INFORMED CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Global Biomedical Technologies, LLC / "Surgical drape with a releasable acrylic adhesive for atraumatic negative pressure wound therapy."**
Protocol Number:	**1 R44 NR021251-01**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

Participant Name or Number:
_____

MRN:_____

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

This consent form is written to address a research participant.

Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.

KEY INFORMATION SECTION

This is an Informed Consent Form (ICF) seeking your voluntary consent to participate in clinical research. This document contains important information to help you decide whether you would like to be a participant in a clinical research study. You are being asked to participate in this study because you have an open wound and your doctor is planning to either apply a single-

use or multiple applications of a negative pressure wound therapy (NPWT) over your wound, and we would like information about the people having this treatment. We have included detailed information after this page. You may ask the research team questions. And, if you have questions later, the contact information for the study doctor in charge of the study at this site is listed above.

Purpose: What is the study about and how long will it last?

The purpose of this study is to compare and evaluate the Comfort Release® drape to the standard drape currently being used in NPWT, to see if it will adhere effectively and be less painful and cause less injury to your skin. We will also evaluate any decreased use of medications for pain and stress related to dressing removal, as well as your doctor's acceptability of the new Comfort Release® drape. For those having multiple applications, we will also measure if the use of Comfort Release® drape increases the likelihood that the participants will complete the full duration of study treatment with NPWT. Comfort Release® has several successful adhesive bandages and dressings with this same technology currently on the market. You can find them at www.comfortrelease.com. But it is important to note that the Comfort Release® Drape is investigational, meaning it has not yet been approved for market use for this purpose by the United States Food and Drug Administration (FDA).

The study site is being paid by Global Biomedical Technologies, LLC, (hereafter also referred to as "the Sponsor") to conduct this research. The study will enroll up to 200 participants at up to 4 sites.

The study procedures begin with the signing of this ICF if you decide after consideration that you would like to participate in this study. The research team will then schedule an evaluation (medical screening) to make sure that you are an appropriate candidate for the study. If eligible, you will be randomly assigned (like a flip of a coin) to either receive wound therapy with the Comfort Release® Drape or the traditional NPWT drape used at your hospital. The study team will then collect your medical information and ask you questions about your pain. Your participation in this study will be less than one week if your drape is put once over a surgical incision. If multiple drape applications occur, your participation in this study will be less than 2 months.

Risks: Key reasons you might choose NOT to volunteer

Potential risks, discomforts, and side effects of this study include discomfort, pain, or skin injury with the Comfort Release® drape, especially if you have sensitive skin or are allergic to the adhesive. You may experience itching, dryness and redness due to the rubbing alcohol.

If you exit the NPWT prescribed study treatment early, we will ask you why. Please know that you do not have to answer any question that you are uncomfortable with. The Possible Risks, Discomforts, and Side Effects section provides more information about the risks.

Finally, there is a slight risk to the privacy of your personal health information. The Confidentiality section below addresses this risk, and what the research team does to try to prevent it.

Benefits: Key reasons you might choose to volunteer

There may be no direct benefit to you for being in this study, and taking part in it may not make your health better. However, your participation could help doctors and researchers understand more about how the skin reacts to Comfort Release® drapes to help improve treatments for people like you in the future.

Voluntary Participation: Do you have to take part in the study?

There are alternatives to being in this study; you do not have to take part in this research to receive medical care for your condition. You should discuss all possible treatment options with your study doctor.

Participation in this study is voluntary. You may choose not to take part in the study or leave it at any time without giving an explanation. Your choice will not result in any penalty or loss of benefits to which you are otherwise entitled.

This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

If you are interested in learning more about this study, please continue reading the ICF below.

1. INTRODUCTION

You are invited to take part in this randomized, controlled trial. You were selected as a possible participant in this study because you have an open wound, and your doctor is planning to either apply a single-use or multiple applications of a negative pressure wound therapy (NPWT) over your wound. This consent form explains why the research is being done and what it will involve if you decide to participate. Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

The purpose of the study, possible benefits or risks, other options, your rights as a participant, and other details about the study are further discussed below. Any new information that could affect your choice to remain in the study will be given to you as a participant. You should ask any questions you have about the study to members of the research team. You may also want to talk about the study with your primary care doctor and family, loved ones, or friends. The choice to participate, or not, is yours. If you decide to participate, please sign and date where indicated at the end of this form.

