UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Open-label, single-arm pilot study of the effects of topical 5% Imiquimod cream on preventing keloid recurrence after surgical keloidectomy
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Why am I being asked to volunteer?

You are being invited to participate in a research study. The purpose of this study is to evaluate whether or not the topical medication 5% Imiquimod cream (Aldara) is able to prevent recurrence of keloids after surgical removal when therapy is initiated one week before the date of surgery and continued for a total of 6 weeks. We hope that the results of this work will help us better understand this condition and identify a better treatment than what is currently available. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the

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conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

What is the purpose of this research study?

Keloids, or abnormally enlarged scars, are common skin concerns for which we currently do not have effective treatments. The purpose of this study is to evaluate whether or not the topical medication 5% Imiquimod cream (Aldara) is able to prevent recurrence of keloids after surgical removal when therapy is initiated one week before the date of surgery and continued for a total of 6 weeks. We will be evaluating both the effectiveness and tolerability of this drug, and we hope that the results of this work will help us better understand this condition and identify a better treatment than what is currently available.

The use of 5% Imiquimod cream for this indication (prevention of keloid recurrence) is still investigational. However, topical application of 5% Imiquimod cream has been approved by the FDA for a number of other skin conditions such as actinic keratosis (a precancerous lesion), superficial basal cell carcinoma, and anogenital warts.

How long will I be in the study? How many other people will be in the study?

Your participation in the study is up to 14 weeks. There are expected to be 10 patients in the study. The study is being conducted at the University of Pennsylvania only.

What am I being asked to do?

If you choose to participate in the study, after reviewing and signing this informed consent, you will be asked to use the study medication, 5% Imiquimod cream (Aldara), 5 times a week at bed time for a total of 6 weeks, starting one week prior to your scheduled keloid excision date. Your keloid removal surgery will be scheduled and performed in accordance with the standard of care. You will also be asked whether or not we would be permitted to collect photographs of the lesion that is to be removed as well as the surgical site at follow-up visits. You will also be asked if a portion of the keloid specimen that was excised can be used for research to study the effects of the medication on the lesions. You will also be asked to return for follow-up visits 2, 4, and 8 weeks after your keloid removal surgery to evaluate for side effects of therapy and evidence of keloid recurrence. Lastly, you will be asked whether you are willing to be contacted by

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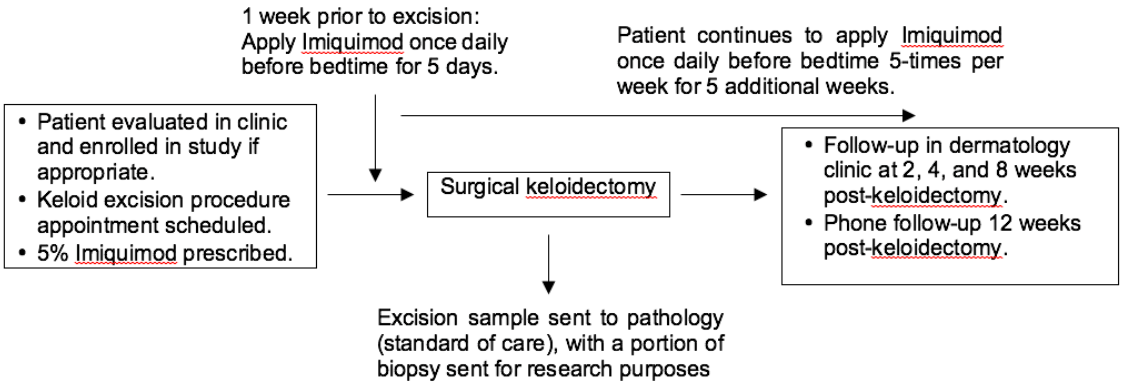
phone 12 weeks after your keloid removal surgery to further inquire about any lasting symptoms and/or keloid recurrence.



