

**PATIENT INFORMED CONSENT  
AND  
AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION**

***Cybernet Medical***

\_\_\_\_\_, voluntarily agrees to participate in this research study, know as *Telewound Care Network*, and authorizes *Charles Bryant, MD*, as principal investigator and/or such assistant as may be selected by him to perform the procedure described herein on you in connection with the research project outlined herein.

You understand:

1. Purpose:  
To demonstrate the effectiveness of utilizing telehealth technology and evidence-based treatment to reduce the days to heal for chronic wounds.
  
2. Description of Study and Procedure:  
The study addresses both direct wound treatment regimen and, if present, underlying diabetes. Study participants will be divided into two groups based on Oklahoma County of residence. Group one, serving as the control group, will receive care from their current healthcare provider as usual. Group two consisting of the patient and their usual caregiver will agree to adhere to the intervention protocol. Subjects will be interviewed initially and at six-month interviews. A follow-up interview will be conducted two months after subject's wound is healed. Photographic documentation of the wound will occur at baseline and at regular intervals, and I hereby specifically consent to the taking of photographs. Duration of the study will be until the wound is healed or until Sept. 30, 2008, whichever comes first.  
  
For the intervention group, wound treatment will be administered by a qualified health care professional utilizing evidence based protocols developed by the clinical specialist co-investigators. The care will be delivered either on-site or via two-way videoconferencing by a wound care specialist. The wound care specialist may seek consultation from wound care experts at the INTEGRIS Baptist Wound Care Center and may refer the patient for evaluation and/or intervention by Center personnel. If diabetes is hindering the healing of the wound, the participant may receive individualized care in the form of a specific evidence based treatment plan, vital sign and blood test monitoring, medication monitoring, and or/education as appropriate. Participant agrees to take reasonable care of loaned equipment and understands that the equipment is to be returned at the end of episode of care.
  
3. Benefits:  
The potential benefits to you for participating in the study may include reduced time for wounds to heal, reduced hospitalizations and surgeries, pain reduction, increased

access to specialist consultation, and an educational component to subject and caregiver. It is possible that you may not benefit from participation in the study.

4. Risks:

There are minimal risks associated with participation in this study. Risks are as with any wound care program including non-healing of wounds and allergic reaction to the products used. Protocols may include use of a two-way video conferencing unit, and your caregivers may administer the actual dressing changes rather than a healthcare provider.

5. Alternative Treatment:

If you choose not to participate in this study, the alternative treatment would be other therapeutic programs for patients with your disease and you have had an opportunity to discuss these with your physician as they might relate to your decision to participate.

6. New Information:

You understand that if during this study no benefit is occurring from the drugs/treatment you are receiving, you will be informed of this and alternative treatment will be discussed at that time. If any significant new information about any of these treatments develops or any other new medical treatment for your condition is discovered, while you are participating in this study, your doctor will tell you.

7. Confidentiality and Patient Identification:

As part of your participation in this study, identifiable health information or protected health information ("PHI") about you will be used and disclosed. The PHI may include demographic information (such as your name and birth date), your medical records, your medical history (such as diseases and medications), the results of physical examinations, surgical and treatment information, photographs, and laboratory and diagnostic test results (such as EEGs, EKGs or MRIs).

By signing this patient informed consent and authorization form (the "Patient Authorization"), you are authorizing the principal investigator, his/her employees and agents (collectively referred to as the "Principal Investigator") to use your PHI in connection with this research study and to further disclose your PHI in connection with this study to (i) the Sponsors of the study **Agency for Health Care Policy and Research, and the National Institute of Health**, its employees, officers, directors, agents, affiliates and contractors; (ii) the Food and Drug Administration ("FDA"), the Department of Health and Human Services ("DHHS"), the Office of Human Research Protections ("OHRP"), the Office of Civil Rights ("OCR") and other U.S. and foreign governmental and/or regulatory agencies; (iii) INTEGRIS Baptist Medical Center, Inc., its medical staff, employees, officers, directors, agents, affiliates and contractors (the "Hospital"); and (iv) the Institutional Review Board ("IRB") of the Hospital, (collectively referred to as the "Third Parties") for use and disclosure by such Third Parties as described in this Patient Authorization. In

addition, the Principal Investigator may disclose your PHI, without prior notice to you, in response to a valid court order by a court or other governmental or regulatory body or as otherwise required by law.

