

RESEARCH INFORMED CONSENT FORM – INTAKE SURVEY

Study Title: Improving Care and the Mental Well-Being of Adults with Heart Failure

Version Date: 29/1/2026

REB # M16-25-028

This survey is being conducted by Dr. Krystal Kehoe MacLeod at the Bruyère Health Research Institute, working under the supervision of Dr. Vivan Welch. The study is funded by the Brain-Heart Interconnectome's Canada First Research Excellence Fund at the University of Ottawa.

Objectives and Summary:

We're testing a new approach called the FRAME intervention. The goal of this work is to improve healthcare settings such as primary care clinics, hospitals, or rehab programs, and support people with heart failure who also experience emotional or mental health challenges like anxiety, depression, or stress. Once you complete this survey, you will receive the FRAME intervention via email in January 2026. FRAME is designed to help people living with heart failure as well as their families and healthcare providers to better recognize, understand, and seek support for mental health concerns such as stress, anxiety, or depression. The tool includes materials such as tips and resources tailored to heart failure and mental health and suggestions for talking to your provider or caregiver about your needs. Since this is a pre-post intervention study, we will be contacting participants who complete this survey in 6-months to complete a follow-up survey and an optional interview to assess changes in experiences, confidence and behaviours of your mental health journey after exposure to the FRAME intervention. We expect that this survey will take about 5-15 minutes to complete. Your participation in this survey is completely voluntary, and you may choose not to take part, or not to answer any of the questions. If you decide to withdraw after you submit the survey, we will remove your responses from survey data if you notify the researcher by email at kmacleod@bruyere.org within two weeks after the submission of your survey.

Risks and Benefits:

You may find some of the questions to be of sensitive nature and may cause emotional or psychological discomfort when reflecting on personal mental health. You may skip any questions of the survey and withdraw from the study at any time without penalty. If you would like to consult mental health resources, you can visit the following resources:

Mental Health Support: Get Help - Canada.ca

Bilingual Health Services - Archipel Ontario Health

Connect to Services - Great River Ontario Health Team

By participating in this survey, you will receive a \$15 gift card delivered through an online platform (GiftBit) that allows them to choose from a variety of stores and venues. Participants will also gain access to the FRAME tool in April 2026 and may have indirect benefits. No guaranteed direct benefit is offered. After exposure to the FRAME tool, you may:

- Gain awareness about the connection between heart health and mental health

- Learn about resources available in the community and have access to guides that will help they self-manage their heart failure and mental well-being.
- Feel empowered to engage in conversations about mental health with their healthcare providers

Confidentiality and Data Storage:

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. However, research records identifying you may be inspected by the Bruyère Health Research Ethics Board for the purpose of auditing the research. The results of this study may be published, but the data will be presented so that it will not be possible to identify you. De-identified data from this study may be shared with other researchers for verification, and to permit them to build upon our findings. All research data will be securely stored, and password protected at the Bruyère Health Research Institute SharePoint page and the RedCAP server (for survey data). Only authorized research personnel will access this data. After the study is completed, your data will be retained for a minimum period of 10 years for future research purposes, or legal orders.

Ethics Review and Contact Information:

This study has been reviewed and approved by the Bruyère Health Research Ethics Board as study # [M16-25-028](#). If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère Health REB: REB@bruyere.org.

Consent:

By clicking “I Agree” you agree to participate in the survey.

Would you like to receive a summary of the results from this study when they are available?

☐ Yes ☐ No

Email: _____