# Permission to Take Part in a Human Research Study

**A randomized control study to examine the influence of a healthy diet on moderate to severe ulcerative colitis patients undergoing tofacitinib induction**

National Clinical Trial (NCT) identified Number: NCT04505410

Principal Investigator: Oriana M. Damas, MD MSCTI

Sponsor: University of Miami Miller School of Medicine

Funded by: Pfizer (PI-initiated Study)

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**Title of Study:** A randomized control study to examine the influence of a healthy diet on moderate to severe ulcerative colitis patients undergoing tofacitinib induction
**Principal Investigator:** Dr. Oriana Damas
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**Study Contact** Dr. Oriana Damas
**Study Contact Telephone Number:** 305-243 2515
**Dietitian Contact**: Luis Garces
**Study Contact Telephone Number:** 305-243-6982 or 305-243-8644 (24-hours)
**Study Contact Email:** lgarces@med.miami.edu

A person who takes part in a research study is called a research or study subject. In this consent form "you" always refers to the research subject.

***Key Information about This Research Study***

You are being asked to volunteer for a research study being conducted on people who have moderate to severe ulcerative colitis (an inflammatory disease of the bowel). You are asked to be in this study because you have this medical condition. This form will tell you about the procedures used for the study, the risk of your participation, and other important information that you will need to know. If you have questions about this form, or find words that are not clear to you, please let the investigators know and they will be happy to answer all your questions.

Almost all research studies involve some risk. Risks of this study are more than minimal. These risks are described in detail later in this document.

The purpose of this study is to use diet as adjunctive treatment (another treatment used together with the primary treatment) for ulcerative colitis (UC) patients who will be starting tofacinitib or other biologic medication induction as part of their plan of care. This study seeks to identify changes in your intestinal flora occurring as a result of the diet intervention combined with your tofacinitib or other biologic medication treatment plan. The diet is not part of your standard of care treatment and is being done for research purposes. It is to be used as an adjunctive therapy to the standard drug therapy prescribed by your doctor. We will also measure baseline diet patterns and stool for changes in the intestinal flora and compare them to any changes occurring after diet intervention. The results of this research study will be used to determine if a diet intervention improves the effects of tofacitinib or other biologic medication on clinical response.

# Permission to Take Part in a Human Research Study

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to and you can leave the study at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to participate or if you leave the study early.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions you need to help decide whether or not to join this study.

***What if I have Questions?***

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team Gabriella Grau at 305-243-6405.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

***How is being in this study different from my regular health care?***

This study is not part of your standard of care and you may choose not to be in the study.

***How is this research funded?***

This research is being funded by Pfizer Global Medical Grants, also called the sponsor. Sponsors may change or be added.

***What happens if I say yes, I want to be in this research?***

To participate in the study, you need to be between the ages of 18 and 70 years old, diagnosed with moderate to severe ulcerative colitis and starting tofacinitib or other biologic medication therapy (as determined by your treating physician). We will be enrolling a total of 76 subjects and we will have two different groups, Arm 1 and Arm 2 (38 subjects per arm), both with an 8-week time duration of dietary recommendations that also coincide with the period of induction with tofacitinib or other biologic medication. Eligible participants will be randomly assigned (like flipping a coin) to either

Arm 1 or Arm 2 by an independent researcher. The patients are blinded to which study arm they will be placed in and therefore you will not be able to know whether you were assigned the dietary intervention.

After you have completed all of the screening criteria and you have qualified for the study, you will be randomly assigned to either Arm 1 or Arm 2 of this study.

