



MFADD-HF



Metabolic Pathways to Fatigue
Anxiety, Depression, &
Dyspnea in Persons with Heart
Failure

Participant Instruction Booklet

Principle Investigator:



Clinical Research Coordinator:



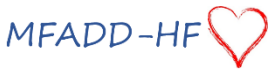
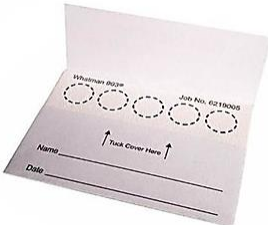







Dear Participant,

Thank you for your interest in participating in our MFADD-HF study to understand that biological pathways that contribute to symptoms of Heart Failure (HF). On the next several pages, you will find instructions on how to use the study kit and materials that have been mailed to you. Please review these materials, but DO NOT proceed with sample collection. **All samples will be collected during your scheduled Collection Appointment.**

BEFORE WE BEGIN CHECKLIST:

- Please call [redacted] during business hours (M-F, 9 am – 5 pm) to confirm that you have received the package and **set up a Collection Appointment.**
- Please complete the **informed consent** form online.
- Please provide time to complete the **surveys** online immediately **AFTER** your collection appointment. It will take about 90 minutes to complete all of the surveys. If you have any questions about the forms before or during completion, please call us at [redacted].
- Please watch the short videos demonstrating stool and blood collection:
 - Stool Collection Instructional Video: <https://www.youtube.com/watch?v=NYI-SCUCdrc>
 - Dry Blood Spot Card Collection <https://www.youtube.com/watch?v=vhVUWoe4-B8>
 - Blood Collection Instructional Video: <https://www.youtube.com/watch?v=8KkaS-8LSBs>
- Please check the package you received. The envelope should contain all of the following items. If anything is missing or broken, please call us at [redacted]

<p>This Instruction Packet</p> 	<p>Dried Blood Spot Card</p> 	<p>Blood Collection Kit</p> 	<p>Stool Collection Kit</p> 
<p>Biohazard Bags</p> 	<p>Return Shipping Materials</p> 	<p>Hand Sanitizer</p> 	<p>Questionnaires</p> <p>Will arrive via email separately</p>



This page presents a summary of the steps required to complete the study.

Note: *It is VERY IMPORTANT that you follow the steps of the study in the order in which they have been presented.*

Table of Contents

Step 1: Join your scheduled collection appointment..... Page 3

Step 2: Blood Collection Page 5

Step 3: Stool Collection Page 7

Step 4: Weight and blood pressure measurement..... Page 8

Step 5: Questionnaires Page 9

Step 6: Study Evaluation Survey Page 10



Collection Appointment

If you have not already done so, please call [REDACTED] during business hours (M-F, 9 am – 5 pm) to **schedule your Collection Appointment**. A confirmation email and/or telephone call will confirm the date and time and will also provide the Zoom link or telephone number for your Collection Appointment.

On the day and time of your Collection Appointment, join your appointment via Zoom or phone to begin the collection procedures.

Appointment Date: _____

Appointment Time: _____

Appointment Link/Number: _____



Please do not continue until your Collection Appointment begins.



BLOOD COLLECTION - COLLECTION ONE

Note: These instructions are accompanied by a video link sent with your visit instructions. Please follow the instructions written here, as some information will differ slightly from the instructions contained in the video. **You should read through each step within this document before you begin.**

A Dried Blood Spot (DBS) is a blood sample collected onto a special absorbent filter paper. The blood is collected from a finger prick and allowed to dry for **4 hours**.

Blood sample collection set up:

- 1) Wash your hands with warm soapy water.
 - a. This will increase blood flow to the fingertips making the sample easier to collect.
- 2) Dry your hands thoroughly with a clean cloth.
- 3) Place the blood spot card within reach, flat down on a table and open.
 - a. Do not touch the circles on the card.
 - b. At this time, you will also place the Mitra Blood Collection Device and instructions within reach.
 - c. Be prepared to utilize the Mitra Device immediately following DBS blood collection. (Step 19 Below.)

