Permission to Take Part in a Human Research Study

Do not sign this consent if today's date is later than the stated expiration date above.

Title of Research Study: A Prospective, Randomized Controlled Trial Evaluating the Effectiveness of the Dolphin Fluid Immersion Simulation® System versus Air Fluidized Systems in the Acute Post-Operative Management of Surgically Closed Pressure Ulcers

Investigator: ***Robert Galiano, MD***

Supported By: ***Joerns Healthcare, LLC***

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Your doctor, who is also the person responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have at least one stage III or IV pressure ulcer that needs surgical closure.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The purpose of this study is to compare two different post-operative management therapies to see how they affect closure and complication rates of pressure ulcers. The two therapies that will be used are Dolphin® Fluid Immersion Simulation® System and Clinitron® Rite Hite® Air Fluidized Bed. These therapies, which are FDA approved, will be delivered after operative debridement and closure of the pressure ulcer. This procedure consists of removing nonviable tissue in your sore, washing the sore afterward with saline, and then determining if the sore can be closed immediately or if other operative debridement must be done prior to closure. Methods of closure can include covering your sore with a flap and/or graft. A flap consists of taking a section of tissue (either skin, muscle, or the layer covering muscle, known as fascia) together with its blood supply and placing it in the area of your sore. A graft involves taking a thin layer of the skin without its

original blood supply and placing it over the sore, with the expectation that this newly transferred skin will grow its own blood vessels to allow for closure of your wound.
The Clinitron® bed is made up of small beads with air forced through to create a fluid-like surface that redistributes pressure. The Dolphin® bed uses an advanced 3D immersion technology in order to automatically simulate a fluid environment, constantly monitoring the support surface over 300 times per second. Thus it is a completely automated system.

How long will the research last and what will I need to do?
We expect that you will be in this research study for 2 weeks (treatment period) and the assessments after the study period will last for one year.

If you consent to participate, you will be randomly (like flipping a coin) assigned to receive one of the following therapies:

- **Dolphin® Fluid Immersion Simulation® System** is a system that simulates a fluid environment, maintaining near normal blood flow to the skin in the points under pressure, optimizing its oxygen delivery, and constantly making adjustments as necessary based on patient repositioning
- **Clinitron® Rite Hite® Air Fluidized Bed** is an air bed which is made up of small beads with air forced through to create a fluid-like surface that redistributes pressure, with the purpose of maintaining near normal blood flow in the skin that is exposed to constant pressure due to position, and optimizing its oxygen delivery.

The study therapy will only be given while you are in the hospital. Investigators will first follow, evaluate, and make clinical decisions regarding wound therapy and readiness for debridement and closure. Only one wound per subject will be included in the study, based on volume. Therapy with either treatment will then begin and continue for two weeks following the initial OR visit and definitive pressure ulcer closure. Therapy may be continued after the first two weeks. However, only additional complications or need for other therapeutic interventions will be measured. After you are released from the hospital, you will be assessed for one year in order to evaluate the incidence of complications. These assessments will occur through monthly telephone interviews.

The study doctor's office is located at Northwestern Memorial Hospital, Plastic Surgery Division at 675 North St. Clair Street, 19th floor-250, Chicago, IL 60611.
You must meet certain qualifications to be in this study. If you choose to take part in this study, your first visit will be to see if you qualify.
You cannot take part in this study if you are in another study at this time. You cannot take part in this study if you took part in another study in the last 30 days.
You must follow instructions given to you by the study staff and come to the hospital and/or the study doctor's office for all study visits. You must tell the study staff your complete medical history and any side effects or symptoms you experience throughout the study. You must tell the study staff about all medicines you are taking or plan to take while you take part in the study.

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More detailed information about the study procedures can be found under the section What happens if I say "Yes, I want to be in this research"?

Is there any way being in this study could be bad for me?