All participants will have initial baseline assessments including: a detailed IBD questionnaire, an IBD Quality of Life (IBD QoL) questionnaire, a Simple Clinical Colitis Activity Index (SCCAI), food/diet assessments, including a 24-hour food recall and general food frequency questionnaire, a serum blood draw, and stool sample measurements of fecal calprotectin, microbiome and metabolites. Food/diet assessments will be repeated during week 4-5, as well as detailed food diaries. Study dietician may provide nutritional supplements and/or other dietary guidance to you. Biosample collection will be repeated again for all participants in week 7. If not possible, we will arrange with a local lab to collect samples and send them with an overnight currier. A last assessment of clinical response, medication updates, IBD QoL and food/diet assessments will be performed at the end of the week 8 induction period. You will receive diet counseling and information on good eating habits by our dietitian, you will need to come only two times to collect stool and collect blood samples. The rest of the follow up will be by phone/emails.

Your participation in the study will last approximately 8 weeks. The tests that will be performed are shown in Table 1. They will consist of measures of inflammation, gut bacteria, body composition, dietary intake, and quality of life.

**Timeline for Study Assessments for Participants with Ulcerative Colitis can be found in Table 1 (next page)**

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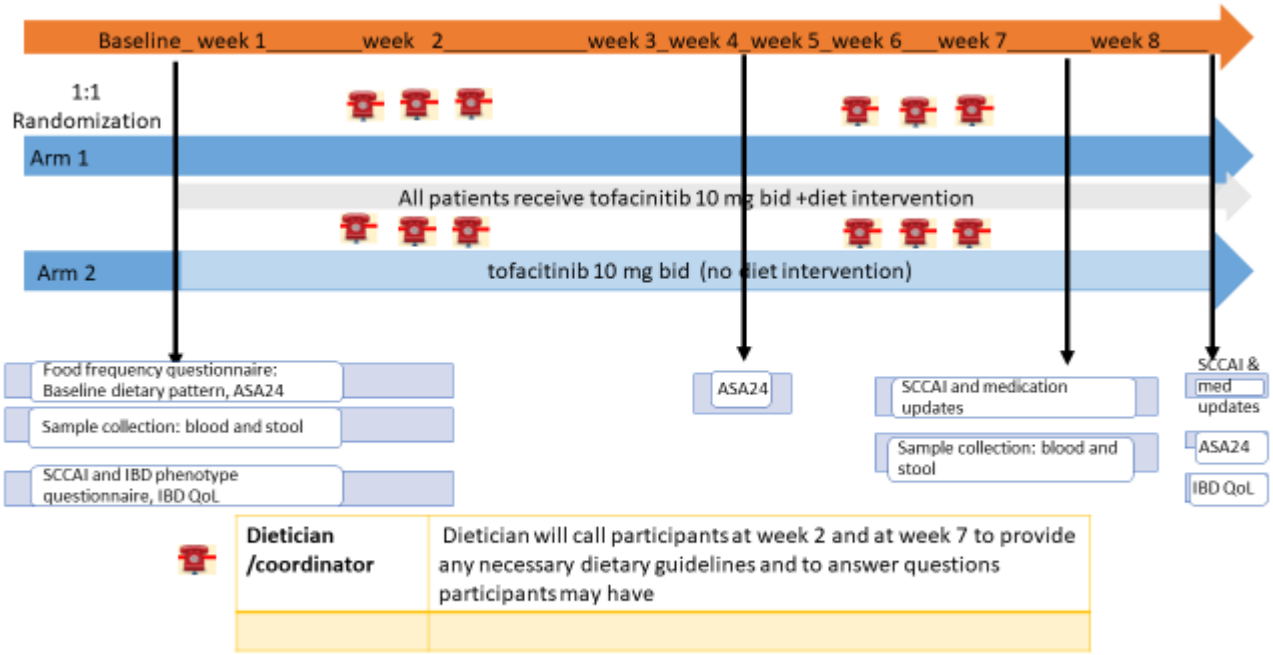
**Table 1.**




If you qualify for and decide to participate in the study, you will come to offices located at either one of our locations 1475 NW 12 Ave or at Crohn's and Colitis Center and 1120 NW 14 street, 14th floor offices at the University of Miami Miller School of Medicine. You will be asked a number of questions about your health, including how you feel and your diet (see Table 1).

