Background information Joint Data Registry Agreement (JDRA)

This document governs:
The legal and organizational aspects of a collectively managed data collection (hereinafter "Data Registry") with a centralised infrastructure

- in which health data of a given patient group are collected (entered by the participating centers: (hereinafter "Partners") and
- in which these data are also issued again (to the Partners) for the purpose of scientific research.

Described is:

- What the data collection consists of
- The role the parties have in this collaboration
- The structure of the organization
- The way in which privacy is safeguarded.
- Under what conditions the data will be provided

Further explanation of some Appendices:

- The Partners are joint controllers with respect to the Data Registry. This is legally regulated in Annex C (joint controller terms and conditions).
- One of the Partners (hereinafter the "Coordinator") manages the Data Registry. In this role, this Partner is a data Processor. To regulate this legally, Appendix B has been added (Processor terms and conditions). The Processor enters into subprocessor agreements with hired subprocessors.
  The Coordinator/Data Registry administrator has 2 roles:
  - the role of Processor in which he is instructed by the controllers to manage the Data Registry, and
  - the role of Partner (entering data into the Data Registry and requesting them for scientific research).
- Accession to the Data Registry is done by signing Appendix E (by the authorized signatory of the Partner). The legal department of the Partner should review the document and determine whether accession to the registry is in accordance with the internal policy/rules of the Partner. After the JDRA is made final, new Partners can only join by accepting the unamended JDRA. Modification of the JDRA is possible only upon revision of the document by the Core Leaders (see revision date), after which the modified version is submitted to the Partners' legal departments for agreement.
- The Coordinator will join the Registry by signing Appendix H.

Advantage:
This document avoids the need for contracts at each data entry and data release.
Note: Data transfer to external parties (those parties that have not signed an accession form) still requires a Data Transfer Agreement (by the Coordinator on behalf of the Partners who are represented by the Core Leaders).

HVS Mitral and Tricuspid Valve Registry

Joint Data Registry Agreement

Version	1.0
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Contents

1. Definitions

1) In this Joint Data Registry Agreement the following terms have the meanings ascribed to them below:

a) **Adequacy Decision**: is considered as providing an adequate level of protection for personal data transferred from the European Union in relation to automated international transfers of personal data from the European Union or, where they are not automated, they are subject to further automated processing in (inter alia) the State of [NAME].

b) **Aggregated data**: refers to raw data collected and expressed in a summary form that is not directly or indirectly identifiable.

c) **Confidential Information:** means any information, in tangible or non-tangible form, and/or physical items or materials, that is marked as confidential by the disclosing Party or that is clearly recognizable as confidential to a reasonable person with no special knowledge of the disclosing Party's activities. If Confidential Information is disclosed orally, the Confidential Information will be identified as confidential at the time of disclosure.

d) **Coordinator**: means the Partner of the Registry who has been assigned this role. In this Registry, Erasmus MC is the Coordinator.

e) **Controller:** means the natural or legal entity, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of Personal Data.

f) **Data:** means the (raw) data collected from Subjects stored in the HVS Mitral and Tricuspid Valve Registry in Pseudonymised (de-identified) form. For the purpose of this Joint Data Registry Agreement, Data are considered Personal Data.

g) **Database:** means the HVS Mitral and Tricuspid Valve Registry containing the Data.

h) **Dataset:** means the Data from the HVS Mitral and Tricuspid Valve Registry made available for the purpose of a Study.

i) **GDPR**: means the General Data Protection Regulation (EU) 2016/679.

j) **Host**: means the party hosting the Data Registry (Castor EDC).

k) **Joint Data Registry Agreement**: means this Agreement including its appendices and any future amendments to it.

l) **Personal Data:** means any information relating to a Subject; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

m) **Partner:** Each Partner of the HVS Mitral and Tricuspid Valve Registry as described in the Registry Project Plan, that has signed the Accession form of this Joint Data Registry Agreement (attached hereto as **Appendix E)**.

n) **Registry Project Plan**: means the document, detailing the aim and, set-up and (most recent) contact details of the Partners of the HVS Mitral and Tricuspid Valve Registry, attached hereto as **Appendix A**.

o) **Processor**: means the Partner who processes the Personal Data on behalf of the Controllers.

p) **Pseudonymised:** means the processing of Personal Data in such a manner that the Personal Data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organizational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person (also called "de-identified").

q) **Registry:** a collectively managed data collection with a centralised infrastructure in which health data from a particular patient group are collected and in which these data are also issued for scientific research purposes.

r) **Researcher:** means any employee (or affiliated physician) of a Partner obtaining access to Data for Studies in accordance with this Joint Data Registry Agreement.

s) **Researcher's Institute**: means the Partner employing (or otherwise engaging) the Researcher and which is liable for the activities of the Researcher in the context of this Joint Data Registry Agreement.

t) **Results:** means all results, know how, data, findings and information and all intellectual property rights therein resulting from a specific Study.

u) **Study:** a project of a Partner within the HVS Mitral and Tricuspid Valve Registry, using a Dataset, in accordance with a Study Proposal approved by the Scientific Committee.

v) **Study Proposal:** The document describing the scope, purposes and methodology of a Study.

w) **Subject:** means any individual whose Data are transferred to the HVS Mitral and Tricuspid Valve Registry in compliance with the terms and conditions of this Joint Data Registry Agreement.

x) **Third party**: means any entity other than a Partner requesting access to Data.

2. The Registry

1) **Background.**
Mitral and tricuspid valve disease are prevalent cardiac conditions affecting millions of people worldwide, with significant implications for mortality and morbidity. Nevertheless, large cohorts with long term follow-up data of treatment outcomes remain scare and heterogenous. Therefore, in 2024 the HVS Mitral and Tricuspid Valve Registry was founded. The HVS Mitral and Tricuspid Valve Registry operates under the auspices of the Heart Valve Society, a non-profit medical society dedicated to the advancement of research and care of patients with heart valve disease.

2) **Main objectives**. The main objectives of the HVS Mitral and Tricuspid Valve Registry are:
The HVS Mitral and Tricuspid Valve Registry is aimed to improve outcomes for patients with mitral and tricuspid valve disease, to enhance uniform scientific reporting, to optimize multidisciplinary patient care, to assess quality of care and to update and improve guidelines. This is done through the research resulting from this Data Registry.

3) **Laws and Regulations**.
The Data Registry is established and located in the Netherlands and subject to the GDPR art. 3. The processing of the Data is subject to terms and conditions of the GDPR. Therefore this Joint Data Registry Agreement is drafted taking into account applicable national and EU law and legislation. Notwithstanding, as the HVS Mitral and Tricuspid Valve Registry is an international collaboration, as the Data Registry contains also Data originating from countries outside the EEA. As it is not feasible to implement all national laws of the Partners into this Joint Data Registry Agreement, their individual national law shall apply to their center and their handling and entry of Data, but shall not apply to the handing of the Data once entered into the Data Registry itself. In collecting Data and making available the Data to the HVS Mitral and Tricuspid Valve Registry, each Partner requires to abide by its national law, including but not limited to privacy law, and ICH-GCP. It is their individual responsibility to ensure that no Data is entered into the HVS Mitral and Tricuspid Valve Registry in violation of their national law, regulations, legislation, and local ethical review board and/or local data protection

authority (if applicable) and that all Data can be used for the purposes of the HVS Mitral and Tricuspid Valve Registry.
The processing of Data must be compliant with the provisions of the consent procedure and/or decision of an ethical review board, and/or a data protection authority/officer if applicable.

4) **Partners outside the EEA**

The HVS Mitral and Tricuspid Valve Registry consists of Partners within and outside the European Economic Area (EEA). The Partners for whom such is applicable will only process or transfer the Personal Data in or to countries outside the EEA under the conditions that such Partner will abide to appropriate safeguards, such as an Adequacy Decision or signing the Standard Contractual Clauses, as attached in **Appendix I**. in accordance with the European Commission's decisions to ensure such transfer.

(a) Standard Contractual Clauses

Partners outside the European Economic Area shall sign the Standard Contractual Clauses **(Appendix I**) as they receive data from the Registry for the purpose of a Study.

(b) Adequacy Decision

For Partners in countries with respect to which the European Commission has issued an Adequacy Decision, the following shall apply. When providing Data from the Data Registry for the purpose of a Study to a Partner in a country with an Adequacy Decision, the Processing of Personal Data shall be in accordance with the national law of the Researcher to whom the data were provided. In the event that this Joint Data Registry Agreement identifies Partners as Joint Controllers in relation to the Data included in the Registry, the GDPR shall apply, whereby Partners are considered Joint Controllers.

3. Data collection and transfer to the HVS Mitral and Tricuspid Valve Registry

1) Each Partner shall transfer into the HVS Mitral and Tricuspid Valve Registry, Data of Subjects that consented (if applicable) to participate in the Registry and that are eligible to participate in the HVS Mitral and Tricuspid Valve Registry. Consent (or necessity hereof) shall be obtained in accordance with applicable national and European law.

2) Transfer of Data into the HVS Mitral and Tricuspid Valve Registry and the use of such Data by the Partners in accordance with this Joint Data Registry Agreement shall be free of charge. A fee for making available Data from the HVS Mitral and Tricuspid Valve Registry to third parties (providing services) for the performance of analyses by the Partners under Section 7.11 shall be determined by the Core Leaders.

3) The Data in the HVS Mitral and Tricuspid Valve Registry shall be used for non-commercial research and regulatory purposes only, such as post-market surveillance.

4) The Data provided is made available by the Partners as a service to the research community. Each Partner shall remain the owner of the source data it transfers into the HVS Mitral and Tricuspid Valve Registry. Transfer of Data into the HVS Mitral and Tricuspid Valve Registry shall not restrict any use of such Data by the Partner that has contributed such Data.

5) It is the responsibility of each Partner transferring Data into the Database, to ensure such transfer is in compliance with the law, including but not limited to privacy laws and that such Data can be used for the purposes of the HVS Mitral and Tricuspid Valve Registry. As a

consequence Registry Project Plan shall be submitted to a local review board, together with the informed consent forms and other relevant documents related to the HVS Mitral and Tricuspid Valve Registry as determined by such review board.

6) Data shall be made available from the HVS Mitral and Tricuspid Valve Registry by the Coordinator as a Data Processor on behalf of the HVS Mitral and Tricuspid Valve Registry Partners for Studies in accordance with **Section 7** hereof.

4. Governance

1) The objectives of the governance structure are to:
   - provide a sustainable infrastructure for standardized sharing of Data for specific and approved scientific research;
   - ensure compliancy with the General Data Protection Regulation (EU) 2016/679 (hereinafter "GDPR") and with respect to Data originating from countries outside the European Economic Area, in accordance with such countries' privacy law provisions;
   - monitor registry activities and supervise conduct of the HVS Mitral and Tricuspid Valve Registry, taking all reasonable steps to ensure credibility and integrity of the Data Registry;
   - provide guidance for the review and approval of publications prior to submission;
   - ensure that research outputs are prepared and curated in a way which helps maximise their value to the HVS Mitral and Tricuspid Valve Registry Partners;
   - ensure that fair credit is given to the authors and to other individuals who have contributed significantly to the work that is described in each publication, report, or presentation.

2) The HVS Mitral and Tricuspid Valve Registry has established a Core Leaders group and a Scientific Committee (SC), both as defined below, in accordance with the Registry Project Plan Erasmus MC shall act as the Coordinator of HVS Mitral and Tricuspid Valve Registry in accordance with **Section 5.4**.

