Children's Healthcare of Atlanta and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory and Children's Healthcare of Atlanta, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or Children's Healthcare of Atlanta employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

Research-Related Treatment
This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory and Children's Healthcare of Atlanta may use and disclose your IIHI to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study.

- National Institutes of Health (NIH) is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory and Children's Healthcare of Atlanta offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory and Children's Healthcare of Atlanta IRBs, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices. IIHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: [redacted] PhD, Division of Gastroenterology, Hepatology, & Nutrition, [redacted] or [redacted].

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact [redacted], PhD, at [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted] or [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact the Director of Research Administration at [redacted].

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**