IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
December 17, 2024

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY
Title of Study: CONFORM Pivotal Study

TITLE: The CONFORM Pivotal Trial An Evaluation of the Safety and Effectiveness of the Conformal CLAAS System for Left Atrial Appendage Occlusion

PROTOCOL NO.: 21-101
WCG IRB Protocol #20216517

SPONSOR: Conformal Medical, Inc.

<<CF-Main Header Block - Investigator>>
INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): <<CF-Main User Defined #1>>
Number
Number (24 hours)
[24-hour number required]

In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

INTRODUCTION
You have been invited to join a research study to evaluate the Conformal CLAAS® System. The device is investigational and not approved by the FDA for your condition at this time. The study is sponsored by Conformal Medical, Inc. The Institutional Review Board or Local Ethics Committee has granted the approval for this clinical trial and use of the study device in the clinical trial settings.

You have been given this consent form so that you may read about the purpose, possible benefits, and risks of participating in this research study. The main goal of research is to gain knowledge that may help you and future patients. We cannot promise this research will benefit you. This research can have side effects that can be minor or serious. You have the right to refuse to participate or you can agree to participate and change your mind later. Whatever you decide, it will not affect your normal care, and it will not involve any penalty or loss of benefits to which you are otherwise entitled.

Please read this consent form carefully. You may agree to participate by signing the last page. Ask questions before you decide to participate. This consent form may contain words that you do not understand. If there are any words you do not understand, please ask your study Physician or the study staff to explain the information that is not clear. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

ABOUT THIS RESEARCH STUDY

The CLAAS System is designed to close the Left Atrial Appendage for the prevention of stroke and stroke related complications due to Atrial Fibrillation. Similar devices are commercially available for use in Left Atrial Appendage Closure. This study is designed to evaluate the safety and effectiveness of the CLAAS System which is designed to provide an efficient means to place a closure device in the target location.

This study is taking place in up to 100 hospitals in North America, European Union/European Economic Area (EU/EEA), and Central Asia and up to 1900 subjects will be enrolled.

ABOUT THE STUDY DEVICE

The CLAAS Implant is an implant made of a porous sponge like foam cup with a special skeleton metallic frame structure using materials that are common to many medical devices. The CLAAS System is manufactured by Conformal Medical, Inc., a medical device company in Nashua, New Hampshire, USA.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this clinical study is to evaluate the safety and effectiveness of the CLAAS Implant in sealing off the left atrial appendage for prevention of stroke and stroke related complications associated with atrial fibrillation.

You are asked to participate in this research study because you have a heart condition in which the upper chambers of your heart to beat irregularly. This condition, also known as atrial fibrillation, can cause blood clots to form in an area of your heart called the left atrial appendage (LAA). Everyone has a left atrial appendage, and it looks like a pouch on the top of your heart. If a clot forms in this appendage, it can increase your chances of having a stroke or other related problems if it is released from the appendage location.

Because you have atrial fibrillation, it is believed that if the left atrial appendage is closed, then blood clots might not be able to form in that area. This study is testing an investigational device called the CLAAS System which is specifically designed to be permanently implanted in the left atrial appendage of your heart and block off any blood flow to the appendage. An investigational device is one which has not been approved for marketing by the United States Food and Drug Administration (FDA).

WHO CAN PARTICIPATE IN THE STUDY?

Before you decide to be in the study, be sure you understand all the information given and ask your study Physician any questions you may have about your participation in this study.

Please understand your consent is required for your study Physician to evaluate you further as a potential candidate for the study. If you decide to participate in this study, you can sign this form which will allow your study Physician to perform additional study-related tests and questionnaires to see if you are a good candidate for this study.

You will not be eligible for the study procedure until your study Physician confirms that you meet all the criteria for inclusion in the study.

You may be considered for this study only if you:

1. Agree in writing to participate in this study (by signing this consent form).
2. Are at least 18 years of age.
3. Meet all eligibility criteria as assessed by your Physician.

WHAT WOULD NOT ALLOW ME TO PARTICIPATE IN THIS STUDY?

There are certain conditions that would not allow you to participate in this study. These conditions are described as eligibility requirements and will be reviewed with you before your participation. Your study doctor will speak with you, review your medical history, and perform some tests to determine if you are an appropriate candidate for this research. If you do not meet all eligibility requirements you will not be able to participate in the study.

Women of childbearing potential should avoid pregnancy for up to one year after the procedure.

