IRB APPROVED CONSENT FORM

DEC - 9 2011

St. Luke's-Roosevelt Hospital Center

CONSENT FOR PARTICIPATION IN RESEARCH

_____ Michael Tirgan, MD.
Print name of subject Principal Investigator

Keloid Radiation Registry
Title of Project

IRB # 11-184

Attached to this form is a full description of the study in which we are asking you to participate. The description tells you about the reason for the study; the procedures, interviews and drugs or devices which may be involved; the duration of the study; and any risks or benefits to you. The description also gives you information about other medical treatments you may receive if you do not want to participate in this study.
If you have questions concerning this research project or your rights as a research subject, or if you have a research-related injury, you may telephone:

Patient Representative at: (212) 523-3700 Principal Investigator at: 212-874-4200

CONSENT TO PARTICIPATE -- ADULT

I have read the attached study description. The purpose of the study, the risks of the study and what it means to participate in the study have all been explained to me, and my questions have been answered. I agree to participate in the study and agree to take all of the tests or procedures mentioned in the study description. If I am injured in the study, I understand only immediate essential medical treatment will be provided free of charge. I understand that participating in the study is voluntary, that I can decline to participate, and that I can stop participating at any time. I also understand that my decision to participate in or to withdraw from the study will not affect the health care I receive, now or in the future. I have been told that records of this investigation will be kept confidential to the extent permitted by law but are subject to inspection by the U.S. Food and Drug Administration and study sponsors.

_____ _____ _____ _____
signature of subject date signature of witness date

_____ _____ _____
signature of authorized representative date relationship to subject

May only be used to enroll subjects until:

DEC 8 2012

I, _____, have clearly and fully explained to the above subject (or person giving consent) the nature, requirements and risks of the study.

_____ _____
Signature of researcher date

DISTRIBUTION:
Original to Research Records, copies for subject (or person giving permission), investigator, and Hospital Chart and Pharmacy where appropriate.

REV 4/19/07

Informed Consent Form for Keloid Radiation Registry
(English Language)

This is a clinical study, which is a type of medical research. Your study doctor will explain this study to you. Clinical studies include only people who choose to take part in them. Please take your time to make your decision about taking part in this study. You may discuss your decision with your friends and family. You can also discuss the study with your health care team. If you have any questions, you can ask your study doctor for more information and further explanations. You are being asked to take part in this study because you have received radiation therapy for your keloid.

Potential Participants 18 years and older:

This is a consent form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would sign this form or electronically acknowledge this form, to confirm your decision. If you sign this form, you will receive a signed copy of this form for your records.

Potential Participants 17 years and younger:

In most localities, anyone who has not reached 18 years of age is considered minor. A parent must sign the consent form for those who have not reached 18 years of age. Teenagers, ages of 13-17 must also agree to participate in this study and sign or electronically acknowledge the consent forms.

Potential Teen Participants:

This form also serves as an assent form. That means that if you are between ages of 13 to 17 and you choose to take part in this research study, you would sign OR electronically acknowledge this form to confirm your choice. Your parent or guardian would also need to give their permission and sign or electronically acknowledge this form for you to join the study.

Parents/Guardians:

You have the option of having your child or teen join this research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign or electronically

acknowledge this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

Why is this study being done?

The purpose of this study is to collect data from several hundred patients who have had keloids and have received radiation therapy for the treatment of their keloids. The purpose is to learn more about long-term side effects of radiation therapy such as developing a cancer. We also want to also learn how effective radiation therapy is in treating keloids.

How many people will take part in the study?

This will be an ongoing international study. It is not limited to a particular number of patients or a geographical area. At least 1,000 patients are likely to participate in this study.

How long will I be in this study?

You may be in the study for a long time, up to 30 years, or for as long as the study is open and you are willing to commit to the study. This is a registry. The purpose of this registry is to follow the registered patients for a long time in order to see if anyone develops any major complications following the radiation therapy they had for treatment of their keloid. We are specifically interested in development of cancers after radiation therapy. You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the study doctor and your family doctor first. Withdrawing from this study will not interfere with your future care.

What am I being asked to do in the study?

As a participant in this research study, you will be asked to provide and disclose information about your keloid, information about the radiation therapy you received for it, and information any serious side effects and complications that may arise as a result of radiation.

We also ask you to provide us with your contact information, your name, and your phone number and email address, so that we can conduct our annual follow-ups with you.