3) The Core Leaders

Partners shall be represented in the Core Leaders, preceded by a Core Leader Chair. Decisions by the Core Leaders shall be made on consensus basis. The composition of the HVS Mitral and Tricuspid Valve Registry Core Leaders is outlined in **Appendix A**. The Core Leaders will be responsible for overall and financial management of the HVS Mitral and Tricuspid Valve Registry on behalf of the Partners. More specifically, the Core Leaders are authorised by the Partners to and shall be responsible for:

- Governance and management regarding the HVS Mitral and Tricuspid Valve Registry collection
- Adjustments of legal documents if appropriate;
- To review and approve the final Registry Project Plan and Amendments;
- To monitor progress of data sharing;
- To select the network of investigators;
- To monitor progress of Study enrolment of centres;
- To address and resolve Study management problems;
- secure in collaboration with the Board of Directors of the Heart Valve Society sustainable; finances for Coordinator, for the management of the Registry.

4) The Scientific Committee

The Scientific Committee consists of 6 members outlined in **Appendix A**. The Scientific Committee will have a role in the assessment of Study Proposals and safeguard scientific integrity of the conducted Studies, encompassing, but not limited to:
- To advice in the analyses and presentation of the Results;
- To asses Study Proposals with a focus on:
    - the quality of the studies,
    - a fair balance between the number of patients involved and the number of research proposals,
    - a fair author list,
    - scientific relevance,
- To asses publications on congruence with Study Proposal and integrity of analyses
- To ensure scientifically sound analyses of the Data used for a Study, eventually by executing an audit.

5) The Coordinator is authorised by the Partners to and shall be responsible for:
   - Making the database available for the purpose of the HVS Mitral and Tricuspid Valve Registry;
   - Governance and management regarding the HVS Mitral and Tricuspid Valve Registry;
   - Maintaining, securing and hosting the HVS Mitral and Tricuspid Valve Registry;
   - Processing the Data in the Data Registry in accordance with the Registry Project Plan and this Joint Data Registry Agreement;
   - Processing and analysing the Data in the Data Registry in accordance with the Registry Project plan and this Joint Data Registry Agreement;
   - Concluding written agreements with new partners and third parties providing services in relation to the HVS Mitral and Tricuspid Valve Registry at the request of the Core Leaders;
   - Concluding written agreements with sub-contractors;
   - Interacting with the subcontractors in maintenance and of central changes in the Data Registry;
   - Contact point for questions from Partners regarding the organization of the Data Registry;
   - Contact point for questions related to Study Proposals;
   - To monitor the data collection process.

6) The Coordinator shall not be liable for any breach of contract by a Partner of a contract concluded by Coordinator pursuant to **Section 5.4**.

7) Coordinator shall provide a copy of each contract concluded under **Section 5.4** to the Core Leaders, who will be responsible for making available such document to the Partners.

8) Pursuant to the decision making procedures of the HVS Mitral and Tricuspid Valve Registry as outlined in **Appendix A**, the Core Leaders may agree with the Coordinator on additional tasks.

6. Privacy

1) The Coordinator shall, as a Data Processor, be responsible for maintaining and hosting the Data Registry base in accordance with the GDPR and any applicable national law of the Partners it is informed of. The Coordinator shall act as a Data Processor on behalf of the Joint Controllers (the Partners) and shall process the Data in accordance with the terms set out in **Appendix B**. It is expressly agreed that none of the Parties shall carry out or attempt to carry

out any procedures with the Data/Dataset- such as linking, comparison, or processing - with which the identity of the Subject could be derived.

2) Each Partner is considered the Controller of its own Data up to the moment of transfer of such Data into the Data Registry base and shall fulfil all obligations of Controller under applicable privacy law.

3) In respect of the use of the Data for the purpose of creating and managing the Data Registry, the Partners are considered to be Joint Controllers. In view of article 26 of the GDPR, the privacy arrangements between the Partners have been determined in the privacy matrix attached to this Agreement as **Appendix D**. In respect of the use of the Data for the purpose of performing a Study, the Partner conducting the Study shall be a separate controller. In the case of several Partners jointly performing the Study, they shall be Joint Controllers in accordance with **Appendix D**.

4) Partners shall ensure that the privacy of the Subjects and the confidentiality of Data are protected in accordance with the statutory requirements applicable in their own country and/or the Netherlands and the policies of the institute of which the Subject is a patient. The Coordinator shall not be responsible or liable for any failure of a Partner to comply with national law and/or institutional policies with regard to the transferring of Data into the HVS Mitral and Tricuspid Valve Registry.

5) Each Partner shall use best efforts to ensure the accuracy of any Data that it enters into the Database and promptly to notify the Coordinator of any errors therein and, if so instructed by the Coordinator, correct such errors.

6) Partners shall transfer Data into the HVS Mitral and Tricuspid Valve Registry in Pseudonymised (de-identified) form only, in accordance with the guidelines and instructions of the Core Leaders. The key to coded Data is held at each Partner's own location for its own Subjects and is the responsibility of the local investigator who has collected the Data.

7) The Coordinator shall inform the Partners about the method of Pseudonymisation and the location of the HVS Mitral and Tricuspid Valve Registry (and any changes to the location).

8) Prior to making available the Data for a Study, the Dataset to be transferred shall be given a new pseudonym by the Coordinator.

7. Conditions for Data Access

Access by Partners

1) Each Partner remains the owner of its Data in the HVS Mitral and Tricuspid Valve Registry and is entitled to extract such Partner Data from the Database for its own uses without the approval of the Core Leader or Scientific Committee. Each Partner shall be responsible and liable for the processing of its own Data in accordance with applicable laws.

Access by Researchers

2) Each Partner shall be responsible for ensuring that Researchers, associated with their institute, shall be bound by this Joint Data Registry Agreement. The applicable conditions must be made known to the Researcher at least prior to the review of the Study Proposal.

3) Researchers requesting Data shall send their Study Proposal to the Coordinator who will submit this Proposal to the Scientific Committee in accordance with this Joint Data Registry Agreement. Only Researchers who are employees of or otherwise associated with a Partner can submit a Study Proposal for Data release to the Coordinator. If the Study includes the collaboration with a non-Partner, the Partner whose Researcher has submitted the Study proposal warrants that a separate contract for this collaboration shall be entered into, reflecting the relevant terms and conditions of this Joint Data Registry Agreement.

4) Making available Data shall be conditional to obtained approval from the Scientific Committee and to the extent applicable to any approvals, permits and licenses as required by the Researcher's national law.

5) If the Scientific Committee approves a Study Proposal, the Researcher will receive a 'Mail of Approval', as attached hereto as **Appendix F**, stipulating the general terms and condition with regard to receipt and use of the Data. In order to have an overview of all Studies performed, all 'Approval emails' will be stored by the Coordinator.

6) The Researcher's Institute shall be considered a Controller under the GDPR in relation to the use of the Dataset for the purpose of the Study. The Mail of Approval may include provisions imposing on the Researcher (as representative of the Partner additional obligations that the Partner has as Controller under the GDPR). The Researcher then sends a confirmation email accepting the terms for use of the Dataset.

7) The Scientific Committee in its reasonable determination, may impose additional conditions on the performance of a specific Study. Such additional conditions will be communicated to the Researcher during the reviewing process and will be added to the Mail of Approval if the Study Proposal is approved.

8) Access to Data shall at least be conditional to the following:
   a) The Researcher's Institute shall be responsible for obtaining the permits and approvals necessary in its own country and required by its internal policies.
   b) The Researcher's Institute shall procure that Researcher shall use the Data for the approved Study only. In case of deviations or changes in the Study the Scientific Committee shall have the right to terminate the use of the Dataset for such Study without any liability at its sole discretion.
   c) The Researcher's Institute shall procure that Researchers shall bear sole responsibility for the handling and use of the Data in accordance with applicable law and legislation and the additional obligations referred to in sections 7.6 and 7.7 of this Joint Data Registry Agreement.
   d) The Researcher's Institute shall procure that Researcher shall not duplicate the Data or have them duplicated unless in accordance with the approved Study proposal.
   e) Researcher's Institute shall procure that Researcher shall not disclose or provide access to the Data to any Third party without the prior written consent of Scientific Committee

and Core Leaders. In case Data are sent to a Third party, a DTA must be concluded between that Party and the Coordinator.

f) The Researcher shall report the progress of the Study and Results to the Coordinator in a manner and frequency as outlined in the Mail of Approval.

g) Results must be shared with the research community at large and therefore be scientifically published in accordance with this Joint Data Registry Agreement.

9) Researchers conditional to the above, shall have access to the Data free of charge unless specifically set forth otherwise in the Mail of Approval.

10) Upon receipt of the Mail of Approval signed by the Chairman of the Scientific Committee and, if applicable, the fee mentioned in the Mail of Approval, the Data set necessary to perform the Study will be selected from the Data Registry and sent to the Researcher.

Commercial Use

11) Parties with commercial purposes will not be provided access to Data from the HVS Mitral and Tricuspid Valve Registry for such commercial purposes. However, companies that make available funding may request certain analyses, based on an analysis plan developed by (a group of) Partners in the form of investigator-initiated research, with reports and/or scientific publication as sole deliverable in accordance with a separate funding agreement to be entered into between the Researcher's Institute and such Third party.

12) Parties with commercial purposes may be granted access to fully anonymised (Aggregated) data, subject to all Partners involved in the Study agree and any additional conditions determined by the Core Leaders in consultation with such Partners. The Coordinator will ensure that the Dataset will have the characteristics of an (Aggregated) Anonymized Dataset and then send it to the Third Party

13) In no event shall Parties with commercial purposes own Results of such analysis.

8. Ownership and Intellectual property rights

1) The intellectual property rights as may apply to any Results of a Study, including but not limited to copyright in the resulting publications or algorithms, shall be owned by the Partner(s) that employed the Researcher(s) or that generated the Results. The (other) Partners shall have a non-exclusive right to use the Results for the purpose of further research in the field of valve research and development of professional and/or medical standards.

2) In case of an opportunity for commercial use of Results, the Partner(s) that generated the Results shall develop an appropriate commercial strategy which strategy shall require prior assessment by and approval of the Core Leaders. When Results are used for commercial purposes by a Partner or a Third party, but in the absence of an approved strategy, the Core Leaders will come up with a proposal. The Coordinator shall act on behalf of the Partners in the Core Leaders in its negotiations with the Partner(s) or Third party involved.

9. Authorship

1) Authorship of any publications with regard to Studies shall follow the principles set out in the ICMJE recommendations 'Defining the Role of Authors and Contributors' as can be found on http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html.

2) It is recommended to publish Results under a multi-author group, in order to credit the contributions of all Partners. When submitting the manuscript, the corresponding author will specify the group members who can take credit for the work as authors, as well as who will be listed as contributors or be acknowledged.

3) Researcher will enable the Core Leaders to review publications before submission in accordance with any publication arrangements that are set out in the Mail of Approval sent to the Researcher and the Registry Project Plan. This review will be limited to potential issues with authorship and data protection rather than a deep scientific review. In case of any contradiction between the publication arrangement in the Mail of Approval and/or this Agreement and/or the Registry Project Plan, the publication arrangement in firstly) the Registry Project Plan, secondly) this Agreement and thirdly) the Mail of Approval shall prevail in the order stated.

10. Accession

An entity becomes a Partner to this Agreement upon signature of the accession document, attached as **Appendix E** to this Joint Data Registry Agreement, by the Coordinator and such entity. Such accession shall have effect from the date identified in the accession document. For sake of clarity, this accession will be subject to the approval of the Core Leaders current Chair.

11. Finance

Partners will not be compensated for providing Data to the Registry. The Coordinator will only be compensated for maintaining the Registry and the associated tasks.

