Left Atrial Anatomy Reconstruction Using Model Based Fast Anatomical Mapping
PI: Vivek Reddy
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BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC
MOUNT SINAI HEALTH SYSTEM

SUBJECT INFORMATION AND INFORMED CONSENT FORM

Title of Study:	Advanced Model Based Fast Anatomical Mapping Software for Atrial Fibrillation Ablation (MFAM 2)
Protocol Number:	mFAM
Sponsor:	Dr. Vivek Reddy
Study Funding Source:	Biosense Webster
Principal Investigator:	Mohit Turagam, MD
Institution:	Icahn School of Medicine at Mount Sinai
Address:	One Gustave L Levy Place, New York, New York 10029
Telephone:	(212) 241-7114
GCO #:_____	

You are being asked to be a subject in a research study because you have been diagnosed with a heart rhythm problem known as atrial fibrillation (AF) for which you are undergoing ablation procedure using electrophysiology (EP) mapping. This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTEREST

Biosense Webster is providing funds for the study. Neither Dr. Choudry (the Principal Investigator of this study) nor Mount Sinai will receive any funding from Biosense Webster to conduct this study.

Dr. Vivek Reddy (a co-investigator in this study and Director of Cardiac Arrhythmia Services for the Mount Sinai Health System) is the Sponsor Investigator of this clinical trial evaluating a Biosense Webster device. The Sponsor Investigator is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational device is examined and evaluated.

In the past, Dr. Reddy received financial compensation as a consultant and lecturer for Biosense Webster (the company which funds this study, and manufactures the Carto system, MFAM software and the ablation catheters being used in this study). Dr. Reddy no longer receives any consulting fees from Biosense Webster however he may receive travel reimbursement.

In addition, Dr. Reddy also holds equity in and receives financial compensation as a consultant, advisory board member and lecturer for other companies that manufacture devices used for the treatment of cardiac arrhythmias.

If you have questions regarding paid relationships that your physician/researcher may have with industry, we encourage you to talk with him or her, or check for industry relationships posted on individual faculty pages on your website at http://icahn.mssm.edu/.

PURPOSE OF THIS RESEARCH STUDY

The purpose of this study is to test if an experimental computer imaging software, called fast anatomical mapping (mFAM) is faster and more accurate, and to measure how much Xray you are exposed to. The new software will be used in conjunction with other standard imaging techniques during the ablation procedure. Experimental means the software is not approved by the United States Food and Drug administration for sale or use outside of scientific research studies.

Atrial fibrillation (AF) is caused by abnormal electrical signals in the upper chambers (atria) of the heart, which causes them to beat rapidly and irregularly. Although this condition is usually not life threatening, AF can affect your health and quality of life. Additionally, patients with AF have a higher risk of stroke than patients in a normal cardiac rhythm.

Doctors may try to treat your AF with medications. However, if medications fail or are undesirable, your doctor may recommend an ablation procedure. Catheter ablation is a minimally invasive procedure that may lessen the number of episodes or treat atrial fibrillation. Ablation is a procedure that cauterizes (heats) heart tissue using catheters. The doctor threads a catheter (a flexible thin tube) through the blood vessels to the heart to stop (ablate) abnormal electrical pathways in the heart tissue.

In this study, the study doctor and sponsor are interested in using mFAM software to find out if it can provide an accurate 3D map (pictures) of the heart and catheter location during ablation procedures for patients with atrial fibrillation, which may then enable the doctors to perform a more effective ablation.

You will undergo a regular catheter ablation procedure for the treatment of your atrial fibrillation. You would undergo an ablation procedure whether or not you agree to be in this study. However, the ablation procedure that is part of this study is not the same as you would have if you were not in the study because of two experimental features on the study ablation procedure, which are discussed below.

EXPECTED LENGTH OF TIME FOR STUDY PARTICIPATION

Participation in this study is expected to last until you are discharged from the hospital following your ablation procedure. Information collected at the time of ablation and during follow up visits will be included in the study database.

NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Approximately 50 subjects are expected to participate in this study at two research sites in the United States.