Please visit the study website (www.Keloid-Radiation.com) and download the study consent forms. Study has three separate consent forms.

A. **Main Study Consent Form**, which this document that you are reading now. Everyone must read this document and agree to it. If you decide to participate in this study, you will be able to electronically acknowledge that you have read this consent form and also you agree to participate in the study.

B. **Consent to Obtain Radiation Therapy Records.** We also ask you to download and sign this consent form, so that we can present it to the facility where you received radiation in order to receive your radiation therapy records from them. You will need to return this consent to us, either by mail, e mail to fax.

C. **Consent to Obtain "Medical" or "Oncology Records".** In case you develop a cancer or other serious side effect from radiation therapy, we ask you to download and sign this consent form so that we can obtain the medical records related to the side effect. You will need to return this consent to us, either by mail, e mail to fax.

What will happen if I take part in this research study?

If you agree to participate in this study, you must agree to share some information with the study doctors. This information includes some details about your keloid and details of radiation therapy you received for its treatment and any serious side effect from radiation. We also ask you to participate in a long-term follow-up. In case you develop a cancer or other serious side effect to radiation therapy, we ask you to share that information with us.

What are the different ways that I participate in this study?

There are three ways for patients to register and participate in this study.

1. **Web Based Recruitment:** One way to participate in this study is to register online on the study website, www.Keloid-Radiation.com. You must read and acknowledge the main study consent form online. You will then gain access to the study questionnaire which allows you to enroll in the study. For those who are under age of 18, a parent or a legal guardian must read and acknowledge the consent forms and answer the online questions. If you elect to participate by this method will also be asked to download the "Consent to Obtain Radiation Therapy Records" and complete and sign this consent form and send it to us by mail, fax or e-mail. We then present this signed consent form

to the facility where you had your radiation, and obtain your radiation records. The main study doctor will give your annual follow-ups. You will receive a phone call or an email from us once a year so that we can obtain an update about your keloid and potential long term side effects of radiation therapy

2. **Radiation Therapy Center:** Another way to participate in this study is by registering through the radiation center where you received treatment for your keloid. We intend to contact many radiation therapy sites. Radiation center where you had your radiation must participate in this study in order for you to register with them and be followed by them. In this case, the radiation therapy facility will input all required information into our website. In this situation, patients sign an informed consent form and provide the consent form to the facility. The radiation facility will then input patient's data into our website and database. Annual follow-ups will take place by your radiation therapy facility and they will input all the data in the study database.

3. **Participating Research Sites:** Another way to participate in this study is by registering through other participating research sites. We intend to contact many dermatologists, plastic surgeon and other physicians who provide medical care to patients who have keloid. Your personal doctor who provides medical care to you for your keloid must participate in this study in order for you to register in this manner. In this case, your study doctor will input all required information into our website. In this situation, patients sign an informed consent form and provide the consent form to their local study doctor who will then input patient's data into our website and database. Annual follow-ups will take place by your study doctor who will input all the data in our website

No matter how you register to participate in this study, you will have annual follow-ups with the study doctors for a long time. This follow-up is performed to learn about the behavior of your keloid and how it evolves over time. The follow-up is also important for tracking serious complications from radiation therapy, such as developing cancer.

Is there an age limit to participate in this study?

There is no age limit to participate in this study. Anyone can who has received radiation therapy as part of treatment for keloid can participate.

Who has approved this study?

Institutional Review Board (IRB) of St. Luke's Roosevelt Hospital Center in New York has approved this study. An IRB is a committee made up of doctors, researchers, and members of the community. The IRB is responsible for protecting patients taking part in research studies and making sure all research is done in a safe and ethical manner.

What benefits do I draw from participation in this study?

The results of this study will be used to better understand the safety of radiation therapy when used in treating keloids. We will also learn how well keloids respond to radiation therapy. You will not have any direct benefits from this study. The study results will not be used to guide doctors to better treat your keloid.

Can I stop being in the study?

Yes. You can decide to stop participating at any time. If you decide now that you would like to participate in this study, but later change your mind, just contact your study doctor or radiation therapy facility and let them know.

What are the risks of taking part in this study?

The risk in this study is related to the possible loss of confidentiality of your medical information. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include: Government agencies, like the Food and Drug Administration (FDA), and the Institutional Review Boars (IRB) involved in keeping research safe for people.