This research study is designed to collect data about the clinical effectiveness and cost-effectiveness of utilizing telehealth technology to reduce the days to heal for chronic wounds and if better outcomes are achieved using telehealth as a continuum of care and to answer questions about this research study. In addition the Principal Investigator and Third Parties will use your PHI to ensure that the study is conducted properly and that your rights and welfare as a patient participating in this study are protected. Although the Principal Investigator will collect your PHI for only *three (3)* years, the Principal Investigator and the Third Parties will continue using your PHI as described in this Patient Authorization indefinitely. This Patient Authorization does not have an ending date.

The Principal Investigator and the Third Parties will take reasonable efforts, consistent with industry standards, to protect the confidentiality and security of your PHI during and after this study. No publication about the research will reveal your identity without your specific written permission. These limitations continue even if you revoke this Patient Authorization. However, once the Principal Investigator has disclosed your PHI to the Third Parties, it is possible that the Third Parties may re-disclose your PHI to other Third Parties. While the Third Parties will make reasonable efforts to maintain the confidentiality of your identity, in certain circumstances, a loss of privacy could occur.

The Principal Investigator is required by Oklahoma law to include the following statement in the Patient Authorization: The information authorized for release may include records which may indicate the presence of a communicable or venereal disease which may include, but are not limited to, diseases such as hepatitis, syphilis, gonorrhea and the Human Immunodeficiency Virus, also known as Acquired Immune Deficiency Syndrome (AIDS).

By signing this consent form, you authorize the use and disclosure of health information about you as described above. You have the right to revoke this authorization, in writing, at any time by sending written notification to Dr. Charles Bryant at 11800 N. Bryant Avenue, Oklahoma City, OK 73131. If you revoke your authorization for use and disclosure of health information for research purposes, you will be discontinued from the research. However, the Principal Investigator, Hospital, Sponsor and its researchers may still use and disclose health information that has already been obtained as permitted in this authorization to maintain the reliability of the research.

8. Cost and Payments:

You will not receive any reimbursement for participating in this study. You understand that laboratory tests (blood and urine), x-rays and other tests will be done at intervals to check the effects of the drugs you are receiving. You understand that these tests are felt to be part of good medical care and are covered by most major insurance companies. You understand that you will be responsible for

all physician or hospital costs incurred with these treatments in the same manner as if you were not part of this study.

9. Compensation for Illness or Injury:

You understand that in the event of physical illness or injury occurring as a result of this treatment, you will be provided with the necessary treatment and care by your regular doctor or by the physician responsible for your care during this study. However, you understand that you will not be reimbursed for medical care or receive other compensation as a result of physical illness or injury.

10. Voluntary Participation:

Your participation in this study is voluntary and you are free to withdraw or refuse participation at any time without penalty or adversely affecting your future care at this institution. Withdrawal will not cause a loss of benefits to which you might otherwise be entitled. Any questions you have pertaining to the research have been and will be answered by your responsible physician, *Dr.* \_\_\_\_\_. If you have any questions about your rights as a research subject, you may take them to Eric Lichtenstein at the Institutional Review Board Office at Cybernet Medical at (734) 668-2567.

11. Signatures:

You certify that you have read this consent form or that it has been read to you and you understand its contents. You freely consent to participate in this study under the conditions described in this document. By signing this consent, you do not automatically waive any of your rights. You have been given a copy of this consent form.

\_\_\_\_\_  
Patient's Printed Name

\_\_\_\_\_  
Patient/Subject Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Physician's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Signature (Person Conducting Interview)

\_\_\_\_\_  
Date