	Visit 1 (Week 1)	Visit 2 (Week 2)	Visit 3 (Week 4)	Visit 4 (Week 6)	Visit 5 (Week 10)	Phone encounter (Week 14)
Informed consent	X					
Urine pregnancy test	X					
Imiquimod application	X (start after visit)	X	X	X		
Keloid excision		X				
Excision specimen sent to pathology as indicated by treatment guidelines		X				
Photograph of lesion	X (optional)	X (optional)	X (optional)	X (optional)	X (optional)	
Evaluation of local site reaction		X	X	X	X	
Evaluation for recurrence			X	X	X	X

Photography

If you decide to volunteer, you will have photographs taken of the lesion that is being removed. Efforts will be taken to ensure that the photograph is not identifiable – jewelry, tattoos, name tags, or unique clothing will not be photographed, if possible. However, if the lesion is near a recognizable feature, such as a tattoo, there is still the possibility that you may be identified by the photograph.

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☐ **I wish to have photographs taken** **Subject initials: _____**

☐ **I do not wish to have photographs taken** **Subject initials: _____**

What are the possible risks or discomforts?

5% Imiquimod (Aldara) is an FDA approved medication for multiple skin conditions. The side effects of this medication is well studied and documented. Areas treated with imiquimod will become inflamed. The symptoms may include itching, burning, redness, ulceration (sores), scabbing, flaking, and pain.
There could be increased sensitivity to the sun in areas of drug application. This could be avoided by proper sun protection such as wearing protective clothing and/or applying sunscreen of SPF 30 or greater 15 minutes prior to sun exposure with reapplication every 2 hours.

Systemic side effects may include “flu-like” symptoms such as fever, fatigue, headache, nausea, diarrhea, and muscle pain. These symptoms are less common and are generally mild.

While every effort will be made to protect your confidentiality there is a potential risk of an inadvertent or unintended breach of confidentiality. While every effort will be made to protect your private information there is a potential risk of loss of that privacy.

Reproductive risks: Because the effects of the drug are not well studied in pregnancy and during breastfeeding, it is possible that there are harmful side effects that are not yet known to both the mother and unborn or breast-feeding child. If you are currently pregnant or breastfeeding, it is important that you inform the investigator because you will not be able participate in the study. If you are able to become pregnant, you will be given a urine pregnancy test before entry into the study. You are asked to use a medically accepted method of birth control (such as oral contraceptives, long-acting reversible contraception, or barrier contraception.) while you participate in the study. You should not become pregnant while you are taking this drug. If you do become pregnant, you must tell the investigator and consult an obstetrician or maternal-fetal specialist.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You may not get any benefit from being in this research study. However, there have been studies and reports indicating that topical imiquimod therapy could be effective in preventing keloid recurrence after surgical removal of the keloid, although it is not guaranteed. Additionally, the information gained from the research may have benefit to society by improving how dermatologists are able to take care of patients with similar skin conditions.

What other choices do I have if I do not participate?

If you choose not to participate in this study, you could discuss with your dermatologic physician about the alternative therapies available, such as pressure dressing, intralesional steroid (Kenolog) injection, and irradiation.

Will I be paid for being in this study?

There is no compensation for participation in this study.

Will I have to pay for anything?

You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. The keloid excision will be performed per standard of care, and the cost of the procedure will be charged to you or your insurance per standard billing procedures.
The study drug, Aldara (5% Imiquimod Cream) will be provided by the study at no cost to you. Follow-up visits in the clinic 2, 4, and 8 weeks after surgery will be covered by the study, and you will not be charged.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the study over? Can I leave the Study before it ends?

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This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician or the principle investigator without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- If additional clinical information such as pathology findings change the diagnosis of your lesion. You will be informed by the investigator if such information becomes available and could be relevant to your clinical care.
- You have not followed study instructions.
- The Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

The study team will do our best to make sure that the personal information obtained during the course of this research study will be kept private. all information will be kept on a secure, password-protected Penn Medicine database that can only be accessed by study personnel. 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.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.
Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

What information about me may be collected, used or shared with others?

The information that will be collected as a part of the study includes:

- Demographic information: race/ethnicity/gender
- Date of birth
- Telephone number
- Current medication list
- Description/documentation of the dermatologic physician's physical exam
- Treatment received and response to treatment
- Symptoms and side effects related to treatment
- Photo documentation of lesions treated

De-identified information collected in this study, including de-identified photographs of the lesion, may be presented in research settings such as published in scientific peer-reviewed journals or presented at scientific conferences.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?

Oversight organizations

- The Office of Human Research Protections
- The study data and safety monitoring board

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the

investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date

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_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date

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