KEY INFORMATION FOR EFFECT OF 16-WEEK DUPILUMAB TREATMENT ON SINONASAL RESPIRATORY SYMPTOMS AND SENSE OF SMELL IN ETHNICALLY DIVERSE PATIENTS WITH CHRONIC RHINOSINUSITIS AND NASAL POLYPOSIS (CRSwNP)

(FOR STUDY PATIENTS)

We are asking you to choose whether or not to volunteer for a research study about the effects of dupilumab (Dupixent) on the sense of smell and respiratory symptoms of patients with polyps in the nose. 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?

This study mirrors the standard of care treatment for nasal polyps. If you decide to participate it would be because you and your doctor decided that Dupixent is the right treatment for you. By doing this study, we hope to learn about the efficacy of dupilumab in patients with polyps in their nose from diverse background. Your participation in this research will last about 12 months. For a complete description of the study, refer to the Consent Document. below.

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

You might choose to participate in the study because this study is not testing any new, non-approved medications. Dupixent has been approved for asthma, nasal polyps, and eczema. If you decide to participate this would be because you would like to try Dupixent to improve your nasal polyp symptoms. You might be interested in measuring your symptom improvement on Dupixent by answering questionnaires, testing your sense of smell, and checking your lung function. 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 might decide not to participate if you prefer not to use Dupixent and prefer not to come to clinic for a total of five follow-up visits.

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 chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Elina Jerschow. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 866 MED TALK (866-633-8255)
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

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**:** Effect of 16-week dupilumab treatment on sinonasal respiratory symptoms and sense of smell in ethnically diverse patients with chronic rhinosinusitis and nasal polyps. 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 Elina Jerschow, MD. You can reach Dr. Jerschow at:
Office Address:
1250 Waters Place, Tower 2, 12th floor, Bronx, NY 10461.
Telephone #: 866 MED TALK (866-633-8255)
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

Support for this research study is provided by **Regeneron/Sanofi.**

Why is this study being done?

The goal of this study is to identify the effects of 16-week dupilumab treatment on nasal polyp symptoms in an ethnically diverse population. It will help us understand the effects of dupilumab on sense of smell in the same cohort with polyps in your nose. It will also help us understand the effects of the 16-week dupilumab treatment on biomarkers such as peripheral blood eosinophil counts, serum IgE and also on lung functions.

Why am I being asked to participate?

You are being asked to participate in this study because you have physician-diagnosed polyps in your nose with or without asthma that meet indication criteria for FDA-approved use of Dupilumab.

How many people will take part in the research study?

You will be one of about 70 people who will be participating in this study.

How long will I take part in this research?

It will take you about 12 months to complete this research study. During this time, we will ask you to make 5 clinic visits to Montefiore Medical Center.

What will happen if I participate in the study (for those with physician-diagnosed nasal polyps with or without asthma)?

The Screening Visit will take about 1hr. During this visit, we will do some tests and procedures to see if you eligible to take part in this research study. The study doctor will review the results of these tests and procedures. If you aren't eligible, the study doctor will tell you why. At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Draw a blood sample
- Ask you for a urine sample
- Test your urine for pregnancy if you are a female able to become pregnant. Pregnant women cannot take part in this research study.
- Give you some questionnaires to fill out about asthma (ACQ), sino-nasal outcome test (SNOT-22) and smell test (UPSIT). A part of these tests and exams is performed on every patient who is interested in Dupixent treatment.

If you are eligible you will be asked to come for a baseline visit at which medication will be administered for the first time and you will be trained to self-administer Dupixent. Dupixent has been approved to be given as an injection underneath the skin with a syringe and a needle. We will train you to self-administer Dupixent as prescribed, every two weeks. If you are not comfortable doing it yourself, you will have the option to get it administered by a nurse in a clinic. Dupixent will be given as a standard of care as long as you wish to take it for control of the nasal polyps, in discussion with your health care provider(s).

Visit 2 will take about 1 hour. At this visit we will:

- Check your vital signs
- Ask you about side effects or health problems since your last visit
- Draw blood samples
- Ask you for a urine sample
- We will collect nasal tissue samples, nasal secretions, and bacterial samples for microbiome analysis. Nasal tissue samples and bacterial swabs will be collected by the ENT as done during regular clinical practice using small curettes and swabs. The nasal secretions will be collected using nasal paper by the study team. These samples will be collected for research-purpose.
- Give you 3 questionnaires to fill out

You will have a follow-up visit in 2 weeks from baseline. This visit will be similar to the baseline visit, but we won't collect nasal tissue, secretions, or microbiome during this visit.