For this study, you will also have blood drawn twice: at baseline and again at week 7 (see Table 1). You do not need to be fasting for any of the blood draws and each blood draw will be approximately 1.5 teaspoons or 7 ml.

You will also be asked to provide morning stool for the study of the gut bacteria and for clinical parameters such as parasites. This will occur twice: at baseline and again at week 7 (see Table 1).

We will be taking several of your physical measurements, including your weight height, and will calculate your body mass index.

You will receive phone calls from your coordinator or dietitian during the study on a scheduled basis.

You will be asked to complete an online dietary assessment. These include a validated food-frequency questionnaire (FFQ) and the ASA-24. The FFQ and ASA-24 will be self-administered, but guidance will be provided if needed by one of our research team staff members. Additionally, you will need to record everyday all the food you eat in a food diary or take pictures of your food and email them to a secure email address. Our research staff will provide the special email address to you.

***What are my responsibilities if I take part in this research?***
If you take part in this research, you will be responsible for:

- Providing samples of blood and stool at baseline and week 7
- Completing all written and electronic study-related questionnaires
- Adhering to study dietary recommendations to the best of your ability
- Recording all the food you eat in written food diary or electronic photos sent to secure email during a designated time period
- Communicating with the study dietitian/coordinator for scheduled phone calls or general questions you may have about the study
- Communicating with your medical provider about any discomforts, side effects, or health-related concerns

***What happens if I want to leave the study?***
Your participation in this study is voluntary. You may decide not to participate, or you may leave the study at any time. If you decide to leave the study, contact the study team so the study doctor can work with you to create a safe plan for your withdrawal. Your decision will not result in any penalty or loss of benefits to which you are entitled. Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any reason, including:
• if it is in your best interest
• if you do not consent to continue in the study after being told of changes in the research that may affect you

If you leave the research, we will keep the information about you and the samples (blood, stool, or other samples) we obtained from you. This data will remain as part of the study database and may not be removed.

If you leave the research, we would like to keep checking on your health. We will ask if we can review your medical record and collect data about your medical care in the future. If you agree to allow us to keep collecting data after you stop being in the study, this new data will be handled the same as the other research data.

If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact University of Miami Human Subjects Research Office at 1500 NW 12th Avenue, Suite 1002, Miami, FL 33136, (305) 243-3195.

***What are my other choices if I do not take part in this study?***
This is not a treatment study. You may choose not to be in this study

***Is there any way being in this study could be bad for me?***
Certain risks are associated with your participation in the study:
The process of interviewing may cause you distress and discomfort because you will be talking about your personal activities and thoughts.

It is possible that some of the questions that are asked of you are similar or the same as others asked by other health professionals and you may wonder why it is necessary to answer them again. It may be tiresome to you to be asked these questions again.

The investigator will also make a judgment about your ability to understand this consent form and your ability to participate in the interview. If in his or her opinion the interview is causing you distress, or you are not yet well enough to participate, you will be thanked for your time and the investigator will not proceed. It may be possible that you will again be invited to participate when your health has improved.

If you find any of these feelings uncomfortable, please report them to any of the study doctors and your participation in the study will be re-evaluated. If you find any of these feelings too uncomfortable, you may ask to be removed from the study.

In addition, you may experience discomfort or fatigue in having the study doctors ask you questions on the phone, in person, and with the questionnaires. The risks of answering questions are minimal, but you can stop at any point if you feel too tired to continue with the assessments.

The risks of blood drawing include fainting, temporary pain, and/or bruising at the site of the needle stick. Rarely, infection or the formation of a small clot or swelling of the vein and surrounding area may occur.

If you are planning to become pregnant, or become pregnant during your participation in this study, you are advised to speak to your medical provider as the dietary recommendations and tofacitinib or other biologic medications may pose unforeseeable risks to you and the embryo or fetus.

Although the samples used for the current study are coded, there is still a risk to your privacy when you share information about yourself. However, all the data that can be linked to the samples is saved with password-protected databases and only authorized personnel can access them.

