

**Six Food vs One Food Eosinophilic Esophagitis Elimination Diet
(SOFEED) Followed by Swallowed Glucocorticoid Trial
NCT Number: NCT02778867**

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CINCINNATI CHILDRENS HOSPITAL MEDICAL CENTER &
<INSERT RELYING INSTITUTION>
INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

STUDY TITLE: Six Food vs One Food Eosinophilic Esophagitis Elimination Diet (SOFEED) followed by Swallowed Glucocorticoid Trial

SPONSOR NAME(S): National Institute of Allergy and Infectious Diseases (NIAID)
Division of Allergy, Immunology and Transplantation (DAIT)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Office of Rare Diseases Research (ORDR)
National Center for Advancing Translational Sciences (NCATS)

INVESTIGATOR INFORMATION:

<INSERT SITE PI NAME>
Principal Investigator Name

<INSERT SITE CONTACT NUMBER>
Telephone Number 24 hr Emergency Contact

Participants Name: _____ Date of Birth: ___/___/___

INTRODUCTION:

This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study.

Your participation is voluntary. We will explain this research study to you. You may ask questions.

- Taking part in this study is your decision.
- You may change your mind at any time.
- You will be given a chance to speak with your doctor and the study clinicians.
- You may stop the study at any time.
- You will be given a copy of this consent form for your records.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you have been diagnosed with Eosinophilic Esophagitis or EoE. EoE is an inflammatory disease in the esophagus (the tube leading



from the mouth to the stomach) that is typically triggered by exposure to certain substances in food. In order for you to participate in this study, you must meet certain criteria and sign the consent form.

WHO IS CONDUCTING THE RESEARCH STUDY?

Dr. Marc E. Rothenberg M.D., Ph.D., a researcher at Cincinnati Childrens Hospital Medical Center (CCHMC), the Division of Allergy and Immunology with collaboration from the Division of Gastroenterology, Hepatology, and Nutrition at Cincinnati Childrens Hospital Medical Center directing this study. Dr. Rothenberg is responsible for the medical supervision of this research.

<INSERT LOCAL PI NAME> is responsible for the medical supervision of this study at <INSERT SITE NAME>.

This research study is funded by the National Institutes of Allergy and Infectious Disease (NIAID), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Office of Rare Diseases Research (ORDR), National Center for Advancing Translational Sciences (NCATS) and the Division of Allergy, Immunology, and Transplantation (DAIT).

WHY IS THIS RESEARCH BEING DONE?

This research study will test the effects (good and bad) of two elimination dietary therapies the 1 food elimination diet (1FED) (milk) vs the 6 food elimination diet (6FED) (milk, egg, wheat, soy, peanut/tree nuts, and fish/shellfish) in people diagnosed with EoE.

This research study will also try to find out how well swallowed glucocorticoids help people diagnosed with EoE. A glucocorticoid is a steroid-like medicine that works to decrease inflammation. The name of the glucocorticoid used in this study is Flovent. This is not a new treatment. In this study it is considered an experimental drug, because it has not been approved to treat people with EoE. However, Flovent is approved by the FDA to treat asthma. Flovent is an inhaler. People with asthma are told to spray the medicine into their mouths while inhaling. The medicine will go into their lungs. People with EoE are told to spray the medication into their mouths and then swallow the medication. If you take the medication this way, it will coat the esophagus (tube leading from your mouth to your stomach) to reduce inflammation. Only some of the study participants will be given Flovent.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

This study consists of two parts, Part 1 and Part 2. Screening can last up to 12 weeks, and parts 1 and 2 are each 6 weeks long. Part 2 is optional, so you may choose whether or not you want to participate in Part 2. You will be in the research study for at least 18 weeks and no more than 27 weeks. Only participants whose EoE does not improve with elimination diet therapy in Part 1 and who choose to continue will continue to Part 2 of this study.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?



About 136 people will be in this study. This research study will take place in multiple centers across the United States.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

The study consists of two phases and a screening. The screening occurs 1 to 12 weeks before the Part 1 visit. The screening is to make sure you are eligible to take part in this study.