There may be other risks associated with this research study that are unknown. In spite of all measures taken to prevent any possible harm, you might develop medical complications or problems from participating in this study. Your condition may not get better or may become worse during this study. There may be difference in effectiveness with one treatment or the other.

It is important to tell the study doctor if you have side effects or changes in your health so you can be checked. Please tell the study doctor about all side effects, even if you do not think they are a result of taking part in this study.

More detailed information about the risks of this study can be found under "Is there any way being in this study could be bad for me?"

Will being in this study help me any way?

You may or may not receive direct benefits for taking part in this study. However, by taking part in this study, you may contribute new information that will help and benefit other people who have a similar medical problem in the future. The possible benefits of taking part in the study may include improved healing of your wound.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

There are other options available. These options can range from the standard air fluidized beds to nutritional supplementation. There are also many different types of procedures and treatments available to treat different types of wounds. Your study doctor will talk to you about other options you can use for wound treatment, including their risks and benefits.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

You can call us with your questions or concerns. If you have any illness or injury during your time on this study, you should call us promptly. Dr. Robert Galiano is the person in charge of this research study. You can call him at 312-695-6022, Monday through Friday, from 9 AM to 5 PM. You can also call Dr. Jing Liu at 312-695-3908 with questions about this research study, Monday through Friday, from 9 AM to 5 PM.

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For problems arising during evenings or weekends, you may call Dr. Robert Galiano at 312-695 6022.

In the event of an emergency, dial 911 immediately. If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor as soon as possible.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

Up to 200 subjects, between ages 18 and 85, will take part in this study, if they have a history of fewer than 3 closures in the site of the pressure ulcer. The study is expected to enroll subjects over a period of 18 months. Up to 100 subjects will be treated with the Dolphin® Fluid Immersion Simulation® System and up to 100 subjects will be treated with Clinitron® Rite Hite® Air Fluidized Bed.

What happens if I say "Yes, I want to be in this research"?

Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group.

In addition to the Clinitron® or Dolphin® Therapy, all subjects in the study will receive the standard of care for wound management in this study. The study doctor or a member of the study staff can answer any questions you may have about which tests and procedures are not part of your regular medical care.

Screening Visit:

The screening visit will take place in the hospital or the study doctor's office and will last about an hour. You will be asked to sign this consent form. You will be asked questions about your medical history and medications. It is important that you give a true and complete medical history to your study doctor. You must tell your study doctor about all of the medicines you take or have taken. If you do not give complete and accurate information there may be serious safety risks to your well-being.

The following is a list of screening procedures that will be done to find out if you can take part in
the study:

- Review and sign this Informed Consent form
- Obtain your demographic information
- Physical exam
- Collection of your medical and surgical history

- Collection of the history of your pressure ulcers
- Collection of wound measurements, characteristics, and appearance, as well as the presence and degree of wound infection (Wound assessments)
- Collection of serum or urine pregnancy testing results (female only), if available
- Collection of laboratory testing results from your medical history and/or from standard of care testing, if available.
- Collection of a list of your current medications

If you qualify for the study, you will participate in the following procedures:

Day of First Surgery:

- Removal of dead tissue from wound (debridement)
- Pictures of your wound before and after the surgery
- Cultures (a test to detect and identify organisms (bacteria or fungi) that may cause infection) of your wound before and after the surgery
- Wound assessment before and after the surgery
- The study doctor will decide if you still qualify to be in the study
- Randomization (like flipping a coin) to either Clinitron® or Dolphin® Therapy beds after initial debridement.
- Irrigation of wound with 5L of normal saline (if needed)
- Collection of current medications
- Collection of any unforeseen, unfavorable changes in your medical health, regardless of whether they are considered related or unrelated to the study device (adverse event information)
- If wound is determined to be ready for closure, closure procedure will be performed and study period will be initiated

Daily Treatments (while in the hospital):

- Wound care prior to closure that is standard of care may include:
    - Wound dressings
    - Topical applications
    - Other therapies such as vacuum-assisted closure or hyperbaric oxygen therapy
- Collection of current medications
- Collection of adverse event information

Additional Surgery (if needed to remove dead tissue or to close the wound):

- Pictures of your wound before and after the surgery
- Cultures of your wound before and after the surgery
- Wound assessment before and after the surgery
- Wound closure or placement of therapy on your wound

- Collect current medications
- Collect adverse event information

Weekly Surveys (while in the hospital):

- Survey determining comfort, mobilization and pain at surgical size while in treatment and

at the end of the treatment period.