12. Subject complaints procedure

Complaints of Subjects relating to or arising from the HVS Mitral and Tricuspid Valve Registry shall be submitted to the institute of the Partner at which the Subject is a patient and/or where Data were collected. The relevant Partner warrants that the complaint shall be handled in accordance with the GDPR and **Appendix D**.

13. Limitation of liability

1) No Partner shall be liable to any other Partner for any loss or damages resulting from that Partner's participation to the Registry or its use of the Data, unless such loss or damage is caused by a breach of this Joint Data Registry Agreement or applicable law by that Partner. In any event no Partner shall be liable to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue, loss of contracts or business opportunities.

2) The exclusions and limitations of liability stated above will not apply in the event the damage is caused by gross negligence or wilful misconduct of that Partner and cannot be restricted or excluded by applicable law.

3) Each Partner shall be solely liable for any loss, damage or injury to third parties resulting from the performance of said Partner's obligations under this Joint Data Registry Agreement or from its use of Data, or Results unless such loss or damage is caused by a breach of this Joint Data Registry Agreement or applicable law by another Partner or if the damage is caused by gross negligence or wilful misconduct of that Partner and cannot be restricted or excluded by applicable law.

4) Partners receiving a claim based on (1) those Partners being Joint Controllers, and (2) a breach of obligations under the GDPR by another Partner, shall have recourse against said Partner regarding any costs, damages and/or fines relating to such breach.

14. Duration and Termination

1) This Joint Data Registry Agreement shall come into effect on the date the Joint Data Registry Agreement has been approved by the Core Leaders ("Effective Date") and shall continue to be in effect until the Partners determine that the HVS Mitral and Tricuspid Valve Registry must be dissolved, in which case the Core Leaders shall prepare a proposal that includes at least transfer, destruction or return of the Data. If the Data are maintained in another Database after the HVS Mitral and Tricuspid Valve Registry is dissolved, the proposal shall contain provisions for access and use of the Partners and third parties. Any transfer of Data into another Database shall be in compliance with the terms of the GDPR. Upon termination, all Data shall be stored for an additional 20 years for verification purposes as required by applicable law and regulations, after expiration of which, the Coordinator shall delete such Data.

2) If any Partner commits any breach of or is in default of any of the terms or conditions of this Joint Data Registry Agreement, and fails to remedy such default or breach within thirty (30) days after the receipt of written notice from the Coordinator, the Coordinator may terminate the Participation of such Partner to the HVS Mitral and Tricuspid Valve Registry. Upon termination, all Data shall be stored for an additional 20 years for verification purposes as required by applicable law and regulation, after expiration of which, the Coordinator shall delete such Data. If such breach is not remedied within that period or is not capable of remedy, the Core Leaders may furthermore declare the Partner to be in default and to decide on the (legal) course of action to be taken.

3) A Partner may request to withdraw from the HVS Mitral and Tricuspid Valve Registry by providing the Coordinator written notice of such withdrawal. In such event the Data already included in the Database shall no longer be used for purposes of the HVS Mitral and Tricuspid Valve Registry, however such Data shall remain in the Database for the period described in Clause 14.1.

15. Confidentiality

Neither Party will disclose to any third party, or use for any purpose except carrying out the Research, any of the other Party's Confidential Information for a period of five (5) years after the initial disclosure of such Confidential Information, provided that the recipient Party's obligation shall not apply to information that:

a) was known to the receiving Party and not already subject to any obligation of confidentiality of the disclosing Party;

b)is or becomes generally known or publicly available without any breach of this Agreement;

c) has been obtained from a third party under no obligation of confidentiality;

d) has been independently developed by a Party;

e) is disclosed pursuant to the requirement of any law or regulation or the order of any court of competent jurisdiction; or

f) is approved for release in writing by an authorised representative of the other Party.

For the avoidance of doubt if the Confidential Information contains Data, this will remain confidential indefinitely.

16. Governing Law

Conflicts relating to this Joint Data Registry Agreement shall be governed by Dutch law and the Court of Rotterdam shall have exclusive jurisdiction in case of involvement of the Coordinator in such conflicts, having its principle office in Rotterdam, The Netherlands. In deviation thereof, the Partners shall be entitled to reach a different settlement with respect to conflicts that do not arise from the Registry.

APPENDIX A: REGISTRY PROJECT PLAN (and AMENDMENTS)

1. Introduction

Mitral and tricuspid valve disease are prevalent cardiac conditions affecting millions of people worldwide, with significant implications for mortality and morbidity (1,2). The management of patients with mitral and tricuspid valve disease may include surgical or transcatheter interventions, depending on the indications, contraindications, risks, and benefits of each procedure (3,4). Importantly, the initial choice of treatment is of great consequence for the ensuing path of specific treatments a patient will undergo. Thus, multiple decisions are required at different stages in a patient's lifetime even though no ideal and clear-cut solution and timing currently exists. Suboptimal decision-making can lead to increased adverse outcomes and reduced quality of life for patients (5). A shift towards a lifetime-oriented approach to mitral and tricuspid valve disease which considers the (un)natural history of it at all ages is needed to optimize decision-making in mitral and tricuspid valve disease and thereby improve patient-outcomes. The Heart Valve Society (HVS) Mitral and Tricuspid Valve Database provides a suitable framework for compiling all components relevant to generating such an approach.

The HVS Mitral and Tricuspid Valve Database is a centralized registry in which individual centers (also called Partners) can share data according to a standardized data protocol. Collectively these partners form the HVS valve research network (VRN). Researchers can request access to the data to conduct studies according to a data access mechanism. The HVS Mitral and Tricuspid Valve Database operates under the auspices of the Heart Valve Society, a non-profit organization dedicated to improve outcomes patients with heart valve disease.

2. General objectives

The HVS Mitral and Tricuspid Valve Database is aimed to improve outcomes for patients undergoing interventions for mitral and/or tricuspid valve disease, to enhance uniform scientific reporting, to optimize multidisciplinary patient care, to assess quality of care and to update and improve guidelines. This is done through the specific research projects using data resulting from this registry.

3. Database design

Longitudinal observational cohort.

4. Study population

The HVS Mitral and Tricuspid Valve Database is a registry that collects data on the characteristics, procedural information, and outcomes of adult patients with mitral and/or tricuspid valve disease, who undergo surgical or transcatheter interventions.

5. Legal basis

Legal basis for the collection of patient data is based on local medical ethical review approval, with informed consent, unless there is an exception for consent on basis of applicable law if applicable. Within each individual center the data may be collected retrospectively and prospectively, according to the local medical ethical protocol. In order to enhance the amount of data collected individual centers are encouraged to follow an ambispective design. The start date specified in the local medical ethical protocol is considered the start data of prospective data collection. The data is made available to the HVS Mitral and Tricuspid Valve Database for further research under the specification outlined in the Joint Data Registry Agreement.

6. Database structure

Study parameters/endpoints

Partners collect data using the standardized data definition as specified in the HVS data dictionary (https://heartvalvesociety-vrn.org/documents), which is aligned with the Heart Valve Disease data set, developed by the International Consortium for Health Outcomes and Measurements (ICHOM) and includes baseline patient characteristics, procedural information, and outcomes (6).

Baseline data

Baseline data covers the following patient characteristics: demographics, diagnosis, and potential risk factors for operative mortality (EuroSCORE ||).

Procedural information

Procedural variables include detailed peri-procedural data, additional clamp session and complications at discharge.

Clinical / echocardiographic / patient reported outcomes

Outcome data includes clinical outcomes such as complications and possible reinterventions, longitudinal echocardiographic and additional MRI data, and patient-reported outcome measures. The patient-reported outcome measures include the EQ-5D-5L. The EQ-5D-5L questionnaire is currently available in over 170 languages.

Frequency of data collection

Data will be collected from medical records at baseline and during at least yearly follow by the individual partners. If patients are eligible for inclusion before the start date of prospective enrolment, baseline and (yearly) follow-up data will be extracted entirely retrospectively. Patients are followed until the end of follow-up due to (elective) retraction or death.

7. Modes of data transfer

Data may be transferred to the HVS Mitral and Tricuspid Valve Database either by a direct case-by-case method using a web-based Case Report Form in a secure data-entry system or by batch uploads which are send to the coordinator via secured file transfer systems. The data entry system is set up according to Good Clinical practice (GCP) guidelines and is compliant with the United States Food and Drug Administration (FDA) (21 CFR part 11), the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA).

8. Governance

The HVS Mitral and Tricuspid Valve Database is officially declared as a Valve Research Network (VRN) of the Heart Valve Society (HVS). The HVS Mitral and Tricuspid VRN consists of the participating centers (Partners), the Core Leaders, the Scientific Committee, the Data Management Team and the HVS board (Figure 1). All members of the HVS Mitral and Tricuspid VRN are welcome to join the Valve Research Network meetings. Controllership is governed by a Joint Data Registry Agreement, which participating centers sign upon joining the database. All participating centers are considered joint controllers and have designated a Core Leaders team to make executive decisions, a Scientific Committee to review research proposals (including data access requests), and a coordinator to process data on behalf of the controllers.

Participating centers (Partners)

Participating centers form the core of the Mitral and Tricuspid VRN. These centers collect data on patients undergoing mitral and tricuspid valve interventions and opt into the database as joint controllers, enabling multicenter research opportunities. The current partners of the database are specified at https://heartvalvesociety-vrn.org/participants-2/. Each center serves as controller with responsibilities to protect the personal data it contributes to the database. Each individual center is the owner of its own submitted data and is responsible for its accuracy and content. Data from individual centers are not accessible for any other center. Each participating center must have at least one member affiliated with the HVS. Local medical ethical regulation is the responsibility of the participating center.

Core Leaders

The Core Leaders are the executive organ of the HVS Mitral and Tricuspid VRN, and are mandated by the Partners to make executive decisions regarding the HVS Mitral and Tricuspid Valve Database. Their tasks in include governance and management regarding the HVS Mitral and Tricuspid Valve Database collection, adjustments of legal documents if appropriate, to review and approve the final Project Plan and Amendments, to monitor progress of data sharing, to select the network of investigators, to monitor progress of study enrolment of centers, to address and resolve study management problems and to secure sustainable finances. Core Leaders meet monthly to discuss ongoing matters and decisions are made on consensus basis. The position and name of current Core Leaders are described in Table 1.

Position	Name	Center
Chair	Evaldas Girdauskas, MD, PhD	University Hospital Augsburg (Germany)

Chair	Michele De Bonis, MD	Vita-Salute San Raffaele University (Milan)
Member	Marta Sitges, MD, PhD	Cardiovascular Institute at Hospital Clínic de Barcelona (Barcelona)
Member	Vinod Thourani, MD	Piedmont Heart Institute (USA)
Member	Victoria Delgado, MD, PhD	University Hospital Germans Trias i Pujol (Spain)
Member	Ralph Stephan von Bardeleben, MD, PhD	University Medical Center of Mainz (Germany)

Table 1: Core Leaders HVS Mitral and Tricuspid Valve Research Network

In case of rotation of Core Leaders, the participating centers (Partners) will be notified via e-mail, and added as amendment to this protocol.

Scientific Committee

The Scientific Committee consists of 7 members, including at least 2 cardiologists, 2 surgeons and 2 scientists. Members of the committee will serve for 3 years. After their term they have to wait 3 years before they can apply again. The Scientific Committee reviews research proposals and scientific papers originating from the registry. The Scientific Committee approves research request by filling out a standardized form following an e-mail-based procedure. The current composition of the Scientific Committee members is described in Table 2.