HOW LONG WILL STUDY LAST?

If you choose to participate, it is expected your participation would last 5 years from the day of your procedure.

Regardless of which implant procedure you receive, your study doctor will schedule follow-up exams at 7 days, 45 days, 6 months, 12 months, and 18 months following your procedure. After this, your doctor will schedule a follow-up exam every year after that for a total time of about 5 years. The yearly evaluations may either be conducted by telehealth (e.g. telephone or video call) or an office visit.

You may also be seen by a Neurologist if you have or suspected to have a history of stroke during baseline or any of the follow-up visits or at any time during the follow up. Your study doctor or the study sponsor may also request additional visits, if necessary.

GENERAL SCREENING PROCEDURE

Once your study Physician determines you are a good candidate for this study, your study Physician will conduct assessments to determine if you are eligible for the study. Some of these are part of your standard evaluation for a left atrial appendage procedure and some are part of the study. These screening assessments include:

- Physical assessments/examinations, including risk assessment scores that predict stroke, deep vein thrombosis (blood clots in the vein) and risk of major bleeding in patients with your condition
- Medical and surgical history,
- Vital signs.
- Medication review.
- Clinical laboratory testing, including a pregnancy test for females of childbearing potential.
- Questionnaire for Verifying Stroke-Free Status (QVSFS).
- Assessment of your neurological status comprised of two assessments called a Stroke Scale (NIHSS and Modified Rankin Scale) that assess severity and impact of stroke on your daily activities.
- ECG: a test to check the electrical activity of your heart.

- Cardiac Imaging: TEE or Cardiac CT. One or more of the following imaging procedures will be done to see if you can have the device implanted in the left atrial appendage of your heart. If you have recently (within the last 6 months) had a TEE or CT of your heart, you likely won't need to have new imaging conducted.
    - Transesophageal Echocardiogram (TEE): (a procedure performed with an ultrasound probe that is passed down your throat that sends harmless sound waves to take pictures of your heart).
    - Cardiac CT: computerized tomography (CT) is an imaging test that looks at the arteries that supply blood to the heart. This test uses a powerful X-ray machine to produce images of the heart and its blood vessels.

GENERAL STUDY AND IMAGING PROCEDURES
If you have had a previous stroke or transient ischemic attack (TIA or "mini stroke") you may have some pictures of your brain taken by a CT scan or MRI scan.

As a participant in the study, the oral anticoagulation medication (blood thinner) you may be currently taking will be adjusted before your procedure. You will be given a medication (sedative) to relax you before you are put to sleep to have the implant procedure. While you are asleep, you will have transesophageal echocardiogram (TEE) evaluation to see if you can have the device implanted in the left atrial appendage of your heart. A TEE is a special tube that is passed down your throat (your food tube) to take special images of your heart. The tube sends harmless sound waves to your heart to provide pictures without interference from your ribs, chest wall and lungs. This is a standard test for your condition and left atrial appendage procedures and is also required for this study.

Additional ultrasound imaging tests (transthoracic echocardiograms) that use harmless sound waves will be done to allow your physician to see your heart by placing the ultrasound probe on your chest using an acoustic gel to enable the imaging.

If the TEE and blood tests confirm you meet all requirements for the CONFORM Pivotal study, you will be randomized to either the control procedure (currently marketed closure device) or the CLAAS Implant procedure. You will have a 50% chance of receiving either device.

ROLL-IN PHASE
Up to four subjects enrolled in the study at this study site will be part of the 'Roll-In' phase, which means the subject will undergo implantation of the CLAAS Implant. Subjects not enrolled in the roll-in phase will be 'randomized'.

RANDOMIZATION
If you meet all requirements for this study, a computer will randomly assign you to receive the control device (currently marketed appendage closure device) or the CLAAS System. Randomization is like flipping a coin.

THE IMPLANT PROCEDURE
The device is placed in your left atrial appendage while you are asleep under general anesthesia. You will receive anticoagulation therapy (or anticoagulants) during the procedure to prevent blood clots.

The Procedure starts by utilizing standard techniques to access the left upper chamber of the heart (left atrium) where the left atrial appendage is located. Using a small needle, your study doctor will puncture the vein in your groin. A long, thin tube, called a catheter, is inserted into the vein and advanced into the right upper chamber (right atrium) of the heart. Using special tubes guiding a long needle, another puncture is made through a thin muscle wall between the two upper chambers of your heart (the right atrium and the left atrium) so that the catheter can be advanced into the left chamber of the heart (the left atrium). A thinner catheter is then advanced into the left atrial appendage under X-ray guidance. Once the catheter is in the correct position, your study doctor will take several pictures of your heart using the transesophageal echocardiogram (TEE).

