Cleveland Clinic Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: WATCHMAN for patients with atrial fibrillation undergoing transcatheter aortic valve replacement (TAVR)

Principal Investigator: (insert site PI)

Sponsor: Cleveland Clinic

Funding Source: Boston Scientific

You are being invited to participate in a research study. Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate**.**

Please note:

- **You are being asked to participate in a research study.**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits and alternatives of the research.**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can withdraw from the study at any time.**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

Why are you being asked to take part in this research?

You are being asked to participate in this research study because you were diagnosed as having atrial fibrillation (AF or AFib) and aortic stenosis (AS) requiring a Transcatheter Aortic Valve Replacement (TAVR). Atrial fibrillation is an irregular heartbeat (arrhythmia) that is found on an electrocardiogram (ECG) or heart rhythm monitor. Atrial fibrillation can affect the heart's pumping capacity, lead to blood clots and place a patient at a higher risk for

experiencing a stroke. During an AFib episode, blood can collect inside the pouch-like structure called the left atrial appendage (LAA), which is part of the upper chamber of the heart.

If a blood clot forms in the LAA and then escapes from the LAA, it can travel to the brain and cause a stroke. Blood thinners, also called anticoagulants can be used to lower risk for blood clots and stroke. Another alternative for prevention of blood clots from traveling outside of the LAA is implanting a permanent left atrial appendage closure device called a WATCHMAN device.

Both the TAVR and WATCHMAN device are FDA approved procedures and all testing and procedures done will be standard of care for each device.

The TAVR procedure, which stands for transcatheter aortic valve replacement, is for individuals who have been diagnosed with a blocked aortic valve and require a non-surgical aortic valve replacement.

Many older patients with heavy calcium deposits on their heart's aortic valve (a condition called aortic stenosis, or AS) are considered too high risk for valve replacement surgery but have an option to undergo transcatheter aortic valve replacement (TAVR).

TAVR is a method of inserting a new aortic valve within a damaged valve through a catheter in a special procedure lab.

The WATCHMAN device acts as a barrier to prevent blood clots from entering the bloodstream from the left atrial appendage, and is inserted through a catheter in a special procedure lab.

Why is this study being done?

The purpose of this study is to look at the safety and effectiveness of the WATCHMAN device procedure when it is done in combination (at the same time) with the TAVR procedure. This combined approach will be compared to the TAVR procedure along with medical treatment only for an extended period of time.

How many people will take part in this study?

The WATCH-TAVR study will be done in approximately 33 hospitals in the United States with approximately 350 patients taking part in the study.

What will happen if I take part in this study?

If you qualify and decide to participate in this research study, you will be asked to sign this consent form. This should be signed only after you thoroughly read this consent form and all your questions are answered to your satisfaction. You may be asked to sign a separate procedural and treatment consent at your physician office visit prior to the procedures being done.

Baseline and Follow-Up Visits

During the initial evaluations with your doctor, you may undergo evaluations that are necessary and part of what is normally done as baseline information prior to either of these procedures being done.

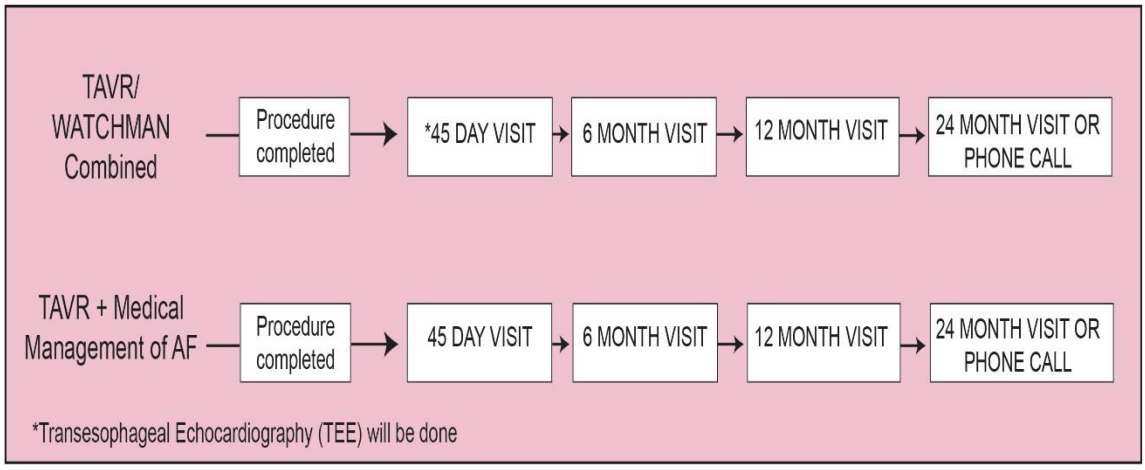
These would include having your vital signs (heart rate and blood pressure) recorded, blood work, and an echocardiogram. A physical exam will be done to assess for any physical impairment caused by a stroke.

