INFORMED CONSENT AND HIPAA AUTHORIZATION
VALVE SCREENING

RESEARCH PURPOSE/PROCEDURES

As your physician explained during your consultation, one of your treatment options is participating in a research study that we are conducting with our industry sponsors. Because each research device is unique and your physical anatomy is an important part of making the determination as to what study you might be eligible for, we are asking you to agree to allow the study team to send information collected as part of your routine care to study sponsors in order for them to review and in collaboration with your physician determine whether or not you are eligible for the research. If it is determined that you are eligible for participation in any of our research studies, our research team will conduct a full and thorough consent process so that you can decide in concert with your family and physicians whether or not you want to participate.

RISKS/BENEFITS

The risk of participation is loss of confidentiality. Although we will take every step to protect your data, complete confidentiality cannot be promised. Please see the confidentiality and authorization sections below for more information about how your data is used and or stored. There are no health benefits to you for signing this screening consent but doing so may expedite the screening process and be more convenient for you in that you will not have to take another trip to the medical center to sign consent to have your data reviewed for eligibility.

ALTERNATIVES

You do not have to sign this screening consent to participate in a research study but you will need to sign in order to allow us to send your data to our collaborating sponsor(s).

CONFIDENTIALITY

The information sent, including echocardiogram, CT scan and/or MRI images along with your medical history, will be sent in a coded manner. Coded means that the information will not include any direct identifiers such as your name but instead will be labeled with a code. The study team will be able to associate the code to your personal information. Being in this study is voluntary. Before you decide if you would like to be in the study, it is important you understand why the study is being done and what it will involve. Please read this form carefully and ask your doctor any questions you may have. After reading this form and asking any questions you have, if you decide to be in this study you will sign and date the last page of this form.

COSTS/COMPENSATION

There will be no cost to you nor compensation involved if you agree to being screened for a valve study.

VOLUNTARY PARTICIPATION

Agreeing to sign this screening consent is voluntary. You do not have to sign a screening consent but if you do not and you want to determine whether you are eligible for a study, you will need to sign a full consent document in order to allow us to send your information to the sponsor.

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

If you agree to sign this screening consent, our sponsors and their agents/contractors and others who work with the study will see coded health information about you.

The Authorization to Use and Disclose Health Information describes how your health information may be used and/or disclosed by your doctor (the study investigator), the hospital or clinic, and their respective staffs. You agree to allow access to and use of your health information in accordance with the Authorization, as well as disclosure to our study sponsors.

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This consent form describes the study, and what the sponsor will do with the study data, including your health information received during the study. The sponsor will keep your health information confidential in accordance with all applicable laws and regulations. The sponsor may use your health information to determine study eligibility.

I agree to permit Columbia University Medical Center, New York Presbyterian Hospital and their staff[s], my doctors, and my other health care providers (together "Providers"), and Dr. _____ and his staff (together "Researchers"), to use and disclose health information about me, including health information in my medical records, as described below.

1. **The health information that may be used and disclosed includes:**
   - Information collected as part of standard of care such as demographic information and imaging in order to determine your eligibility for various research studies.
   - Health information in your medical records that is relevant to screening for eligibility.

2. **The Providers may disclose health information in my medical records:**
   - to the Researchers and to the sponsor of the Research and its agents and
   - as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.
   - The investigator, study staff, Columbia University Staff, New York Presbyterian Hospital Staff and other medical professionals who may be evaluating the study
   - The Office of Human Research Protections ('OHRP')
   - The FDA, Medicare, Medicaid, Notified Bodies, Competent Authorities and other regulatory agencies Authorities from Columbia University and New York Presbyterian Hospital, including the Columbia University Institutional Review Board ('IRB')

3. **The Researchers may:**
   - use and share your limited health information among themselves and with other participating researchers to conduct the screening activities;
   - disclose your health information to sponsors; and
   - disclose your health information as required by law and to representatives of government organizations, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research.

4. **Once my health information has been disclosed to a third party:**
   - it may be subject to further disclosure by recipients, and federal privacy laws may no longer protect it from further disclosure.

5. **Please note that:**
   - You do not have to sign this Authorization, but if you do not, we cannot send your screening information to the study sponsor.
   - You may change your mind and revoke this authorization at any time. To revoke this Authorization, you must write to Dr. Tamim Nazif at 171 Fort Washington Avenue, New York, NY, 10032. However, if you revoke this Authorization, you will no longer be allowed to participate in the Research. Also, even if you revoke this Authorization, the information already obtained

by the Researchers and the sponsor may be used and disclosed as permitted by this Authorization and the Informed Consent.

6. **This Authorization does not have an expiration (ending) date.**

7. **You will be given a copy of this Authorization after you have signed it.**

Who can I call with questions, complaints or if I'm concerned about my rights as a participant?

You are encouraged and have the right to ask questions at any time concerning potential and/or known risks of this study. The study doctor will inform you of any new significant information, when it becomes available, which may affect your willingness to continue to participate in this study. If you have any questions about this study or if you experience any health problems or believe you have a research related injury, you should contact Dr. _____.

If you have questions regarding your rights as a Study subject, contact:

Statement of Consent:

I have read this Informed Consent/HIPAA Authorization Form and the research study has been explained to me. My questions have been answered to my satisfaction. I understand that by signing this form, I have not waived my legal rights nor released anyone from negligence. I choose to volunteer for the study. I have been given a copy of this form.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date