/NCT Number:	NCT03791060
Official Title:	Secukinumab for NLD (Cosentyx) in Patients With Necrobiosis Lipoidica Diabeticorum (NLD)
Document Type:	Informed Consent
Document Date:	09/18/2020

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Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations:

Consent Approval Date: 9/18/2020

Protocol Number: 2018P000634

BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE COMMITTEE ON CLINICAL INVESTIGATIONS
08/23/2021
APPROVAL EXPIRATION DATE

INFORMED CONSENT FORM TO TAKE PART IN A RESEARCH STUDY

SUBJECT'S NAME:
TITLE OF RESEARCH PROTOCOL: An open-label proof of concept study regarding the use of Secukinumab (Cosentyx) in patients with necrobiosis lipoidica diabeticorum
PRINCIPAL INVESTIGATOR: **Martina Porter, MD**
PROTOCOL NUMBER: **2018P000634**

INTRODUCTION:

- This is a research study;
- Your participation is voluntary;
- A research study includes only people who choose to take part;
- You may or may not benefit from participating in the study. However, your participation may help others in the future as a result of knowledge gained from the research;
- You may leave the study at any time;
- If you choose not to take part, or if you leave the study, your decision will in no way harm your relationship with any member of the research team or any other individuals at Beth Israel Deaconess Medical Center.

Please read this consent form carefully and ask the investigators or study staff to explain any words or information that you do not clearly understand. Once you read this consent form and understand what your participation in this study will involve, you will be asked to sign this form if you wish to take part. You will be given a signed copy of the form to keep for your records.

DISCLOSURE OF SPECIAL INTERESTS OF BIDMC AND INVESTIGATORS

This study is being conducted by *Dr. Martina Porter* and is funded by Novartis. The funding agency in this study, *Novartis,* is paying Beth Israel Deaconess Medical Center *and Dr. Martina Porter* to perform this research. Drs. Alexa Kimball and Martina Porter are paid consultants for Novartis.

WHOM TO CONTACT IF YOU HAVE QUESTIONS OR PROBLEMS

If you have any questions, concerns or complaints about this research or experience any problems, you should contact Dr. Martina Porter at (617) 667-5834.

PURPOSE

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The study is being done to see and how well secukinumab will work to help people with Necrobiosis Lipoidica Diabeticorum (NLD). We are also conducting this study to see if there are any changes to your skin under the microscope after you receive secukinumab.

The *drug i*nvolved in this study is investigational. This means that the study *drug* is still being tested in research studies and is not approved by the Food and Drug Administration [FDA] for the way that it is being used in this study. This particular investigational agent, *Secukinumab,* has been approved by the FDA for use in other diseases or conditions, but we do not yet know if it is useful or safe as a treatment for NLD .

Secukinumab is a medicine called a biologic that works by suppressing the immune system. Specifically, secukinumab targets a protein in the body called IL-17. There is some evidence to suggest that IL-17 may play a role in the development of NLD. Therefore, inhibiting IL-17 with secukinumab may be a potential treatment for NLD.

STUDY PARTICIPANTS

You have been asked to be in the study *because you have Necrobiosis Lipoidica Diabeticorum (NLD).*

Approximately *18* people will take part in this study at Beth Israel Deaconess Medical Center. A total of *18* people will take part in this study at all study sites.

DESCRIPTION OF STUDY DETAILS

If you agree to be in this study, you will be asked to read and sign this consent form. After you sign the consent form, the following things will happen:

The study has 3 periods:

- Screening period (up to 4 weeks before you receive your first dose of study drug)
- Treatment period (26 weeks)
- Follow-up period (12 weeks)

1. Screening Period (Visit 1, approx. 3 hours): Screening procedures are tests and procedures that will be done to determine if you are eligible to take part in the research study. For this research study, the screening procedures include:

    - Test your urine for pregnancy, if you are a female able to become pregnant. Pregnant women can't take part in this research study.
    - Take your medical history, including any medications you are currently taking or have taken in the past. You will need to tell the study doctor about all medications or therapies you have used for your NLD in the past, even if you are not using them

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now.