DESCRIPTION OF WHAT'S INVOLVED

Screening Procedures

Your study doctor will check your health by looking at your medical records. You will have to

meet the study requirements in order to continue in this study to have the ablation with Model Based Fast Anatomical Mapping (mFAM mapping). There may be reasons why you cannot participate in this study. Your study doctor will discuss these with you.

Mapping using mFAM

If eligible after screening, you will undergo a regular (standard of care) catheter ablation procedure for the treatment of atrial fibrillation. During the procedure, your anatomical information will be recorded in the standard fashion. It will also be analyzed by the experimental mFAM software to create an additional map of your heart. These maps will be used during the procedure in conjunction with other standard techniques to assess anatomy, including intra-cardiac echocardiography and fluoroscopy, as is standard practice in routine ablation cases. The mFAM map is available for use in addition to the standard modalities that we use during the procedure. The doctor, informed with this information, will then decide how to best treat you with catheter ablation.

Ablation

Atrial fibrillation ablation is a routine, standard of care procedure. The catheters that will be used are routinely used for intermittent and persistent AF ablations but are currently only approved for intermittent AF. Thus, in this study, the use of the catheters listed below to treat persistent AF is considered experimental. The names of the catheters that may be used are in this study are:

- Biosense Thermocool SF
- Biosense Smart Touch SF (STSF)

The first step of a radiofrequency ablation procedure is the placement of several types of catheters into your heart through the groin to record the electrical activity from areas that may be starting or maintaining the AF. Fluoroscopy, a type of light x-ray, will be used to help guide the placement and movement of the catheters. The groin area will be numbed to make the procedure more comfortable. You may also be given medications to help you relax or sleep based on your doctor's discretion.

Some of the catheters will be placed in the left side of your heart. To reach the left side, a small puncture is made in the area of the heart that separates the left from the right atrium, called the septum. These catheters may also be used to pace your heart in different regions, and possibly start the AF. This will provide your study doctor with information about where the AF may be originating and where to ablate in efforts to eliminate the AF. The areas in the heart that will be targeted are around the pulmonary veins (veins that take blood from both of the lungs to the left side of the heart). These areas have been shown in other studies to be frequently involved in the cause of AF. Other areas may be ablated as well.

Once your study doctor locates the areas in your heart to be ablated, energy will be applied through the catheter. This procedure may last several hours. At the end of the ablation procedure, your heart may once again be paced to try and start the AF. This is necessary to verify that the areas in the heart which were targeted have been successfully ablated.

During the ablation procedure, your study doctor will determine the amount of fluid being used to cool the ablation tools and treat you accordingly. Diuretics are drugs used to increase the excretion

of water from the body. If there is too much build-up of liquid inside your body, diuretics will help to get rid of it through your urine.

After completing the ablation procedure, you will be monitored in the hospital. You will probably remain in the hospital for one or two days after the procedure.

If atrial fibrillation returns, your doctor may decide to repeat the procedure, and medication may also be prescribed to keep your heart rate under control.

Hospital Discharge

The following procedures will be done:

- Review medication use, including treatment for anticoagulation and atrial arrhythmias
- Adverse event (a bad effect) recording

Information Collected for Study

For research study purposes, information will be collected about your general medical and cardiac heart rhythm history, office blood pressure measurements, baseline tests such as echocardiogram, transthoracic echo (TTE) and computerized tomography (CT) scan or magnetic resonance imaging (MRI) scan, blood work and, if you have one, information from your implantable cardioverter defibrillator also known as ICD. These assessments are part of your standard of care that you would have even if you are not in the study. You will not have a TTE or imaging scans only for the study.

Information collected about you will be stored and identified using a unique 5-digit subject number and your initials. The study doctor will keep a separate log in which the unique study numbers are matched to the subjects names and medical record number. Study records will be maintained at the site for at least 2 years after the research study is terminated.

Information about you as described above will be collected at the office visit before your scheduled ablation procedure, during the procedure and at all your follow up visits with your treating physician.