A questionnaire (KCCQ-12) that is part of the research study will be completed to determine baseline information on your activity level over the past 2 weeks.

Once you have completed all baseline procedures and it is determined that you meet the eligibility criteria, you will be randomized (e.g. randomly selected as if you tossed a coin) to either having:

- The TAVR procedure alone with medical management of your AFib
  or
- Having the TAVR procedure and the WATCHMAN procedure at the same time.

Follow-up visits will be at scheduled as illustrated below in the diagram once your procedure is completed.



During these follow up visits, standard of care procedures will be done including recording your vital signs (heart rate and blood pressure), blood work, a physical assessment to evaluate for any impairment caused by a stroke, and the research questionnaire KCCQ-12 will be done to evaluate your level of activity during these intervals**.**

If you have the TAVR along with the WATCHMAN device, a thin layer of tissue will grow over the surface of the WATCHMAN Implant within about 45 days to close the LAA.

If the TEE that is performed at approximately 45 days shows that the opening of the left atrial appendage is *not* adequately closed, another TEE may be scheduled at approximately 6 months to re-evaluate whether adequate closure of the left atrial appendage has occurred.

It is extremely important for you to take the recommended medications (warfarin, clopidogrel, and aspirin) at the recommended time. If you stop taking these medications or change their dosage before being instructed to do so by your doctor, the chances of blood clot formation, subsequent stroke, or even death are increased. Talk to your doctor before stopping your medications or changing the dosage.

If you do require premature discontinuation of these medications because of significant bleeding, your doctor will carefully monitor you for possible complications. Once your condition has stabilized, your doctor may restart these medications. Talk to your doctor before restarting medications or changing their doses.

How long will I be in the study?

Your participation in the study will last 2 years after you have completed your procedure follow up care.

Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

Maintaining Contact with the Study Team

If you are not able to attend a planned study visit or maintain telephone contact, the study doctor or his/her representative may use other ways of trying to contact you to determine whether or not you have experienced a serious health event. The study doctor or one of the staff members would like to keep in contact with you regularly for as long as you permit. If you have moved or otherwise lost contact with the study doctor and study staff they may try to locate you by searching for your details in the public domain, for example social media to learn if your contact information has changed. This could involve making contact with your next of kin, your family doctor, hospitals/clinics that treat you, or attempts to determine your health status via other

means (if approved by local laws) such as national registries/databases, hospital or pharmacy records, and voter records.

What risks, side effects or discomforts can I expect from being in the study?

There are no experimental medications or devices used in this research study. Both the TAVR valve and the WATCHMAN device are FDA approved and already used widely around the country.

Your physician will further explain the TAVR and WATCHMAN procedures and review the risks, benefits and alternatives, as well as answer any questions concerning the procedure.

Although you may take an anticoagulant (blood thinning medication) called warfarin to reduce the risk of stroke for approximately 45 days to 6 months following the WATCHMAN implant, it is an alternative to long-term use of this drug. The benefits and risks of warfarin and/or the benefits and risks of other approved anticoagulant medication that are used to reduce the risk of stroke in atrial fibrillation should be considered.

If you are randomized to TAVR along with medical therapy, your doctor will prescribe medical treatment for your AFib; this will continue following your TAVR procedure and is considered standard of care. Patients who receive the TAVR procedure without the WATCHMAN device may need to take blood thinning medications which could include warfarin or other types of medications to reduce the risk of stroke at the discretion of your treating physician.