- Physical exam**,** may include a measurement of your weight, height, blood pressure, heart rate, body temperature
- Examine and grade your NLD.
- The study doctor will ask you to rate your pain from your NLD
- Have blood drawn (to test your blood counts, electrolytes, kidney and liver function tests, HIV screening, Hepatitis B screening, Hepatitis C screening, and tuberculosis screening test)
- Take photos of your NLD.

2. Treatment Period (10-11 visits, approx. 1-3 hours per visit): Visits will occur every week through week 4, then every four weeks through week 24, then at week 26. If you qualify to take part in this research study, you will undergo these research procedures:

- Test your urine for pregnancy, if you are a female able to become pregnant. Pregnant women can't take part in this research study.
- Ask you about any changes in your health and medications since your last visit.
- Physical exam**,** may include a measurement of your weight, height, blood pressure, heart rate, body temperature
- Examine and grade your NLD.
- Questionnaires: you will be asked to rate your pain from your NLD and how it impacts your quality of life
- Blood for routine laboratory tests: have blood drawn to test your blood counts, electrolytes, kidney and liver function tests
    - The amount of blood collected at each visit is as follows
        - Screening: approximately 33 milliliters
        - Baseline: approximately 9 milliliters
        - Visits 4, 8, 12, 16, 20, 24 – approximately 9 milliliters at each visit
        - In total approximately 96 milliliters will be collected
- Take photos of your NLD.
- A skin biopsy will be taken from one area where you have NLD
- Administration of study drug
    - Secukinumab will be given for 24 weeks
        - It will be given weekly a week 0, 1, 2, 3 and 4 then every four weeks after that for a total of 9 doses
        - It is dosed at 300 mg of secukinumab at each visit (given as 2 injections of 150 mg each) and is given subcutaneously (meaning under the skin)
- Suture removal: Removal of any stitches placed 2 weeks after the skin biopsy

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See Table 1 below for a summary of study procedures.

3. Monitoring/Follow-Up Period (One telephone call, approx. 30 min). Procedures performed to evaluate the effectiveness and safety of the research procedures are called "monitoring" or "follow-up" procedures.

You will be asked to complete one study visit after you have stopped taking the study drug that will occur over the phone. You will receive a phone call from our study staff at Week 36. During this phone call, we will ask about any changes in your health and medications since your last visit.

4. Early Termination Visit

If you stop or you are withdrawn from the study, you will be asked to return for an early termination visit. This visit will occur within 2 weeks after study withdrawal. The procedures at this visit will be the same as at the week 26 visit.

- Review adverse events
- Suture removal, if applicable

See Table 1 below for a summary of study procedures.

Table 1. Summary of Study Procedures

Study Procedures	Screening	BASELINE/WK0	Wk1	Wk2	Wk3	Wk4	Wk8	Wk12	Wk16	Wk20	Wk24	Wk26*	Follow Up Call (Wk 36)
Medical history, including any medications you are currently taking or have taken in the past	✓	✓											
NLD history	✓												
Eligibility criteria	✓	✓											
Vital signs	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Complete Physical Exam, including height and weight	✓	✓					✓				✓		
Any changes in your health and medications since your last visit		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓

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Examination and grading of your NLD	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Questionnaires		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
If you are a woman who can have children, a pregnancy test will be done	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Blood for routine laboratory	✓	✓				✓	✓	✓	✓	✓	✓		
Blood for HIV, Hepatitis B screening, Hepatitis C screening, and tuberculosis screening test	✓												
Photographs of your NLD		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		
Review Adverse Events		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Skin biopsy		✓									✓		
Suture removal*				✓								✓	
Administration of the Study Drug		✓	✓	✓	✓	✓	✓	✓	✓	✓			

HOW ARE THE SKIN BIOPSY SPECIMENS COLLECTED AND STORED?

Skin Samples to be Collected

The skin samples will be collected by a procedure called a skin biopsy. The procedure will be performed by your study doctor.

At the baseline visit (Week 0), a skin biopsy will be taken from an area of your skin that is affected by NLD. The study doctor will determine the exact location after examining your skin.