RISKS AND DISCOMFORTS

Risks Associated mFAM Mapping

Risks and discomforts will be consistent with those of standard of care catheter ablation procedures.

There is no known additional risk associated with the mFAM software.

Risks Associated with Ablation Procedure

There are risks associated with any electrophysiology procedure using ablation catheters. Although the overall percent (how often it occurs) of each risk is provided, these may be different at your hospital. Check with your treating physician. The risks described below are no different than those that may occur in a routine, standard of care, ablation procedure.

- Death
- Stroke: may cause an interruption in the blood supply to a part of the brain and cause paralysis or weakness on one side of the body, or interfere with speech.
- Pericarditis: inflammation may occur in the outer lining of the heart, which may cause chest pain or heart failure (<1%, less than 1 in 100 people).
- Fluid build-up around the heart. A hole in your heart wall (perforation) could result in bleeding into the sac (pericardium), which surrounds your heart (cardiac tamponade). This may be treated by insertion of a needle, through your chest wall, into the sac and removal of the blood. This type of hole sometimes requires surgical repair
- Heart valve injury: an injury to a valve structure resulting in a loss and/or worsening of function (heart failure) (<1%).
- Fluid build-up in the lungs (<1%).
- Blockage of a pulmonary artery: a blood clot from a vein may get stuck in the lungs. This is usually treated with blood-thinning drugs (<1%).
- An obstruction or perforation or damage to the blood vessel system (2%).
- Clot formation in the artery or vein, which may cause impaired blood flow to the part of the body where that artery or vein is located (1.5%).
- An abnormal passageway (such as a hole, fistula) between an artery and a vein: this may allow blood to go between the arteries and veins and not through the entire body. This may cause some part of the body to not receive the usual amount of blood. This may heal on its own, but may require surgical repair (1.5%).
- Bleeding or bruising from the site of catheter placement: This may go away without treatment, but may require manual compression or surgical repair. If excessive bleeding at the site of the catheter placement continues, this could result in anemia requiring medical intervention (2%).
- Reduced oxygen supply to tissue (<1%).
- Localized or systemic (throughout body) infection: an infection may occur anywhere an incision or cut is made during the procedure (<1%).
- Blood clots in the groin vein where the catheter is inserted (<1%).
- Damage to the nerve that controls the diaphragm and may affect your breathing. Symptoms may be temporary but in some cases can be permanent (respiratory arrest) and lead to death or the need to be on a ventilator permanently (<1%).
- Pneumonia: infection of lungs by bacteria or viruses (<1%).
- Development of a false pouch in a blood vessel wall. This can be caused by movement of catheters in the blood vessels. This may heal on its own, but sometimes need surgical repair (<1%).
- Radiation injury resulting in dermatitis (skin burns): (<1%).
- Respiratory failure: damage to breathing that can be permanent (respiratory arrest) and lead to death or the need to be on a ventilator permanently (<1%).
- Radiation exposure to the body during the fluoroscopic imaging of the catheters during ablation (see radiation risks below) (<1%).
- Excessive fluid built up could result in lung edema: congestive heart failure may occur or may be worsened due to delivery of sterile salt water (saline) during the procedure (these risks are specific to open irrigated ablation catheters) (1.5%).

Unknown Risks
In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems or possible side effects throughout the duration of the study to the research staff.

Radiation Exposure
Radiation exposure will be consistent with that of other approved catheter ablation procedures.

The more radiation you receive during your life, the greater the risk of causing changes to the cells in your body or of having cancerous tumors. The changes to your body's cells possibly could cause abnormalities or diseases in your future children. Exposure to radiation can slightly increase the risk of a fatal tumor occurring (1 in 1000) or of your unborn child developing a genetic (hereditary) defect (1 in 2 million). The radiation from this study is not expected to greatly increase these risks, but the exact increase in such risks is not known. The dose of radiation will be monitored during the operation. Women who are pregnant should not receive unnecessary radiation and cannot participate in this study.

NEW INFORMATION
Any new information that develops during this study, which might affect your decision to participate, will be given to you promptly.