Position	**Name**	**Center**
Member	Marianna Adamo, MD	ASST Spedali Civili di Brescia (Italy)
Member	Jasimuddin Ahamed, PhD	Oklahoma Medical Research Foundation (USA)
Member	Rebacca Hahn, MD	Columbia University Irving Medical Center (USA)
Member	Hoda Hatoum, PhD	Michigan Technological University (USA)
Member	Meindert Palmen, MD, PhD	Leiden University Medical Centre (The Netherlands)
Member	Kevin Veen, MD, PhD	Erasmus University Medical Center (The Netherlands)
Member	Moritz Wyler von Ballmoos, MD, PhD	Texas Health Harris Methodist Hospital (USA)

Table 2: Scientific Committee HVS Mitral and Tricuspid Valve Research Network

In case of rotation of scientific committee members, the participating centers will be notified by e-mail, and added as amendment to this protocol.

Data Management Team (Coordinator)

All partners agreed to appoint one partner who is responsible for management and processing data in the registry. This is called the coordinator (synonym data management team). Currently the Coordinator is Erasmus MC, located in Rotterdam, The Netherlands. The Coordinator is the first point of contact regarding practical issues. Processing tasks include, but are not limited to, preparing datasets to be used by researchers, creating annual feedback and benchmark reports for centers, and monitor timely entry of data.

HVS board

The HVS Mitral and Tricuspid Valve Database operates under the auspices of the HVS, meaning the registry can leverage on the extensive network of the HVS and make use of HVS branding. The HVS is however not considered an joint-controller of the data and does not have access to the data. The HVS may promote the HVS Mitral and Tricuspid Valve Database and (at least one individual) of a Partners institution should be a paying member of the HVS.

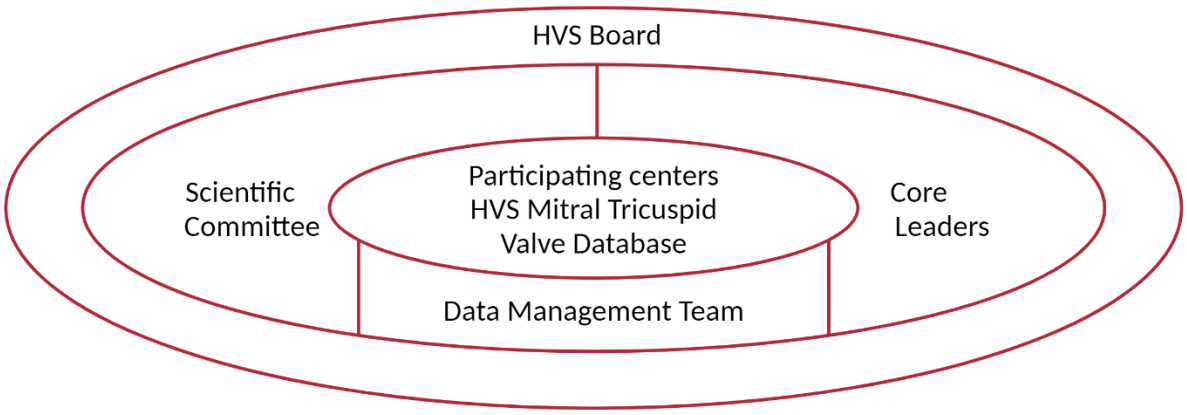

Figure 1: Governance HVS Mitral and Tricuspid Valve Research Network

9. Data Access mechanisms

Data can be accessed for the use of a study according to the following data access mechanisms.

Single Center data access by Partner

Each center can extract his own submitted data for local analysis. Online extractions can be performed whenever desired. Within the online application, reports and graphs will be developed. Individual center data are not visible for any other center. In a report with summary statistics single center data will be presented aside with aggregated results of the entire database. Data of centers other than your own are only visible for the Database Management Team (Coordinator) for the purpose of data validation to enhance data quality. Partners asked to mention the HVS Mitral and Tricuspid Valve Database when single center results based on data standards of the registry are presented or published, however this is not mandatory.

Multicenter data access by Partner

Research proposal

For analysis of multicenter data, a scientific research proposal is needed. Applications should be submitted to the Scientific Committee. Research proposals follow a standardized structure (https://heartvalvesociety-vrn.org/submit-a-research/). Before Partners submit a research proposal, they are advised to contact the data manager to assess feasibly of the research study and overlap with ongoing research. If this is not the case the database manager will receive the proposal and send the proposal to the Scientific Committee.

The data manager will send the research proposal to the Scientific Committee. The Scientific Committee will review the proposal to assess the validity of the research question and proper use of the data. The Scientific Committee can reject, accept or accept the proposal with changes. The researchers will receive 1 round of feedback on their proposal. The Scientific committee will review the researcher's response and accept or reject. In case of no consensus the proposal is discussed in the Core Leader meeting.
Each partner of whom data can be used in the research will be notified about the accepted proposal, and their data will be used if they do not oppose within two weeks (non-opposition procedure). If a partner opposes to the use of their data, they should justify their opposition to the Scientific Committee.
The research team will receive a double-pseudonymized data set, without patient and center identifying variables. After data extraction by the database manager, the researcher team will be given a deadline of 6 months to perform the analysis and write a draft publication (Figure 2). If the deadline is exceeded, the topic can be passed on to another research team.

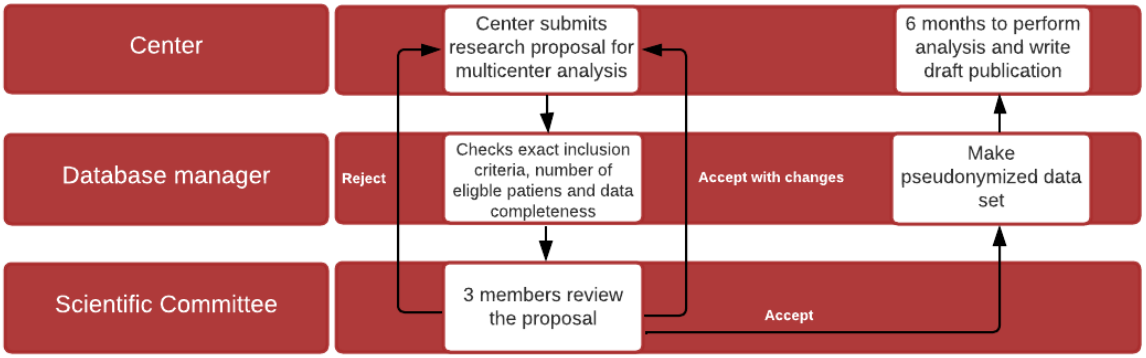

Figure 2: Request multicenter research by research proposal.

Project-proposal

Centers are able to request data by proposing a project. Projects are defined as a pre-specified patient population within mitral and/or tricuspid valve disease domain and pre-specified timeframe of collection, which can be retrospective or prospective data collection. Partners embarking on a project are responsible for their own local medical ethical board or IRB approval. The HVS Mitral and Tricuspid Valve Database is used as effective tool to share and reuse the data. Data collection in the project should adhere to the HVS Mitral and Tricuspid Valve Database data standards. Centers do not have to be a Partner when they propose a project but will have to become a Partner to participate.

Applications should also be submitted to the Scientific Committee. Research proposals follow a standardized structure (https://heartvalvesociety-vrn.org/submit-a-research/). Before Partners submit a research proposal, they are advised to contact the data manager to assess feasibly of the research study and overlap with ongoing research. If this is not the case the database manager will receive the proposal and send the proposal to the Scientific Committee.

The data manager will send the research proposal to the Scientific Committee. The Scientific Committee will review the proposal to assess the validity of the research question and proper use of the data. The Scientific Committee can reject, accept or accept the proposal with changes. The researchers will receive 1 round of feedback on their proposal. The Scientific committee will review the researcher's response and accept or reject. In case of no consensus the proposal is discussed in the Core Leader meeting. Subsequently the proposal will be discussed in the Core Leaders' meeting, and they will make a final decision.

Each partner of whom data can be used in the research will be notified about the accepted proposal, and their data will be used if they do not oppose within two weeks (non-opposition procedure). If a partner opposes to the use of their data, they should justify their opposition to the Scientific Committee.
The research team will receive a double-pseudonymized data set (if applicable within the project scope), without patient and center identifying variables. After data extraction by the database manager, the researcher team will be given a deadline of 6 months to perform the analysis and write a draft publication (Figure 2). If the deadline is exceeded, the topic can be passed on to another research team.
After the project is completed, all participating centers can request the multicenter data within this project.

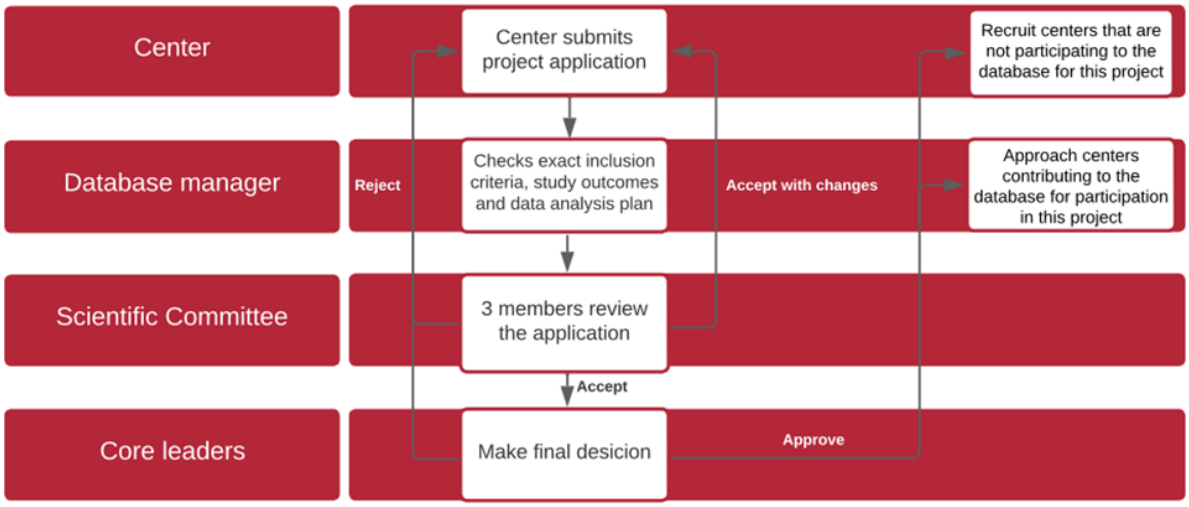

Figure 3: Project Proposal

Non-Partner access

The existence and maintenance of the database are dependent and made possible through the funding provided by external parties. In exchange for their crucial support, partners may share the data anonymously with these funding entities, in collaboration with a Partner. Thus, prior to any data exchange with these parties, aside from pseudonymizing the data after each extraction, anonymization procedures are implemented to guarantee patient privacy and adhere to legislations. To anonymize data to be shared with external parties, the key files generated after each extraction, as described above, will be destroyed by the coordinator. Additionally, all external collaborators will be bound by confidentiality agreements, reinforcing our commitment to ethical data handling. Any data provided by the HVS Mitral and Tricuspid Valve Database Registry to a Non-Partner is subject to separate Data Transfer Agreements, and subject to unanimous decision by the Core Leaders, even if a Partner is involved in the study.

10. Publication

Researchers who want to publish papers based on the HVS Mitral and Tricuspid Valve Database must send end products to the Scientific Committee for review. The Scientific Committee will check the quality and accuracy of the analysis and congruence with the Research Proposal and may suggest possible improvements with a maximum of two rounds. Researchers can revise their work accordingly. The Scientific Committee can halt publication of the manuscript if the quality is not deemed satisfactory after two rounds of feedback or is incongruent with the Research Proposal. In this case the Scientific Committee and researchers will meet and discuss a suitable solution.