You may not like the particular dietary guidance given to you and the food may not be to your liking. You may also have more hunger than when on your normal diet if you have a baseline diet that is high in calories.

***New Findings***

You will be told about any new information that might change your decision to be in this study.

***Will being in this study help me in any way?***

You may not benefit directly from participating in this study, although it is possible that you experience improvement in your medical symptoms if the diet intervention is effective. However, this benefit may decrease or end once you stop participating in the study and if you choose to go back to eating your regular diet.

Any information obtained from this research study that is important to your health will be shared with you.

You may wish to discuss continuing to learn more about diet and nutrition with your physician if you feel that this type of diet is helpful for your medical symptoms.

***Will being in this study cost me anything?***

# Permission to Take Part in a Human Research Study

You will not incur any direct costs by participating in this study. You and/or your health-care payer/insurance company will not be billed for study visits or procedures or for the research tests that are described in this form required by the study.

You or your healthcare payer/insurance company will still be responsible for any diagnostic evaluations or treatment, including medications, required by your medical condition.

There are no costs to you for participating in this research study. All the tests, procedures and delivered meals and snacks for this study will be provided to you at no cost.

***Will I be paid or receive anything for being in this study?***

For your participation in this study you will be compensated a total of $60 in monetary gift cards.

Study compensation will be disbursed in the following order: You will receive a $30 gift card after completing Visit 1, this includes your initial baseline questionnaires, blood draw and stool kit. You will receive a $30 gift card after completing Visit 2 (week 7), this includes follow-up questionnaires, and a second set of blood draw and stool kit. If you choose to receive the total of $60 gift cards at once, you can receive them at the end of Visit 2, and only after completion of Visit 1 and Visit 2.

If you decide to withdraw from the study, you will only be compensated for any study visit completed.

We will also provide you with instructions and possible dietary recommendations.

Additionally, you will receive the tofacitinib pills if prescribed by your doctor for a total of 8 weeks. This will not be processed through your insurance and will not require authorization. However, authorization of your insurance will be required for tofacinitib after 8 weeks. If you are starting other biologic medications, authorization of your insurance will be required.

If you drive to our medical center and park in the valet parking at the Sylvester Comprehensive Cancer Center, your parking ticket will be validated each time you have to visit the clinic through your participation in this study.

The University of Miami may retain, preserve, or dispose of study specimens and may use these specimens for research which may result in commercial applications. You will not receive money for donating blood, urine or tissue samples nor will you receive money from any future proceeds as a result of this research project

# Permission to Take Part in a Human Research Study

***What happens to the information collected for the research?***

We will do our best to limit the use or disclosure of your personal information, including information from this research study and from your medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of Miami representatives responsible for the management or oversight of this study.
We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you.
We will remove identifiable information from the data we collect about you. After we remove all of the identifiers, we will place a code on the information. The code will be linked to your identity, but the link will be kept in a location that is separate from your study data. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need the access to properly conduct the study.

The information we send to the sponsor will not include information that directly identifies you. Instead, a code will be applied to the data and link between the code and your identity will be kept at the research site.

We may publish and present what we learn from this study, but none of this information will identify you directly without your permission. Information which can identify you may be removed from the data or samples we collect, and after such removal, the data or samples could be used for future research studies or provided to another researcher for future research without additional informed consent.
The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research
- U.S. Office for Human Research Protections
- The U.S. Food and Drug Administration (FDA)
- Regulatory Authorities from other countries
- The study sponsor
- Collaborating researchers outside of the University of Miami, including researchers at Emory University

The study doctor and research team may publish the results of this research. However, they will keep your name and other identifying information confidential.

# Permission to Take Part in a Human Research Study

If you are, or have been, a patient at a University of Miami facility, you will have a University of Miami medical record. We use an electronic medical record system known as UChart, which improves access to information important to your medical care. UChart will show that you are in a research study and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all of your study-related research information may also be placed in UChart. This specifically includes investigational drugs, devices, biologics, or anything else that may, separately or together with other substances or activities, interfere with your clinical treatment or place you at greater risk of harm. Other information from the research study may be included as well. Including this information in the electronic medical record system is intended only to give information to caregivers providing treatment for you while you are on this study.