During Part 1, you will be randomly assigned (like flipping a coin) to one of the two diets (1FED or 6FED). You cannot pick which diet group you will be in for the study. The choice of which diet you will be asked to follow is random, meaning that there is an equal chance of being in either group. You will be on the diet for 6 weeks.

If your EoE is no longer active after being on one of the diets, you will be done with the study.

If you are on the 1 FED or 6 FED in Part 1 and improve you complete the study. If you do not improve you may choose to continue to Part 2. If you are on the 1 FED and do not improve you will start the 6 FED. You will stay on this diet for 6 weeks. If you are on the 6 FED in Part 1 and do not improve you will start to use Flovent (the medicine that you spray into your mouth and swallow) two times a day for 6 weeks. After 6 weeks you will finish the study.

This study will consist of 6 to 10 visits. For some of the visits you will come to the doctors office. Some of the visits will be over the phone.

What might happen at study visits?

The following may happen at your doctor visits

- You will answer some questions about your family, your diet, about yourself, and about your health.
- The doctor will examine your ears, nose, throat, chest and skin
- Your height, weight, blood pressure, heart rate, breathing rate, and temperature will be checked
- We may collect about 7 tablespoons (105 ml) of blood during the study. Blood is usually collected at every visit. This is to learn more about your EoE and health. We can usually collect all of the blood in one try. If the blood samples are lost, damaged, or need to be repeated, we may ask for additional samples from you.
- We may ask you to collect a stool sample (twice) and bring it to two of your appointments.
- Collection of up to 4 extra esophageal biopsies (taken during endoscopy) A biopsy is a small piece of tissue from your esophagus. This measures your bodys response to diet and/or swallowed Flovent therapy
- Study questionnaires



- The questionnaires will ask you about your quality of life, symptoms, and dietary intake and will take about 15 to 20 minutes for you to complete. You may be able to complete the questionnaires at home if you do not finish.
- Pregnancy test - For females, we will ask you to give us a small sample of urine for a pregnancy test. Results of the pregnancy test will be reported directly to you. If your pregnancy test is positive, you cannot be in the study.
- Prick Skin testing for allergies. You will have a skin test for allergy. The skin test takes about 15 to 20 minutes. A drop of allergen is placed on the skin. Small pricks are made to let the solution enter the skin. The area may become red, raised, and itchy.
- Patch skin testing. A solution with an allergen is placed on a pad that is taped to the skin for 24 to 72 hours. If a red, raised itchy area develops, the person is probably allergic to the allergen being tested.

Your Diet and Other Medications

Throughout the study you should not eat foods that are not part of the diet you have been assigned (1FED or 6FED) or take any medication that is not allowed, if possible. To help you understand your diet, instruction will be provided by a Registered Dietitian. If there are changes to your diet or medication at any time, you should contact a research staff member.

Endoscopies (EGDs)

You will have 2 - 3 endoscopies during the time that you are in the study. This is to test how your EoE is doing. EGDs are considered standard of care for individuals with EoE. The EGDs are not study procedures. We will review the pathology reports and biopsy slides from your EGDs as a part of the study to see how your EoE is doing. We ask your permission for your doctor to take 4 extra biopsies during the EGDs. We will examine the tissue to see if you are getting better. Before you come in for an endoscopy you may be asked to collect a stool sample and bring it to your appointment.

Unscheduled Visits

The study clinician may want to follow up on something from one of your study visits. If this happens, the study team may ask you to come in for extra visits.

Genetic Tests (DNA)

The testing we do using the biopsy is not a genetic test. However, the optional blood samples will be stored for future genetic testing. All DNA resulting from blood samples will be processed and stored at CCHMC.

Genetic and DNA testing in this study is to find risk factor genes for eosinophilic disease. You will not receive results.

Genetic Information Nondiscrimination Act (GINA)

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies, group health plans and employers as outlined above must follow this law. Please note that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Esophageal Biopsies

Likely

Fluid may come out of the site that the tissue sample (biopsy) is taken

Less Likely

A hole in the esophagus, stomach, and/or intestines

To minimize the risks of taking extra biopsies during an endoscopy, the endoscopist will only collect extra biopsies if he/she feels you are able to tolerate the extra biopsies.

Diet Therapy

Less Likely

Lack of proper nutrition

Swallowed Steroids

Likely

Development of oral thrush, (a yeast infection in the mouth/esophagus), which is a known side effect of topical swallowed steroid use.