The device will then be guided to your heart through this same catheter. After the device is put into place, additional measurements and pictures will be taken to make sure the device is in the correct position. Once your study doctor is satisfied, the device will be released and the implant will remain in that location of your heart where it is intended to stay permanently to ensure the left atrial appendage closure.

With this type of procedure, you will be required to stay at least 4 hours post-procedure and you may need to stay in the hospital overnight. If you are assigned to the CLAAS Implant procedure, you will start taking two different blood thinners (aspirin and Clopidogrel) if the implant procedure is successful. If you are known to be a non-responder or have an intolerance to Clopidogrel, an alternative may be prescribed at the discretion of your study doctor. You may also have to take blood thinners if the device is implanted but does not effectively seal off the left atrial appendage. If you are assigned to the CLAAS Implant procedure and it is unsuccessful, you may still be eligible for treatment with the standard of care based on your physician's assessment.

After you have the device implanted in your heart and prior to being discharged from the hospital, the following assessments will be completed:

- Neurologic assessment comprised of two assessments that assess severity and impact of stroke on your daily activities.
- Questions about changes in your health and medications.

After discharge, you will return to see your study doctor for follow-up exams, so your study doctor can check the status of the device. **For the purposes of this research, it is very important that you return for all of the follow up exams.**

GENERAL FOLLOW-UP PROCEDURES – IMPLANTED SUBJECTS

If you received an implant, at every follow up visit, study site staff will ask you questions about changes in your health and medications. You will also be asked questions by site staff to determine if you have had a stroke. If you are suspected to have had a stroke or systemic embolism, you may be examined by a neurologist and be subject to additional imaging such as TEE, MRI or CT scan to monitor your health.

Additionally, you may have unscheduled visits (visits not specifically outlined below) if you experience a complication that may require an additional visit to the Study Doctor.

7 Day Follow-Up Procedure (Telehealth-phone call or video link)

- Questions about changes in your health and medications.
- Questionnaire to assess if you have had a stroke.

45 Day Follow-Up Procedure (Clinic Visit/Telehealth + Imaging)

- Questions about changes in your health and medications.
- Questionnaire to assess if you have had a stroke.
- TEE and/or Cardiac CT imaging.
- TTE may be required to evaluate pericardial effusion/tamponade (compression of the heart due to fluid buildup).

6 Months Follow-Up Procedure (Telehealth/Imaging)

- Questions about changes in your health, medications.
- Questionnaire to assess if you have had a stroke.
- TEE imaging, only if your 45 Day TEE imaging shows ineffective seal of the left atrial appendage.

12 Months Follow-Up Procedure (Clinic Visit/Telehealth + Imaging)

- Questions about changes in your health and medications.
- Questionnaire to assess if you have had a stroke.
- Cardiac CT and/or TEE imaging.
- TTE may be required to evaluate pericardial effusion/tamponade (compression of the heart due to fluid buildup).

18 Months Follow-Up Procedure (Clinic Visit/Telehealth)

- Questions about changes in your health and medications.
- Questionnaire to assess if you have had a stroke.
- Neurologic assessment comprised of two assessments that assess severity and impact of stroke on your daily activities.

2 Years, 3 Years, 4 Years, 5 Years Follow-Up Procedure (Telehealth)

- Questions about changes in your health and medications.
- Questionnaire to assess if you have had a stroke.

Unscheduled Visits (Clinic Visit + Imaging)

If you have a suspected stroke, you will be asked to come in to complete the following assessments:

- Questions about changes in your health and medications.
- Neurologic assessment comprised of two assessments that assess severity and impact of stroke on your daily activities.
- Questionnaire to assess if you have had a stroke.
- TEE imaging of your heart.
- CT, and/or MRI imaging of your brain.
- Physical assessments/examinations.

Upon completion of the study (i.e., your last study visit), you should undergo follow-up treatment and care according to your study physician's standard of care for patients undergoing LAA closure.

