Title of Research Study: ***HeartShare Deep Phenotyping Study - Fat Tissue Biopsy***

Site Principal Investigator: Dalane W. Kitzman, MD and Nicole Cyrille-Superville, MD
Co-Investigator: ***Sanjiv Shah, MD (Northwestern University)***

You are invited to participate in this optional testing because you have agreed to take part in the HeartShare Deep Phenotyping Study. The information in this consent form is provided to help you make an informed decision about whether to participate or not. If you have any questions, please do not hesitate to ask.

What happens if I say "Yes, I want to participate in this optional component"?
In the main study consent, the procedures, and risks of two biopsies were discussed. This information is repeated here for your review before deciding whether to participate.

Fat tissue biopsy: We may also obtain a small amount of fat. This procedure is used to sample fat cells from the abdomen (belly). After cleaning the skin on the front of your abdomen with iodine, a local anesthetic will be injected under the skin. The doctor or a trained/certified designee will make a small incision in the skin of your abdomen and inject additional lidocaine and some saline (salt water solution) that allows for easier removal of the fat cells using a needle with a suction device. The needle may be inserted through the incision up to 3 times to obtain adequate/enough fat. Suction will continue for several minutes if necessary. About 3 grams (approximately 1 teaspoon size) of fat will be removed. After the fat sample is completed, the skin will be held closed with sterile adhesive strips and a bandage. Of note, you will not be allowed to swim or soak in a bathtub/whirlpool/hot tub for 72 hours after this procedure.

Risks
Fat tissue biopsy: The biopsy will cause some transient mild pain and discomfort from the local anesthesia (numbing medicine). Bruising is very likely from the biopsy and bleeding is possible. It is possible, but not likely that you could get an infection or skin numbness from damaging a skin nerve (<1%), the latter is almost always temporary.. There will likely be a small scar from the biopsy. You may be asked to stop or reduce your blood thinner(s) if you take them (for example, anti-platelet therapy or anti-coagulation therapy) during the week leading up to a study muscle biopsy procedure. Stopping or reducing your anti-platelet therapy or anti-coagulation therapy during this week may increase your risk of a heart attack or stroke.

Choosing not to be in this optional testing will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to participate in this optional testing will not negatively affect your right to any present or future medical treatment or affect your ability to participate in the main HeartShare Deep Phenotyping Study.

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 336-716-3274 or 704-355-4794.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (336) 716-4542 if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

You may also contact the Northwestern University (the research study's Main/Central IRB) at (312) 503-9338 or irbcompliance@northwestern.edu.

Your signature documents your permission to take part in this optional research biopsy. You will be provided a copy of this signed document.

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Signature of Participant Date

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Printed Name of Participant

I decline to participate in the optional research biopsy