RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Canady Helios Cold Plasma™ Scalpel Treatment at the Surgical Margin and Macroscopic Tumor Sites

Sponsor(s): Jerome Canady Research Institute for Advanced Biological and Technological Sciences®, (JCRI_ABTS)® and ©US Medical Innovations, LLC, (USMI)

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to evaluate an investigational medical device called the **Canady Helios Cold Plasma™ Scalpel (CHCPS)** as a possible treatment for the killing of macroscopic (seen by the naked eye) and microscopic (not seen by the naked eye at the margins/edges of the gross tumor) cancer cells while leaving normal cells unharmed. An "investigational device" means that the U.S. Food and Drug Administration (FDA) has not yet approved or cleared this device for use in the general population and it must be tested to see if it is a safe and effective treatment for the disease or condition being studied. The goal of this pilot study is to show the FDA that the CHCPS can be used safely in patients who have a certain type of cancer and will have surgery to treat it.

If you agree to participate in this study, your participation may last up to 12 months and you will be asked to complete six (6) study visits. We will also ask you to complete a quality of life (QOL) survey periodically during the study. You will not have to stop taking any of your regular medication or chemotherapy during the treatment. If you stop taking your regular medication or chemotherapy, your cancer might come back or your health might get worse.

The study visits are divided into three (3) phases: Screening, Treatment, and Follow-Up.

1. Screening Phase (30 days up to the day before surgery)—Visit #1:
   We will review your medical chart to find out if you are eligible to take part in the study.
   - If we find that you can be in the study, and you choose to take part, then you will move to the Treatment Phase.
   - If we find that you cannot be in the study, you will still have your surgical procedure as planned, but without the extra treatment using the CHCPS device. You will not move to the Treatment Phase and your participation in this study will end at this time.
2. Treatment Phase (Day-0)—Visit #2:
   You will have your surgical procedure as planned including the extra treatment using the CHCPS device. We will ask you to complete a quality of life (QOL) survey. We will draw blood in the operating room while you are asleep before and after removal of the tissue and tumor for a total amount of about 7 tablespoons. A small portion of the tissue and tumor specimens removed from your surgery will have additional testing to show the FDA how the CHCPS worked during this study. The QOL survey and extra tests on the blood and tissues are being done for research purposes only.
3. Follow-Up Phase (Up to 12 months after surgery)—Visits #3-6:
   - Visit #3: Following surgery, you will be cared for according to the normal practice at

the hospital until discharge. We will monitor how well you are recovering and for any side effects from the CHCPS used during your surgery.

- Visit #4-6: After discharge from the hospital, your follow-up visits will occur at the outpatient clinics at Rush University Medical Center. We will not perform any additional tests (e.g., routine blood tests and imaging scans) or therapies (e.g., chemotherapy, radiation therapy, etc.) that you would not normally have. The timing and how often the office visits occur is the same whether you choose to participate in this study or not.
- Chart Review: The use of cold plasma in humans is limited and the long-term risks of cold plasma are yet unknown. We will continue to monitor your safety and progress for 12 months after treatment with the CHCPS.

For a detailed list of study procedures, please see the "*What are the activities you will be doing if you participate in this study?*" section of this consent form.

There may be risks to you for participating in this study, some of which may be serious, life threatening, or may not go away. In this study, there is a risk your cancer may not improve or may worsen while participating. You may experience some discomfort associated with the surgery that has not already been reported which includes your cancer getting worse or even death.

For a detailed list of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

To date, there have been no reports of an FDA commercially approved or cleared cold plasma or electrosurgical device (a tool using an electric current to cut, remove, or destroy tissue) that is known to kill cancer cells without damaging normal cells. It is hoped that treatment with the Canady Helios Cold Plasma™ Scalpel (CHCPS) improves your chances of survival or stops your cancer progression (worsening) but the safety and effectiveness (helpfulness) of the CHCPS has yet to be proven.

There are other options available to you if you decide not to participate in this study. You can move forward with your surgical procedure as planned without extra treatment using the CHCPS device. You should discuss other options with your study doctor.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being invited to participate in this pilot safety study because you have cancer from a solid tumor and are scheduled to undergo surgical treatment for it. Examples of solid tumors are **carcinoma** (begins in the skin or the lining of organs like the lungs, breasts, colon, kidneys, and pancreas), **melanoma** (begins in the cells that makes the color in skin), **sarcoma** (begins in connective tissue like bone, muscle, fat, and blood vessels).