GENERAL FOLLOW-UP PROCEDURES – NON-IMPLANTED SUBJECTS

If you are enrolled, but no longer meet eligibility criteria and do not have a procedure attempt, you will only be required to attend the 7-Day Follow Up Visit (via telehealth/phone call) and the 45 Day Follow Up Visit (via telehealth/phone call). Imaging is not required and medication therapy is not required. After the 45-Day Visit, you will have completed all required study assessments.

If for any reason you consented, met eligibility criteria, and enrolled into the study, but were unable to receive an implant on the day of the procedure, you will be required to attend the 7-Day, 45-Day, 6-Month, 12-Month, and 18-Month Follow Up Visits via telehealth/phone call Imaging is not required and medication therapy is not required. After the 18-Month visit, you will have completed all required study assessments.

RISKS AND DISCOMFORTS

There might be unexpected risks from being in this type of study. New information from this research study may give the Sponsor useful information to improve the device and procedure to treat your medical condition. This may help support further research studies with the device.

The CLAAS System has been used in a feasibility study in the US and Europe. The side effects that were seen in that experience are similar to the events that have been reported with the currently marketed left atrial appendage devices. It is important to remember that there may be other risks that are unforeseen at this time. Precautions will be taken to avoid harmful side effects as a result of participation in this study. Your physician will closely monitor your health status throughout the study.

POTENTIAL RISKS FOR STUDY DEVICE, CONTROL DEVICE, AND PROCEDURE

There are certain risks associated with the use of the CLAAS Implant or commercially available device and the left atrial appendage closure procedure. Not all risks associated with the use of the study device and procedure are currently known.

A list of the potential risks of the device and procedure:

- Acute kidney injury potentially requiring need for dialysis.
- Air embolus (air bubble in blood vessel).
- Air embolism (air in the blood stream).
- Allergic reaction to contrast media necessary for imaging during procedure.
- Altered mental status or post-procedure confusion.
- Anesthesia risks (e.g. nausea/vomiting, aspiration pneumonia).
- Anoxic encephalopathy (lack of oxygen to the brain).
- Arrhythmia (irregular heartbeat).
- Bleeding/anemia requiring transfusion.

- Cardiac perforation, puncture, tamponade (compression of the heart due to excess fluid) and/or effusion (accumulation of excess fluid in the sac around the heart) requiring drainage and/or "open heart" surgery.
- Chest pain/angina.
- Congestive heart failure.
- Contrast related nephropathy (kidney disease due to imaging contrast).
- Damage to cardiac structure (e.g. valve, chordae).
- Death.
- Deep vein thrombosis (blood clot in the vein) or pulmonary embolism (blood clot in the lung).
- Device embolism or thrombosis (a clot that forms on the device and breaks off to block an artery or vein).
- Device malfunction/breakage requiring intervention.
- Device migration (the device moved from its original insertion site) requiring intervention.
- Dyspnea
- Edema (swelling caused by excess fluid in body tissues).
- Electrolyte imbalance.
- Fever.
- Heart failure.
- Hematuria (blood in urine).
- Hemodynamic instability (low blood pressure/high blood pressure).
- Hemoptysis (coughing up blood).
- Hemothorax (blood collection between lungs and chest).
- Hypotension (low blood pressure).
- Hypoxia (low oxygen).
- Iatrogenic atrial septal defect requiring treatment (a hole in the wall of the heart).
- Improper wound healing.
- Inability to reposition, recapture, or retrieve the device.
- Interatrial septal thrombus (blood clot in the interatrial wall).
- Infection.
- Major bleed requiring transfusion.
- Myocardial erosion (a hole or injury to a wall of the heart caused by gradual pressure or motion over time).
- Myocardial ischemia or infarction including ST segment elevation (chest pain or heart attack).
- Nausea, vomiting or GI distress.
- Pericardial Effusion/Tamponade (compression of the heart due to fluid buildup).
- Pericarditis (infection in the heart).
- Pleural effusion (buildup of fluid in tissue lining the lungs).
- Prolonged procedure time risk.
- Pulmonary edema (excess fluid in the lungs).
- Renal failure (kidney function decline).
- Re-intervention due to incomplete seal.
- Re-intervention to remove device.

- Residual leak in LAA.
- Respiratory failure.
- Stroke/Transient ischemic attack or systemic embolization.
- Systemic infection, including pneumonia.
- TEE/intubation including throat pain, trauma to airway or esophagus (with or without bleeding).
- Thrombocytopenia (low platelet count).
- Thromboembolic event.
- Thrombus formation.
- Vasovagal reactions (rapid fall in blood pressure).
- Venous access site complications including pain, AV fistula (a hole between a vein and an artery at the puncture site), pseudoaneurysm (a bulge within the wall of an artery that communicates with the inside of an artery), infection, hematoma, bleeding requiring transfusion and/or the need for surgical repair.