This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care, or who are otherwise allowed to access your information. The confidentiality of the results and other documents in UChart will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-University of Miami doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.
information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be kept confidential to the extent permissible under the law. The health department may contact you with resources for counseling and medical care, if you need them and want them.

The monitors, auditors, IRB, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations. By signing this consent document, you authorize such access.

Federal law provides additional protections of your medical records and related health information. These protections are described in the University of Miami HIPAA authorization for research, part 2 of this document.

***Will I receive any results from this research?***

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research, with your identifiable information or samples, gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

# Permission to Take Part in a Human Research Study

***Will information or leftover specimens be used for other research?***

Information collected about you and biospecimens collected from you will be used for this research and may also be used for other research studies here at the University of Miami. We may also share the information and specimens with other institutions for research. Before using the information and specimens for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information and specimens came from. We will not ask for additional consent from you to use your information and specimens for the additional research.

***May we contact you by e-mail?***

We are requesting your email address so we can send surveys that you may need to complete in a timely manner. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact **Odalys Guerrero** 305-243-6405.

You do not have to provide your email address to participate in this study. Please initial one of the lines below.

_____ Yes, may use email to contact me for this study. My email address is: _____

_____ No, I do not want to be contacted by email.

***Confidentiality***

There is a slight risk that you may be identified if you take part in this study. However, every effort will be made to protect your identity. The blood sample will be assigned a number Your records and results will not be identified as pertaining to you in any publication without your expressed permission. The Investigator and his collaborators, staff, and the sponsor will consider your records confidential to the extent permitted by law. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.

If you should seek treatment at the University of Miami, information from this study may be given to the treating physicians and other medical staff at the Miller School of Medicine. In turn, the treating physicians and other medical staff at the Miller School of Medicine may provide information about your treatment and care to the study doctor and/or agents for the study doctor.

***What happens if I am injured or get sick because of this study?***

Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, the sponsor will pay for the cost of treating the injury. The University of Miami and the sponsor are not planning to pay for pain, lost wages, and other costs you incur because you were hurt. You do not give up any of your legal rights to obtain payment for an injury if you sign this consent. This policy does not prevent you from trying to obtain compensation through the legal system.

***Future Contact***

We would like to be able to contact you in the future for any modifications of this study or for any future studies. Your decision will not affect your ability to participate in this study.

Please initial next to one of the following responses:

_____ Yes, I agree to be contacted in the future.

_____ No, I do not wish to be contacted in the future.

**WHERE CAN YOU FIND MORE INFORMATION ABOUT THIS STUDY**?

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.

**WHOM TO CONTACT FOR ANSWERS**

If you have any questions or concerns about this research, feel free to ask for additional information from the study doctor or if at any time you feel you have experienced a research-related injury, contact Oriana M. Damas, M.D. at 305-243-8644 (UMGI) 24h a day, 7 days a week; or
Should you have questions regarding your rights as a research subject, you may contact:

University of Miami

# Permission to Take Part in a Human Research Study

Human Subjects Research Office
1400 NW 10th Avenue, Suite 1200A
Miami, FL 33136
Phone: 305-243-3195

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

**HIPAA Protections**
Federal law provides additional protections of your medical records and related health information. These protections are described in the second part of this document, University of Miami HIPAA Authorization for Research.