Less Likely

Other potential side effects include a cold or upper respiratory infection, throat irritation, headache, fever, diarrhea, ear infection, vomiting, bronchitis, inflammation of the nose and throat, and viral infection.

Rare but Serious

It is also possible that the body's internal production of steroids could be affected, and this could increase risk for growth failure and problems with infection and response to other physiological stress. Additional reported concerns include behavior changes, problems sleeping, bone demineralization, hypertension, eye changes (e.g. glaucoma, cataracts), adrenal suppression, and immunosuppression. If you experience any side effect that bothers you or that does not go away, talk to the study staff and/or your doctor. Your health will be monitored by study staff throughout the duration of the study.

Blood collection

Likely

The risk of having blood taken may include pain, bleeding, or bruising.

Less Likely

Lightheadedness and fainting rarely occur.

To decrease the pain or stinging sensation you can request the study team use EMLA or Spray and Stretch Spray before any blood test.

Physical Exam

There are no known risks for the physical exam.

Skin Testing for Allergies (Prick or Patch)

Likely

If you have a positive skin test there will be redness, swelling, and itching of the skin at the site of the test. This may last for 1 to 2 hours.

Less Likely

Redness, swelling, and itching of the skin at the site of the test could occur up to 1 or 2 days after the skin test. The study clinician may prescribe a cream to treat these symptoms.

There is a very small chance that you could have hives, congestion, asthma symptoms or fainting during the test. A study Clinician will always be available to treat these rare symptoms, if they occur.

Rare but Serious

While it is very rare, anaphylactic shock (a whole-body allergic reaction) can occur with allergy skin testing. Anaphylaxis can be life threatening, but a study clinician will always be available when you receive the injection and during the waiting period, and will be prepared to treat this serious reaction.

Stool Sample

There are no known risks.

Study Questionnaires

There are no foreseeable physical discomforts or significant risks related to answering the study questionnaires. However, some questions may be difficult and may be uncomfortable to answer. You may also feel inconvenienced to complete the questionnaires. You may refuse to answer any questions asked on the survey. The study questionnaires typically take approximately 20 to 30 minutes to complete. You will be given ample time to complete the surveys.

Other Risks

There is the unlikely chance that your information is viewed by someone outside the research team who is not authorized to see your health information.

Treatment and procedures in this research study may involve risks that are not possible to predict. You will be informed of any new risks that may be identified during the study. Please ask your study doctor or the research staff to explain any procedures or risks that you do not understand.

WHAT ARE THE REPRODUCTION RISKS?

There is no way to guarantee that the study drug will not have a harmful effect on a developing baby (embryo, fetus, or infant). Therefore, you will not be able to take part in this study if you are pregnant or nursing. If you are sexually active, you may participate in this study if you use an effective form of contraception. You should discuss birth control options with your study doctor.

WHAT ARE THE RISKS OF STOPPING STUDY TREATMENTS?

During the study, treatment for your EoE will be managed by the research staff. You should not stop or alter study medication dosage and/or dietary therapy on your own.

ARE THERE DIRECT BENEFITS TO TAKING PART IN THE RESEARCH STUDY?



If you agree to take part in this research study, there may not be any direct medical benefits to you. Other studies of swallowed fluticasone have shown some benefit for people with EoE. The 1FED and 6FED elimination diet therapies have not been formally proven in EoE. The information learned from this research study may benefit other patients with EoE in the future.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this research study, you may choose not to participate. You do not have to be a part of this study to receive treatment for your EoE. There may be other therapies that could be prescribed for your EoE. You should discuss the alternatives with your doctor.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE?

Making sure that information about you remains private is important to us. To protect your privacy in this research study we will do the following:

- Electronic records will be protected with passwords
- Paper records will be secured in locked cabinets
- Access to records will be limited to only research staff members
- You will be assigned and identified by a unique study identification number
- The link to your study identification number and PHI will be kept in a secure location.
- A copy of this consent form will be included in your research medical record

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. The information from the research study may also be published; however, you will not be identified in such a publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

The Food and Drug Administration (FDA) may choose to inspect your records since you are a participant in this investigation of an unapproved drug.

