Title: Effectiveness of Fractionated Laser Resurfacing to Protect Geriatric Skin from Actinic Neoplasia

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Department of Veterans Affairs	**VA Research Consent Form**

Name:		**Date:**
Title of Study:	**Effectiveness of fractionated laser resurfacing to protect geriatric skin from actinic neoplasia**	
Principal Investigator:	**Jeffrey B. Travers, M.D., Ph.D.**	**VAMC: Dayton (552)**

Purpose:
You are invited to participate in a research study to test whether the fractionated resurfacing laser (a rejuvenating laser that makes tiny holes in the very superficial part of your skin) can provide protection against the future development of precancerous actinic keratosis and non-melanoma skin cancers. We have shown that use of this laser to geriatric skin results in the skin responding to sunlight in a much safer way with possibly less chance of developing mutated cells that could turn into actinic keratosis or skin cancers. You were selected as a possible subject because you meet the criteria for this study. You are aged 60 and older, get your routine skin care from the Dayton VA Dermatology clinics, and you have less than 20 actinic keratosis or skin cancers on your forearms within the past 6 months. If you participate in the study, we will treat one arm with the rejuvenation laser and then you will follow up in our clinics for routine visits at 3 months then every 6 months for up to 5 years. At these visits we will be seeing how many actinic keratosis and skin cancers you develop on your arms as part of your routine care, and of course will be treating them appropriately. You will be one of 72 volunteers. This study is temporarily funded by WSU Department of Pharmacology and Toxicology. The study is taking place in the Dermatology clinics at the Dayton VA, except for the laser treatment which will take place at Wright State Physicians building, and is being conducted under the direction of Dr. Jeffrey Travers, Principal Investigator.

Description of the study:
The purpose of this study is to follow up on our previous studies that have demonstrated that geriatric subjects respond differently to sunlight than young people. In particular, small amounts of sunlight can cause the formation of skin cells that are mutated to remain in their skin. These mutated cells we believe are responsible for forming precancerous actinic keratosis and skin cancers. We have found that this is due to a protein IGF-1 produced by skin cells in the dermis (part of your skin right under the top part). As we age, our skin makes much less of this IGF-1 protein. Thus, we believe this is why older people get these actinic keratosis and skin cancers. We have demonstrated that treatment of geriatric skin with a rejuvenation laser which pokes tiny holes into your skin results in a superficial wounding response that then causes more IGF-1 to be made and thus changes how the geriatric skin responds to sunlight—making it respond like a young person's skin.

The present studies will test to see if treatment of one forearm, wrist and dorsal hand with the fractionated resurfacing laser (FLR) will decrease the numbers of actinic keratosis and skin cancers you develop on that arm over the next 5 years, in comparison to untreated arm. You may not participate if you have any serious health disorder that compromises your immune system or wound

Subjects Initials_____

healing problems, abnormal scarring or are not planning to be coming to the Dayton VA Dermatology clinics for the next ~ 5years. You can only be a part of this study if you are being treated for pre-cancerous lesions (actinic keratosis), and have had one on your forearm/wrist/hand in the past 6 months and/or have them now.

If you agree to be in the study, your participation in the study will consist of two parts. First, we will treat one upper forearm from your arm crease to your knuckles with the FLR. We are randomizing people as follows: If the last digit of your Social Security Number is an odd number, we will treat your left side; even number-right side. Obviously if you have a preference we will take that into consideration. Before doing that we will be photographing your arms and counting actinic keratosis and possible skin cancers. We of course will be treating these lesions here in the VA Dermatology clinics as per usual. The laser treatment will be scheduled at Wright State, in the Wright State Physicians building. We will then have you return to the VA Dermatology Clinics in 3 months, and then every 6 months for your routine clinic visits. As part of the clinic visit, we will be taking pictures of your arms and hands and will be counting the numbers of actinic keratosis you have at that time, and will be treating them (with cryotherapy for example). We would like to be able to follow you as part of this study for up to 5 years with at least every 6 month visits.

Participation is entirely voluntary. The PI has the right to withdraw you from the study due to safety reasons such as developing 20 or more actinic keratosis on one arm.

Procedures:
If you agree to be in the study, you will be one of 72 subjects over the age of 59 who will be participating in this research. You will do the following things:

<u>DAY 0.</u> Laser treatment (At Wright State Physicians Building).

- At the WSP building second floor dermatology clinic, Dr. Travers will take pictures of both of your arms and count actinic keratosis.
- One arm from arm crease to knuckles will be treated with the Fractionated Resurfacing Laser. First, (if your arm is hairy) we will shave the areas with a safety razor. We will clean the area with an alcohol pad. We will apply a topical anesthetic (4% xylocaine cream and let it set on for 20 minutes.
- We will treat the areas with the laser, and cover the treated area with a thin coat of Vaseline and give you samples of this to put on the area.

Subjects Initials_____

DAY 90 + every 6 months for 5 years (VA DERMATOLOGY CLINICS)

- You will be seen in follow up in the VA Dermatology clinic for a routine clinic visit. As part of the visit, we will photograph your arms and count and treat any actinic keratosis/skin cancers noted.

