INFORMATION SHEET FOR RESEARCH PARTICIPANTS (ICF)

Certificate of Approval No 1880/GCN-HMUIBR dated 14/04/2025

INFORMATION SHEET FOR RESEARCH PARTICIPANTS (ICF)

I. GENERAL INFORMATION

Study Title: Effectiveness of Cardiac Rehabilitation with Remote Connection Device for Patients After Surgery for Acquired Valvular Heart Disease
Principal Investigator: Trịnh Bảo Trâm
Implementing Institution: Hanoi Medical University
Funding Source: Self-funded
Study Duration: February 2025 to December 2027
Study Sites:

- Cardiovascular Center – Hanoi Medical University Hospital, Ton That Tung Campus
- Cardiology Department – Hanoi Medical University Hospital, Hoang Mai Campus

Participant ID Code:

II. INTRODUCTION

Hello Sir/Madam/Friend, thank you for taking the time for this interview.

My name is **TRỊNH BẢO TRÂM**.
I am a researcher working at the **Department of Rehabilitation Medicine – Hanoi Medical University**.

I am conducting a study titled:
" Effectiveness of Cardiac Rehabilitation with Remote Connection Device for Patients After Surgery for Acquired Valvular Heart Disease."

I have been thoroughly trained in the study procedures and ensure compliance with ethical standards in research and good clinical practice.

I am providing you with information about this study in order to invite you or the individual under your guardianship to participate in this research with us.

You are invited to participate in this study because you **or the person under your guardianship** has been indicated for a first-time valve surgery, including aortic valve, mitral valve, tricuspid valve, pulmonary valve, or a combination of these due to acquired valvular heart disease, and you are between **18 and 70 years old**.

Participation in this study is entirely voluntary. You may choose to join or not to join, and you can withdraw from the study at any time you wish. Your decision not to participate or to withdraw will **not** affect your medical care, treatment, or any other benefits you are currently entitled to.

I will provide you with all necessary information about this study. During this process, if you have any questions, feel free to ask so that you can fully understand the study.

III. RESEARCH INFORMATION

1. Why is this study being conducted?

In developed countries, patients who undergo heart valve surgery are typically covered by insurance for cardiac rehabilitation programs that last several weeks after surgery. These programs have shown positive outcomes in terms of physical capacity and quality of life.
In Vietnam, although cardiac rehabilitation (CR) has recently been introduced for post-valve surgery patients, it is typically limited to a short duration (around one week) immediately after surgery during hospitalization.
Currently, there is a lack of domestic research evaluating the long-term effectiveness of CR in these patients, especially after they return home. Therefore, we are conducting this study to assess the effectiveness of CR beginning in the early postoperative phase and continuing for one month after hospital discharge.

2. What will I or the person under my guardianship need to do if I agree to participate?

You will participate in a cardiac rehabilitation program starting in the immediate postoperative period at the hospital, and receive training and monitoring for one month after discharge.

If you agree to participate in this study, we will ask you to do the following:

- Participate in acute-phase CR for about one week after surgery, followed by early-phase CR for approximately another week in the hospital.
- After discharge, you will continue CR at home following the Japanese Circulation Society's 2021 rehabilitation protocol for one month.
- Undergo physical capacity assessments at specific time points: pre-surgery, at the end of the acute-phase CR, at hospital discharge, and one-month post-discharge.

3. How many other people will participate in this study?

More than 44 patients will participate in this study.

Inclusion Criteria:

- Patients undergoing first-time surgery for acquired valvular heart disease (valve replacement or repair), including aortic, mitral, tricuspid, or pulmonary valves, or multiple valves.
- Aged 18 to 70 years.
- Provide consent to participate.

Exclusion Criteria:

- Contraindications to cardiac rehabilitation.
- Patient death after hospital discharge during the study.
- Loss of contact during the study period.

4. What risks or inconveniences might I or the person under my guardianship experience?
Global studies have shown that cardiac rehabilitation is generally safe. However, potential risks during exercise sessions may include fatigue, fluctuations in blood pressure or heart rate, and arrhythmias—though the incidence is very low.

5. What care will I or the person under my guardianship receive in the event of health-related risks or side effects?
Before and after each session, your pulse and blood pressure will be measured using a personal device, and oxygen saturation (SpO2) will be monitored throughout the session. If any abnormalities arise, we will promptly take appropriate actions.

6. What are the potential benefits of participating in this study for me or my family member?

- Receive professional CR consultation and a personalized exercise regimen based on up-to-date international guidelines, with continuous follow-up throughout the study.
- Receive education about heart disease and reminders for cardiology check-ups during the study.
- Receive a **Jumper JPD-500D (LED) pulse oximeter** (for patients doing home monitoring).
- Receive **VND 50,000 per physical capacity assessment**.

7. Will I still receive treatment if I choose not to participate?
Yes. If you do not participate in the study, you will still receive standard treatment, including medication and scheduled cardiology follow-ups.

8. How will my or my dependent's personal information and records be protected?
All personal data and records will be kept confidential and used only for scientific research purposes.

9. Who can I contact if I have more questions about the study?

- **Principal Investigator:** Trịnh Bảo Trâm
  Address: Department of Rehabilitation, Hanoi Medical University Hospital
  Phone: +84 354176044
- **Sponsoring/Implementing Institution:** Hanoi Medical University

- **Institutional Ethics Committee in Biomedical Research, Hanoi Medical University**
  Room 426, Building A1, Hanoi Medical University
  No. 1 Ton That Tung, Dong Da District, Hanoi
  Phone: 024 388 527 622
  Email: irb@hmu.edu.vn

Thank you very much for taking the time to participate in this discussion!

Date: … / … / …	Date: … / … / …
Information Provider	**Participant**
(Sign and print full name)	(Sign and print full name)

VOLUNTARY PARTICIPATION CONSENT FORM

I,
[Name]

Hereby confirm that:

- I have read the information provided for the study titled ***" Effectiveness of Cardiac Rehabilitation with Remote Connection Device for Patients After Surgery for Acquired Valvular Heart Disease"*** conducted at the Cardiovascular Center – Hanoi Medical University Hospital, ICF Version No. ... dated … / … / …, … pages, and I have been given a full explanation of the study and the procedures for voluntary participation by the research staff.
- I have had the opportunity to ask questions regarding this study and am satisfied with the answers and explanations provided.
- I have had sufficient time and opportunity to consider my participation in this study.
- I understand that I have the right to access the data as described in the information sheet by the responsible persons.
- I understand that I have the right to withdraw from the study at any time and for any reason.

I agree that my primary healthcare providers (if any) may be informed of my participation in this study.

☐ I agree ☐ I do not agree
(to participate in this study — your decision will not affect your eligibility to participate)

Full name and signature of the participant
OR **legal guardian** (for studies involving children or elderly persons lacking decision-making capacity)
..... Date: … / … / …

If applicable:
Full name and signature of the witness
..... Date: … / … / …

Full name and signature of the researcher
..... Date: … / … / …