This study is being conducted to determine whether the Comfort Release® drape performs better than the standard drape, typically the KCI V.A.C.® brand.

The study will enroll up to 300 participants at up to 4 sites in the United States. If you decide to participate, and your medical history shows that you meet the criteria to be included, you will be one of 300 participants in this study.

2. WHY IS THIS STUDY BEING DONE?

Negative pressure wound therapy (NPWT) has become a common wound care treatment and has been shown to be effective in helping complex wounds heal faster. However, this treatment is not without its challenges. The strong adhesive drape that is needed to maintain an airtight seal can also cause significant pain and skin injury, when the drape is removed from the skin. This is especially true for individuals with frail or sensitive skin. The secure Comfort Release® adhesive bond can be turned off with rubbing alcohol so that it removes from the skin more gently. The rubbing alcohol is applied using alcohol prep pads or swab sticks on the underside of the drape, where it is glued to the skin. This skin-friendly drape removal is expected to lead to a reduction in pain and skin injuries compared to the standard drape.

The purpose of this study is to evaluate if Comfort Release® drape can deliver an airtight seal for the NPWT and cause less or no pain and less or no skin irritation/trauma when removed from the skin with simple rubbing alcohol.

3. STUDY SCHEDULE AND PROCEDURES

If you agree to be in this study, we will go over the procedure below, and if you meet the study criteria, we will enroll you in the study to start with your first NPWT dressing.

You will be asked to evaluate the pain experienced when the dressing is removed by stating a number on a standard pain scale. After the dressing is removed, your skin condition will be evaluated by a study-trained clinician using the Medical Adhesive-Related Skin Injury (MARSI) scale scoring method for degree of redness and skin irritation.

We will enroll participants having either a single application or multiple applications of NPWT over either a surgical incision or over a wound, while being treated in the hospital or in an outpatient clinic.

We will collect information about you, including your medical history and allergies to adhesive products.

We will ask half of the participants to allow the study doctor to apply the standard NPWT, which is typically the V.A.C. drape by KCI Technologies, Inc.

We will ask half of the participants to allow the study doctor to apply a Comfort Release® drape substituted for the standard drape, or V.A.C. drape by KCI Technologies, Inc. All other aspects of the NPWT dressing components will be the same as the previous group.

The table below shows that all participants will receive the same standard of care and most of the same products.

The difference will be that half of the participants will receive the investigational drapes, in place of the standard, or KCI drapes.

The investigational drapes are removed from the skin with rubbing alcohol and the standard drapes are not.

50% of participants have the new drape	**50% of participants have the standard drape**
Both groups: KCI V.A.C ® or Standard Negative Pressure Wound Therapy pump and Kit	
Comfort Release® Drape	KCI V.A.C.® or Standard Drape
Dressing removal: Tab on the side of the drape is lifted and rubbing alcohol is applied to skin/drape to decrease adhesive bond and remove the drape gently from the skin.	Dressing removal: Drape is pulled from skin as gently as possible, per standard care.
Both groups: Using a standard number scale, rate pain or discomfort, if any during drape removal.	
Both groups: Any pain medicine received is recorded (if given).	
Both groups: Study staff will record any skin changes, including skin redness or swelling, as a result of wearing the drape.	
Both groups: anyone who finishes NPWT earlier than prescribed will be asked to answer a few questions: Early Exit questionnaire.	

4. POSSIBLE RISKS, DISCOMFORTS AND SIDE EFFECTS

Risk of the Comfort Release Drape:
Similar to the KCI V.A.C.® or standard drape, you may experience discomfort, pain, irritation, or skin injury with the use of the Comfort Release® drape. You will not participate in this study if you have known sensitivity to acrylic adhesive on the skin.

As with any NPWT drape on the market, the airtight seal on your NPWT may leak air even when the Comfort Release® drape is applied correctly.

Risks of Rubbing Alcohol:
Anyone with known sensitivity to rubbing alcohol on the skin should not participate in this study. Rubbing alcohol or our standard acrylic adhesives may irritate the skin of some individuals.