The fourth visit in 16 weeks from baseline. There will be two long-term follow-up visits in 36 weeks and in 52 weeks. These three visits will be identical to the baseline visit. During these visits we will compare your current sinonasal and smell test scores from your previous visits to understand the benefit of the treatment over time.

To obtain the blood sample, we will wipe the skin on your arm with alcohol to clean it. Then, we will insert a small needle into a vein 4 tubes[s] of blood will be drawn, about 6-8 tablespoons.

If you decide to undergo an endoscopic sinus surgery after consultation with your physician/ENT, we will collect a portion of the nasal polyp tissue obtained during the surgery. We will collect the leftover nasal polyp tissues after the remaining has been used for clinical care purposes. As part of this study we will review your medical records and put the information we collect in our research records.

Genetic Testing

This study will not involve genetic research or genetic testing.

Specimen Banking (Future Use and Storage)

We will store your specimens and information about you in a "biobank", which is a library of information and specimens (tissue and blood) from many studies. These specimens and information cannot be linked to you. In the future, researchers can apply for permission to use the specimens and information for new studies to prevent, diagnose, or treat disease. Your specimens and information may be kept for a long time, perhaps longer than 10 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 biobank 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 specimens and information about me used for future research studies.
_____ I do NOT consent to have my specimens and information about me 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 $50 for screening visit and $50 for each subsequent visit with a total of $300 for 5 study visits. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed.

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?

If you take part in this study, your insurance or Dupixent Myway Program will pay for the medication. You and/or your insurance company will have to pay for any costs that are part of your regular medical care.

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

Industry Sponsored Research
Injury language in the consent document must match language in contract. Contact the Office of Clinical Trials at OCT@montefiore.org or the Institutional Review Board at IRB@einstein.yu.edu for further assistance.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including "over-the-counter" remedies and nutritional supplements or herbs.
- You must take your study drug as instructed.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- ***Drugs may cause a reaction that, if not treated promptly, could be life-threatening. It is important that you report all symptoms, reactions and other complaints to the research study doctor.***
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor's name and phone number.
- You may carry out all your normal daily activities.

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.

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 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.

Questionnaire
You may feel uncomfortable answering questions about your previous polyp- and asthma-related events and some personal issues. You can choose not to answer questions that make you feel uncomfortable.

Blood Draw
Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

Risks of Taking dupilumab (dupixent)
Side effects:

- Conjunctivitis or keratitis
- Hypersensitivity reactions (urticaria, rash, erythema nodosum, anaphylaxis, and serum sickness)
- Vasculitis rash, worsening pulmonary symptoms, and/or neuropathy

There may be other risks of dupilumab/dupixent that are currently unknown.

Taking Study Drug with Other Medications

For your safety during this study, call your study doctor BEFORE you take any:

- New medications prescribed by your doctor
- Other medications sold over the counter without a prescription
- Dietary or herbal supplements

Allergic Reaction to Study Drug
Any drug can cause an allergic reaction which could be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you are having trouble breathing, call 911 immediately.

Risks of tissue donation during endoscopic sinus surgery
The collection of nasal or sinus tissue for research purposes will not affect the surgery. If the surgeon performing the polypectomy feels that the removed tissue should be further evaluated

and not donated for research purposes, then the tissue is not being collected or used in this study.

Risks of sinonasal epithelium collection with Rhino-Pro Currette:
The use of the curette may potentially lead to irritation of the nasal mucosa, bleeding, and, rarely, an infection that may require antibiotic treatment. Participants may have some soreness around the nose or sinuses for 1 or 2 days after the endoscopy. To minimize patient discomfort, we will use a local anesthetic (topical lidocaine, 4%), as it is a routine during rhinoscopy. A minimal bleeding may occur and will be treated with vasoconstrictor oxymethazoline.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The study will give help us identify the effects of 16-week dupilumab treatment on nasal polyp symptoms in an ethnically diverse population. It will help us understand the effects of dupilumab on sense of smell in the same cohort with polyps in the nose. It will also help us understand the effects of the 16-week dupilumab treatment on biomarkers such as peripheral blood eosinophil counts, serum IgE.

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 and the sponsor 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.

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. The final study visit will take about 60 mins. At this visit, we will:

- Collect blood and urine samples
- We will give you questionnaires to fill out.
- Perform breathing tests called spirometry an determine the nasal peak flow and nasal fractioned exhaled nitric oxide (N-FeNO)
- Collect nasal tissue, fluid and microbiome samples

Can the study end my participation early?

Sometimes the company sponsoring the research, or the research study doctor may stop your part in the study. They might do this because you fail to follow instructions given to you by the research study doctor, or if you are a woman, you become pregnant. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

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	Time
Printed name of the person conducting the consent process	Signature	Date	Time