CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Study Title:	**Randomized Trial of Prolonged Use of Negative Pressure Wound Therapy in Patients Undergoing Surgical Procedures for the Management of Gastrointestinal Malignancies**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator: (Study Doctor)	**Jose M. Pimiento, MD**
Telephone: (24 hour number)	**813-745-6898 (office) 800-456-3434; 813-745-8000 [24 hours]**
Address:	**Moffitt Cancer Center 12902 Magnolia Drive Tampa, FL 33612**

You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate.

The purpose of the study is to determine if negative pressure wound therapy (NPWT), a common type of surgical wound care treatment that is approved by the FDA, can reduce the risk of surgical site infections and help your surgical wound heal more quickly after gastrointestinal cancer surgery. You will be randomly assigned to receive NPWT or standard wound therapy as part of your wound management after surgery. If you are in the NPWT group, you will have the NPWT for up to 7 days. You will be asked to spend about 60-90 days for the first 7 visits along with a 6-month follow up in this study that align with standard surgical and post-surgical cancer care.

You are being asked to take part in this study because you are scheduled to have surgery to remove your gastrointestinal cancer.

About 300 participants will take part in this study at Moffitt Cancer Center.

Your participation is voluntary, and you may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study include caring for your condition without being in the study.

We do not know if you will receive any benefit from your participation. NPWT have rare risks, including bleeding and wound infection. These complications, which are not unique NPWT and may not be directly caused by NPWT, can result in serious participant injury. Additional risks are described later in

this consent form.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

WHAT IS THIS STUDY ABOUT?

You are being asked to take part in this study because you were diagnosed with gastrointestinal cancer, and you are scheduled to have surgery to remove the cancer. We are conducting this study to determine if negative pressure wound therapy (NPWT), a type of surgical wound care, can reduce the risk of surgical site infections in cancer patients.

A surgical site infection, also known as wound infection, is an infection that occurs after surgery in the part of the body where the surgery takes place. Most patients who have surgery do not develop infection. NPWT is a type of therapy to help surgical wounds heal. During the study treatment, NPWT decreases air pressure on the wound and draws out fluid from the wound over time. This can help the wound heal more quickly.

The purpose of this research study is to:

- Test the effectiveness of NPWT in healing wounds and reducing wound infections.
- Look at differences in decreasing surgical site infections between standard wound therapy versus NPWT after gastrointestinal cancer surgery.

NPWT is approved by the United States Food and Drug Administration (FDA) for the treatment of wounds. NPWT has several parts. A foam or gauze dressing is put directly on the wound. An adhesive film covers and seals the dressing and wound. A drainage tube leads from under the adhesive film and connects to a portable vacuum pump. This pump removes air pressure over the wound. If you decide to participate in the study, you will be randomly assigned to receive either NPWT or standard wound therapy, which includes staples and/or sutures. More details are listed below in **STUDY GROUPS.**

WHAT WILL HAPPEN DURING THIS STUDY?

Before you can start the study, the study doctor or study staff will talk to you about the study. You have to sign and date this form before the study doctor or study staff can begin and see if you qualify to be in the study. Study participation includes several things that you will need to complete during a visit with the study staff or study doctor. It also includes things that you will give us permission to complete at a later time (reviewing your medical record). Another section (**STUDY PROCEDURES**) will describe in detail the study procedures that you will go through.

If you decide to take part in this research study (and sign and date this form), you will need to complete a screening visit (Visit 1) to see if you are eligible to participate during your regular preoperative visits. The study doctor will determine if you can participate in the study. The study includes a total of 8 visits. Four (4) of the study visits (Visits 1-3 and 5) correspond with your

appointments at the hospital, and the remaining 4 visits will be done via telephone (for example, the research coordinator will call you to obtain study information).

In cases where the study procedure results may seem abnormal, for safety reasons it may be appropriate to perform additional procedures or tests to confirm or clarify the results. Signing and dating this form allows for additional safety procedures to be performed, only if necessary. Any additional procedures will be discussed with you in advance.

STUDY GROUPS

Participants who join the study will be divided into two (2) groups: Study Treatment (NPWT) and Control Group (Standard wound dressing). On the day of scheduled surgery, you will be randomly assigned (like the flip of a coin) to receive either the study treatment or control. You will have a 2 in 3 chance of being assigned to the Study Treatment (NPWT) group, and a 1 in 3 chance of being assigned to the Control Group. The study doctor and study staff will watch each group carefully.

Group Name	**Study Treatment Arm**	**Number of Participants**
Study Treatment	Negative Pressure Wound Therapy	200 participants
Control Group	Standard Wound Dressing	100 participants

Study Treatment: If you are randomly assigned to the study treatment group, you will receive NPWT. The study treatment will be placed at the end of your surgical procedure. NPWT will be applied after the surgical site is completely cleaned. The study treatment will be removed and replaced during Visit 3, and removed/discontinued on Visit 4. If the NPWT malfunctions and the seal is lost, the NPWT will be replaced with standard wound dressing (control group).