How many participants will take part in this study?
About twenty (20) participants are expected to take part in this study in up to three (3) centers in the United States. Of these, at least 10 participants will be from Rush University Medical Center.

What are the activities you will be doing if you participate in this study?
If you agree to be in this study, you must first sign this consent form. Afterwards, you will be asked to participate in the following activities:

DAY / TIME	WHAT WILL HAPPEN
SCREENING ***[Visit 1: Up to 30 days before Surgery]***	During your routine visit, we will review your medical chart to find out if you are eligible to take part in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. Information we will collect include: • Demographics (such as gender, age, and race) • Medical, surgical, and medication history • Performance status • Physical exam including vitals, height and weight • Electrocardiogram (ECG test, which measures the electrical activity of the heart) if needed • Routine pre-op laboratory blood test results and imaging scan radiology reports related to your cancer diagnosis. • Serum pregnancy test for women of child-bearing potential. Results must be negative. If the review shows that you **can** be in the study, and you choose to take part, then you will move forward with your surgery as planned including the extra treatment using the CHCPS device. See next section, "SURGERY & Treatment with CHCPS". If the review shows that you **cannot** be in the study, you will still have your surgical procedure as planned but without the extra treatment using the CHCPS device. You will receive the same care that you would have received if you had not taken part in the study. Your study participation in this study will end at this time.

DAY / TIME	WHAT WILL HAPPEN
SURGERY + COLD PLASMA TREATMENT + RESEARCH-RELATED (QOL SURVEYS, BLOOD DRAWS & TISSUE COLLECTIONS) ***[Visit 2: Day 0]***	**SURGERY & Treatment with CHCPS**: Your planned treatment will take place in the operating room and will consist of two parts. 1. The first part of your surgical treatment is removing the malignant tumor (a mass of tissue containing cancer cells) and some extra tissue beyond the edge or border of the tumor (known as the "margin"). The surgical procedure used to remove the tumor and margin **is not** investigational and will be done by your surgeon in same manner he/she usually does. A pathologist, a doctor who has special training to examine cells and tissues, will check the removed tumor and tissue for cancer cells as normally done. 2. The second part of your treatment is using the **Canady Helios Cold Plasma™ Scalpel (CHCPS)** in the area where the tumor and margin tissue was removed (known as the tumor bed). This area is "sprayed" with a cold plasma (helium gas) that is being tested to kill cancerous cells and other cancer lesions (abnormal tissue with the potential of spreading cancer to other parts of the body) that may be present while the healthy normal tissue is left unharmed. The **CHCPS** and the spraying treatment **is** investigational. It has not been proven to cure, kill, or eliminate cancer in humans but the CHCPS has shown promising results in laboratory experiments and limited use in humans. Observations from three (3) advanced stage cancer patients who had no other remaining treatment options had received allowance for treatment using the investigational CHCPS under the FDA's Emergency & Compassionate Use Program. This program is a way to provide an investigational therapy to a patient who is not eligible to receive that therapy in a clinical trial, but who has a serious or life-threatening illness for which other treatments are not available. Compassionate use allows patients to receive promising but not yet fully studied or approved cancer therapies when no other treatment option exists. We estimate this extra step with the CHCPS will take roughly 15 minutes for carcinoma and melanoma patients and 30 minutes for sarcoma patients. **RESEARCH-RELATED ASSESSMENTS**: 1. European Organisation for Research & Treatment of Cancer: EORTC C-30 – **Completed by Carcinoma or Melanoma patients only**. This is a 30 question, self-reported, general survey to communicate the way you feel and how cancer affects your daily life. The survey