Authorship

Authorship will be awarded according to the latest ICJME guidelines for authorship criteria (8) and amount of data supplied for the research. Data selection from the entire database will take into account data completeness. Follow-up completeness will be represented with the C* ratio: the total observed follow-up years divided by the total potential follow-up years (taking the observed death rate into account) (9). Each selected center can propose at least one author for the studies using its data. Authors will be listed based on their ranking in data completeness divided by 100 and multiplied by volume (from high to low). The number of authors will depend on journal requirements. Ideally, all participating partners in the research dataset will be represented or publish under an author group. In case there is a limit, centers with the highest 'data quality *volume factor' will come first

11. Data quality

The quality of the data stored in the HVS Mitral and Tricuspid Valve Database is crucial for ensuring reliable and accurate publications. To guarantee the quality of the data and analyses, the following measures are taken:

a. The data dictionary
b. Monitoring timely and complete entry
c. Feedback and benchmark reports

<u>The data dictionary</u>

The HVS Mitral and Tricuspid Valve data dictionary describes all variables for each registration. It

provides definitions for each variable, specifies whether it is required or not, and outlines the allowed values. Variables that are not allowed will be declined in the eCRF.

Monitoring timely and complete delivery

The Coordinator monitors the delivery and completeness of the submitted data. If a center fails to submit its data on time or if the data is incomplete, the center is requested to provide the missing information.

Feedback and benchmark reports

Feedback and benchmark reports are generated annually for each center. These reports assess the completeness and correctness of the data and compare them with other centers in the database. Based on these reports, centers are requested to supplement their data.

12. Patient Identifiable Data

When centers put the data in the eCRF, a patient code is automatically generated by the data capture system. This patient code is unique to each patient, and the identifying key file remains with each participating center. Individual center data are not visible for any other center.

Any information from this study, if published in scientific journals or presented at scientific meetings, will not reveal patient identities. Collected data will be secured against unauthorized access.

Researchers requesting data from multiple centers receive datasets where center codes are double-pseudonymized to ensure that clustering of patients within a center remains unobservable. This measure is necessary because subject IDs in the registry, by default, include center codes, which could potentially reveal large centers' identities. During this process, all subject IDs are replaced with randomly generated combinations of letters and numbers, unique to each data extract. The original subject ID keys are securely stored in separate key files managed by the Coordinator. If full anonymization is required, these key files are permanently deleted.

13. Costs and funding

For Partners joining the HVS Mitral and Tricuspid Valve Database is free of cost. Partners are not provided fees for sharing data. The HVS Mitral and Tricuspid Valve Database operates under a cost-recovery model to cover the cost made by the coordinator in managing the registry.

14. References

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APPENDIX B: DATA PROCESSOR TERMS (Coordinator)

Article 1. Background

Based on article 6.1 of the "**HVS Mitral and Tricuspid Valve Registry**" Joint Data Registry Agreement", the Core Leaders have engaged the services of a data Processor to hold and maintain the **HVS Mitral and Tricuspid Valve Registry** and the Data contained therein.

Article 2. Definitions

2.1. In this Appendix B, capitalised terms shall have the meaning defined in the Joint Data Registry Agreement of the **HVS Mitral and Tricuspid Valve** Registry. Additional capitalised words shall have the following meaning:

a.	Incident	i a complaint or request for information by a Subject with regard to the processing of Data by the Processor; ii an investigation or confiscation of Data by government officials or a suspicion that such may occur at some point in the future; and/or iii a personal data breach as meant in Article 4.12 of the GDPR.
b.	Sub-Processor	Any non-subordinate third party hired by the Processor to help process Data.
c.	Processor	The Processor within the meaning of Article 4.8 of the GDPR. The Core Leaders have designated the Coordinator as the Processor.
d.	Controller	Each Partner making its Data available to the HVS Mitral and Tricuspid Valve Registry and submitting it in the Database.

Article 3. The processing of the Data

3.1. The Processor shall only process Data on behalf of the Controller for the purposes outlined in the Joint Data Registry Agreement or as additionally agreed otherwise between the Processor and the Core Leaders.

3.2. Without prejudice to the provisions of Article 3.1, the Processor shall be allowed to process Data if it is required to do so by a statutory provision (including the court order or administrative decisions based on it). In such cases, the Processor shall to the extent permitted by law, notify the relevant Controller(s) of the intended processing of the Data and of the statutory provision prior to the processing. Processor shall minimise the extent of the enforced processing to the maximum extent possible.

3.3. The Processor shall process the Data in a proper manner, in accordance with the requirements to which it is subject under the GDPR and to the extent known to the Processor, the national privacy law of the Partners.

3.4. In processing the Data, the Processor shall reasonably ensure that its procedures shall not violate health care legislation.

Article 4. The security and monitoring of Data

4.1. To protect the Data from loss, unauthorised inspection, damage or any other form of unlawful processing, and to guarantee the availability of the Data when due, the Processor shall implement appropriate and effective technological and organisational measures, which, considering the current state of the art and the costs associated with it, shall be in accordance with the nature of the Data to be processed. These security measures shall include the following:

a.) measures designed to guarantee that only authorised employees can access the Data for the purposes outlined;

b.) measures involving the Processor only granting its employees and Sub-Processors access to Data through individual named accounts, with the use of said accounts being adequately logged and with the accounts concerned only granting their users access to those Data whose access is necessary for the legal person concerned;

c.) measures designed to protect the Data from unintentional or unlawful destruction, unintentional loss or changes and unauthorised or unlawful retention, processing, access or disclosure;

d.) measures designed to identify weaknesses with regard to the processing of Data in the systems used to provide services to the Controller(s);

e.) measures designed to guarantee that Data are separated in a sensible manner from the Data the Processor processes on its own behalf or on third parties' behalf;

f.) other measures agreed between the Controller(s) and the Processor [Optional: in the Annex to this Appendix B].

4.2. The Processor's security measures shall comply with the requirements of the GDPR. Furthermore, the Processor has implemented an appropriate, written security policy for the processing of the Data.

4.3. Upon the request of a Partner and provided that such certificate is in place, the Processor shall submit a certificate issued by an independent and competent third party that shows that the Processor's methods comply with the requirements arising from this article 4.

4.4. Each Partner is entitled to monitor (or have monitored) the Processor's compliance with this article 4 and shall enable such Partner to inspect the Processor's processing methods, but no more frequent than once per year, unless such Partner has reasonable doubts that the Data are not processed in accordance with the Joint Data Registry Agreement, this or applicable law.

4.5. If, in response to such inspection, the Partner reasonably instructs the Processor to adjust or update its security policy, the Processor shall reasonably comply.

4.6. The Processor shall ensure that persons authorised to process the Personal Data on its behalf, have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality

Article 5. Monitoring, obligation to provide information and incident management

5.1. When an Incident occurs, has occurred or may be about to occur, the Processor shall to the extent reasonably possible, undertake the activities necessary to undo the damage caused by the Incident as soon as possible or minimise the consequences to the maximum extent possible.

5.2. In addition, the Processor shall notify the relevant Controller(s) without undue delay and to provide any relevant information on:
a.) the nature of the Incident;
b.) the Data that (may) have been affected;
c.) the actual and likely consequences of the Incident; and
d.) the measures which have been or will be taken to resolve the Incident or to minimise the consequences or damage to the maximum extent possible.

5.3. The Processor shall consult the relevant Controller(s) on further arrangements to be undertaken with respect to the Incident and to prevent future Incidents.

5.4. The Processor shall cooperate with the relevant Controller (s) any time, shall follow the reasonable instructions of the relevant Controller (s) and shall enable the relevant Controller (s) to conduct an appropriate investigation of the Incident, formulate a response to the Incident and take appropriate subsequent steps, including notifying the Dutch Data Protection Authority and/or the Subject.

5.5. The Processor shall at all times have written procedural guidelines in place covering the handling of Incidents and shall furnish the relevant Controller (s) with a copy of such procedural guidelines upon the request.

5.6. Alerts under this article 5 shall be addressed to chair of the relevant Controller (s) or any other designee indicated by the relevant Controller (s).

5.7. The Processor shall not provide third parties any information on Incidents, except in cases where the Processor is legally required to do so or the Parties have otherwise agreed.

Article 6. Obligation of cooperation

6.1. The Processor shall fully cooperate with the relevant Controller(s) to enable and the relevant Controller (s) to fulfil their obligations under the GDPR. The Processor and relevant Controller (s) shall agree on procedures to comply with the rights of Subjects under the GDPR.

Article 7. The hiring of Sub-Processors

7.1. The Processor shall not outsource the processing of Data to a Sub-Processor without prior written permission from the Controller(s). The foregoing does not apply to the Sub-Processors listed in Appendix C.

7.2. If the Controller agrees to the hiring of a Sub-Processor, the Processor will enter into a processor agreement with the Sub-Processor based on the BOZ template The Processor shall remain fully responsible for the processing of the Data by the Sub-Processor as if it has performed the processing itself.

7.3. The Processor shall not transfer any Personal Data to a country outside the European Economic Area (EEA), unless the Controller has expressly authorized such transfer in writing.

Article 8. Duration and termination

8.1. This Appendix B shall enter into force on the effective date of the Joint Data Registry Agreement and terminate upon termination of the Mitral and Tricuspid Valve Registry or so much earlier as foreseen in the Joint Data Registry Agreement or this Appendix B.

8.2. Obligations which, by their very nature, are meant to continue to apply even after the termination of this Appendix B shall continue to apply after the termination of this Appendix B. Such provisions shall include those which arise from provisions governing confidentiality, liability, dispute resolution and applicable law.

8.3. Upon expiration of the initial term of the HVS Mitral and Tricuspid Valve Registry or upon earlier termination in accordance with the Joint Data Registry Agreement, the Processor shall discuss with the Core Leaders the feasibility and possibility of continuing the Registry or to destroy HVS Mitral and Tricuspid Valve Registry and the data contained therein.

8.4. In In the event that funding for the HVS Mitral and Tricuspid Valve Registry ceases, the Processor shall not be obligated to continue performing tasks associated with the Registry. Any continuation of the Processor's responsibilities shall be subject to mutual agreement between the Processor and the Core Leaders, as discussed under Section 8.3. If an agreement is not reached, the Processor may terminate its involvement in accordance with the terms set forth in this Appendix B and the Joint Data Registry Agreement.

8.5. If the Processor terminates its involvement as described in Section 8.4, the role of the Processor may be transferred to another center. This transfer shall be subject to approval by the Core Leaders and must comply with all applicable requirements set forth in the Joint Data Registry Agreement. The new Processor shall assume the responsibilities and obligations associated with the HVS Mitral and Tricuspid Valve Registry as outlined in this Agreement.

8.6.

Article 9. Retention period, restoration and destruction of Data

9.1. The Processor shall not retain the Data longer than strictly necessary for the HVS Mitral and Tricuspid Valve Registry and applicable law.

Article 10. Intellectual property rights

10.1. If the (collection of) Data is protected by any intellectual property rights, the Processor is herewith granted permission to process the Data as foreseen in the Joint Data Registry Agreement.

APPENDIX C: TECHNICAL AND ORGANISATIONAL CONTROL MEASURES

Erasmus MC sees Data Security as an integral part of the processes within the organization. This is implemented by appropriate technical and organizational measures where necessary throughout the entire organization. Data are processed under our NEN7510 certified information security system. NEN7510 is the Dutch equivalent of ISO27001/2 with special additions for health care data.