At Week 24), a skin biopsy will only be taken from an area of your skin that is affected by NLD.

Before each of the skin biopsies, the area of your skin will be cleansed with an antiseptic solution (alcohol), and then numbed with a local anesthetic such as lidocaine, similar to what is used by a dentist. Injection of the lidocaine may cause a brief burning sensation. The doctor will use a small tube-like instrument, which will remove a very small piece of skin (4 mm) from your affected skin. The area may need to be closed with one or two stiches or gel foam, and then covered with a Vaseline and bandage. The doctor will give you instructions on how to care for the area after the procedure. After 2 weeks, you will need to come to the study site so the study staff can remove your stitches.

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Skin Biopsy Evaluation
A dermatopathologist, who is a specially trained doctor that looks at skin biopsies under the microscope, will review your skin biopsies for signs of inflammation. He will also evaluate for biomarkers, or compounds in your body that can be used to tell if people suffer from certain diseases and how they may respond to medication, to see if your skin has changed under the microscope in response to the study drug. Your skin biopsies will be stored in the pathology laboratory at BIDMC during the course of the entire study and will be destroyed upon study completion.

RISKS AND DISCOMFORTS
A risk to taking part in this study is the likelihood of receiving a drug or dose of a drug that may not be effective in helping to treat your disease. This means that you may spend time and experience side effects taking a drug that may not provide you with any health-related benefits.

As a result of your participation in this study, you are at risk for side effects listed in this section. You should discuss these with the investigator and with your regular doctor if you choose.

<u>Common</u>
- Sore throat and stuffy nose (upper respiratory tract infection, nasopharyngitis),
- Runny nose (rhinitis), diarrhea
- Cold sores (oral herpes)

<u>Rare</u>
- Oral thrush (oral candidiasis),
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia),
- athlete's foot (tinea pedis),
- infection of the external ear (otitis externa),
- discharge from the eye with itching,
- redness and swelling (conjunctivitis),
- itchy rash (urticaria)

<u>Pre-treatment Evaluation for Tuberculosis</u>: Before receiving treatment with Secukinumab you will be evaluated for tuberculosis (TB) infection. You will not be eligible for this study, if you have an active TB infection or latent TB infection.

Those subjects found to have latent TB will be referred to Infectious Disease for treatment.

<u>Hypersensitivity reactions</u>: Allergic reactions have been seen in patients treated with Secukinumab

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during studies, including nettle rash or hives in up to 10% of patients, but most reactions were not serious and were mild to moderate in nature. If you have a history of severe hypersensitivity to any of the ingredients of the medicine, you should not be treated with Secukinumab and cannot participate in this trial. The removable cap of the Secukinumab prefilled syringe contains natural rubber latex which may cause an allergic reaction in latex-sensitive individuals. Severe allergic reaction with shock (anaphylactic reaction) and cases of urticaria occurred rarely in Secukinumab treated patients in clinical trials (<0.1% of treated patients). If a serious allergic reaction occurs, Secukinumab treatment should be stopped immediately and appropriate therapy started. Signs of serious allergic reaction may include difficulty breathing or swallowing, low blood pressure, which can cause dizziness or light-headedness, swelling of the face, lips, tongue or throat, severe itching of the skin, with a red rash or raised bumps.

Cancers and tumors that may be malignant: Some medicines that influence the immune system may increase the risk of developing cancers. This is therefore a theoretical risk with Secukinumab, although currently there is no evidence that Secukinumab increases the risk of cancer. There is no adequate data available on the use of Secukinumab in patients who have, or have previously had, cancer.

If you are pregnant or become pregnant, this treatment may involve risks to the embryo or fetus which are currently unforeseeable.

PREGNANCY

Because of the effects of this (these) study medication(s) on the developing fetus is (are) not known, you may not participate in this study if you are pregnant. You will be required to take a pregnancy test to verify that you are not pregnant before receiving your first dose of the study medication(s).

For the duration of the study, if you are engaged in sexual activity that could cause you or your partner(s) to become pregnant, you and your partner(s) must agree to use a highly effective method of birth control or abstain from sexual activity that could cause you or your partner(s) to become pregnant.