The FLR laser treatment will take place at the WSP building next to WSU. All subsequent clinic visits will take place at the Dermatology outpatient clinic at the Dayton VA.

Risks:
While on the study, the risks are:

Photography - the risk of photography is the possible loss of confidentiality. Pictures will not be of recognizable body parts or markings. Photos will be labeled with the study number and a code that does not identify you. Photos will not include any identifying information.

Fractionated Laser Resurfacing - The risk of the FLR treatments is that they can be slightly painful during the treatment. We will use a small amount of topical xylocaine cream to reduce the pain. The laser result in many little tiny holes formed which heal within several days to no more than a week. We will give you instructions on how to take care of the area. Sometimes changes in pigmentation of your skin (lighter or darker) or very rarely very superficial scarring can occur.

Please inform the investigators if you have a history of abnormal scars (keloids) or poor wound healing.

Pain could result from the FLR. If acetaminophen (Tylenol) is not helping, then we would ask you to contact Dr. Travers at 937-775-2463 or 937-245-7200/224-7546 and ask for the Dr. Travers or Wright State/VA dermatologist on call. We do not supply acetaminophen or other pain relievers.

In addition, you may suffer harms that we have not seen before.

Benefits of Taking Part in the Study:
There are no direct benefits to you from your participation in this research study. However, the knowledge gained from this study may help others should the results prove useful.

Alternate Courses of Action or treatment:

Subjects Initials_____

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If you decide not to participate in this study, you have other choices. For example:

- You may choose to have the usual standard of care procedures that do not include the research study
- You may choose to take part in a different research study, if one is available.

Statement of Use of Research Results:
The results of this study may be published, but your records or identity will not be revealed unless required by law. You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by the PI if he determines that it is necessary.

Identifiers might be removed from your identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your (or your legally authorized representative's) consent.

Storage of Data:
All personally identifiable data collected during the study will be kept at the Dayton VA in Dr. Travers' office or electronic data will be kept on a network drive that only Dr. Travers has access to.

Confidentiality:
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your identity will be held in confidence in reports in which the study may be published.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the investigator and his/her research associates, the study sponsor.

In addition, organizations and agencies responsible for assuring the safety of human subjects in research may also view your research records. These include: the Wright State University Institutional Review Board or its designees, the VA Research and Development Committee or its designees, The VA Office of Research Oversight, the VA Office of Research & Development, the government Accountability Office, the Office of Human Research Protections, and, when applicable, the Food and Drug Administration (when medications or medical devices are involved).

Subjects Initials_____

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Research Subject Costs:

1. There will be no costs to you for any of the treatment or testing done as part of this research study. Eligibility for medical care at a VA Medical Center is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
2. The study is sponsored by WSU Department of Pharmacology and Toxicology.
3. You will not be required to pay for medical care or services received as a participant in a VA research project except as follows:
   Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Compensation:

1. You will receive payment for taking part in this study. If you complete all study visits, you will receive a maximum compensation of $400. Compensation is based upon completed study visits and overall study completion; you will be compensated even if you are unable to complete all study visits. Per visit compensation values are broken down as follows: $150 for the laser treatment and $25 each visit for returning in clinic 3 months and every 6 months afterwards for up to 5 years.
2. The VA medical facilities shall provide necessary medical treatment to a research subject injured as a result of participation in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. This does not apply to: (1) treatment for injuries due to noncompliance by a subject with study procedures; or (2) research conducted for VA under a contract with an individual or a non-VA institution.
3. Financial compensation for research-related injuries is not available, except through legal action. By signing this form, you do not give up your legal rights to seek such compensation through the courts.

Participation in Other Research Studies
You may take part in this study if you are currently in another research study. It is important to let the investigator know if you are in another research study.

Subjects Initials_____

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RESEARCH SUBJECT'S RIGHTS:

Participation in this study is entirely voluntary. You may refuse to participate. Refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits. You will receive a copy of this consent form.

In case there are medical problems or questions, Dr. Travers may be called at 937-775-2463 during the day and Dr. Travers at 937-245-7200/224-7546 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

If you have any questions regarding your rights as a study subject, you may contact the ACOS for Research & Development, Dayton VAMC, at (937) 262-3393 *(Obtain answers to questions about the research from someone not associated with the protocol)*, Patient Representative, Dayton VAMC at (937) 268-6511, ext. 2164 *(Voice concern or complaints about the research)*, and/or the Wright State University Institutional Review Board at (937) 775-4462 *(Voice concern or complaints about the research from someone not associated with the protocol)*.

The study has been explained to me and all of my questions have been answered. The risks or discomforts and possible benefits of the study have been described. Other choices of available treatment have been explained.

_____	_____	_____
Subject's Signature	Printed Name of Subject	Date

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SSAN

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Signature of Person Obtaining Consent	Printed Name of Person Obtaining Consent	Date

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