Data quality ensurance

The quality of the data stored in the HVS Mitral and Tricuspid Valve Registry is crucial for ensuring reliable and accurate publications. To guarantee the quality of the data and analyses, the following measures are taken by the importer:

a. The data dictionary;
b. Monitoring timely and complete entry;
c. Feedback and benchmark reports;
d. Audits.

The data dictionary

The HVS Mitral and Tricuspid Valve Registry dictionary describes all variables for each registration. It provides definitions for each variable, specifies whether it is required or not and outlines the allowed values. Variables that are not allowed will be declined in the eCRF.

Monitoring timely and complete entry

The HVS Mitral and Tricuspid Valve Registry management team monitors the delivery and completeness of the submitted data. If a center fails to submit its data on time or if the data is incomplete, the center is requested to provide the missing information. If they fail to do so, the center will be put on 'silent', where data of their center will not be used for data extraction.

Feedback and benchmark reports

Feedback and benchmark reports are generated annually for each center. These reports assess the completeness and correctness of the data and compare them with other centers in the HVS Mitral and Tricuspid Valve Registry. Based on these reports, centers are requested to supplement their data.

Audits

Biannual audits are conducted by the HVS Mitral and Tricuspid Valve Registry management team to thoroughly examine the accuracy and completeness of the data supplied to HVS. The results of these audits are discussed during the HVS Valve Research Network meetings. Any striking or discrepant results are analyzed, and findings from these audits are used to continuously improve data quality.

Security controls

The HVS Mitral and Tricuspid Valve Registry is hosted in Castor EDC. Data will be stored in Castor EDC. Castor complies with all applicable laws and regulations, including ICH E6 Good Clinical Practice (GCP), 21 CFR Part 11, EU Annex 11, General Data Protection Regulation (GDPR), HIPAA (US), ISO 9001 and ISO 27001. By using Castor, researchers are enabled to comply with these laws and regulations. Castor is a validated system and approved by external auditors.

Flow of data

Data can be entered into the data capture system on a case-by-case basis using the web-based electronic Case Report Form. Centers who participate are also able to upload batches through the Castor EDC inferface. They are responsible for the patient selection and (temporarily) storing the exported file in a safe environment before uploading. Alternatively, centers may share the batch file through "SURFfilesender" to the HVS Mitral and Tricuspid Valve Registry management team. SURFfilesender is a secure file sending tool, providing encryption in-transit and 2FA.

Authorizations

Participating centers can only access their own uploaded/provided data. The HVS Mitral and Tricuspid Valve Registry management team has the ability to access all data from all centers. Researchers may do a Research Proposal (see the Protocol for the process of request and approval). When a Research Proposal is approved, a data extraction is composed from the requested data in the database. The results is a CSV file. Accounts are managed (created, configured and removed) by the HVS Mitral and Tricuspid Valve Registry management team.

Pseudonymization and Anonymization

The data in the database contains medical data as well as the patient's age (not the birth date) and gender at birth. The original Patient ID (PID) from the originating EHR-system is substituted with a pseudonymized PID for use in Castor. Only the originating center holds the key to identify the original patient in their EHR-system. When extracting data from the database, identifying fields are again substituted (double-pseudonymization). For extracting data for a Research proposal, the HVS Mitral and Tricuspid Valve Registry management team will hold the key file. For extracting data for a third party, there will be no key file (anonymous).

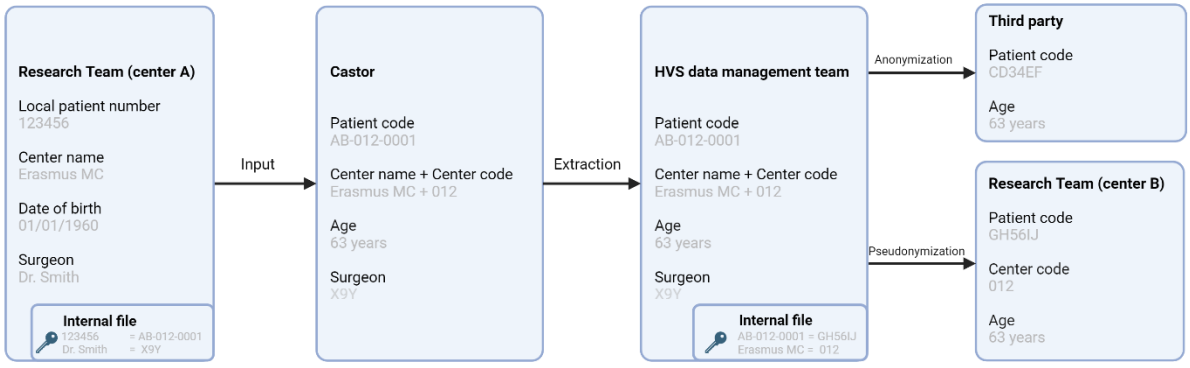

Figure 1. Visibility patient identifying information

Authorization and user account roles

Authorized users access the database through the Castor EDC web interface. Three account types exist: Admin, Monitor and Data-entry.

The Principal Investigor (PI) of a center will have the Admin role, giving them full control of their own data. They can still not see the data of other participating centers. The Monitor-role is to view the data in the database. The Data-entry role allows a user to also enter data into the database.

APPENDIX D: JOINT CONTROLLER TERMS (Partners)

Part I: Description of the Data:

Data subjects The Personal Data transferred concern the following categories of data subjects:	Patients undergoing interventions for mitral and tricuspid (valve) disease
Purposes of contribution of Data The Data is contributed for the following purpose	The Data is contributed for the purposes of the HVS Mitral and Tricuspid Valve Registry which aims to collect, maintain and make available for research use data on paediatric patients with mitral and tricuspid valve disease
Categories of Data The Personal Data transferred concern the following categories of data:	Baseline characteristics, procedure characteristics and follow-up outcomes including echocardiographic parameters
Sensitive data The Personal Data contributed concern the following categories of sensitive data:	Health related data as specified in the HVS data dictionary
Method of transfer	Transfer to Registy: Direct database entry in eCRF (Castor EDC), batch upload via Castor EDC. Data sharing for study (transfer from Registry): Encryped sending via Surffile sender.
Method of data storage and security measures (e.g. method of encoding)	The HVS Mitral and Tricuspid Valve Registry is compliant with GCP, GDPR, and 21 CRF Part 11. It is located in a secure and fully certified data centre in the Netherlands. The HVS Mitral and Tricuspid Valve Registry is certified to store medical data (NEN7510, ISO 9001 and 27001:2017). Data will be entered encoded and will be stored encrypted; the key to coded information is held at each Partner for its own Subjects and is the responsibility of the local investigator. Handling of Personal Data by the HVS Mitral and Tricuspid Valve Registry is in compliance with the GDPR.

Authorized sub-processors Identified at the Effective Date	Castor EDC

Part II: Privacy arrangements **The Partners are Joint Controllers with regard to the Personal Data that will be processed by virtue of the HVS Mitral and Tricuspid Valve Registry. In this context Parties determine and agree on- in accordance with article 26 of the GDPR- their respective obligations with regard to compliance with the GDPR.**	
Privacy obligation *(please mention below the applicable privacy obligations).*	*Please mention below with regard to each obligation: the name of the responsible Party, the Personal Data and processing activities involved and if necessary the arrangement(s) about how to fulfill the obligation.*
1. Provide information on the processing of the Personal Data to data subjects (in accordance with article 13, 14 GDPR).	Each Partner is responsible for providing information on the processing of Personal Data to the Subject in accordance with the GDPR.
2. Safeguarding that informed consent for the processing of the Personal Data is obtained or that another legitimate basis for the processing of the Personal Data is in place (article 6 GDPR).	Each Partner is responsible that informed (if applicable) consent from Subjects is obtained and filed. These filed data may be subject to monitoring purposes.
3. Safeguarding that the data subjects can exercise their right of access, to rectification, erasure, restriction of processing and to object to the processing (articles 15 to 18 and article 21 GDPR).	If a Subject exercises any of its rights mentioned in the GDPR, the first addressed Partner shall discuss with the Coordinator on the manner to safeguard the Subject's rights in accordance with this Joint Data Registry.
4. Safeguarding that the data subjects can exercise their right to data portability (article 20 GDPR),	Each Partner shall include a local contact person in the patient information brochure to whom the Subject can turn.
5. Safeguarding that the data subjects can exercise their right to object to the processing (article 21 GDPR)	Each Partner is responsible for giving Subjects the opportunity to object to the processing of the data.
6. Safeguarding the security of the Personal Data (in accordance with article 32 GDPR and) in accordance with other arrangements in this Agreement.	Each Partner is responsible for the safeguarding of the Personal Data (in accordance with article 32 GDPR) for its locally stored data. Each service provider, research party and other parties who might get access to the data of other parties are responsible for safeguarding the transfer of data, data monitoring, data cleaning and data analysis.

	The Coordinator is responsible for maintaining the HVS Mitral and Tricuspid Valve Registry. The Registry is compliant with GCP and GDPR. It is located in a secure and fully certified data centre in the Netherlands. The HVS Mitral and Tricuspid Valve Registry is certified to store medical data (NEN7510, ISO 9001 and 27001:2013). Data will be entered encoded; the key to coded information is held at each Partner for its own Subjects and is the responsibility of the local investigator. Handling of Personal Data by the HVS Mitral and Tricuspid Valve Registry is in compliance with the GDPR. Each Partner is responsible for correct Data input, their login accounts and local trial master files.
7. Comply with data breach obligations (articles 33 and 34 GDPR).	The Coordinator, Partner and their Researchers shall comply with data breach obligations. If the Coordinator or any other Party identifies such a Data Breach within its sphere of control (Identifying Party), the Identifying Party: A. inform the Coordinator and the Party that provided the Dataset without undue delay, though not later than twenty-four (24) hours after discovering the Data Leak, about the nature of the Data Leak, the possible impact of the Data Leak on the Providing Party, and/or the Data Subject(s), and also about measures Identifying Party has taken or will take in order to correct the security breach and/or limit its consequences; B. will immediately, at its own expense, take all measures to correct the shortcomings in security that resulted in the Data Leak and to limit its consequences; C. will work together with the Providing Party to investigate the cause of the Data Leak and take all measures that Providing Party deems necessary to prevent a similar incident; and D. will grant full cooperation in timely (within forty-eight (48) hours) and adequately informing the Dutch Data Protection Authority (‘Autoriteit Persoonsgegevens’) and, if necessary, the Data Subjects (e.g., patients) within the framework of the obligation to report Data Leaks;

	Data Protection Officer of the Coordinator can be reached at: E-mail: functionaris.gegevensbescherming@erasmusmc.nl
8. Safeguarding that employees who have access to Personal Data are instructed by a binding agreement (in accordance with Article 32 lid 4 GDPR), to process the Personal Data in conformity with the instructions of de Controllers to the Personal Data, including observing the duty of confidentiality with regard to the Personal Data.	All personnel involved in registering and processing the Data are registered as such in the delegation log form per Partner. The Partner is responsible for the accuracy of the log form, which is kept in the local trial master file by the local investigator. Partner and Coordinator will safeguard that employees who have access to Personal Data are instructed by a binding agreement in accordance with Article 32 lid 4 GDPR, to process the Personal Data in conformity with the instructions of the controllers to the Personal Data, including observing the duty of confidentiality with regard to the Personal Data.
9. Safeguarding that engaged (sub) Processors who have access to Personal Data are instructed by a binding agreement (data Processor agreement) to process the Personal Data in accordance with this Joint Data Registry Agreement (in accordance with article 28 of the GDPR), including among others the documented instruction of the Controllers to the Personal Data and all other GDPR requirements applicable to the Processor.	The Coordinator is responsible for the security level of the HVS Mitral and Tricuspid Valve Registry. The Coordinator will safeguard that engaged (sub) Processors who have access to Personal Data are instructed by a binding agreement (data Processor agreement) to process the Data in accordance with the requirements stated in article 28 of the GDPR, including among others the documented instruction of the Controllers to the Personal Data and all other GDPR requirements applicable to the Processor.
10. Safeguarding that: (1) regular monitoring takes place in order to assess if the processing of the Personal Data by the (sub) Processor is in compliance with the data Processor agreement entered into with the (sub) Processor; and (2) that breach of the data Processor agreement is addressed by appropriate measures.	The Coordinator together with the Core Leaders responsible for monitoring any sub-processors and following up on any breaches by the sub-processors.
11. Safeguarding that the transfer of Personal Data takes place in accordance with this Joint Data Registry Agreement(in accordance with transfer requirements of the GDPR).	The Coordinator, Researcher and other parties who might get access to the data of other parties are responsible for the safeguarding that the transfer of Personal Data takes place in accordance with the transfer requirements of this Joint Data Registry Agreement.