RISKS ASSOCIATED WITH ANTICOAGULATION THERAPY DURING THE PROCEDURE:

- Bleeding
- Allergic reaction
- Low platelets

RISKS ASSOCIATED WITH MEDICAL TREATMENT

The potential risks associated with blood thinning medicines (warfarin, other Oral Anticoagulants OACs, e.g., aspirin, clopidogrel, apixaban, rivaroxaban, prasugrel, and ticagrelor) include, but are not limited to:

- Increased bleeding time
- Bleeding from the stomach or bowels
- Cranial/brain bleed
- Drowsiness
- Dizziness
- Headache
- Heartburn
- Stomach pain
- Loss of appetite
- Nausea
- Vomiting
- Hives
- Rash
- Itching
- Bruising
- Swelling
- Chest pain
- Infection

Computed Tomography (CT) Scans

- This test will expose you to radiation. There is also a potential risk for allergic reaction to the dye for the CT scan that could be serious including death. There is a risk of kidney damage from the dye especially if you already have kidney problems or are dehydrated.

Magnetic Resonance Imaging (MRI) Scans

- Contrast dye may be used, which has a small possibility of a severe allergic reaction and may also cause kidney problems, especially if you are dehydrated or have poor kidney function.

Inconveniences include but are not limited to:

- The inconveniences of recovery from the procedure,
- required follow-up examinations including the tests mentioned above, and
- following your study doctor's recommendations for recovery.

You and your study doctor should discuss all of the possible risks in detail as part of participating in this study.

There is also a risk of loss of confidentiality.

ARE THERE ANY UNKNOWN RISKS?

Due to the investigational nature of this study, there may be other potential risks that are not currently known. It is important that you report any reactions to your doctor. Study personnel will monitor you for problems that you may experience.

WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING IN THIS STUDY?

It is possible that there may be no direct therapeutic benefit from participation; however, the results of the trial may contribute to improved treatments that could benefit future patients who require LAA closure for the prevention of stroke and systemic embolism.

OTHER TREATMENTS AVAILABLE

It is not necessary for you to be enrolled in this study to protect you from stroke or related complications from blood clots. Alternative therapies for your medical condition may include long term medication that thins your blood or LAA Closure with one of the currently marketed products. Your Physician will discuss your situation with you and will recommend the best treatment for you, including how the experimental therapy would differ from the standard of care.

WILL I BE INFORMED OF ANY NEW FINDINGS?

You will be provided with any significant information that develops during the course of the study which might change your decision to be in this study.

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.

YOUR PARTICIPATION IS VOLUNTARY

Your participation in this study is entirely voluntary. If you wish to participate in this study, you will be asked to sign this form. You are free to refuse participation in this study or to withdraw your participation at any time before or after the procedure without any negative consequences to the medical care, education or other services you may receive from this clinic or hospital. Simply inform your study doctor of this decision. You do not need to specify the reason for your withdrawal. If you withdraw or are withdrawn from the study, you will still be able to undergo follow-up treatment and care according to your study physician's standard of care for patients undergoing LAA closure. Your study Physician will discuss with you whether any testing or follow-up may need to be done for your safety.

Your Physician or the sponsor can remove you from the study at any time without your approval. If your study participation is stopped, you may be asked to undergo a routine medical exam and/or medical testing for safety reasons. Any patient who is withdrawn from the study for any reason may not re-enter the study at any time.

STUDY RELATED INJURY

If physical injury happens to you because of your involvement in this study, medical treatment will be available, if appropriate, at the hospital. Contact your study Physician if you experience a study related injury.

WHAT ARE THE COSTS OF PARTICIPATING?

Costs which are associated with examinations especially for this clinical study, (including costs for TTE, TEE blood tests, and/or brain x-ray to assess eligibility) will be covered through an established contract between Conformal and your hospital. The cost of your usual medical care that would have been incurred regardless of your enrollment in the study will be billed to you or your insurance as outlined below.

WILL I BE PAID FOR PARTICIPATING IN THE STUDY?