SURGERY + COLD PLASMA TREATMENT + RESEARCH-RELATED (QOL SURVEYS, BLOOD DRAWS & TISSUE COLLECTIONS) ***[Visit 2: Day 0]***	is composed of nine (9) multi-item scales and five (5) single-item symptom measures. It will take about 10 minutes to complete. • Multi-Item Scales: Five (5) functional scales (physical, role, cognitive (mental), emotional, and social); three (3) symptom scales (fatigue, pain, and nausea and vomiting); a global health and quality-of-life scale • Single-Item Scales: Appetite loss, constipation, diarrhea, dyspnea (shortness of breath) and sleep disturbances. 2. Patient-Reported Outcomes Measurement Information System (PROMIS) – **Completed by Sarcoma patients only**. These measures are self-reported surveys that evaluates and monitors physical, mental and social well-being in the general population and with people living with chronic (long-lasting) conditions such as cancer. The surveys are designed to improve communication between doctors and patients. This study will use three (3) surveys totaling 26 questions. It will take about 10 minutes to complete. • Global Health Scale: Overall evaluation of one's physical and mental health. (10 items) • Physical Function Scale: Capability of one's physical activities including one's ability to do certain daily living activities associated with an independent lifestyle such as preparing meals, running errands, etc. (10 items) • Pain Interference Scale: How pain affects your daily life with respect to social, cognitive (mental), emotional, physical and recreational activities. (6 items) 3. Musculoskeletal Tumor Society (MSTS) Score for Upper & Lower Extremity Sarcomas – **Completed by Sarcoma doctors only**. This rating system completed by a doctor to evaluate the physical and mental function of a patient with sarcoma involving the upper extremity (arms) or lower extremity (legs). 4. BLOOD SPECIMENS: A total of about seven (7) tablespoons will be collected in the operating room while you are asleep. Your blood will be drawn either from a needle stick into a vein in the arm, or if applicable, from a port-a-cath (large vein accessed usually under the skin in the chest) used for delivering chemotherapy. Researchers will look (test) for certain types of cells in your bloodstream before and after surgical treatment. • About 3.5 tablespoons will be collected after anesthesia is started but before the surgical incision (cut) is made to your skin. • About 3.5 tablespoons will be collected after the tumor and margin is removed but before treatment with the CHCPS.

	5. TISSUE & TUMOR SPECIMENS: Small portions of the tissue and tumor specimens removed during your surgery will undergo additional testing to show the FDA how the CHCPS worked during this study. 6. TEMPERATURE READINGS: An infra-red camera will be used during your surgery to take real-time temperature measurements before, during, and after treatment with the CHCPS. The purpose is to look for thermal damage to surrounding healthy tissues. ********** Information we will collect include: • Laboratory reports from blood collections • Surgery report (such as procedures performed, blood loss, complications if applicable, etc.) • Pathology report (such as standard examination/test results of the removed tissues. This will include both cold plasma sprayed and unsprayed tissues as applicable.) • Performance status • Physical exam including vitals and weight • Updates to medications you are taking • Any adverse events (symptoms) and serious adverse events
POST-OP FOLLOW-UPS ***Up to 12 months after Surgery + Cold Plasma Treatment*** ***Visit 3****: Before hospital discharge* ***CLINIC VISITS*** *After hospital discharge* ***Visit 4****: Day 14* ***Visit 5****: Day 30 ± 14 d* ***Visit 6****: Day 60 ± 30 d* ***CHART REVIEW*** *Through 12 months after Surgery*	Following surgery, you will be cared for according to the hospital's normal standard practices until discharge, and then managed according to your surgeon's normal standard practices and cancer care after discharge. We will not perform any additional tests that you would not normally have. The research-related activity (QOL surveys) will take about 10 minutes to complete. The use of cold plasma in humans is limited and long-term risks of cold plasma are yet unknown. We will continue to monitor your safety and progress for 12 months. Information we will collect include: • Performance status as applicable • Physical exam including vitals and weight as applicable • Routine laboratory tests for disease surveillance • Routine imaging scan for disease surveillance • Information regarding any further treatment of your disease since your surgery and CHCPS treatment (such as additional surgery, radiation, chemotherapy, hormone therapy, etc.) • Updates to medications you are taking • Any adverse events (symptoms) and serious adverse events • EORTC C-30 QOL (for Carcinoma or Melanoma patients) or PROMIS QOL (for Sarcoma patients): Research-related surveys self-reported by you. We will ask you to complete the survey at the Visit 5 follow-up. It is identical to the one you completed on

********** *After Visit 6 Follow-Up (if applicable)*	the day of surgery. • Musculoskeletal Tumor Society (MSTS) Score for Upper & Lower Extremity Sarcomas – Research-related rating of patient function completed by Sarcoma doctors only. ********** A follow-up will be done if we find you are experiencing an **adverse event** (symptoms or changes to your health or well-being) or **serious adverse event** that started sometime after signing the informed consent form and was still ongoing or was not stabilized at Visit 6. Your doctor will decide if the follow-up is a phone call or a return to the clinic.

