Information notice:

**Heart Valve Society Mitral Tricuspid Valve database**

Dear Madam or Sir,

We kindly ask you to participate in the international Heart Valve Society (HVS) Mitral Tricuspid Valve database. It is established to investigate key epidemiological and therapeutic issues and standardize indications for interventions for mitral and/or tricuspid valve disease.

You decide yourself if you are willing to participate or not. To make that decision, it is important that you know more about the HVS Mitral and Tricuspid Valve database. Please, read this information letter carefully. Discuss it with your family and friends if necessary. Do you have any questions after reading the letter? Feel free to contact \*contact details\*.

**1. What is the purpose of the HVS Mitral and Tricuspid Valve database?**

You have undergone interventions for mitral and/or tricuspid valve disease. It is important to know the natural history and the long-term results of interventions for these diseases. With this information, guidelines can be improved and it will help surgeons and patients choose the best treatment option.

**2. How will the HVS Mitral and Tricuspid Valve database be performed?**

We want to include patients that have undergone an intervention for mitral and/or tricuspid valve disease in the HVS Mitral and Tricuspid Valve database. We will collect data before, during, the first days after the intervention and annually. These are standard data that are necessary to plan and evaluate the operation and will be performed in all patients (also in patients that do not want to participate in the HVS Mitral and Tricuspid Valve database).

**3. What do we ask of you?**

During your initial stay in the hospital at the time of surgery, no additional examinations are necessary. Only data will be collected during your stay. You do not have to do anything for that.

(Optional: paragraph on Patient Reported Outcome questionnaires).

*Ex. For this study, we would like to ask you to complete two short questionnaires. The first questionnaire is the EQ-5D-3L questionnaire, measuring the impact of daily life. The second questionnaire is about the impact of the study on your mental health and daily activities. If you decide to participate in this study, we will send you these questionnaires by email. You can complete them at your convenience and return them to us.*

**4. What are the possible advantages and disadvantages of participating in the HVS Mitral and Tricuspid Valve database?**

The advantage in participating in the HVS Mitral and Tricuspid Valve database is to benefit future patients of the most updated medical follow up according to scientific knowledge. Your commitment to the HVS Mitral and Tricuspid Valve database will be beneficial for future generations of patients to define the best surgical treatment for your heart disease.

**5. What happens if you do not want to participate in the HVS Mitral and Tricuspid Valve database?**

You decide yourself if you want to participate in the HVS Mitral and Tricuspid Valve database. Participation is entirely voluntarily. If you decide not to participate you do not have to do anything. You do not have to tell why you will not participate. You get the same treatment as you would have had if you participated. If you are willing to participate you can always at any time change your mind and stop.

**6. What is happening with the data?**

The data will be registered by the cardiac surgeons that are members of the HVS and transferred to the mitral and tricuspid valve research network. The international HVS Mitral and Tricuspid Valve database itself will be managed in the Erasmus Medical Centre in Rotterdam, the Netherlands. Inspection of the data will be restricted to the members of the HVS mitral and tricuspid data management team.

**7. Are there extra costs/ is there a fee for participation?**

There is no fee and no extra cost for participation.

**8. Which Medical Ethical Committee has approved the HVS Mitral and Tricuspid Valve database?**

The Medical Ethical Committee of the \*name of the hospital\* has registered the HVS Mitral and Tricuspid Valve database and decided that the HVS Mitral and Tricuspid Valve database does not fall within the scope of medical research with people.

**9. Do you have any other questions?**

If you have any other question, please feel free to contact the researcher:

\*Name researcher\*

If you decide to participate in the HVS Mitral and Tricuspid Valve database, please fill in the form attached, together with the researcher.

Thank you very much and kind regards,

The HVS Mitral and Tricuspid Valve database team

**Permission form for participation in the HVS Mitral and Tricuspid Valve database**

* I have read the information letter about participation in the HVS Mitral and Tricuspid Valve database. It was possible to ask additional questions. My questions have been answered satisfactorily.
* I had enough time to decide to participate.
* I know that participation is entirely voluntary.
* I know that I can decide to stop participation at any time during the study. I do not have to give a reason.
* I know that some people have access to my data. Those people are listed in the information letter.

I give/do give not\* permission to register my data on behalf of the HVS Mitral and Tricuspid Valve database.

Name:

Signature: Date: \_\_ / \_\_ / \_\_

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I declare that I have informed the subject on the HVS Mitral and Tricuspid Valve database.

Name researcher (or his/her representative):

Signature: Date: \_\_ / \_\_ / \_\_

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\* Delete, as necessary.