Confidentiality:

All your information will be kept confidential and will not be released without your prior written permission, except as described in this section or as required by law. All of the information you provide is considered research record and will be subject to state and federal laws and regulations dealing with the confidentiality and privacy of medical and research records. Your personal information and entire research record may be used and disclosed, to the extent

necessary, among the research staff, with the Institutional Review Board and research oversight staff or as required by law.

We intend to publish the results of this study. Your name will not be reported in any publication; only the data obtained as a result of your participation in this study will be made public. This informed consent in itself may be included in the research record of the study and will be subject to state and federal laws and regulations dealing with the confidentiality and privacy of medical and research records. The following persons and entities will have access to all your research records:

Your Study Doctor: Michael H. Tirgan MD,
23 West 73rd street, # GD, New York, NY 10023
Phone: (212) 874 4200

Your responses will be kept completely confidential. We will NOT record your IP address when you use internet to respond to this survey. All information will be stored electronically in a password protected folder; a hard copy will be stored in a locked filing cabinet. All this will be kept confidential. Only the researchers will see your individual survey responses and the results of the analysis of your answers. Since you consent to provide your contact information for this research, your identity will be connected to all the information you will be providing in this survey. Complete confidentiality language is contained in a separate attachment. Please see that last three pages of this form.

What are the costs of taking part in this study?
There are no costs to you to participate in this study. Costs associated with retrieving your radiation records from other institutions are all absorbed by the study. Your permission to obtain, store and use your radiation records in this research will not cost you before, during or after the study. There will never be any cost to you for your participation in this study.

You will not be paid for taking part in this study.
Your participation in this study is totally voluntary. You will not be paid to participate in this study.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No

matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from your doctor.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. *(This is a multi center study. Each study site must provide the name of study physician and the contact information here).* Here is the contact information for your study doctor:

Michael H. Tirgan, MD,
23 West 73rd Street, Suite GD.
New York, NY 10023
Phone # (212) 874 4200.
E mail: htirgan@aol.com

For questions about your rights while taking part in this study, you can call the St' Luke's Roosevelt Patient Representative at 523-3700.

Do I have other alternatives?

Your participation in this study is voluntary. As this is not part of your medical care, you have the alternative of not participating in this study.

How do I express my wiliness to participate in this study?

Please read this section carefully. Below is a numbered list of different choices for you to make. Think about these choices carefully. After reading each choice, circle "Yes" or "No" and write your initials where indicated. If there is a section below that does not apply to you, please leave it blank.

PATIENT ABOVE AGE OF 18

Complete this section if you are the patient who received radiation for treatment of keloid and you are at least 18 years of age:

1. I am at least 18 years of age. YES NO Your Initials: .....

2. My study doctor has my permission to obtain, review and store my radiation therapy records, and use it for keloid related research.

   YES NO Your Initials: .....

3. I agree to have follow-ups every 12 months. The follow up may be conducted by telephone or by email. I agree to receive phone calls or emails from the study doctors.

   YES NO Your Initials: .....

4. I agree to share my name, phone number(s) and email address with the study doctors so that they can contact me by phone or email for follow up.

   My Full name is: .....

   My e mail address is: .....

   My home phone number is: .....

   My mobile phone number is: .....

.....	.....	.....
Participant's Full Name:	Participant's Signature:	Dated:
.....	.....	.....
Witness's Full Name:	Witness's Signature:	Dated:

ASSENT FOR TEENAGERS

Complete this section if you are the patient who received radiation for treatment of keloid and you are between ages of 13 to 17:

1. Please state how old you are: Your Age : .....
2. Your Date of Birth: DOB: .....
3. My study doctor has my permission to obtain, review and store my radiation therapy records, and use it for keloid related research.

   YES NO Your Initials: .....

4. I agree to have follow-ups every 12 months. The follow up may be conducted by telephone or by email. I agree for my parent to receive phone calls or emails from the study doctors.

   YES NO Your Initials: .....

5. I agree to share my name with the study doctors so that they can contact my parents by phone or email for follow up.

   My Full name is: .....

.....	.....	.....
Teenage Participant's Full Name:	Participant's Signature:	Dated:
.....	.....	.....
Witness's Full Name:	Witness's Signature:	Dated:

PARENT OR LEGAL GUARDIAN

Complete this section if you are the parent or legal guardian of a child who is 17 years of age or younger, and has received radiation for treatment of keloid.

