

Subject _____ Date: _____

Title of Study: Pressure Ulcer Assessment Via TelemedicinePrincipal Investigator: Dr. Julie Lowery VAMC: _____**Description of Research by Investigator:**

A. Purpose - the goal of this study is to test a computer-based method for treating ulcers including pressure sores (bed sores), venous stasis ulcers, and diabetic ulcers. The study hopes to find out whether the computer-based method is as good as the way doctors treat ulcers now. The study is expected to last from 1998-2000.

B. Description - If I agree to participate, I will undergo the procedures listed below **as well as** the care I would normally receive for an ulcer. My participation in the study will last up to several weeks, depending on how long my ulcer takes to heal. The procedures will be done by a nurse and the results sent by computer to the study's doctor. All of the procedures below will take place during each visit with the study nurse. These data will be collected six times.

1. **Photography:** The study nurse will take photographs of my ulcer.
2. **Wound Volume:** If my ulcer is open, the nurse will measure the depth by using Jeltrate, a harmless gel-like substance applied to the sore.
3. **Additional Data:** Data such as my general health, age and sex will also be entered into a computer for the doctor's use.
4. **Skin Measurement:** The skin around the ulcer will be tested for softness using a pen-like device called a durometer that is rested against the skin. (No pressure is applied.)
5. **Questionnaire:** I will be asked to answer some questions about pain, satisfaction with care, coping, depression and distress during the study. During the first visit, the questions should take about 45 minutes to complete. The questions asked during all other visits should only take 5-15 minutes. (To a patient guardian: please answer the questions on the patient's behalf.)

All of these procedures will take about 30-40 minutes to complete per visit. The first visit will be longer, maybe 1-1 ½ hours due to the questionnaire.

If you have more than one ulcer, we would like to include all ulcers in the study.

C. Risks: Possible risks will be those normally associated with the treatment of a pressure sore. Care will be taken to avoid risks and discomforts resulting from the procedures. You will receive the same care as non-study patients.

Subject's Identification (I.D. plate or give Last, First, Middle Name):

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D. Benefits: You will be paid \$10 per visit with the study nurse as partial compensation for your time. Also, this study may help future patients with ulcers. It may help to reduce the amount of time a patient with a pressure sore spends in the hospital. It may help patients at home to get medical care if it is difficult to travel to a doctor's office or the hospital. This study may also help to reduce the cost of treating ulcers.

E. Alternate Courses of Action: If you choose not to participate in the study, you will receive the same care that ulcer patients usually receive.

F. Statement of Research Results: Results from this study may be published in a book or a journal. You will not be identified by name in any of the results.

If the researchers learn new information during this project that may affect your decision to be in this study, we will tell you this information. To find out more about any aspect of this study, including your rights, you may contact the persons whose names, addresses and telephone numbers are below:

Site Research Nurse Coordinator

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Department of Veterans' Affairs
2215 Fuller Road
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(734) 769-7100 extension 5571

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Principal Investigator: Dr. Julie Lowery **VAMC:** _____

RESEARCH SUBJECT'S RIGHTS: I have read or have had read to me all of the above.

The study nurse coordinator has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Riley Rees, Chief of Plastic Surgery at (734) 769-7100 ext. 5938 during the day and the on-call Plastic Surgery resident at (734) 936-6267 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

Subject's Signature

Date

Signature of Subject's Representative*

Subject's Representative

Signature of Witness

Witness (print)

Signature of Investigator

* Only required if subject is not competent.

IF MORE THAN ONE PAGE IS USED, EACH PAGE (VAF 10-1086A) MUST BE CONSECUTIVELY NUMBERED AND SIGNED.