Does this study involve genetic testing?

Yes, this study involves measuring DNA, RNA, and proteins for genes causing cancer. (See the next section below for more information.) The use of genetic material in research to study the causes of disease and to help understand how individuals respond to drug treatments is called genetic research. The cells of your body contain a molecule called deoxyribonucleic acid (DNA). DNA is received from your parents and carries a code in the form of genes, which determine your physical characteristics such as the color of your hair and eyes. Ribonucleic acid or RNA for short also acts as a messenger to tell your cells to produce certain features. Just as differences in our genetic codes help explain why we all look different, these differences can also help explain why some people develop certain diseases and others do not. They may also help explain why some drugs are safe and effective for some people but not for others.

What do you need to know regarding the collection of biospecimens?

Biospecimens may include blood, tissue, urine, bone marrow, saliva, cells, etc. For this study we will collect blood and tissue specimens on the day of your surgical treatment.

Blood and tissue specimens will be sent to the Rush University Medical Center (RUMC) Pathology Department and the Jerome Canady Research Institute for Advanced Biological and Technological Sciences, (JCRI_ABTS®) Translational and Molecular Center in Takoma Park, MD for additional testing for research purposes only.

RUMC: The pathologist will evaluate the sprayed and unsprayed tissue samples in the usual manner. Pathology will report what the tissues and cells look like and if there is evidence of thermal damage. Slides will be stored indefinitely (forever). Left over samples will be destroyed.

JCRI_ABTS®: The tissue samples will be used for establishing cell lines (i.e., make cells from the tumor grown in the lab in plastic or glass containers in a liquid mix containing nutrients to support growth). The cell lines will be grown in short term cultures and various experiments will be performed before and after cold atmospheric plasma (CAP) treatment to try to determine how and the methods of action CAP treatment has on cancer and normal cells. Examples of experiments include measuring DNA, RNA, and proteins for genes causing cancer, and the how these various genes affect cell growth and cell death. These samples may be used for purposes that are currently unknown. There are no plans for performing whole genome sequencing, which involves mapping (identifying the location of genes and the distance between them) of all of your

DNA. Samples will be stored in locked freezers contained in a secured building at JCRI_ABTS®. Samples collected will be stored for one year and then destroyed by burning.

Results will be reported to the FDA as grouped data only. Individual results will not be provided.

Will your information or biospecimens be used for research in the future?
Information or biospecimens collected from you for this study may be used for future JCRI_ABTS® cancer research studies that have been approved by an Institutional Review Board. We ask you for permission to keep leftover blood and leftover tissue for future research. Indicate your choice by selecting ONE checkbox. Initial and date below.

"I agree to the storage and use of my excess blood and tissue for future JCRI_ABTS® cancer research studies"

☐ YES ☐ NO INITIAL _____ DATE _____

Will your cells, tissues, blood or other biological materials (biospecimens) be used to develop commercial products?
There is a chance that the samples collected may be used in other research studies and may have some commercial value. Should your donated samples lead to the development of a commercial product, JCRI_ABTS® and USMI® jointly, will own it and may take action to patent and license the product. Neither RUMC, nor JCRI_ABTS®, ©USMI or parent company ©US Patent Innovations, LLC or Canady Life Sciences™, Inc intends to provide you with any compensation for your participation in surgery using the CHCPS investigational device, nor for any future value that the samples you give may be found to have. You will not profit financially from such a product. You will not receive any notice of future use of your samples.

What are the risks and discomforts of participating in this study?
Side effects, risks, and/or discomforts from participation in this study may include:

KNOWN POTENTIAL RISKS:

1. Immediate risks
   - Electrosurgery (surgery using a high-frequency electric current to heat and cut tissue and stop bleeding by sealing blood vessels) has been used in surgery for more than 90 years. Plasma gases (argon and helium) is used routinely as surgical tools for various purposes. Therefore, replacing currently used electrosurgical devices with the investigational CHCPS device should not expose patients to risks, other than risks of the surgical procedure itself when operated by a board-certified surgeon.
2. Risk of thermal injury (injury from heated objects)
   - Current electrosurgical tools create heat that may damage surrounding tissue. These tools can cause tissue to reach temperatures of 200 degrees Fahrenheit and higher. For this reason, surgeons avoid using these types of tools near sensitive tissues such as key structures vital for life.