All medications prescribed by your doctor will have a drug package insert that will describe all side effects. As with any treatment, side effects (unwanted experiences) cannot be totally predicted and unexpected complications may occur. Your doctor will be able to tell you the specific side effects for the medication prescribed to treat your AFib and answer your questions concerning the medication.

The potential risks associated with both the TAVR and WATCHMAN do not change as a result of your participation in this study, and may include:

TAVR: Bleeding and vascular access complications, aortic dissection, valvular complications, stroke, myocardial ischemia/injury (heart damage), acute kidney injury, heart rhythm problems, valve thrombosis, embolization, infection, regurgitation, late bleeding.

WATCHMAN: With all medical procedures there are risks associated with the implant procedure and the use of the device. The risks include but are not limited to accidental heart puncture, air embolism, allergic reaction, anemia, anesthesia risks, arrhythmias, AV (Arterio-venous) fistula, bleeding or throat pain from the TEE (Trans Esophageal Echo) probe, blood clot or air bubbles in the lungs or other organs, bruising at the catheter insertion site, clot formation on the WATCHMAN™ Closure Device, cranial bleed, excessive bleeding, gastrointestinal bleeding, groin puncture bleed, hypotension, infection/pneumonia, pneumothorax, pulmonary edema, pulmonary vein obstruction, renal failure, stroke, thrombosis and transient ischemic attack. In rare cases death can occur.

Other risks
The KCCQ-12 questionnaire may involve risk of loss of confidentiality, psychological stress and inconvenience. Every effort will be made to keep your information confidential, however this cannot be guaranteed.

Women of Childbearing Potential
If you are a woman of child-bearing age, you cannot be pregnant or plan to become pregnant while you are in the study. You will need to use an effective method of birth control while you are in the study, unless you are post-menopausal or surgically sterile.

What benefits can I expect from being in the study?

Participating in this study may help to improve your condition, it may stay the same or it is also possible that your condition may worsen. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide additional information that may be beneficial for other patients, society or science in the future.

If you are randomized to the TAVR +WATCHMAN combined procedure, you will have only one catheter inserted in your groin blood vessel for both devices. If you were to receive the TAVR at one time and the WATCHMAN at another point in time as part of your routine care, then you would have two separate catheters inserted, one for each procedure.

What other choices do I have if I do not take part in the study?

Whether or not you decide to join this research study you will continue to receive the same standard treatments for your condition that your doctor thinks are necessary. Which would also include both the TAVR and the WATCHMAN procedures. You can choose not to participate in this study. If you do not participate, the study doctor can discuss other treatment options with you.

What are the costs of taking part in this study?

There are no additional costs to you for participation in this research study. All of the tests and procedures in this study are routinely done for patients undergoing either the TAVR and/or WATCHMAN procedure and would be done even if you were not participating in this study. The WATCHMAN device will be provided to you at no cost to you or your insurance. The costs for these routine tests and procedures will be billed to you or your insurance provider.

What happens if I am injured because I took part in this study?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at (Institution's IRB number).

What are my rights if I take part in this study?

Taking part in this study is voluntary. If you do not want to participate, your regular medical care and legal rights will not be affected. **Even if you join the study, you may stop at any time. You will be told of any new relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.**

Your participation in this study may be discontinued without your consent by the study doctor, the IRB, or the Sponsor at any time if:

- You fail to follow the instructions of the study doctor or study staff
- The study doctor decides that continued participation could be harmful to you
- The study is cancelled
- Other reasons

Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

In addition, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state agencies.
- U.S. Food and Drug Administration.
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical study will be available on *http://www.ClinicalTrials.gov*, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research;
- Records about the study device;
- Hospital and physician billing records to compare the costs of both procedures

II. Who may use and give out information about you?

Researchers and study staff.

III. 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.

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

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;

V. 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 correctly.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. 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 researchers. 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.

VIII. 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. However, if you are being treated as a patient here, you will still be able to receive care.

IX. 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. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact _____.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact _____ *[Insert name and contact information for the appropriate HIPAA Privacy contact]*.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact *(Insert Contact)*

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact _____.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject** **AM/PM** **Date and time**
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)** **AM/PM**
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent** **AM/PM** **Date and time**