Preparing to take your sample:

- 4) Choose a finger from your non-dominant hand to collect the blood sample.
 - a. It is easier to collect from the middle and ring fingers.
- 5) Remove any rings on the finger you plan to use to avoid restricting blood flow.
- 6) Use the alcohol wipe (or sanitizer) provided to clean the selected finger.
 - a. Allow the alcohol (or sanitizer) to dry completely.

Taking your sample:

- 7) Seat yourself in a chair.
- 8) Open the package containing the lancets.
 - a. Remove all lancets, placing them in front of you.
- 9) Make sure the cap is on the lancet.
 - a. This ensures the lancet is sterile and suitable for use.
 - b. Do not use the lancet if the sterile cap has come off.
- 10) Twist and remove the cap to break the seal.
 - a. The lancet is now ready to use.
- 11) To collect the blood sample, place the lancet against your finger.
 - a. You should place the lancet on the top-side of your finger, not in the middle of the finger pad.
- 12) Press the lancet firmly against your finger until you hear a click.
 - a. If you need another attempt, repeat this step with a new lancet.
- 13) Remove the lancet from your finger.



- a. A small drop of blood will form at the puncture site.
- 14) Using gauze (or clean tissue) wipe away the first drop of blood.
- 15) Point your hand down and massage the finger from the base of the finger.
 - a. A new drop of blood will form.
 - b. Do not squeeze the end of your finger.
- 16) Allow blood drop to drop onto the first circle on the blood card.
 - a. The blood spot should fill the circle.
- 17) Once the circle is full, move to the next circle with the next drop of blood.
 - a. Do this until each circle is filled.
 - b. Do not touch your finger to the card or rub the blood onto the paper.
- 18) Do not top off a circle with more blood if the first drop does not fill it.
 - a. Don't worry if you miss the circle and blood falls outside the dotted circle.
 - b. Just be sure the blood spots don't overlap.
- 19) Fill each circle on the blood spot card.
 - a. **Once each circle contains blood, move on to the Mitra Device for collection two while the DBS card is allowed to dry.**
 - b. **Do Not close the card.**
 - c. Complete steps 21-27 for proper drying and storage of the DBS card.

COLLECTION TWO

- 20) Begin using the Mitra Device to continue with blood collection.
 - a. Use instructions provided for proper collection.

COLLECTION ONE – DRYING PROCESS

- 21) Leave the blood spot card open to dry by folding the upper flap back to prop up the card. The card needs to dry in the air for at least **4 hours but no more than 24 hours.**
- 22) Do Not place the DBS card near an open window, or anywhere it could be knocked over.
- 23) Do Not expose the direct sunlight or place the card near any heat or air source.
- 24) When the blood spots are dry, they will turn a uniform brown color with no red areas.
- 25) When the blood spot card is completely dry, fold down the cover as shown on the card.
- 26) Place the card inside the plastic biohazard bag (with the orange symbol) along with the desiccant pack provided.
- 27) Make sure the bag is well sealed.

Note: You will return the DBS card along with the other samples collected in the pre-labeled, prepaid FedEx shipping package provided.

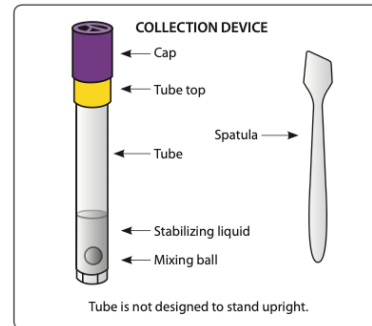


Stool Collection

You will need the stool collection kit and biohazard bag.

Please view the collection instruction video PRIOR to collection:

<https://youtu.be/nxdAc5HJbXQ>



Place capped tube in biohazard bag and set aside in a safe place at room temperature until shipping.

Note: These instructions can also be found in the Stool Collection Kit.

Questionnaires

Please complete the remaining questionnaires using the secure link provided in your email. Please contact us at [REDACTED] would like us to provide you with the link again.

You will receive a separate link via email for the questionnaires:

- Demographics and symptoms questionnaires
- Food and Activity Questionnaire