- The main advantage of the CHCPS technology is that the amount of energy needed to kill cancerous cells does not create tissue temperatures over 86 degrees Fahrenheit. (For comparison, normal body temperature is 98.6 degrees.)

3. Risk of bleeding
   - The main reason for using electrosurgical devices in the operating room (OR) is to lessen bleeding from the dissected (cut up) tissues. Using plasma coagulators in the OR is highly useful in treating bleeding surfaces thus reducing the amount of blood loss. Argon plasma coagulators are often used for joint replacement, endoscopic (using scopes going through small cuts in the skin or natural body openings), plastic, and general surgery.
4. Long-range risks
   - Cold atmospheric plasma (CAP) devices are used in the clinical setting only for limited period of time. Therefore, long-term risks are yet unknown.
   - There is no available data regarding the impact of CAP on embryonic (unborn baby for the first eight weeks following fertilization) development so if you are pregnant or plan to become pregnant within 12 months after CHCPS treatment, you will not be able to take part in the study
5. Risk from blood draw
   - The risks of taking blood by a needle stick into the arm include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.
6. Extension of Operation Time
   - The extra step using the CHCPS device is estimated to extend your surgical procedure roughly 15 minutes for carcinoma and melanoma patients and 30 minutes for sarcoma patients. There are no known risks if the surgery is prolonged or extended by any time period.

As in any clinical study, there is a risk of potential disclosure of protected health information (PHI). PHI is anything that can directly identify you such as your name. To reduce this risk, a code number will be assigned to each subject and this code number will be used on all data collection forms. The master list linking identifying information such as name and medical record to the code number will be kept in a secure location by the study staff

There may be other risks that may happen that we cannot predict.

What are the reproductive risks of participating in this study?

Women

If you are pregnant or breastfeeding, you cannot take part in this study. A pregnancy test is required and will be given before you start treatment. You are responsible for using an effective birth control method such as birth control pills, barrier method (such as condoms or diaphragms), intrauterine device (IUD), hormone implants or surgical sterility for at least one (1) month prior to Screening and agree to use such method while you are taking part in this study. You may discontinue birth

control once your participation in this study is completed. If you become pregnant, you must notify the study doctor immediately.

What are the risks involving genetic information?
While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research. Your privacy will be protected to the fullest extent possible. Certain health concerns that affect you and your blood relatives might be found as inherited traits are studied. Even though your genes are unique, you share some of the same genes with your blood relatives. Genetic information is considered health information and is protected under the Health Insurance Portability and Accountability Act (HIPAA) as is your other health information. While very rare, information could be misused by employers, insurance companies and others. For example, life insurance companies may charge a higher rate based on this information. A federal law called the Genetic Information Non-Discrimination Act (GINA) should help lower the risk from unfair health insurance or employment policies. To learn more about the GINA Law, please go to http://www.ginahelp.org/GINAhelp.pdf or ask the study staff.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study especially if you leave before the final study visit.

We ask that you return to the clinic for a final visit. If we find you are experiencing an adverse event (symptoms or changes to your health or well-being) or serious adverse event that started sometime after signing the informed consent form and is still ongoing or has not stabilized, we ask that you allow us to keep track of you for a little while longer. This will be another seven (7) days for non-serious AEs or another 30 days for serious AEs. Your study doctor can decide if you need to return to the clinic or not. All adverse event outcomes will be reported to the Sponsor and the FDA.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Steven Gitelis, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Gitelis and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. Some of this information will come from your medical record. The health information that Rush may use or disclose for this research includes:

- Demographics (such as gender, age, and race)
- Medical, surgical, and medication history
- Performance status
- Physical exam including vitals, height and weight
- EKG test (electrical activity of the heart) if applicable
- Laboratory, pathology, and imaging scan reports related to your cancer diagnosis/surveillance
- Laboratory, pathology, and imaging scan reports related to your participation in this study
- Progress notes from office visits, hospital admissions, emergency department visits, etc.