Please tell the study doctor or study staff right away if you experience any pain, itching, irritation, or rash while wearing the Comfort Release® drape. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study device. There may be side effects that are not known.

Unknown Risks
There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Discomfort with Questionnaires
There may be an exit questionnaire if you choose to end the study early. You do not need to answer any questions that you are not comfortable with.

Loss of Confidentiality
A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the 'Confidentiality' section of this consent form.

Loss of Privacy-Photographs of Participants
You may have photographs of your skin taken for this study. It is possible that you may be recognizable and your identity may be known.

5. POSSIBLE BENEFITS
You may benefit from using the Comfort Release® drape because you may experience less or no pain or discomfort or additional skin problems that are sometimes associated with the standard drape removal. There may be no direct benefit to you for participating in this research; however, the information collected from this research may help others in the future. This study could help many, especially those with sensitive or frail skin, or are exposed to many applications of adhesive drapes, have a pain-free and much less traumatic experience.

6. ALTERNATIVE TREATMENTS
You will receive the same quality of care whether you take part in the study or not. You can say no to being in this study and should discuss all other treatment options available with your doctor**. Other types of treatment include the standard NPWT with V.A.C. KCI or other standard drape.**

7. SIGNIFICANT NEW FINDINGS AND INFORMATION
You will be told of any significant new findings or information discovered during the course of this study that might affect your willingness to continue participating in this research. This new information may mean that you can no longer participate in this research. Or, you may need to read, consider, and sign a revised Informed Consent Form (ICF) if you want to continue being in the study. You will also be told of any findings the study doctors may notice in your research results that could be important to your health. A medical professional on the study may first approach you verbally, making sure to explain the observations in writing as well.

If you wish, the study doctors can talk with your private physician about any incidental findings. If you do not have a private physician, we can refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for those costs.

8. COSTS AND COMPENSATION

There should be no cost to you for any tests, additional products, such as the Comfort Release® drapes, study doctor visits, or procedures that are required specifically for this study. You or your insurance company will be responsible for the cost of the medical care that would normally be a part of the treatment for your condition. You will remain responsible for all insurance premiums, copayments, deductibles, and coinsurance expenses associated with your regular medical care. You may want to talk with your insurance company about its coverage policy for standard medical care given to during participation in this study.

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***[“following each completed visit”, “monthly”, “quarterly”, “at the end of your participation in the research study”, “following each completed visit or at the end of your participation in the research study, whichever you prefer”]***.

If you have any questions regarding your compensation for participation, please contact the study staff.
[OR]

No payment: You will not receive any payment or other compensation for taking part in this study.

The study sponsor, Global Biomedical Technologies, LLC, is compensating the study site for its time and effort in conducting this study. No member of the study team will receive a personal financial benefit from your involvement in this study (other than their ordinary wages).

9. RESEARCH-RELATED INJURY

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and

inform the study doctor. In the event of an emergency, you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the study doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance. In general, the study sponsor may pay these providers for any reasonable medical expenses to treat your injury. The study sponsor, however, is not offering to pay for medical expenses that are covered by your insurance provider or if your injury was not caused by the study device or a study procedure.

The study site is not offering to provide you the device after the termination of the study or to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in this study. However, you do not waive any of your legal rights in signing this form.

10. VOLUNTARY PARTICIPATION AND WITHDRAWAL

Taking part in this study is entirely voluntary. If you agree to participate in the research study and sign this consent form, you are authorizing your health information to be used and disclosed. You may choose not to be in this study or to leave the study at any time. If you choose not to be in the study or to leave it once you have already joined it, there will be no penalty, and you will not lose any treatment or benefits to which you are entitled. Your regular care and your relationship with the hospital or clinic and your doctors will not be affected.

If you revoke your consent to be a part of this study, you will not be allowed to continue taking part in this research. The study doctor and relevant study staff will stop collecting personal information from you. However, personal information and health data already collected will be retained and may be disclosed to ensure that the results of the study can be measured and properly analyzed. The Sponsor, sponsor's representatives and government agencies will still have access to your records to audit and confirm the information gathered before your termination.

If you choose to stop participation in the study, you will be asked to complete an exit survey.

11. FUTURE USE

Your data collected as part of this study could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. All private information that can identify you will be removed prior to sharing any information for future research.