	A Partner may only transfer the Data outside the European Economic Area, provided that the following conditions are met 1) the Core Leaders has approved such transfer; 2) the Coordinator has put in place appropriate safeguards such as signing the Standard Contractual Clauses in accordance with decisions by the European Commission to safeguards such transfer (to the extent the importer is located in a country outside the EEA for which no adequacy decision is in place); 3) such Third parties are only allowed to process Data in accordance with the Joint Data Registry Agreement; 4) Coordinator will on request provide information about the Third party, where Data is transferred to, including copies of safeguards that is governing such transfer 5) Subjects have been adequately informed of such transfer; 6) only pseudonymized data will be shared and 7) the Partner will carry out a Data Transfer Impact Assessment (DTIA).
12. Safeguarding the compliance with the requirements regarding retention periods, destruction, return and/or migration of the Personal Data.	All source data will be kept for a period of 20 years after termination of the registry, as will be the eCRF's.
13. Safeguarding that a Privacy Impact Assessment (PIA) is executed prior to the collection, including obtaining and further processing of the Personal Data (Article 35 AVG).	A Registry wide DPIA has been performed in collaboration with the DPO of the Coordinator. Each Partner is separately responsible for compliance with the DPIA obligation, if so applicable.
14. Further agreements regarding privacy responsibilities.	If the arrangements in this matrix appear to be incomplete or incorrect, the parties shall amend this matrix so as to be compliant with this Joint Data Registry Agreement.

APPENDIX E: MODEL ACCESSION FORM

Accession of a Party to the HVS Mitral and Tricuspid Valve Registry

Version 1.0 Joint Data Registry Agreement HVS Mitral and Tricuspid Valve Registry (12-2024)

[**NAME INSTITUTE**], having its registered office and principal place of business at [ADDRESS INSTITUTE], lawfully represented by [NAME of the institute's authorized signatory], in her/his function as [FUNCTION OF THE INSTITUTE'S AUTHORIZED SIGNATORY], hereinafter referred to as "[**SHORT NAME INSTITUTE**]";

hereby consents to become a Party to the [name] Registry identified above and accepts all the rights and obligations of a Party starting [DATE].

Erasmsus MC, having its registered office and principal place of business in at Dr. Molewaterplein 40, 3015 GD Rotterdam, the Netherlands, legally represented by Kevin Veen, MD, PhD of the Coordinator's authorized signatory, hereinafter referred to as "**COORDINATOR"**

acting on behalf of the Core Leaders in accordance with Section 5 of the HVS Mitral and Tricuspid Joint Data Registry Agreement.

hereby certifies that the Core Leaders has accepted the accession of **[PARTY'S SHORT NAME]** to the HVS Mitral and Tricuspid Valve Registry.

Each Party agrees that this declaration of accession will be executed in electronic PDF format only and the Partner signing this declaration of accession explicitly acknowledges and agrees that its signature in such format shall be regarded as an original signature and that this declaration of accession shall be effective upon delivery by electronic mail to the Coordinator and thereafter shall be deemed an original signed agreement.

[insert name of the new Partner]

Signature(s)
Name(s)
Title(s)

[Date and Place]

Erasmus MC
Acting as Coordinator of the HVS Mitral and Tricuspid Valve Registry in accordance with the Joint Data Registry Agreement

Signature:

Name: Kevin M. Veen, MD, PhD

Title: Heart Valve Society (HVS) Valve Research Network Coordinator

[Date and Place]

APPENDIX F: MAIL OF APPROVAL FORMAT

Dear Investigator,

The Scientific Committee (SC) of the HVS Mitral and Tricuspid Valve Registry has received in good order the study proposal [NAME PROJECT] you submitted to it. The proposal was subsequently discussed between the SC members.

The Scientific Committee considered the following documents in its review:

- Study Proposal version [VERSION], dated [DATE].

The Scientific Committee of the HVS Mitral and Tricuspid Valve Registry has determined that the study falls within the Main Objectives as stated in the 'HVS Mitral and Tricuspid Valve Joint Data Registry Agreement' which justifies the release of data for the execution of the aforementioned Study proposal.

Please note: The Data will not be made available until you have sent a confirmation email accepting the terms of use.

The Scientific Committee reminds you of your duties with respect to the Data. You are expected to:

(a) use the Data in accordance with the GDPR and other applicable laws and regulations. You are fully responsible for this.

b) to make no attempt to trace the identity of the patients.

(c) Use the Data only for the approved Study Proposal. In the event of deviations or changes to the study proposal, the SC has the right, in its sole discretion, to terminate access to the Database without liability.

(d) not disclose or provide access to the Data to any third party without the prior written consent of the Scientific Committee. In the event that you send data to a non-HVS Mitral and Tricuspid Valve Registry party for the purposes of an approved study proposal, you must enter into a contract with that party.

(e) report on a regular basis the progress and results of the study to the Coordinator.

(f) publish scientifically in accordance with the provisions of the HVS Mitral and Tricuspid Valve Registry Joint Data Registry Agreement.

(g) immediately report any data breach if it still occurs despite all the necessary safeguards.

On behalf of the Scientific Committee of the HVS Mitral and Tricuspid Valve Registry, I wish you luck with your research project.

Sincerely,

On behalf of the Scientific Committee,

Donna de Geest, MSc, database manager HVS Mitral and Tricuspid Valve Registry

APPENDIX G: FINANCIAL ARRANGEMENTS

The HVS Mitral and Tricuspid Valve Registry is supported by The Heart Valve Society, an organization dedicated to advancing the science and practice of heart valve care. The Society's headquarters are located at 500 Cummings Center, Suite 4400, Beverly, Massachusetts 01915, USA. The responsibility of securing financial support for the registry's coordination falls jointly upon the Heart Valve Society Board and the Core Leaders. These entities work collaboratively to identify and secure funding sources to ensure the efficient operation of the registry.

The financial support for the HVS Mitral and Tricuspid Valve Registry may come from various sources. Potential funding channels include, but are not limited to, research grants from the healthcare industry, charitable donations from individuals or organizations, and in-kind contributions from partners involved in the project. These contributions are essential to ensuring the proper functioning of the registry, which plays a critical role in collecting and analyzing data related to mitral and tricuspid valve procedures and patient outcomes.

Allocation of Funds

The funds obtained for the registry are used specifically for the coordination and management of the HVS Mitral and Tricuspid Valve Registry. This involves the organization of data collection, maintenance of the database, coordinating meetings of the Scientific Committee/Core Leaders, and overseeing the accuracy and quality of the information gathered. Currently, partner institutions or individuals who contribute data to the registry do not receive financial compensation for their efforts. The Core Leaders and HVS Board of Directors are jointly responsible for the allocation of funds.

Exploration of New Funding Opportunities

Should the Heart Valve Society engage with a third-party organization to secure additional funding for the coordination of the registry, all partners associated with the registry will be informed promptly. This communication will be sent via email to ensure transparency and maintain the integrity of the partnership. The involvement of third parties could open new avenues for funding, which might further enhance the registry's capabilities and ensure its long-term sustainability

APPENDIX H: DECLARATION OF ACCEPTANCE

Declaration of acceptance by the Coordinating Partner of the Joint Data Registry Agreement of the "HVS Mitral and Tricuspid Valve Registry "

Erasmus MC, having its registered office and principal place of business at Dr. Molewaterplein 40, 3015 GD Rotterdam, legally represented by Dr. ir. P.A.M. Boomkamp**, hereinafter referred to as "COORDINATOR"**

hereby accepts all the rights and obligations stated in the aforementioned Agreement effective 28-09-2024

This Declaration of Acceptance has been executed in 2 originals, duly signed by the undersigned authorized representative.

Erasmus MC
Signature(s)

Name(s) legal representative: Dr. ir. P.A.M. Boomkamp
Title(s)
MD, PhD

[Date and Place] Rotterdam, 10/1/2025

APPENDIX I: STANDARD CONTRACTUAL CLAUSES

EU STANDARD CONTRACTUAL CLAUSES vs. 4 June 2021 (MODULE ONE: Transfer controller to controller)

SECTION I

Clause 1

Purpose and scope

(a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (1) for the transfer of personal data to a third country.

(b) The Parties:

(i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter 'entity/ies') transferring the personal data, as listed in Annex I.A (hereinafter each 'data exporter'), and

(ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A (hereinafter each 'data importer')

have agreed to these standard contractual clauses (hereinafter: 'Clauses').

(c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.

(d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

Clause 2

Effect and invariability of the Clauses

(a) These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46(2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.

(b) These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

Clause 3

Third-party beneficiaries

(a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:

(i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;

(ii) Clause 8 – Clause 8.5 (e) and Clause 8.9(b);

(iii) Clause 9 – N.A.;

(iv) Clause 12 – Clause 12(a) and (d);;

(v) Clause 13;

(vi) Clause 15.1(c), (d) and (e);

(vii) Clause 16(e);

(viii) Clause 18 –Clause 18(a) and (b);

(b) Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

Clause 4

Interpretation

(a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.

(b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.

(c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

Clause 5

Hierarchy

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

Clause 6

Description of the transfer(s)

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

Clause 7 – Optional

Docking clause

(a) An entity that is not a Party to these Clauses may, with the agreement of the Parties, accede to

these Clauses at any time, either as a data exporter or as a data importer, by completing the Appendix and signing Annex I.A.

(b) Once it has completed the Appendix and signed Annex I.A, the acceding entity shall become a Party to these Clauses and have the rights and obligations of a data exporter or data importer in accordance with its designation in Annex I.A.

(c) The acceding entity shall have no rights or obligations arising under these Clauses from the period prior to becoming a Party.

SECTION II – OBLIGATIONS OF THE PARTIES

Clause 8

Data protection safeguards

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

8.1 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B. It may only process the personal data for another purpose:

(i) where it has obtained the data subject's prior consent;

(ii) where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or

(iii) where necessary in order to protect the vital interests of the data subject or of another natural person.

8.2 Transparency

(a) In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:

(i) of its identity and contact details;

(ii) of the categories of personal data processed;

(iii) of the right to obtain a copy of these Clauses;

(iv) where it intends to onward transfer the personal data to any third party/ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.

(b) Paragraph (a) shall not apply where the data subject already has the information, including when such information has already been provided by the data exporter, or providing the information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.

(c) On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business

secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.

(d) Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

8.3 Accuracy and data minimisation

(a) Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.

(b) If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become outdated, it shall inform the other Party without undue delay.