**AGREEMENT OF DECISION TO PARTICIPATE**
*I have read this consent, which is printed in English (a language which I read and understand). This study has been explained to my satisfaction and all of my questions relating to the study procedures, risks and discomforts, and side effects have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to give permission (consent) for me to take part in this study.*

_____
Printed name of participant

_____ _____
Signature of participant Date

_____
Printed Name of person conducting informed consent

_____ _____
Signature of person conducting Informed Consent Date

# Permission to Take Part in a Human Research Study

## PART 2: UNIVERSITY OF MIAMI/JACKSON HEALTH SYSTEMS

## HIPAA AUTHORIZATION FOR RESEARCH

**What is the purpose of this part of the form?**
State and federal privacy laws protect the use and release of your personal health information. Under these laws, your health care providers generally cannot release your health information for the research listed above unless you give your permission. You will use this form to give your permission. By signing this form, you authorize the University of Miami, Jackson Health Systems, the Principal Investigator and his/her/their/its collaborators and staff to obtain, use and disclose your health information, as described below. These people and institutions are called "Providers" in this form.

**What Personal Health Information will be used or shared?**
You are authorizing the use and sharing of all of the information collected or created during this research as described in the first part of this document, including information in your medical records that is relevant to this research study. Information that may be relevant includes:

- Your past medical history,
- Medical information from your primary care physician,
- All other medical information relating to your participation in the study listed at the top of this document

**Who may receive my Personal Health Information?**
The Providers may use and share your health information with:

- The Principal Investigator and his/her research staff
- Representatives of government agencies that have oversight of the study or who the law permits to access the information such as the U.S. Food and Drug Administration, the Department of Health and Human Services, and the Florida Department of Health
- Groups that collaborate and sponsor research (Cooperative Groups)
- Institutional Review Boards (groups of people who oversee research)
- Other persons who watch over the safety, effectiveness, and conduct of research
- The Sponsor of the research, its agents, monitors, and contractors
- Other participating researchers; and
- Independent data and safety monitoring boards

Authorized staff such as doctors and nurses who are taking care of your but are not involved in this

research may be aware that you are participating in a research study and may have access to research information about you. If the study is related to your medical care, any study-related information may be placed in your permanent hospital, clinic, or physician's office records.

**Why will my Personal Health Information be used and disclosed?**

- Researchers (those individuals in charge of the study) and research team members will use your information to conduct the research study described in this informed consent document and other activities related to the research, such as evaluating the safety of the study.
- The research sponsor and its authorized representatives, business partners, clinical research organizations and affiliates will use your information for the purposes described in this informed consent document and for other activities related to the research, such as assessing the safety or effectiveness of the drug, device or treatment being studied, improving designs of future studies or obtaining approval for new drugs, devices or health care products.
- The University of Miami's clinical trial organizations will use your information to review and support clinical trials at the University.
- Other University of Miami offices involved in regulatory compliance, including the Institutional Review Board (IRB), Offices of General Counsel and Compliance, may use your information to ensure the research is performed correctly.
- U.S. government agencies, such as the Food and Drug Administration and the Office for Human Research Protections, government agencies from other countries, and others who are authorized by law may use your information to review or oversee this research or to see if a new drug, device or other health care product should be approved for marketing.

**What other information should I know?**

1. Once your information has been disclosed to a third party, the federal privacy law may no longer protect the information from further disclosure.
2. You do not have to sign this Authorization, but if you do not sign it, you may not participate in the research and receive the research treatment; however, your right to other medical treatment will not be affected.
3. You may change your mind and revoke (take back) this Authorization at any time and for any reason. To revoke this Authorization, you must write to the study doctor or to the Human Subjects Research Office at 1400 NW 10th AVE, Suite 1200A, Miami FL 33136.
4. If you revoke this Authorization, you will not be able to continue taking part in the research. Also, even if you revoke this authorization, the institutions and people listed above will continue to use and disclose the personal information they have already collected if the information is needed to protect the reliability of the research.
5. While the research is in progress, you will not be allowed to see your health information that is created or collected by the institutions and people listed above. After the research is finished, you may see your health information.

6. This Authorization does not have an expiration date. There is no set date at which your information will be destroyed or no longer used because the research will need to analyze the information for many years and it is not possible to know when they will complete the analysis.
7. You will be given a copy of this authorization after you sign it.

_____ _____

*Signature of participant or participant's legal representative* Date

_____

*Printed name of participant*