Dr. Gitelis and his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers;
- The study Sponsor, US Medical Innovations, LLC, (USMI) and Jerome Canady Research Institute for Advanced Biological and Technological Sciences, (JCRI_ABTS), and its representatives, the Data Safety Monitoring Group, and Denise Johnson Miller, MD (Independent Reviewer);
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Gitelis is not required to release to your study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. The videos or photographs containing images taken during use with the cold plasma spray will be collected for research purposes and will be identified by a study code. No facial or identifiable features will be videoed or photographed. Representative images may be included in the final report to the FDA.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Steven Gitelis at Rush University Medical Center, Orthopaedics Bldg., Suite 400, 1653 W. Congress Parkway, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Research data will be maintained in paper format in a secure location at RUMC, in locked cabinets residing in the study coordinator's workstations and dedicated locked storage space in the Orthopaedics Building. Research data will also be entered and stored electronically on a secure, dedicated server in an encrypted file with password protection. Only authorized individuals will have access to it. No direct personal information that will make it possible to identify you will be used. Instead, the study doctors will replace any direct personal identifiers with a study code. This study code will consist of an assigned identification (ID) number. The study doctors will keep a master list that matches the ID number to your name/medical record number/date of birth for research data verification purposes only. This list will not be sent to the study Sponsor. However, the study forms will contain other identifying information about you (initials and "dates".) Examples of "dates" include birth date, surgery date, office visit dates, and adverse event start-end dates.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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.

What are the costs to participate in this study?

All costs that are part of your usual medical care will be charged to you or your insurance company. These include the costs associated with your hospitalization, surgical procedure, surgeon and anesthesia fees, imaging tests (X-ray, CT scans, MRI, Ultrasounds, Mammograms), laboratory

procedures, outpatient clinic visits (pre-surgery, post-surgery follow-up), therapies to manage your disease (such as chemotherapy, radiation therapy, and physical therapy), and anything related to managing your disease (such as surveillance, treating symptoms, and supportive care). You or your insurer will be responsible for paying for these costs.

The following items and services will be will be provided to you free of charge by the study Sponsors US Medical Innovations LLC (USMI) and Jerome Canady Research Institute for Advanced Biological and Technological Sciences (JCRI_ABTS).

- The investigational Canady Helios™ Cold Plasma Scalpel (CHCPS) device and supplies
- Research-related collection and tests performed on the blood, tissues, and tumor specimens. A full listing and description of the Research-Related Assessments may be found in the "**What are the activities you will be doing if you participate in this study? -- SURGERY & Treatment with CHCPS**" section of this consent form.

If you have health insurance, the insurance may or may not pay for the costs associated with your participation in this study. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires. You should check with your insurance company before you enroll in this research study.

If you do not have insurance, you will be billed for the amount you have to pay.

Will you be paid for your participation in this study?
You will not be paid for being in this study.

What if you are injured as a result of your participation in this study?
If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Steven Gitelis at telephone number (877) 891-8234.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

If you get ill or injured as the direct result of being in this study, the US Medical Innovations LLC (USMI) and Jerome Canady Research Institute for Advanced Biological and Technological Sciences (JCRI_ABTS) will pay the costs for your medical treatment of the illness or injury if it:

(1) Is not a medical condition that you had before you started the study;
(2) Is not the result of the natural progression of your disease or condition;
(3) Is not caused by your failure to follow the study protocol; and
(4) Is not proved to be directly caused by the negligence of a Rush employee. "Negligence" is the failure to follow a standard duty of care.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What other information should you know about?

Investigator Financial Disclosure
Rush University Medical Center is being paid by study Sponsors US Medical Innovations LLC (USMI) and Jerome Canady Research Institute for Advanced Biological and Technological Sciences (JCRI_ABTS) to conduct this research. A portion of this money may go to the study doctor to compensate for other institutional research related costs. The study doctors do not have any other financial relationship with the sponsor and they have no financial interest in the outcome of this study.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call:

- Dr. Steven Gitelis at (877) 891-8234 or email him at Steven_Gitelis@rush.edu
- Dr. Keith Millikan at (312) 942-5500 or email him at Keith_W_Millikan@rush.edu

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Steven Gitelis in writing at the address on the first page. Dr. Gitelis may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).

SIGNATURE BY WITNESS/INTERPRETER:
I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant and the person signing the form has done so voluntarily.

Name of Witness/Interpreter

Signature of Witness/Interpreter	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR:
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.