You will not be identified in any publication or in the sharing of your data about this study. After the study is completed, the data may be placed in a central storage location. These data will not include your name or other information that can identify you. The purpose is to make study data available to other researchers. Information from this study may be put into databases along with information from other studies. There are different kinds of databases; some are publicly accessible and some are restricted. Anyone on the internet can access publicly accessible databases. Only researchers who apply and are approved can access restricted databases. Traditionally used identifying information about you (such as name, phone number, address) will NOT be included or shared with others.



While we will not use information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It is also possible there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you. There may also be other privacy risks that we have not foreseen.

The clinical information collected for this study will be stored at the Data Management and Coordinating Center at the University of South Florida in Tampa, FL and also sent to a Federal data repository. The data management center uses several layers of protection for the clinical data stored there. It meets all of the local and federal security requirements for research datacenters. Your information is stored only using a study ID.

WILL THE RESULTS OF MY RESEARCH-RELATED TESTS BE AVAILABLE?

Some research-related test results and information obtained from this study will be made directly available to you. After the results from the EGD you have at the end of Part 1 are known, you will be told if you should continue on to study Part 2. The information collected from the quality of life questionnaires are for research purposes only and will not have a direct affect in your care. For information regarding the study, including the research and the research participants rights, you may contact the research study team physician, <INSERT LOCAL PI NAME, PHONE NUMBER, and ADDRESS>.

WHAT IF NEW INFORMATION BECOMES AVAILABLE DURING THE RESEARCH?

A member of the research study team will tell you about new information from this or other studies that may affect your health, welfare, or willingness to remain in this study. The information from this research study may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

All study visits and study treatments are provided to you without charge. Study treatments include:

- allergy skin testing
- research blood draws
- physical examinations and vital signs
- pregnancy tests
- research biopsies



During the study, treatment for your EoE will be managed by the research staff. Care of your other medical conditions will continue to be provided by your regular doctor. The costs associated with EGDs and treatment of your other medical conditions will not be paid for by the study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

You will not incur additional medical costs associated with your participation in this research. You will receive the following reimbursement for the time associated with your participation in the study for the study visits outlined below:

Visit	Reimbursement amount for time
Screening and Enrollment	\$125
EOT Phase 1	\$125
Phase 2 Visit 1	\$125
EOT Phase 2 (participation required)	\$125
Total for completion of all study visits	\$500

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

If you believe that you have been injured as a result of participation in biomedical or behavioral research, you are to contact <INSERT PI NAME>, to discuss your concerns.

<INSERT SITE SPECIFIC COMPENSATION INFORMATION>

IF SITE SPECIFIC COMPENSATION POLICY NOT ENTERED USE:

Doctors at the clinic or hospital can arrange for emergency medical care, <INSERT SITE NAME>

The Hospital and the Study Sponsors do not offer compensation or payment for injuries due to participation in this research study. You and your insurance company will be billed for the costs of any care or injuries.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Taking part in this study is completely **voluntary**. You may choose either to take part or not to take part in this research study. Your decision as to whether or not to take part will not result in any penalty or loss of benefits to you and the standard medical care for your EoE will remain available to you.



If you decide to take part in the research study, you are **free to withdraw** your consent and discontinue your participation at any time. Leaving the study will not result in any penalty or loss of benefits to you. If you choose to withdraw from the study, you should contact your doctor to seek alternative treatment for your EoE.

The research study team doctor may stop your participation in the study at any time without your consent if, in their opinion, you require alternative or additional treatment for your EoE, you experience side effects that require your permanent withdrawal, or for other reasons. You may also be removed from the study if the study is stopped by the Institution, the Sponsor(s), or other health authorities.

If you have questions about the study, you will have a chance to talk to one of the research study team members or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

ABILITY TO CONDITION TREATMENT ON PARTICIPATION IN THIS STUDY

You have a right to refuse to sign this consent form and Authorization to use/disclose your Protected Health Information for research purposes. If you refuse to sign this consent, you may not be able to receive research-related treatment. If you refuse to sign this consent, your rights concerning treatment, payment for services, and enrollment in a health plan or eligibility for benefits will not be affected.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study or to report a research-related injury, you can contact the research study team physician, **<INSERT LOCAL PI NAME>** at **<INSERT PHONE AND ADDRESS>**. Research study team members are available to answer any questions you may have about the research at any time.

