Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigators: Dr. Chirayu Patel and Dr. Austin Kirschner
Study Title: Prospective Observational Trial of Low-Dose Skin Electron Therapy in Mycosis Fungoides Using Rotisserie Technique
Institution/Hospital: Vanderbilt University Medical Center
Version 2 (10/19/15)

This informed consent applies to adults.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have a cutaneous T-cell lymphoma (mycosis fungoides) which has not been sufficiently controlled by medications and for which your doctor has recommended low-dose total skin electron therapy. The purpose of this study is to collect data regarding your response to this therapy, both in terms of changes in the skin and in terms of your quality of life following treatment. Your involvement in this study does not change your actual low-dose total skin electron therapy; your treatment would take place in the same manner without regard to your decision to take part in this research study. At Vanderbilt, total skin electron therapy is administered in a manner in which you would stand on a rotating platform during treatment – with this study, we hope to gather data to better predict response to this therapy.

2. What will happen and how long will you be in the study?

Day 0: In the department of radiation oncology, you will be given the opportunity to enroll in this clinical trial during the radiation consultation appointment. You may choose to think about this trial and return at any time in the future to enroll, if the trial is still open. If you agree to enroll, you will be given a self-reported questionnaire to fill out so that we can determine your baseline quality of life, called the Skindex-29 questionnaire – this will take you approximately 10 minutes to complete. This will ask questions about how you mycosis fungoides affects your daily life, including emotional state. You will also undergo grading of your skin findings by your radiation oncologist using mSWAT (modified severity-weighted assessment tool). This tool allows your radiation oncologist to follow your treatment response, by accurately grading the severity of your skin findings. From your medical record, information regarding date of diagnosis, previous treatments, and response to previous treatments will be collected, as well as which, if any, current treatments you are on.

All female patients of childbearing potential will have a laboratory urine pregnancy test documented in your patient chart. Pregnancy testing is a standard test for all patients receiving any radiation treatment. You must have a NEGATIVE pregnancy test to receive further imaging and radiation treatment.

Day 3 (approximately): You will undergo radiation treatment planning, which will consist of measurements being obtained and positioning being verified to assist in radiation planning – expect to be in the department for under 1 hour.

Day 10-21 (approximately): You will undergo total skin electron therapy – expect to be in the department for under 1 hour each day on an outpatient basis. You will see your radiation oncologist once per week; however, you are encouraged to speak to the nurse anytime you have a concern, as a radiation oncologist would be available to speak to you any day that you are being treated.

Following radiation treatment: at 6 weeks, at 12 weeks, and thereafter every 3 months:
You will again complete Skindex-29 questionnaire – this will take you 10 minutes to complete. You will also undergo grading of your skin findings by your radiation oncologist using mSWAT (modified severity-weighted assessment tool).

Follow-up visits will continue until there is change in your disease which necessitates a change in course of therapy. You will also continue to see your dermatologist on a regular basis following radiation therapy.

3. Costs to you if you take part in this study:

You are still responsible for paying for the usual care you would normally receive for the treatment of your illness – there are no experimental procedures involved in this study. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance. The pregnancy test and radiation treatment are standard of care procedures that could be provided off-trial and thus would be considered normal treatment for your illness. Only the quality of life questionnaires and grading scales used at follow-up, but not the follow-up visit with radiation oncologist itself, are additions to usual care.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

The investigational portion of this research study involves collecting quality of life (QOL) questionnaire data from you as well as collecting objective measurements of your skin response, which are obtained by your radiation oncologist. The risk of this investigational portion of the study are minimal and primarily associated with any potential breach of confidentiality. All precautions are taken to minimize this risk, as your questionnaire and skin assessment data are maintained as securely as your other medical records.

5. Risks that are not known:
None

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study include demonstrating efficacy and decrease in side effects of low-dose total skin electron therapy.

b) The benefits you might get from being in this study include improving your quality of life and more precise documentation of your treatment response due to the use of a detailed scale.

8. Payments for your time spent taking part in this study or expenses:

There are no payments to the participant for participating in this study.

9. Reasons why the study doctor may take you out of this study:

If we are unable to perform the complete course of total skin electron treatment for any reason, you cannot participate in this study since no radiation treatment will be performed. If you are removed from the study for any reason, we will inform you of the reason you have been taken out of the study.

10. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

11. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Chirayu Patel at 615-322-2555 or my Faculty Advisor**,** Dr. Austin Kirschner, at 615-322-2555. If you cannot reach the research staff, please page the study doctor at 615-835-9687

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

12.Confidentiality:

Records and data collected in this study will be maintained in your Vanderbilt University Medical Center patient chart accessible by the medical staff that performs direct medical care for you. Data analyzed in this clinical trial will be stored in a secure online database (RedCap) and accessed by secure computers on the Vanderbilt network.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Chirayu Patel and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

13. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Chirayu Patel and his study team may share the results of your study and/or non-study linked results (such as radiation planning records), as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and insurance companies for billing purposes. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Chirayu Patel in writing and let him know that you withdraw your consent. His mailing address is Vanderbilt Department of Radiation Oncology, 2220 Pierce Ave, PRB B-1003, Nashville, TN 37232. At that time, we

will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title