The methods of highly effective birth control for this study are below:

1. Contraceptive implant, such as Nexplanon or Implanon
2. Levonorgestrel or copper intrauterine device (IUD), such as Mirena, Skyla, ParaGard or Liletta
3. Permanent female sterilization, such as tubal ligation or Essure with confirmed tubal occlusion
4. Male partner(s) has had a vasectomy more than three months before study enrollment
5. Oral contraceptives pill, patch or ring
6. Injectable contraception, such as Depo Provera
7. Consistent use of a barrier method, such as diaphragm with spermicide or condoms

If you believe you have become pregnant while participating in this study, you must inform your study doctor

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immediately. Participants who become pregnant during the course of the study will immediately be withdrawn from the study, and the study doctors may ask to monitor your pregnancy, your health, and your baby's health after you are withdrawn from the study.

If you are a man capable of fathering children, you must use adequate contraception while participating in this study. For the purposes of this study, adequate birth control means;

1. use of a condom
2. your partner must use an approved method of birth control as listed above.

Other Risks Related to Study Procedures

- **Blood Tests:** The risks and discomforts of blood drawing from a vein include the possibility of pain or bruising at the site of the blood draw, occasional feeling of lightheadedness, and rarely, infection at the site of the blood draw.

- **Subcutaneous (SC) Injection:** A needle will be used to inject the medicine in the tissues under your skin, causing a small hole or puncture. For most people, needle punctures for SC shots do not cause any serious problems. Sometimes they may cause bleeding or bruising where the shot is given. Sometimes people complain of discomfort, infections, and/or pain at the site of the shot. Infection may happen with SC shots because the needle breaks the skin. Then germs can get into the skin underneath. Shots may cause abscesses or skin and soft tissue infections. Additionally, if a blood vessel is hit by the needle, the risk of infection will be even greater if germs are taken into the blood system.

- **Skin Biopsy:** Minor bleeding at the site of the skin removal is the most common side effect. The biopsy may cause pain that typically resolves within several hours. There is a small risk of infection at the biopsy sites. After the procedure, if you have any bleeding, feel warmth, swelling, tenderness, or redness at the biopsy site, contact the study doctor. You may have to come to the clinic so the doctor can check your biopsy site. Additionally, although rare, the biopsy site may develop a small scar.

- **Surveys/Questionnaires**: Some of the questions we will ask as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in the study at any time.

- **HIV testing:** Because the results of the HIV test done as part of this study may become a permanent part of your medical record, and because disclosure of a positive HIV test may have a negative impact on your insurability, employment, and social relationships, you may wish to seek a private confidential HIV test before enrolling in this study. Again, if you choose to enroll in this study even after having the HIV test done privately, the HIV test will be done again as part of your participation in the study and therefore the results may become a permanent part of your medical record. HIV is the cause of AIDS

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(the Acquired Immunodeficiency Syndrome). A positive test result means that you are infected by HIV, but does not tell you that you have AIDS. For antibody tests, a negative test usually means that a person is not infected. However, it can take 3 to 6 months for the HIV antibody test to become positive after infection. Having an HIV test is voluntary; however, if you choose to participate in this study HIV testing must be done to assure your safety (for example, in circumstances where a study drug would potentially have a negative effect on your ability to fight off infection and disease if you are HIV positive), to establish whether you are eligible to participate, and/or for other reasons required by the research protocol. If you choose not to have HIV testing, you will not be able to participate in this study. Massachusetts state law requires that you provide verbal informed consent before diagnostic testing for HIV is performed, and additional information relevant to the decision whether to get tested may be provided to you in connection with receiving the test; you are free to ask questions specifically about the implications of HIV testing.