1. My study doctor has my permission to obtain, review and store my child's radiation therapy records, and use it for keloid related research.

   YES NO Your Initials: .....

2. I agree to have follow-ups every 12 months. The follow up may be conducted by telephone or by email. I agree to receive phone calls or emails from the study doctors.

   YES NO Your Initials: .....

3. I agree to share my name, phone number(s) and email address with the study doctors so that they can contact me by phone or email for follow up.

   My child's full name is: .....

   My full name is: .....

   My e mail address is: .....

   My home phone number is: .....

   My mobile phone number is: .....

.....	.....	.....
Parent/Guardian's Full Name:	Parent/Guardian's Signature:	Dated:
.....	.....	.....
Witness's Full Name:	Witness's Signature:	Dated:

PRIVACY BOARD APPROVED

DEC 9 2011

ST. LUKE'S-ROOSEVELT HOSPITAL CENTER

RESEARCH AUTHORIZATION

Patient Name: _____ **ID Number:**

IRB Study Number: 11-184

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your written authorization before we may use or disclose your protected health information for the research purposes described below. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

You or your representative should read the information on this form before signing it. A representative of St. Luke's-Roosevelt-Hospital Center *must have filled in the answers to the questions below before providing this authorization form to you and must answer any questions you may have before you sign the form. DO NOT SIGN A BLANK FORM.*

Who will disclose, receive, and/or use the information? All of the following person(s), class(es) of persons, and/or organization(s) listed in Part A and those indicated by a checked box in Part B may disclose, use, and receive the information and they may use the information and disclose it to the other parties on this list, to you or your personal representative, or as required by law.

Part A

- This Hospital Center's research staff and medical staff
- Every health care provider who provides services to you in connection with this study
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
- The United States Food and Drug Administration and any other government agency that oversees research
- The members and staff of the hospital's affiliated Institutional Review Board
- The members and staff of the hospital's affiliated Privacy Board
- Principal Investigator: Michael H. Tirgan MD
- Study Coordinator: _____
- Members of the Research Team and the physician fellows and data managers at St. Luke's-Roosevelt Hospital Center who are assisting the Principal Investigator on this research project.

Part B

- o All other research sites for this study, including each site's research staff and medical staff

What information will be used or disclosed? The appropriate boxes must be checked below and the descriptions should be in enough detail so that you (or any organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.

☑ **The entire research record**

❑ Any medical records held by the hospital may be used and disclosed.

❑ The following information:

_____

_____

_____

❑ HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is prohibited from redisclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450. These agencies are responsible for protecting your rights.

PRIVACY BOARD APPROVED

DEC 9 2011

SPECIFIC UNDERSTANDINGS

By signing this research authorization form, you authorize the use and/or disclosure of your protected health information described above. The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your medical (and research-related) treatment (when applicable), and to run the business operations of the hospital.

St. Luke's-Roosevelt staff members and physicians who are performing this research will use and disclose your information only as described earlier. However, once we disclose it to others for research purposes, St. Luke's-Roosevelt cannot directly control their future uses and disclosures of it. For this reason, St. Luke's-Roosevelt has requested that the research sponsor and its agents use your information only for this research and not for other purposes. You have the right to request to review your medical records but for the duration of this study (if it is blinded) you agree to waive your right to review any aspect of the research record that would result in your knowing to which of the research groups you have been assigned.

You have a right to refuse to sign this authorization. While your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form, you will not be able to participate in the research described in this authorization. If you sign this authorization, you will have the right to revoke it at any time, except to the extent that the hospital has already taken action based upon your authorization or needs the information to complete analysis and reports of data for this research. This authorization will never expire unless and until you revoke it. To revoke this authorization, please write to the Principal Investigator Michael H. Tirgan MD at 23 West 73rd Street, Suite GD, New York, New York 10023. You will receive a copy of this form after you have signed it.

SIGNATURE

I have read this form and all of my questions about this form have been answered. By signing below, I acknowledge that I have read and accept all of the above.

Signature of Subject or Personal Representative	Date
Print Name of Subject or Personal Representative	Address of Subject or Personal Representative
Description of Personal Representative's Authority	Telephone Number(s) of Subject or Personal Representative

THE SUBJECT OR HIS OR HER PERSONAL REPRESENTATIVE MUST BE PROVIDED WITH A COPY OF THIS FORM AFTER IT HAS BEEN SIGNED.