COSTS AND/OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION
All components of this study, except the mFAM mapping, are consistent with that of a standard atrial fibrillation ablation procedure. Therefore, you and/or your insurance company will be responsible for medical costs of participating in this study. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Your insurance company may not pay for the costs resulting from your participation in this study.

There will be no charge to either you or your insurance to have the mFAM software used during the ablation procedure.

REIMBURSEMENT FOR PARTICIPATION
You will not be paid for taking part in this study. You will not receive reimbursement for out of pocket study visit expenses such as travel, parking, and meals.

POSSIBLE BENEFITS
There is no medical benefit to you from your participation in this research. However, the information that is learned from this study may help physicians understand more about AF ablation and may benefit other people in the future with the same condition.

ALTERNATIVES TO STUDY PARTICIPATION
You do not have to be in this study to be treated for your condition. If you decide not to participate in this study, other care is available to you. The other treatment choices available for atrial fibrillation include the following:

- Manage your condition with medications
- Make changes in your life (for example, more exercise, lose weight and watch what kinds of food you eat)
- See if any other conditions are causing your AF and treat those conditions
- Treat your AF with a different type of arrhythmia surgery

You may choose no treatment at all. Your study doctor will discuss the risks, side effects and benefits of study alternatives with your to determine the best option for you.

IN CASE OF INJURY DURING THIS STUDY

If you believe that you have suffered an injury or made sick related to this research as a subject in this study, medical care will be provided. Generally, this medical care will be billed to you and/or your health care insurance. In some cases, the costs of this care may be paid by someone else. If you believe that you have suffered an injury related to this research as a subject in this study, you should contact Dr. Subbarao Choudry at 212-241-7114. No compensation will be offered by Biosense Webster or Mount Sinai Health System or Biomedical Research Alliance of New York.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

ENDING PARTICIPATION IN THE STUDY

Participation in this research study is voluntary. You may choose not to participate or, once started, you may stop participating at any time without any penalty. This will not affect your ability to receive medical care at your study institution or to receive any benefits to which you are otherwise entitled. You should tell the study doctor if you want to stop being in the study. You may be asked to return for a final safety visit.

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the study doctor. Even if you withdraw your permission, the study doctor may still use the information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event from participating in the study.

The study doctor, the institution, the sponsor, the FDA or other regulatory authorities may stop your involvement in this research study at any time without your consent and for any reason. This may happen because the research study is being stopped, you did not follow the instructions of the study team, it is not in your best interest, or for any other reason. If specimens or information have been stored as part of the research study, they too can be destroyed without your consent.

CONTACTS - QUESTIONS, CONCERNS

If you have any questions or requests for information, at any time, about this research study or your participation in it, or if you want to voice a complaint or concern about this research, or want to discuss any possible study-related injuries, please contact Dr. Subbarao Choudry at 212-241-7114. If you experience an emergency during your participation in this research, contact the Emergency Department or call 911.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

CONFIDENTIALITY – HIPAA AUTHORIZATION

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA, the Institutional Review Board, and other regulatory agencies, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/or publications.

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.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration

- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

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 at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the

research by the research staff and the study sponsor, but will not be shared with others without your authorization unless permitted to do so under federal or state law. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights or New York City Commission on Human Rights, the agencies responsible for protecting your rights.

CONSENT TO PARTICIPATE IN THE RESEARCH - SIGNATURES

I have read this entire consent for research. I have had the opportunity to ask questions and all of the questions I asked were answered to my satisfaction. If I do not choose to participate in this research, or if I choose to withdraw from this research at any time, this will not affect my ability to receive medical care outside of this research study. I agree to be a subject in this research.

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Subject: Name (Print) Signature Date

I have fully explained all parts of the study to the potential subject, including any alternatives and risks. I believe that the potential volunteer understands the nature, purposes, benefits, and risks of participation in this research. I will give a copy of the signed consent to the subject. I have also offered to answer any questions and have fully and completely answered all such questions.

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Person who obtained consent: Name (print) Signature Date