Control Group: Participants randomized to the control group (standard wound dressing) will have their surgical wounds closed in the standard fashion. Standard wound dressing includes the use of staples or sutures.

STUDY PROCEDURES

The **TABLE** below lists the procedures or tests that the study doctor will perform at each study visit. An "X" in the column tells you the procedures that will be done during that visit. If the information in the table below is not clear to you, please ask the study doctor or study staff to explain to you.

Table. Study Procedures

	STUDY VISITS							
	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Visit 8**
Timeline (in days)	*Initial visit*	*Surgical Procedure*	*3 days after surgery*	*Hospital discharge*	*10-15 days after discharge*	*30-45 days after discharge*	*60-90 days after discharge*	*6-month follow up after surgery*

Inclusion/exclusion criteria confirmed	X							
Informed consent	X							
Medical/surgical history review	X	X			X	X	X	
Physical examination	X	X	X		X[1]			
Measure your blood pressure, heart rate, breathing rate and body temperature	X	X	X		X[1]			
Review of general health/performance status					X	X	X	
Draw blood to check general health	X	X						
Surgical procedure		X						
Study group placement (randomly selected)		X						
Review medications you are taking	X	X	X	X	X	X	X	
Review side effects and illnesses			X	X	X	X	X	
Review surgical incision			X*	X*	X	X	X	
Telephone interview						X	X	
Review Secondary Outcomes: Return to Intended Oncologic Therapy								X

X[1]: Not applicable if the post-operative follow-up (Visit 5) is a virtual visit

VISIT 1

If you decide to join the study (after signing and dating this form), we will review your medical history and records and perform an exam (known as screening tests) to see if you are eligible to participate. The initial visit will align with participant's clinic visit with surgical oncologist prior to surgical procedure. After obtaining informed consent for the study, the following procedures and assessments will be completed during the first study visit:

- Review imaging from routine clinical care (to determine eligibility)
- Review medical and surgical history
- Perform routine physical exam (including measuring height and weight)
- Measure your blood pressure, heart rate, breathing rate, and body temperature
- Ask questions about your general health and performance status, and your ability to do daily activities
- Draw sample of blood for routine tests to check your general health and liver health, blood sample results from up to two weeks prior can be utilized for this visit requirement Review prior and current medications that you are taking, including vitamins, herbs,

supplements and other over-the-counter medications

If the study doctor decides that your screening tests are acceptable, you will continue to be part of the study.

VISIT 2: Day of Scheduled Surgery
Surgical resection will be performed as part of routine care for the treatment of gastrointestinal cancer (as recommended by your cancer doctor) and is not a research-specific procedure for this study. You will receive a separate consent for this procedure to help you better understand what will happen before, during and after the surgery and explain all risks associated with this type of surgery.

The following procedures will be completed on the date of the planned surgery:

- Review medical and surgical history
- Perform routine physical exam (including measuring height and weight)
- Measure your blood pressure, heart rate, breathing rate, and body temperature
- Draw sample of blood for routine tests to check your general health and liver health
- Review prior and current medications that you are taking, including vitamins, herbs, supplements and other over-the-counter medications

VISIT 3
The third visit will occur while you are in the hospital; three days after your surgery. During this visit, you will undergo the following assessments:

- Perform routine physical exam
- Measure your blood pressure, heart rate, breathing rate, and body temperature
- Review prior and current medications that you are taking, including vitamins, herbs, supplements and other over-the-counter medications
- Review your health for illnesses and side effects
- Surgical site review: Surgical incision and surgical dressing will be reviewed

If you get discharged during **Visit 3** (three days after scheduled surgery): Dressing will be removed and data regarding surgical site will be recorded. The replacement dressing will be placed on surgical site and you will have replacement dressing removed by home health 7-9 days after surgical procedure.

VISIT 4
The fourth visit will be the date of hospital discharge after your surgical procedure. At this time, the dressing will be removed and data regarding the surgical site will be recorded.

Study staff will also review your medical records to collect data related to your surgery and surgical wound.

The following will be discussed or looked at in your medical record during **Visit 4** (Date of hospital discharge):

- Review prior and current medications that you are taking, including vitamins, herbs, supplements and other over-the-counter medications
- Review your health for illnesses and side effects
- Surgical site review: You will be asked if there are any problems with the surgical incision or received any incisional care at another facility. The surgical site will be evaluated by surgical staff via telemedicine appointment or in person if concerns are reported to study staff during this visit.

