COLUMBIA UNIVERSITY INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

Protocol #IRB-AAAV1506

1 R44 NR021251-01: Surgical drape with a releasable acrylic adhesive for atraumatic negative pressure wound therapy.

Principal Investigator:	Jarrod Bogue, MD	**(212) 305-9612**
Clinical Research Team:		**(212) 305-3009**
Study Sponsor:	Global Biomedical Technologies, LLC	

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.

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 clinician'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 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 Columbia University Irving Medical Center (CUIMC)/ The New York and Presbyterian Hospital (NYPH) 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 300 participants at up to 2 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 kits 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.

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 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.

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 patients like you in the future.

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.

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. This consent form explains why the research is being done and what it will involve if you decide to participate. Please read the following information carefully and feel free to discuss this with your family or your doctor.

This study is being conducted to see if Comfort Release® drape performs better than the standard KCI V.A.C.® drape.

The study will enroll up to 300 participants at up to 2 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.

If you decide to take part in this study, you will be asked to sign, date, and put your name in the consent section of this form.

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 by 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.

Comfort Release® drape technology has combined a strong adhesive that can be turned off with rubbing alcohol, allowing for easy removal of the drape from the skin.
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 after surgery.

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 clinician using the Medical Adhesive-Related Skin Injury (MARSI) scale scoring method for degree of redness.

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.
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 clinician to apply the standard NPWT, the V.A.C. drape by KCI Technologies, Inc.
We will ask half of the participants to allow a clinician to apply a Comfort Release® drape substituted for the 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 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 ® Negative Pressure Wound Therapy pump and Kit.	
Comfort Release® Drape	KCI V.A.C.® 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: Clinician 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.® 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. There may be other risks or discomforts to you that are not known at this time.

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.

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 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.

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 Columbia University Irving Medical Center (CUIMC)/The New York and Presbyterian Hospital (NYPH) 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, **Dr. Jarrod Bogue, MD** at **(212) 305-9612**. 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 New York-Presbyterian Hospital (NYPH), a Columbia 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.

Columbia University and New York-Presbyterian Hospital (NYPH) are 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.

In order to leave the study, you must notify the principal investigator in writing at:

Dr. Jarrod Bogue, MD
Columbia University Irving Medical Center
161 Fort Washington Avenue
New York, NY 10032

If you revoke your consent and authorization 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

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. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and The New York and Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical records system. 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.

The research information that is shared with people outside of Columbia University Irving Medical Center (CUIMC) and New York-Presbyterian Hospital (NYPH) 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 investigator 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 investigator, Columbia University staff, The New York and Presbyterian Hospital staff, study staff, and medical professionals who may be evaluating the study.
- Authorities from CUIMC and NYPH including the Institutional Review Board ('IRB')
- Office of Human Research Protections (OHRP) and the 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. You may change your mind and revoke (take back) this consent and authorization at any time and for any reason, by following the instructions in the Voluntary Participation and Withdrawal section. Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this study.

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.

14. WHO SHOULD I CONTACT IF I HAVE ANY QUESTIONS?

If you have any questions, concerns or complaints about this study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the study doctor, **Dr. Jarrod Bogue, MD, at (212) 305-9612**. You should also contact the study doctor at any time if you feel you have been hurt by being a part of this study.

If you have questions regarding your rights as a study participant or questions about research studies in general, you may contact:

Institutional Review Board (IRB)
Columbia University Irving Medical Center (CUIMC)
154 Haven Avenue, 2nd Floor
New York, NY 10032
Telephone: (212) 305-5883
E-mail: irboffice@columbia.edu

STATEMENT OF CONSENT AND HIPAA AUTHORIZATION

I have read the consent and HIPAA authorization form and talked about this research study, including the purpose, procedures, risks, benefits, and alternatives with the researcher. 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 and HIPAA authorization 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

If participant is unable to read or write:

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 (if applicable)	Signature or 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, or
- □ a person who is physically not able to read, talk or write.