If you have general questions about your rights as a research participant in this research study, or questions, concerns, or complaints about the research, you can call the **<INSTITUTION NAME>** Institutional Review Board at **<IRB PHONE NUMBER>**. You can also call the Cincinnati Childrens Hospital Medical Center Institutional Review Board at 513-636-8039. You can also call these numbers if the research team members could not be reached, or if you wish to talk to someone other than the research team members.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH



To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your protected health information (called PHI for short).

What protected health information will be used and shared during this study?

- Your medical records
- Your research record for this study

The types of information that will be used and shared from these records include:

- Your laboratory test results
- Clinical and research observations made during your participation in the study
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- Your medical record if it contains information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes)

<INSERT SITE SPECIFIC HIPAA LANGUAGE OR PROVIDE SEPARATE HIPAA AUTHORIZATION FORM FOR REVIEW
IF YOUR SITE DOES NOT HAVE SITE SPECIFIC HIPAA LANGUAGE USE THE FOLLOWING>.

Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the <INSTITUTION NAME> to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than <INSTITUTION NAME> who are also involved in the research and listed below.

WHO WILL SHARE, RECEIVE AND/OR USE YOUR PROTECTED HEALTH INFORMATION IN THIS STUDY?

This form authorizes the following to disclose, use and receive your PHI:

- Every research site of the study (including Cincinnati Childrens and each sites research and medical staff)
- Every health care provider who provides services to you in connection with the study
- Any laboratories and other individuals and organizations that analyze your PHI in connection with the study
- Data Safety Monitoring Board for this study



- The National Institute of Allergy and Infectious Diseases (NIAID), sponsor of the research, and the people and companies they use to oversee, administer and/or conduct the study
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- Office of Rare Diseases Research (ORDR), National Center for Advancing Translational Sciences (NCATS)
- Federal regulatory agencies, such as the Food and Drug Administration (FDA), other foreign regulatory agencies, and others as required by law
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs
- The Principal Investigator and research staff members
- The clinical information collected for this study will be stored in a computer database at the Data Management and Coordinating Center at the University of South Florida in Tampa, FL

HOW WILL YOU KNOW THAT YOUR PHI IS NOT MISUSED?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by Federal Privacy Laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by laws that apply to them.

CAN YOU CHANGE YOUR MIND?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your PHI, you need to notify the study doctor, listed on the first page of the document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

When you withdraw permission, you are no longer part of the study. No new information about you will be gathered for the study except when it is on an adverse (unfavorable) event that is related or potentially related to the study. If one happens, your entire medical record may need to be reviewed.

CAN I SEE MY PHI RELATED TO THE STUDY?

You may have the right to see and copy your protected health information related to the study for as long as this information is held by the study doctor or the healthcare institution. However, to ensure the scientific integrity of the study, you agree that you may not be able to review some of your records related to the study until after the study has been completed.



WILL THIS PERMISSION EXPIRE?

Your permission will expire at the end of the study.

FUTURE USE OF YOUR DATA/BIOLOGICAL MATERIALS

We are asking your permission to store blood or saliva, stool, and tissue samples of biological specimens collected during the course of this study to be used in the future for tests that are not yet planned. These tests may or may not be related to the study of EoE.

Your stored samples will be used to obtain knowledge about genetic information in relation to your disease. Genetic tests study an individual's inherited characteristics, found in DNA, which is present in each of the cells of your body. DNA contains information needed to construct and operate the human body.

The results of tests performed on stored samples or reports resulting from the analysis of your samples will not be given to you or your doctor and they will not be put in your medical record. They will not identify you and will not affect your routine medical care.

There is no benefit to you from the storage of samples and information. However, the use of your samples and information may help researchers learn more about your disease or the genetics related to a specific condition. The purpose of storage and sharing data is to make information available for use in health research and to share what is stored with other researchers. Collecting, storing, sharing information and making it available for other studies may help people in the future. Coded information put into databases together with other stored information from many studies conducted in different places allow researchers to study the combined information and learn even more about health and many different diseases.