VISIT 5

The following assessments will be performed during the participant's routine outpatient follow-up visit with the surgical oncologist (for wound care) 10-15 days after hospital discharge. Routine follow-up visit may be in-person or a virtual visit:

- Review medical and surgical history
- Perform routine physical exam (including measuring height and weight)
- If in-person visit, measure your blood pressure, heart rate, breathing rate, and body temperature
- Ask questions about your general health and performance status, and your ability to do daily activities
- Review prior and current medications that you are taking, including vitamins, herbs, supplements and other over-the-counter medications
- Review your health for illnesses and side effects
- Surgical site review: Surgical incision and surgical dressing will be reviewed

VISIT 6

You will be contacted by a study coordinator via telephone 30-45 days after discharge date. The study coordinator will follow a structured telephone guide to assess whether there are any problems with the surgical incision or if you received any incisional care at another facility. He/she will also review your medical records to collect data related to your surgery and surgical wound.

The following will be discussed on the phone or looked at in your medical record during **Visit 6**:

- Review medical and surgical history
- Ask questions about your general health and performance status, and your ability to do daily activities
- Review prior and current medications that you are taking, including vitamins, herbs, supplements and other over-the-counter medications
- Review your health for illnesses and side effects
- Surgical site review: You will be asked if there are any problems with the surgical incision or received any incisional care at another facility. The surgical site will be evaluated by surgical staff via telemedicine appointment or in person if concerns are reported to study staff during this visit

Visit 7

The final visit will be 60-90 days after your discharge date. The study coordinator will contact you via telephone.

The study coordinator will follow a structured telephone guide to assess whether there are any problems with the surgical incision or if you received any incisional care at another facility. He/she will also review your medical records to collect data related to your surgery and surgical wound.

The following will be discussed on the phone or looked at in your medical record during **Visit 7**:

- Review medical and surgical history
- Ask questions about your general health and performance status, and your ability to do daily activities
- Review prior and current medications that you are taking, including vitamins, herbs, supplements and other over-the-counter medications
- Review your health for illnesses and side effects
- Surgical site review: You will be asked if there are any problems with the surgical incision or received any incisional care at another facility. The surgical site will be evaluated by surgical staff via telemedicine appointment or in person if concerns are reported to study staff during this visit

6-MONTH FOLLOW UP

The 6-month follow up will be conducted 6 months after your surgery through either a medical records review and/or telephone contact. This follow up will not collect any information on your surgical wound, but it will be conducted with the intent to determine whether you have returned to treatment as part of the secondary outcome for the study (Return to Intended Oncologic Therapy), as deemed appropriate based on your plan of care following your surgery.

WHO IS PAYING FOR THIS STUDY?

Moffitt Cancer Center.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

You and/or your insurance company will not be responsible for paying for study related items and services that are specifically required for this research study and are not considered part of the routine management of your disease, if these procedures are performed at Moffitt Cancer Center.

Medicare Advantage: If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

WILL BEING IN THIS STUDY HELP ME?

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

The study treatment might not help. Right now, we do not know if the study treatment will help in preventing surgical site infections. If it does not help, you may get a wound infection that is treatable.

- You may have problems because of the study treatment used in this study. These problems are called side effects. Some side effects are just bothersome. Others could harm you. There may be some side effects that we do not know about yet. The research might involve risks to you that are currently unforeseeable. Your study staff may give you medicines to help lessen side effects. Side effects may go away soon after you stop using the study treatment. In some cases, side effects can be serious, long lasting, or may never go away.
- There is always a chance that any medical treatment may cause you some discomfort or harm and the study treatment and procedures in this study are no different.
- You may experience discomfort around the surgical site. These side effects usually are not serious and will go away. If you have any of these problems, tell the study doctor at your next visit. If these side effects bother or worry you, or if you have other problems, call your study doctor.
- The study treatment, NPWT, has rare risks to study participants, such as: excessive bleeding and wound infection. These complications can result in serious participant injury. These side effects may be serious, may require medical care, and may cause permanent or lasting problems. If you have any of these problems, call your study doctor immediately.
- As with any study treatment, unforeseen risks are possible. There is always a chance that any medical treatment may cause you some discomfort or harm and NPWT in this study is no different. You should talk to your study doctor when you experience any side effects that you have while taking part in the study.

Ask the study doctor or study staff if you have questions about the signs or symptoms of any side affects you read about in this consent form.

It is not uncommon for the medical treatment that you would receive as your standard of care to also cause problems.

RISKS ASSOCIATED WITH STANDARD OF CARE OR ALTERNATIVE TREATMENT:
As with any treatment, there may be risks, known and unknown.
A more complete listing of side effects for standard wound care may be available for you to review if you wish. Please talk with your study doctor about the risks of both NPWT and standard wound therapy that are available.