If you decide to participate and agree to be tested for HIV, the results of the HIV testing will be entered into your study chart in **Dr. Martina Porter's** office, and may also be added to your medical record. Information derived from this study and from your medical record may be reviewed and photocopied by state and federal regulatory agencies, including the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) where applicable, and the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center, with protection of confidentiality so far as permitted by applicable law. Your physician is required by law to report positive HIV test results to health officials, including the Massachusetts Department of Public Health (MDPH) HIV/AIDS Surveillance Program. Reports to the MDPH will include your full name, address, medical record number, social security number, date or birth and gender. These reports may also include information about your medical history, health condition, and treatment. Your written approval is not required for this mandatory reporting, assuming you agree to participate in this study and receive an HIV test as a result of that participation. In general, releases of your HIV test results outside BIDMC (with the exception of required reporting to public health officials) require your written informed consent. By signing this form, you agree that those individuals who need to see your medical information, including the results of your HIV test, in order to conduct the study (including the BIDMC researchers, any collaborators, the sponsor of the study, the BIDMC Committee on Clinical Investigations and other groups that oversee the research at BIDMC, and the government agencies that have jurisdiction over the research) may receive the results of your test.

By signing here you acknowledge that all of your questions have been answered and you consent to the release of your HIV test results by BIDMC as necessary to complete the research study.

_____

Patient name (print): **Date**

LOSS OF CONFIDENTIALITY

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information.

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CONFIDENTIALITY

Information learned from your participation in this study and from your *medical record* may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or other federal and state regulatory agencies, and by the drug manufacturer, *Novartis,* accreditation agencies, the Committee on Clinical Investigations, the Human Subjects Protection Office and others involved in research administration of the Beth Israel Deaconess Medical Center. Information resulting from this study and from your *medical record* may be used for research purposes and may be published; however, you will not be identified by name in such publications.

MEDICAL RECORD

A copy of this consent form and information collected during this research may become part of your medical record, if the information is relevant to the care you receive at Beth Israel Deaconess Medical Center. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Beth Israel Deaconess Medical Center and may be reviewed by staff when carrying out their responsibilities, as well as by external parties such as health care insurers and others in certain circumstances. If you are not currently a patient at Beth Israel Deaconess Medical Center and do not have a medical record at Beth Israel Deaconess Medical Center, one may be created for you for your participation in this research. You may also be required to register as a patient of Beth Israel Deaconess Medical Center in order to participate in this research.

POSSIBLE BENEFITS

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

OTHER AVAILABLE OPTIONS

Taking part in this study is voluntary. Instead of being in this study, you have the following options:

- Topical steroids – topical means that the medicine is applied to the surface of the skin
- Intralesional steroids – intralesional means that the medicine is injected under the surface of the skin

- Surgery, laser, or phototherapy (phototherapy is when light treatments are used to help treat skin conditions)
- Other immunosuppressive medications – these are medications that decrease the immune system

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It is important to note that it is possible to get Secukinumab *at this institution and other locations* even if you do not take part in the study. Secukinumab has not been approved by the FDA for treatment of your condition, however, many doctors in the community commonly prescribe the drug to treat psoriasis, psoriatic arthritis, and ankylosing spondylitis. Please be aware that not all doctors may agree to prescribe this drug for you, and that not all health insurance companies will pay for the drug when it is prescribed for NLD.

This research study is not meant to diagnose or treat medical problems. Participation in this research study does not take the place of routine physical examinations or visits to your regular doctor.

We recommend that you discuss these and other options with the investigator and your regular doctor so that you can make a well-informed decision about participating in this study.

IF YOU DECIDE NOT TO TAKE PART IN THE STUDY

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you. The investigators will tell you about new information that may affect your willingness to stay in this study.

If you decide not to participate in the study or decide to leave the study early, your decision will not affect your relationship with the research team or any other individual at Beth Israel Deaconess Medical Center.

INVESTIGATORS RIGHT TO STOP THE STUDY

The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, or if it would be dangerous for you to continue, or if you do not follow study procedures as directed by the investigators. Beth Israel Deaconess Medical Center or the funding source may stop the study at any time.

COSTS AND/OR PAYMENTS TO YOU

COSTS COVERED BY STUDY

You will not be charged for *tests, procedures, or medications* that are part of this research study. However, you and your insurance company will be charged for other tests, procedures or medications of this study that are considered standard treatment for your medical condition.