Samples will be stored at *Cincinnati Children's Hospital Medical Center (CCHMC)* and/or at the **Data Management and Coordinating Center at the University of South Florida**. If you decide to allow storage, your samples and information may be stored for an unknown length of time.

Although your stored research samples will not be sold, the information obtained from the research performed on your samples may in the future lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

There may be unknown risks associated with the storage of samples and information. For example, if the future research involves genetic testing it is possible that it could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known.

You can change your mind at any time and ask to have your samples destroyed. This request should be made in writing to the study doctor. If you make this request, all remaining stored samples will be destroyed. However, the results of any previous tests using your stored samples will be used. Your



decision regarding the storage of samples or the information resulting from the analysis of your samples will not affect your ability to participate in this study. The future use of your samples and information may contribute to learning more about disease or help to study the genetics related to a specific condition.



Please indicate your response below:

I agree to the collection of additional biopsies (up to 4) for research.
 Yes No _____
Initials of Research Subject

I agree to the collection of 7 tablespoons (105 ml) of blood for research.
 Yes No _____
Initials of Research Subject

I agree to the collection of saliva (spit into a tube) for research.
 Yes No _____
Initials of Research Subject

I agree to collect a stool sample (if I am asked to do so)
 Yes No _____
Initials of Research Subject

I agree to the storage and sharing of samples (blood, saliva, and tissue) for genetic tests not currently planned.
 Yes No _____
Initials of Research Subject

I agree to the storage and sharing of samples (blood, saliva, stool, and tissue) and information resulting from the analysis of my samples for other tests not currently planned.
 Yes No _____
Initials of Research Subject

I choose to participate in Part 2 of the study
 Yes No _____
Initials of Research Subject

May we contact you in the future regarding this study or to inform you of additional studies that may be related to this disease that we are studying?
 Yes No _____
Initials of Research Subject



SIGNATURES:

I have read the information given above. The investigator or his/her designee have personally discussed the research study with me and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I should participate in this study. I hereby give my consent to take part in this study as a research study participant. I will receive a copy of this signed form for my records.

Signature of Participant indicating consent Date

Signature of Participants Personal Representative* Date

*Complete below if signed by a Personal Representative (parent, legal guardian, etc.)

Description of Personal Representatives Authority to Sign for Participant

Printed Name of Personal Representative

Person Obtaining Consent and Authorization Date



Schedule of Study Assessments

Phase	Pre-treatment	Treatment Phase 1					Optional Treatment Phase 2			
Visit Number	1	2	3	4	5	6	7	8	9	10
Visit Description	Screening	Enrollment/ Baseline	Phone Visit #1	Phone Visit #2	Phone Visit #3	EOT or Early Withdrawal	Phase 2 Visit 1	Phone Visit #4	Phone Visit #5	EOT or Early Withdrawal
Week	-12 to -1	0	1	3	5	6	10	11	15	16
Perform Informed Consent										
Assess Eligibility (inclusion/exclusion criteria)										
Obtain medical & dietary history										
Assess con-meds and/or con-therapies										
Vitals (height, weight, BP, heart rate, respiratory rate, temperature)										
Physical Exam										
Research Biopsies (taken during SOC EGD)										
Study Questionnaires										
DSQ										
Dietary Questionnaires										
Skin testing for allergies (prick and patch)										
Research Lab Samples	a	a a a				a a o a a				
Morning cortisol (serum)										
CBC with differential										
Stool sample										
Pregnancy test (urine)										
Assess AEs										
Provide food diary										
Provide instructions for diet or medication										
Determine compliance with treatment								a l	a l	a l
Dispense SGC										
Collect SGC										
Collect compliance logs										

^a First SOC EGD used to determine eligibility may be conducted within 4 weeks prior to enrollment visit.

^b This EOT SOC EGD pertains only to Phase 1 Non-Responders.

^c Other refers to collection of blood or saliva for future genetic testing. These samples will only be collected once, but may be collected at any of the visits indicated.

^d Stool samples may be collected at some participating centers from subjects who consent to stool collection. Stool may be obtained either at Screening/Baseline OR Enrollment, as well as at EOT Phase 1.

^e The DSQ should be completed daily in the 2 weeks prior to each endoscopy.

Each visit window (for visits 2-10) is ±3 days.