KEY INFORMATION FOR DIGITAL BEHAVIORAL INTERVENTIONS IN INFLAMMATORY BOWEL DISEASE

We are asking you to choose whether or not to volunteer for a research study *about digital behavioral interventions in inflammatory bowel disease (IBD).* This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn whether patients with IBD and elevated perceived stress, anxiety, or depression will benefit from digital behavioral interventions. We also want to find out what factors may help or hinder use of digital behavioral interventions. Your participation in this research will last about four weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The study may directly benefit you providing you with a way to address your perceived stress, anxiety, or depression. By participating, you could also contribute to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may not want to participate in this study if you are not comfortable answering questions about perceived stress, anxiety, or depression. You may also not want to participate in this study if you do not wish to use a digital application to address these issues. It is important to note that digital behavioral interventions are not a replacement for a mental health specialist. For a complete description of risks, refer to the Consent Document below*. As an alternative, you may choose to address any stress, anxiety, or depression you may have with a trained mental health specialist.* For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is *Dr. Ruby Greywoode.* If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: email *rgreywoode@momntefiore.org or telephone (347) 671-8205.*

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

A description of this clinical trial will be available on 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.

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Digital Behavioral Interventions in Inflammatory Bowel Disease**. Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." **Her** name is **Ruby Greywoode**. You can reach Dr. **Greywoode** at: **Office Address: 3303 Rochambeau Ave, Bronx, NY, 10467** **Telephone #: 347-671-8205** For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.	The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einstein.yu.edu, or by mail: Einstein IRB Albert Einstein College of Medicine 1300 Morris Park Ave., Belfer Bldg #1002 Bronx, New York 10461
National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH) Clinical Translational Science Awards grant number UL1TR002556-05	

Why is this study being done?

Psychological distress – meaning perceived stress, anxiety, or depression – is common among people with inflammatory bowel disease (IBD). Psychological distress has also been linked to increased IBD symptoms. Not many tools have been developed to help IBD patients who have increased psychological distress. Often, the tools that are developed are not evaluated among people of color.

One way to increase the accessibility of tools to help improve psychological distress is through digital behavioral interventions. Digital behavioral interventions are digital applications designed to help people identify and/or change their thinking and behavior to help them improve their psychological wellbeing. The goal of this study is to evaluate if digital behavioral interventions improve levels of psychological distress in people of color with IBD. We also want to understand some of the factors that may help or hinder patients' use of digital behavioral interventions.

Why am I being asked to participate?

You are being asked to participate in this study because you are a patient with either Crohn's disease or ulcerative colitis at least 18 years of age or older. You have been identified as a person with access to the internet with a reported race or ethnicity of "Black/African-American" or "Hispanic/Latino." If you have a current or history of suicide attempts or psychiatric hospitalization, you are not eligible to take part in this study. We anticipate a total of 50

participants will be enrolled in this study. This study will take place at Montefiore Medical Center.

What will happen if I participate in the study?

This study is a randomized trial, meaning a research study in which an experimental treatment is compared to another treatment. As part of this study, we will review your medical records and put some of the information we collect in our research records.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the digital [**therapy**] group or the [**digital mood tracking**] group. You and the study doctor cannot choose your study group. You will have **an equal chance** of being assigned to either group.

First, you will be asked to complete a questionnaire that collects information about you, such as, your birthplace, education, employment status, IBD symptoms, and levels of stress, anxiety, or depression. Based on your responses, you may be eligible to be randomly assigned to one of two groups. Each group will receive one of two digital behavioral interventions.

If you are assigned to one of the two digital behavioral intervention groups, you will receive access to use a digital application (app) for 4 weeks. The app features may include daily mood and symptom tracking, meditation, goal setting, and/or negative thought redirecting activities. You may choose which features of the app you use and how much time each day you want to use the app.

Regardless of which digital behavioral intervention group you are assigned to, you will receive some initial information about stress relief and be asked to complete a follow-up questionnaire at the end of 4 weeks. You will also have the option to talk to the research study team about your experience at the end of the study.

A description of this clinical trial will be available on 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.

How many people will take part in the research study?

You will be one of about **50** people who will be participating in this study taking place at Montefiore Medical Center/Albert Einstein College of Medicine.

Will there be audio and/or video recording?

If you decide to share about your experience with the research study team at the end of the study, your voice may be recorded during the conversation. The recording would only be used to help the researchers put together their notes and would be destroyed after that.

Information Banking (Future Use and Storage)

We will store information about you in a "bank", which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease,

including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will receive a total of $40 for completing 2 study questionnaires. You will receive a $20 gift card for completing a questionnaire at the beginning of the study. You will receive a $20 gift card for completing a second questionnaire at the end of the study. If you choose to withdraw from the study before all questionnaires are completed, you will be paid only for the questionnaire you complete.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

What will happen if I am injured because I took part in this study?

Federally Funded Research

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the Montefiore Medical Center, a Montefiore doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Albert Einstein College of Medicine and Montefiore Medical Center are not offering to provide you the drug/device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Ruby Greywoode, MD (347) 671-8205.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc. In addition, the researchers wish to review information pertaining to your psychiatric treatment records. By law, you must specifically authorize access to these records:

☐ Yes, I authorize the use and disclosure of my information pertaining to psychiatric treatment.
Initial: _____ Date: _____

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any times you would not keep my data confidential?

If you give us information that you may hurt yourself, we would be obligated to share that information with healthcare professionals outside of this research study.

If you give us information that you may hurt someone else, we would be obligated to share that information with authorities outside of this research study.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

You may feel uncomfortable answering questions about stress, anxiety and depression or managing your emotions. You can choose not to answer questions that make you feel uncomfortable.

You may feel uncomfortable dealing with stress, anxiety, depression or other emotions through a digital application. You can choose to stop using the digital application at any time. It is important to understand that a digital behavioral intervention is not a replacement for a trained mental health specialist. If at any time, you have severe psychological symptoms, you should seek immediate medical attention.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include mental health counseling through a digital application, improvement in your levels of stress, anxiety, depression and/or improvement in your IBD symptoms.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date

Printed name of the person conducting the consent process	Signature	Date

Spanish Interpreter [] Yes [] No

Interpreter Number

CONSENT TO PARTICIPATE

Do you have any questions?

Do you voluntarily consent to participate in this research? (Record potential subject's response)
[ ] Yes [ ] No

Printed name of participant		Date

Printed name of the person conducting the consent process	Signature	Date

Spanish Interpreter [] Yes [] No

Interpreter Number