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 **"**A Phase I Study of Low Dose Radiotherapy for Advanced Hidradenitis Suppurativa**".** 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." His name is Dr. Steven Cohen. You can reach Dr. Cohen at:
Office Address: Montefiore Medical Center Medicine (Dermatology) 111 East 210th Street, Bronx, NY 10467 Telephone #: 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

Why is this study being done?

The goal of this study is to determine the safety and efficacy of treating patients with advanced hidradenitits suppurativa (HS) with radiotherapy.

Why am I being asked to participate?

You are being asked to participate in this study because you have been referred to our Montefiore Hidradenitis Suppurativa Treatment Center, you are over 20 years old, and have advanced Hidradenitis Suppurativa and other treatments have not been successful. We hope to enroll at least 20 patients at our single site study.

How long will I take part in this research?

It will take you about 3-4 months to complete this research study. During this time, we will ask you to make about 8-10 study visits. You will have the choice to decide to continue to complete questionnaires, have photos taken, and blood tests for up to 12 months after treatment.

What will happen if I participate in the study?

This is a prospective Phase 1 treatment study. You will be treated at the Montefiore Hidradenitis Suppurativa Treatment Center and Montefiore Medical Park, Radiation Oncology Clinic. The procedures involved in this study include data collection and photos, X-Ray treatment, blood tests, wound discharge sampling, and skin biopsies.

Study participation will last for about 3-4 months, and optionally for an additional 6-12 months after radiotherapy treatment. Four-five of these visits will be during the X-ray treatment week; the other visits will be before and after treatment. You will be asked to schedule follow-up appoints at the Montefiore Hidradenitits Suppurativa Treatment Center.

The Screening Visit will take about 30 minutes. During this visit, we will do some tests and procedures before you 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:

- Review your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Skin imaging (photos & ultrasound of affected area)
- Draw a blood sample
- Sample of skin discharge and skin biopsy
- 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 your general health, well-being, and quality of life.

Visits for X-ray treatment will take up to 2 hours long. At these visits we will:

- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Skin imaging (photos & optional ultrasound) and possible CT scan
- Give you some questionnaires to fill out about your general health, well-being, and quality of life.
- Ask you about side effects or health problems since your last visit

Follow-up visits will take up to 30 minutes long. At these visits we will:

- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Skin imaging (photos & optional ultrasound)
- Give you some questionnaires to fill out about your general health, well-being, and quality of life.
- Ask you about side effects or health problems since your last visit
- Draw a blood sample, ultrasound, discharge sampling, and skin biopsy 3 months after treatment

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. One tubes of blood will be drawn, about 1-2 teaspoons

To obtain a skin biopsy, a small area of skin will be cleaned and injected with numbing medicine. A 3-6mm circle of skin will be removed and the area will be closed with a stitch. Instructions for looking after the biopsy area will be provided. This stitch will need to be removed within 1-2 weeks.

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.

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 can 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, including genetic research. 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. Your specimens and information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy remaining specimens and information but if these were already shared with other researchers, we cannot get them back.

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.

INITIAL YOUR CHOICE BELOW

_____ I consent to be contacted in the future to learn about:

_____ New research protocols that I may wish to join.

_____ General information about research findings.

_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

You will not receive any payment or other compensation for taking part in this study.

Will it cost me anything to participate in this study?

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

If you take part in this study, you or your insurance will pay for radiotherapy procedures. You will be responsible for transportation and co-payments or deductibles.

What will happen if I am injured because I took part in this study?
If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital, will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to Dr. Steven Cohen at **866-633-8255** .

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.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- 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

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information and specimens will be kept as long as they are useful for this research.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

The only people who can see your research records are:

- The research team and staff who work with them
- Organizations and institutions involved in this research: Albert Einstein College of Medicine & Montefiore Medical Center
- Groups that review research (the Einstein IRB, and the Office for Human Research Protections

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any risks to me?

- This protocol is considered greater than minimal risk, due to radiation exposure and the skin biopsy procedure.
- The initial risk of radiotherapy is temporary discomfort and inconvenience during the treatment period.
- This dose of radiotherapy may cause a temporary hair loss for a few months.
- The known risk of both acute and chronic radiation-induced dermatitis is very low with this dosage of radiotherapy.
- The risk of low-intermediate dose radiation include Radiation Induced Cancer (RIC) such as skin cancer (BCC, SCC, melanoma) [2]. In patients treated for benign disease with intermediate dose radiotherapy (Range 3-50 Gy, mean approximately 20Gy), most normal tissue side effects are rare or minimal. RIC is normally very small, and decreases further with increasing age.
- Blood draw may cause discomfort, pain, and bruising. The risk of skin biopsy may include temporary pain during the procedure; a small chance of infection, and the biopsy leaves a small scar.
- A psychological risk is that the treatment will not have any clinical improvement.
- Breach of confidentiality is a possible risk if data is lost or stolen.

Risks to Women Who Are or May Become Pregnant

The effect of radiotherapy on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these unknown risks, women cannot take part in this study if they are:

- Pregnant
- Trying to become pregnant
- Breastfeeding or sharing breast milk

If you are a menopausal woman and have not had a menstrual period for the past 12 months or more, you will not need to have a pregnancy test. Also, you will not need to have a pregnancy

test if you have had a hysterectomy (surgical removal of your uterus and/or ovaries). All other female subjects must have a negative pregnancy test before starting the study drug.

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use birth control for 12 months.

Acceptable birth control methods for use in this study are: [**refer to Protocol for acceptable birth control methods – examples below**]

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you miss a period, or think you might be pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you must stop receiving radiotherapy immediately.

Therapeutic Radiation Risks

You will be receiving additional radiation as part of the study treatment. One of the goals of this research is studying whether this is effective or not. We do not know exactly what long-term risks may be the result of this additional radiation. There is a very small risk (less than 1%) of developing a cancer in the future due to radiation.

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 possible benefits of taking part in this study include improvement or resolution of hidradenitits symptoms.

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

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

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

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

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and he 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.

Can the study end my participation early?

We will not let you participate in the study any more if you have a serious adverse event**.** In addition, your participation will end if the investigator 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