<<CF-Main Payment for Part. Paragraph>>Compensation will be provided for each in-clinic visit to help offset time and travel to return to the study site. You will be compensated <<$[Insert Patient Stipend here [>>00 dollars for the following visits: Screening, 45-Day Follow-up (if not done through Telehealth), 12 Month Follow-up (if not done through Telehealth), and 18 Month Follow-up.

In order to receive your compensation, you <<may/will>> be required to complete an IRS W-9 Form and will be asked for your social security number. A gift card or check for the amount of the reimbursement as paid by Conformal Medical, Inc. will be provided to you at the conclusion of your visit or mailed directly to you by the study site.
<<CF-Main Financial Disclosure>>

RIGHTS AND COMPENSATION

Some of the services or items will be considered part of your routine medical care. These would be performed or used even if you were not in this study.

<<For OUS Only>>You will not be responsible for any cost for participation int the study. All the expenses are covered by the sponsor. You will be responsible for standard of care anticoagulation treatment, that you would administer in any case, but not for the surgery, hospitalization etc.

You or your insurance company will be billed for the cost of your LAA closure procedure, any costs related to your stay in the hospital, and your usual medical care and that would have been incurred regardless of your enrollment in the study. This includes physician services, hospitalization charges, routine tests and medicines and any care you need after being discharged from the hospital. You will be responsible for normal co-payments, coinsurance and deductibles.

The sponsor of this study is paying <<CF-Main User Defined #2>>[Site] a specific amount of money for each person who agrees to take part in the study. This money is to cover the cost of doing the study and pay for such things as study supplies, staff salaries, etc.

By signing this form, you do not give up any of your legal rights and you do not release the study Physician or other participating institutions from their legal and professional duties.

INJURY STATEMENT

If you become ill or physically injured as a result of your participation in this study, any immediate medical treatment that is necessary will be provided to you. However, no monetary compensation or subsidized medical treatment will be routinely provided to you by any person involved in this study including the study Physicians, the hospital, or the study sponsor. You will be charged for normal co-payments, coinsurance and deductibles relating to any subject injury.

You should immediately report any injury resulting from participation in this study to <<CF-Main Investigator Full Name-Title>>[Name] at the following phone number <<CF-Main User Defined #3>>[Number] (24 hours).

WHAT IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions, concerns or complaints about taking part in this study, or if you think you may have been injured because of your participation in the study, call <<CF-Main Emerg. Phone Number>>[Name] at [Number]. If you have any questions about your rights as a study patient, or if you have questions, concerns or complaints about the research, you can call WCG IRB at 855-818-2289. You should also inform your study Physician if you have been injured or hospitalized for any reason during the study.

WHAT IS THE ROLE OF THE SPONSOR'S REPRESENTATIVE?

A sponsor representative is designated by the sponsor (the entity initiating the study) to represent their interests and oversee various aspects of the trial. This representative may work closely with investigators, monitor the progress of the study, ensure compliance with regulatory requirements, and address any issues that may arise during the course of the investigation.

The sponsor's representatives, regulatory authorities, and IRB representatives involved in the study may have direct access to your medical records. Your personal medical information will remain confidential in accordance with national data protection laws.

Trained Sponsor personnel may be present at the study procedure (such as a field clinical specialist). The role of the field clinical specialist is to give technical support.

All of these actions will be done under the careful direction of your study doctor.

CONFIDENTIALITY OF STUDY RECORDS AND MEDICAL RECORDS

Your participation and any information collected for this study is confidential. Access to your personal medical information will be limited to the purposes of collection and processing information necessary for the completion of this study. Your privacy is important. You will only be identified in the study by a code. This number is not derived from any of your personal information. Should results of this study be published (in a medical journal), you will not be identified through your name or other personal information. Data collected and reported to the sponsor for this study are the property of the sponsor. Your study records are just like hospital records. They may be subpoenaed by court order or may be inspected by federal regulatory authorities, including the Food and Drug Administration, and WCG IRB.

Your personal doctor will be informed of your participation in this study only upon your approval.

The Sponsor is considered the Data Controller which means they are responsible for deciding how study data (that does not contain your name) is processed and kept safe. The Data Controller will only allow further access of the study data to authorized individuals. The study data and your personal data will be processed/ stored in keeping with current local data privacy and protection requirements. You have the right to ask for updated information on recorded study and personal data, the right to access your personal data and the right to have your personal data corrected, if it is incorrect. Because the Data Controller is receiving study data from the study doctor or his/her institution, the Data Controller cannot guarantee what the study doctor or the institution does with your data. The study doctor is required by law to protect your health information.