Day of Hospital Release:

- Foam dressing replacement or removal (if needed)
- Wound assessment
- Pictures of your wound
- Collection of current medications
- Collection of adverse event information

You will be discharged from inpatient care when deemed appropriate. Monthly phone interviews will be conducted to assess additional wound complications.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to:

- Follow all directions given by your doctor or study staff regarding pre- and post-operative care

What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

If you stop being in the research, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to:
Dr. Robert D. Galiano,
Division of Plastic Surgery, Galter 19-250
675 North St. Clair Street
Chicago, IL 60611
P: 312-695-6022
F: 312-695-5672
Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment

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If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Detailed Risks: Is there any way being in this study could be bad for me?

Risks related to the treatment:

- Risk of entrapment, meaning that a limb or the head get caught between the bedframe and the mattress, may occur when the equipment is placed on bed frames that leave gaps of even a few inches between the mattress and the head panel, foot panel, and bed or side rails.
- Risk of fire if used in the presence of flammabledrugs or gases, smoking materials or open flame.

For decreasing these risks, the healthcare providers are trained on the position and location of the matress and appropriate bedframe. Additionally, the bed is only used in a specialized care facility, which decreases the risk of contact with flammable gases.In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: "What happens to the information collected for the research?".

Will it cost me anything to participate in this research study?

There will be tests and procedures that are done only for this study and other tests and procedures that are part of your conventional medical care.

- The sponsor, Joerns Healthcare, LLC, will completely cover the costs of the bed assigned to receive (support surface)
- The cost of your conventional medical care will be billed to you or to your health insurance company in the usual way. However, some health insurance plans will not pay the costs for people taking part in studies.

Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular treatment. If your insurance does not pay, you will be responsible for the charges of your conventional medical care.

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Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include: Improved healing of your wound and you may contribute new information that will help and benefit other people who have a similar medical problem in the future.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Photographs

During your study visits, your wound will be measured by a device that also takes a photograph of your wound.

By signing this consent you agree to allow photographs to be taken of your wound at specified study visits by Dr. Galiano or a trained staff member. You also consent to these photographs being used as part of the medical record of this study, and that they may also be used for medical research, teaching or corporate communication of the study results. Again there are no personal identifiers on the photographs. The photos of your wound may be viewable in print and electronic media (medical publication and the internet) indefinitely.

Can I be removed from the research without my OK?

The study doctor, the sponsor, or regulatory authority may stop your participation in this study at

any time without your consent for any of the following reasons:

- it is in your best interest;
- you do not later consent to any future changes that may be made to the study;
- you need to use medications that are prohibited in this study;
- you do not follow the instructions;

- the sponsor stops the study for any reason;
- if your wound becomes infected and does not respond to the standard antibiotic treatment before completing the study;

or for any other reason related to your safety or the conduct of the study.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information
- HIV testing results

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except

that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and the Shirley Ryan AbilityLab") workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Joerns Healthcare, LLC, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.
Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:
PI's Name: Dr. Robert D. Galiano,Institution: Northwestern Memorial Hospital
Department: Plastic and Reconstruction Surgery
Address: Division of Plastic Surgery, Galter 19-250
675 North St. Clair Street
Chicago, IL 60611
P: 312-695-6022

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F: 312-695-5672

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

Subject unable to sign due to _____. Subject gave verbal permission.

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____

Signature of Witness to Consent Process Date

_____

Printed Name of Person Witnessing Consent Process