COULD I HAVE AN ALLERGIC REACTION?
Occasionally, people have allergic reactions to medications which may require medical treatment. A severe allergic reaction could be life-threatening. Examples of an allergic reaction include:

- A rash
- Shortness of breath
- Wheezing
- Difficulty breathing
- Sudden drop in blood pressure

- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

You should get immediate medical help and contact the study doctor if you have any of these or any other side effects during the study.

IS THERE ANY RISK TO YOUR UNBORN CHILDREN IF YOU TAKE PART IN THIS STUDY?
FOR WOMEN:
If you are pregnant, you cannot participate in this study, because there may be risks to you and your unborn baby that are currently unforeseeable; risks that we do not know about yet.

Breastfeeding (nursing) mothers will not be included in this study, since it is not known whether ingredients in the study treatment in this study will be passed on to the baby in mother's milk. If you are currently breastfeeding and wish to continue breastfeeding, your study doctor may recommend another treatment.

COULD I HAVE ANY OTHER PROBLEMS WITH MY HEALTH IF I DO THIS RESEARCH STUDY?
It is possible that you could have problems and side effects of NPWT that nobody knows about yet, which include your surgical wound getting worse or even death. If the study doctor learns any new information about NPWT that might change your mind about continuing in the study, the study doctor or study staff will tell you about it. The study doctor will also tell you if new treatments become available for your surgical wound.

OTHER INVASIVE PROCEDURES
You may have to sign a separate consent form for your planned surgical procedure.

RISK OF LOSS OF CONFIDENTIALITY
There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?
If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you experience a side effect or a change in the way that you feel, call the study doctor at the telephone number listed on the first page of this form.

By signing and dating this informed consent and research authorization form, you have not given up any legal rights to seek compensation for injuries from the sponsor**.**

MOFFITT CANCER CENTER INJURY STATEMENT
If you believe you have been injured as a result of your participation in this study or if you have questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-7882. Moffitt Cancer Center and its investigators have made no provision for monetary compensation in the event of physical illness or injury resulting from this study. Likewise, Moffitt Cancer Center and its investigators have made no provision for payment of lost wages, disability, or discomfort in the event of physical illness or injury resulting from this study. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries and are limited by law.

WILL I GET PAID?
You will not get paid for being in this study. You will not be reimbursed for expenses for travel and/or lodging while taking part in this study.

WHILE YOU ARE IN THE STUDY, YOU MUST:
- Follow the instructions you are given.
- Come to the study center for all visits with the study doctor.
- Give correct and accurate information about your medical history and current medical condition.
- Tell the study doctor about any health problems you have during the study.
- Tell the study doctor about any new medicine or drug you take during the study.
- Not take any other drugs or remedies unless the study doctor has approved them beforehand. This includes prescription drugs and over the counter medicine (including vitamins and herbal remedies) that you buy without a prescription.
- Not participate in other medical research studies.
- Not get pregnant or cause your partner to become pregnant.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

DO I HAVE TO REMAIN ON THIS STUDY ONCE I JOIN?
If you want to stop being in the study, tell the study doctor or study staff.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more tests or return for a final study visit.

ARE THERE REASONS THE STUDY DOCTOR OR SPONSOR MIGHT TAKE ME OUT OF THE STUDY LATER?
Even if you want to stay in the study, there may be reasons the study doctor or study staff will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following:
- If the study doctor believes, for any reason, that it is in your best interest.

- If at any time while you are receiving the study treatment the study doctor discovers that your disease has worsened.
- If you develop side effects that the study doctor considers unacceptable.
- If you refuse to receive the study treatment or return for follow-up as recommended by your study doctor, or do not follow the study doctor's instructions.
- If you refuse to have tests that are needed to determine whether the study treatment is safe and effective.
- If you require treatment with drugs that are not allowed on this study.
- If other causes prevent you from continuing in this study.
- If the Sponsor decides to end the study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?
We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing and dating this form, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Your private information or biospecimens collected during this study will not be used or distributed for future research studies, even if identifiers are removed.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?
Your records are confidential, and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: Moffitt Cancer Center.
- Any federal, state, or local governmental agency that regulates the study (The U.S. Food and Drug Administration (FDA), and Florida Department of Health (FDH)).
- Other government agencies in this or other countries.

- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?
By signing and dating below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on the first page of this form.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You do not need to sign this form, but if you do not, you cannot participate in this study.
You will receive a signed and dated copy of this form.

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, please contact the Investigator 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, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Participant 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 Participant Adviser: Pro00045395.

WHERE CAN I GET MORE INFORMATION?

You may call the National Cancer Institute's (NCI) Information Service at: 1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

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.

STATEMENT OF CONSENT AND AUTHORIZATION

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

Printed Name of Participant

Signature of Participant | Date | Time

STATEMENT OF PERSON OBTAINING INFORMED CONSENT / RESEARCH AUTHORIZATION

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent | Date | Time