(c) The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

8.4 Storage limitation

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation (2) of the data and all back-ups at the end of the retention period.

8.5 Security of processing

(a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter 'personal data breach'). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.

(b) The Parties have agreed on the technical and organisational measures set out in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.

(c) The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

(d) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.

(e) In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.

(f) In case of a personal data breach that is likely to result in a high risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.

(g) The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

8.6 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter 'sensitive data'), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional restrictions with respect to further disclosure.

8.7 Onward transfers

The data importer shall not disclose the personal data to a third party located outside the European Union (3) (in the same country as the data importer or in another third country, hereinafter 'onward transfer') unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

(i) it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;

(ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;

(iii) the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;

(iv) it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;

(v) it is necessary in order to protect the vital interests of the data subject or of another natural person; or

(vi) where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible risks of such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.8 Processing under the authority of the data importer

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

8.9 Documentation and compliance

(a) Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.

(b) The data importer shall make such documentation available to the competent supervisory authority on request.

Clause 9

Use of sub-processors

N.A.

Clause 10

Data subject rights

(a) The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest within one month of the receipt of the enquiry or request. (10) The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.

(b) In particular, upon request by the data subject the data importer shall, free of charge:

(i) provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing

meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);

(ii) rectify inaccurate or incomplete data concerning the data subject;

(iii) erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.

(c) Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.

(d) The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter 'automated decision'), which would produce legal effects concerning the data subject or similarly significantly affect him/her, unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lays down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary in cooperation with the data exporter:

(i) inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and

(ii) implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being.

(e) Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.

(f) The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.

(g) If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.

Clause 11

Redress

(a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.

[OPTION: The data importer agrees that data subjects may also lodge a complaint with an independent dispute resolution body [11] at no cost to the data subject. It shall inform the data subjects, in the manner set out in paragraph (a), of such redress mechanism and that they are not required to use it, or follow a particular sequence in seeking redress.]

(b) In case of a dispute between a data subject and one of the Parties as regards compliance with

these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.

(c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:

(i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;

(ii) refer the dispute to the competent courts within the meaning of Clause 18.

(d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.

(e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.

(f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

Clause 12

Liability

(a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.

(b) Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.

(c) Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.

(d) The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.

(e) The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

Clause 13

Supervision

(a) [Where the data exporter is established in an EU Member State:] The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.

[Where the data exporter is not established in an EU Member State, but falls within the territorial

scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) and has appointed a representative pursuant to Article 27(1) of Regulation (EU) 2016/679:] The supervisory authority of the Member State in which the representative within the meaning of Article 27(1) of Regulation (EU) 2016/679 is established, as indicated in Annex I.C, shall act as competent supervisory authority.

[Where the data exporter is not established in an EU Member State, but falls within the territorial scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) without however having to appoint a representative pursuant to Article 27(2) of Regulation (EU) 2016/679:] The supervisory authority of one of the Member States in which the data subjects whose personal data is transferred under these Clauses in relation to the offering of goods or services to them, or whose behaviour is monitored, are located, as indicated in Annex I.C, shall act as competent supervisory authority.

(b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES

Clause 14

Local laws and practices affecting compliance with the Clauses

(a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.

(b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:

(i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;

(ii) the laws and practices of the third country of destination– including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards (12);

(iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.

(c) The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.

(d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.

(e) The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a). [For Module Three: The data exporter shall forward the notification to the controller.]

(f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation [for Module Three:, if appropriate in consultation with the controller]. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by [for Module Three: the controller or] the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

Clause 15

Obligations of the data importer in case of access by public authorities

15.1 Notification

(a) The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:

(i) receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or

(ii) becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.

(b) If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.

(c) Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).

(d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.

(e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

15.2 Review of legality and data minimisation

(a) The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).

(b) The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request.

(c) The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

SECTION IV – FINAL PROVISIONS

Clause 16

Non-compliance with the Clauses and termination

(a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.

(b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until

compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).

(c) The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:

(i) the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;

(ii) the data importer is in substantial or persistent breach of these Clauses; or

(iii) the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.

In these cases, it shall inform the competent supervisory authority of such non-compliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise.

(d) Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data. The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.

(e) Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

Clause 17

Governing law

OPTION 1: These Clauses shall be governed by the law of one of the EU Member States, provided such law allows for third-party beneficiary rights. The Parties agree that this shall be the law of The Netherlands.

Clause 18

Choice of forum and jurisdiction

(a) Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.

(b) The Parties agree that those shall be the courts of[fill in country].

(c) A data subject may also bring legal proceedings against the data exporter and/or data importer

before the courts of the Member State in which he/she has his/her habitual residence.

(d)The Parties agree to submit themselves to the jurisdiction of such courts.

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(1) Where the data exporter is a processor subject to Regulation (EU) 2016/679 acting on behalf of a Union institution or body as controller, reliance on these Clauses when engaging another processor (sub-processing) not subject to Regulation (EU) 2016/679 also ensures compliance with Article 29(4) of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39), to the extent these Clauses and the data protection obligations as set out in the contract or other legal act between the controller and the processor pursuant to Article 29(3) of Regulation (EU) 2018/1725 are aligned. This will in particular be the case where the controller and processor rely on the standard contractual clauses included in Decision 2021/915.

(2) This requires rendering the data anonymous in such a way that the individual is no longer identifiable by anyone, in line with recital 26 of Regulation (EU) 2016/679, and that this process is irreversible.

(3) The Agreement on the European Economic Area (EEA Agreement) provides for the extension of the European Union's internal market to the three EEA States Iceland, Liechtenstein and Norway. The Union data protection legislation, including Regulation (EU) 2016/679, is covered by the EEA Agreement and has been incorporated into Annex XI thereto. Therefore, any disclosure by the data importer to a third party located in the EEA does not qualify as an onward transfer for the purpose of these Clauses.

(4) The Agreement on the European Economic Area (EEA Agreement) provides for the extension of the European Union's internal market to the three EEA States Iceland, Liechtenstein and Norway. The Union data protection legislation, including Regulation (EU) 2016/679, is covered by the EEA Agreement and has been incorporated into Annex XI thereto. Therefore, any disclosure by the data importer to a third party located in the EEA does not qualify as an onward transfer for the purpose of these Clauses.

(5) See Article 28(4) of Regulation (EU) 2016/679 and, where the controller is an EU institution or body, Article 29(4) of Regulation (EU) 2018/1725.

(6) The Agreement on the European Economic Area (EEA Agreement) provides for the extension of the European Union's internal market to the three EEA States Iceland, Liechtenstein and Norway. The Union data protection legislation, including Regulation (EU) 2016/679, is covered by the EEA Agreement and has been incorporated into Annex XI thereto. Therefore, any disclosure by the data importer to a third party located in the EEA does not qualify as an onward transfer for the purposes of these Clauses.

(7) This includes whether the transfer and further processing involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences.

(8) This requirement may be satisfied by the sub-processor acceding to these Clauses under the appropriate Module, in accordance with Clause 7.

(9) This requirement may be satisfied by the sub-processor acceding to these Clauses under the appropriate Module, in accordance with Clause 7.

(10) That period may be extended by a maximum of two more months, to the extent necessary taking into account the complexity and number of requests. The data importer shall duly and promptly inform the data subject of any such extension.

(11) The data importer may offer independent dispute resolution through an arbitration body only if it is established in a country that has ratified the New York Convention on Enforcement of Arbitration Awards.

(12) As regards the impact of such laws and practices on compliance with these Clauses, different elements may be considered as part of an overall assessment. Such elements may include relevant and documented practical experience with prior instances of requests for disclosure from public authorities, or the absence of such requests, covering a sufficiently representative time-frame. This refers in particular to internal records or other documentation, drawn up on a continuous basis in accordance with due diligence and certified at senior management level, provided that this information can be lawfully shared with third parties. Where this practical experience is relied upon to conclude that the data importer will not be prevented from complying with these Clauses, it needs to be supported by other relevant, objective elements, and it is for the Parties to consider carefully whether these elements together carry sufficient weight, in terms of their reliability and representativeness, to support this conclusion. In particular, the Parties have to take into account whether their practical experience is corroborated and not contradicted by publicly available or otherwise accessible, reliable information on the existence or absence of requests within the same sector and/or the application of the law in practice, such as case law and

reports by independent oversight bodies.

APPENDIX

EXPLANATORY NOTE:

It must be possible to clearly distinguish the information applicable to each transfer or category of transfers and, in this regard, to determine the respective role(s) of the Parties as data exporter(s) and/or data importer(s). This does not necessarily require completing and signing separate appendices for each transfer/category of transfers and/or contractual relationship, where this transparency can achieved through one appendix. However, where necessary to ensure sufficient clarity, separate appendices should be used.

ANNEX I

A. LIST OF PARTIES

Data exporter(s): [*Identity and contact details of the data exporter(s) and, where applicable, of its/their data protection officer and/or representative in the European Union]*

1. Name: …
   Address: …
   Contact person's name, position and contact details: …
   Activities relevant to the data transferred under these Clauses: …
   Signature and date: …
   Role (controller/processor): …
2. …

Data importer(s): [*Identity and contact details of the data importer(s), including any contact person with responsibility for data protection]*

1. Name: …
   Address: …
   Contact person's name, position and contact details: …
   Activities relevant to the data transferred under these Clauses: …
   Signature and date: …
2. Role (controller/processor): ……

B. DESCRIPTION OF TRANSFER

Categories of data subjects whose personal data is transferred

...

Categories of personal data transferred

...

Sensitive data transferred (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.

...

The frequency of the transfer (e.g. whether the data is transferred on a one-off or continuous basis).

...

Nature of the processing

...

Purpose(s) of the data transfer and further processing

...

The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period

...

For transfers to (sub-)processors, also specify subject matter, nature and duration of the processing

...

C. COMPETENT SUPERVISORY AUTHORITY

Identify the competent supervisory authority/ies in accordance with Clause 13

ANNEX II

TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA

MODULE ONE: Transfer controller to controller

EXPLANATORY NOTE:

The technical and organisational measures must be described in specific (and not generic) terms. See also the general comment on the first page of the Appendix, in particular on the need to clearly indicate which measures apply to each transfer/set of transfers.

Description of the technical and organisational measures implemented by the data importer(s) (including any relevant certifications) to ensure an appropriate level of security, taking into account the nature, scope, context and purpose of the processing, and the risks for the rights and freedoms of natural persons.

[Examples of possible measures:

- *Measures of pseudonymisation and encryption of personal data*
- *Measures for ensuring ongoing confidentiality, integrity, availability and resilience of processing systems and services*
- *Measures for ensuring the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident*
- *Processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures in order to ensure the security of the processing*
- *Measures for user identification and authorisation*
- *Measures for the protection of data during transmission*
- *Measures for the protection of data during storage*
- *Measures for ensuring physical security of locations at which personal data are processed*
- *Measures for ensuring events logging*
- *Measures for ensuring system configuration, including default configuration*
- *Measures for internal IT and IT security governance and management*
- *Measures for certification/assurance of processes and products*
- *Measures for ensuring data minimisation*
- *Measures for ensuring data quality*
- *Measures for ensuring limited data retention*
- *Measures for ensuring accountability*
- *Measures for allowing data portability and ensuring erasure]*

For transfers to (sub-) processors, also describe the specific technical and organisational measures to be taken by the (sub-) processor to be able to provide assistance to the controller and, for transfers from a processor to a sub-processor, to the data exporter

Transport

Access and storageTechnical measures.
The technical measures include:

Organizational measures
The organizational measures include:

Other measures:

ANNEX III

LIST OF SUB-PROCESSORS