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PAYMENTS TO YOU:

You will be paid for the following: $50 per scheduled study visit from Screening to Week 26 and an additional $100 for visits where a biopsy is performed (Week 0/baseline and Week 26 or Early Termination Visit).

If you complete the entire study, the total payment will be in the amount of $600. If you complete both biopsies, you will receive an extra $200. Payment will be made by check after every 2 visits. If you do not complete all visits, you can get paid at any time. Your payment will be prorated based on the number of visits that you completed.

It may take up to 8 weeks for you to receive payment by check.

Any payments made to you may be taxable income to you. This does not include any payments you may receive to reimburse (pay you back) you for certain expenses like parking fees or travel. We are required to obtain your name and social security number for preparation and submission of Internal Revenue Service (IRS) Form 1099-Misc. You may receive an Internal Revenue Service Form 1099 from BIDMC if you receive more than $600 or more in one calendar year for taking part in one or more research studies at BIDMC. Questions about your own tax status should be referred to your personal tax advisor.

You will be reimbursed for the following: *parking*
The amount of reimbursement will be based on receipts for these expenses up to $20 per visit.

COST OF RESEARCH RELATED INJURY:

If you are injured as a direct result of your participation in this study, you should contact the Investigator at the number provided under the section "Who to Call if You Have Questions" in this form. You will be offered the necessary care to treat your injury. We reserve the right to bill your insurance company or the sponsor, if appropriate, for the care you get for the injury. We will try to get these costs paid for, but you may be responsible for some of them. You may be responsible for all co-payments and deductibles required under your insurance. At this time there is no plan to reimburse you for items such as lost wages or lost time from work. By signing this consent form you have not given up any legal rights.

OTHER IMPORTANT INFORMATION

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.

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BETH ISRAEL DEACONESS MEDICAL CENTER
APPROVED BY THE
COMMITTEE ON CLINICAL INVESTIGATIONS
08/23/2021
APPROVAL EXPIRATION DATE

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use [internally at BIDMC] and disclose [to people and organizations outside the BIDMC workforce identified in this consent] health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records if applicable as well as any new information generated as part of this study. This is your Protected Health Information.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects.

PEOPLE/GROUPS OUTSIDE OF BIDMC WITH WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE SHARED

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this study:

- The other hospitals and medical centers taking part in this study and research collaborators at those institutions
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of any other IRBs (beyond the BIDMC Committee on Clinical

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PRINCIPAL INVESTIGATOR'S NAME: **Martina Porter, MD**
PROTOCOL #: 2018P000634

Investigations) that oversee the research
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The main reason for using and sharing your Protected Health Information is to conduct and oversee the research as described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to *Martina Porter,* 330 Brookline Ave., Boston, MA 02215. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for

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Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

ADDITIONAL CONTACT FOR QUESTIONS OR CONCERNS

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

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08/23/2021
APPROVAL EXPIRATION DATE

THE FOLLOWING PARAGRAPHS CONTAIN SOME STANDARD INFORMATION WHICH GENERALLY APPLIES TO INDIVIDUALS PARTICIPATING IN A RESEARCH STUDY.

CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page[s] of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Human Subjects Protection Office (HSPO).

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____ _____

Signature of Subject or Legally Authorized Representative (Parent if the subject is a minor) — Date

_____

Relationship of Legally Authorized Representative to Subject

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____

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SIGNATURE OF INVESTIGATOR/Co-Investigator DATE

_____

PRINT INVESTIGATOR'S/Co-Investigator's NAME

A signing co-investigator must be listed on the study's approved Research Staffing Form at the time of consent.

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THE FOLLOWING SECTIONS ARE NOT NEEDED FOR ALL STUDIES AND SHOULD BE UTILIZED AS INDICATED:

If the subject is able to speak and understand English but is not able to read or write

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is able to understand English but is not physically able to read or write or see

I was present during the entire oral presentation of the informed consent and witnessed the subject's agreement to participate in the study.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

If the subject is not English speaking and signed the translated Short Form in lieu of the English consent document.

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As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Signature of Interpreter: _____

Printed name of Interpreter: _____

Date: _____