PROTECTED HEALTH INFORMATION

Who may use and disclose information about you?

The people who may use your Private Health Information include the study physician, <<CF-Main Investigator Full Name-Title>>[Name] and his/her staff; the Institutional Review Board and its staff; legal counsel; audit and compliance staff; and other people who need to see the information to help the study or make sure it is being done correctly. These people may disclose your Private Health Information to staff of the entities listed in the next section.

Who may see your health information?

Your Private Health Information may be disclosed to people associated with the following entities:

- Governmental agencies that have the right to see or review your health information, such as the Office of Human Research Protections and the Food and Drug Administration.

- Other institutions that are participating in the study. The sponsor of the study <<CF-Main SMO Company 1>><<CF-Main Affiliated IN Language 1>>and organizations that the sponsor may contract with for the study. The name of the sponsor is Conformal Medical, Inc.

Why will your information be used and disclosed?
Your information will be used and disclosed in order to carry out the study and to evaluate the results of the study. Your information may also be used to meet the reporting requirements of governmental agencies. The Sponsor, Contract Research Organization (CRO), its affiliates may inspect and/or copy your research records for quality assurance and data analysis.

Can you decide not to authorize the use and disclosure of your Private Health Information?
Yes. You do not have to authorize the use or disclosure of your Private Health Information. However, if you do not sign this authorization, then you cannot participate in the study.

Can you revoke your authorization?
Yes. You may revoke your authorization to allow your Private Health Information to be used or disclosed at any time by sending a written notice to the principal investigator, <<CF-Main User Defined #4>>[Name] at [Address].

If you revoke your authorization, you will be withdrawn from the study, and no health information about you will be gathered after that date. However, information gathered before that date may be used or disclosed if it is needed for the study analysis.

Is your health information protected after it has been disclosed to others?
If your health information is disclosed to someone who is not required to follow the Privacy Rule, then that information may no longer be protected, and it may be used or disclosed without your permission.

The Sponsor of the study, Conformal Medical, Inc., the Investigator and all involved third parties have agreed to be bound by the provisions of the Privacy Rule of the Health Insurance Portability and Accountability Act.

Can you see your health information?
Yes. You may see and copy your information after the study ends.

Does your authorization have an expiration date?
<<CF-Main User Defined #6>>Your authorization to use and disclose health information will continue until the end of the study and any necessary data analysis follow-up activities for the study. However, the information and data that are collected during your authorization period is effective can continue to be used and disclosed after your authorization has expired.

<<OUS Sites Only>>Please check below if you want or do not want your primary care doctor to be informed of your participation in this study:

☐ Yes, please inform my doctor
Please, provide contact information: _____
☐ DO NOT inform my doctor
☐ The Study Doctor is my physician.
☐ Not applicable, I do not have a primary doctor

SUBJECT'S STATEMENT

I have been given a chance to ask questions about this study. These questions have been answered to my satisfaction. If I have any more questions about taking part in this study, I may contact <<CF-Main Emerg. Phone Number>>[Name] at [Number].

I understand that my participation in this study is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might otherwise be entitled. I understand that there might be other treatment alternatives for me. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study. If I have any questions about my rights as a patient in this study, I may contact WCG IRB at 855-818-2289.

- All subjects unable to consent are required to assent.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

By signing this consent form, I have not waived any of my legal rights or released the parties involved in this study from liability for negligence.

<<OUS Sites Only>>I give the study team permission to inform my personal physician of my participation in this study.
[Name] at [Number]
I agree with the sponsor personnel being present during my study visits at the site.
I acknowledge that sensitive data (e.g.: health related data) will be collected.

I have read and understand the above information. I agree to participate in this study. I have been given a copy of this form for my own records<<CF-Main California Bill of Rights>>.

Signature of Study Participant _____

Print Name of Study Participant _____

Date _____

Signature of Legal Representative _____

Print Name of Legal Representative _____

Date _____

❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ _____

Signature of person obtaining Assent/Consent Date

_____ _____

Print name of person conducting informed Assent/Consent discussion Date

Signature of Principal Investigator _____

Print Name of Principal Investigator _____

Date _____

<<CF-Main California HIPAA>>

****For Sites in California****

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records.
- Research records.
- Records about phone calls made as part of this research.
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB).

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject/ Legally Authorized Representative	**Date**
Legally Authorized Representative Relationship	**Date**