Any future testing or research using your data may lead to the development and use of information, products, tests and treatments having commercial value. You will not receive any compensation that may result from these tests or treatments.

12. CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure. However, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although this is highly unlikely.

Your participation in this research study will be documented in your electronic medical record. Study monitors and others who provide oversight of the study may also need to access this record.

Access to your health information is required to be part of this study to carry out the objectives of the research study. If you choose to take part in this study, you are giving us the authorization (i.e., your permission) to use the protected health information and information collected during the research that can identify you.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose, including age, race, and medical history that relates to the study, such as skin conditions and allergies.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study device works and is safe.
- To compare the study device to other devices.
- For other research activities related to the study device.

The research information that is shared with people outside of the study site will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure. All research data, pictures of skin, questionnaire responses, and health information will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in an encrypted data file and only the study doctor and authorized study staff will have access to the file.

The following individuals and/or agencies will be able to look at, copy, use, and share your research information:

- The study doctor and study team, and medical professionals who may be evaluating the study.
- The Advarra Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services
- United States Food and Drug Administration (FDA)
- The sponsor of this study, Global Biomedical Technologies, their agents, and their contractors
- Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure. The results of this study may be presented at scientific or medical meetings or published in scientific journals.

A description of this clinical trial will be available on 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.

This authorization to use and share your health information does not expire. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign this authorization document.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason, by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

Name of Participant (Please Print):

_____

Signature: _____ Date: _____ Time: _____

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Subject

If participant is unable to read or write (if applicable):

I have attended the entire authorization discussion. I attest that the information in the authorization form and any other written information was accurately explained to, and apparently understood by, the participant. Authorization was freely given by the participant.

Name of Witness (Please Print):

_____

Signature of Witness: _____ Date: _____

The signature of a witness is only required when obtaining authorization from:

- ❒ a Non-English-Speaking research participant using the short form process,
- ❒ a person who is physically not able to read, talk or write.

13. PARTICIPANT RESPONSIBILITIES

As a participant in this study, you are responsible for:

- Being honest with your study doctor and the study team about your health and medication history
- Attending all visits scheduled with the study doctor.
- Calling the study doctor's office to reschedule any missed visit as soon as possible.
- Reporting any injuries, hospitalizations, emergency department visits, or other medical visits, symptoms, or complaints to the study doctor or research staff as soon as possible.
- Telling the study doctor/ study staff about any changes in your health or the way you feel.
- Telling the study doctor/ study staff if you are participating in other research or want to stop being in the study at any time.

Your study doctor and/or Global Biomedical Technologies, LLC may stop your participation in the study at any time, without your consent, for any reason, including for not upholding the Participant's Responsibilities detailed above.

If you are removed early from the study, you may seek other treatments for your symptoms.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

14. WHOM TO CONTACT ABOUT THIS STUDY?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00090548.

STATEMENT OF CONSENT

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits, and alternatives with the study staff. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a signed copy of this consent form to keep for my records.

- I declare my voluntary consent to the clinical study and to follow the Study Doctor's instructions.
- I am aware that I can refuse to participate or withdraw my consent at any time without incurring any penalties or disadvantages.
- I agree that my Study Data, including my protected health information, may be used and disclosed as set forth in this consent, including being disclosed to representatives of the Sponsor, regulatory agencies and representatives of the IRB, and others as set forth in this consent.
- Finally, I agree to scientific publication of the research results where my identity or participation in the study will not be revealed.

Name of Participant (Please Print):

_____

Signature: _____ Date: _____ Time: _____

Name of Person Obtaining Consent (Please Print):

_____

Signature: _____ Date: _____ Time: _____

Participant consent is required for participation in the study

_____
Printed Name of Legally Authorized Representative

_____ _____
Signature of Legally Authorized Representative Date

_____
Authority of Legally Authorized Representative to act on behalf of Subject

If participant is unable to read or write (if applicable):
I have attended the entire informed consent discussion. I attest that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant. Informed consent was freely given by the participant.

Name of Witness (Please Print):

_____

Signature of Witness: _____ Date: _____

The signature of a witness is only required when obtaining Consent from:

- ❒a Non-English-Speaking research participant using the short form process,
- ❒a person who is physically not able to read, talk or write.