

DATA SHARING AGREEMENT

between

UNIVERSITY OF SHEFFIELD

and

SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST

and

PRECISION CARDIOVASCULAR
LTD

Data Sharing Agreement (anonymized data) Sponsor
Ref: STH 14169
Recipient Ref: Study 051
Provider Ref: DAT/0678

DATA SHARING AGREEMENT (GENERAL)

between

University of Sheffield, a charitable body registered in England under registration number RC000667 incorporated under Royal Charter and having its main administrative offices at Firth Court, Western Bank, Sheffield S10 2TN, United Kingdom (the "Provider Institution")

and

Precision Cardiovascular Ltd, having its registered and postal address at Greenham Business Park, 2 Communications Road, Thatcham RG19 6AB and its operational address at The Magdi Yacoub Institute, Harefield Hospital, Harefield, Uxbridge UB9 6JH ("Recipient Institution")

And

Sheffield Teaching Hospitals NHS Foundation Trust with Trust Headquarters at 8 Beech Hill Road, Sheffield, S10 2SB ("Sponsor")

hereinafter referred to as "the Parties" and each of them being "a Party"

BACKGROUND

- (A) The Recipient Institution is conducting a research project entitled "**Addition of Continuous Cardiac Output measurements to improve care of patients with pulmonary hypertension chronic cardiac conditions.**" as detailed at Schedule 1 (the "Research") under the direction of Chris McLeod, Josh Purchase and Rafael Cordero Alvarez ("the Recipient Scientists").
- (B) The Recipient Institution wishes to access and use the data specified in Schedule 2 (the "Data") for the purpose of the Research.
- (C) The Sponsor is the legal person who determines the purposes and means of processing of the Data, specified in Schedule 2, and is the proprietor of this Data, as Sponsor and Data Controller to the original project.
- (D) The Sponsor wishes to instruct the Provider Institution as Data Processors, to carry out the anonymisation and transfer of the Data in relation to the Research specified in Schedule 1.
- (E) The Provider Institution is willing to supply the Data to the Recipient Institution and the Recipient Institution is willing to receive, use, store and dispose of the Data in accordance with the terms and conditions contained within this agreement (the "Agreement").

TERMS AND CONDITIONS

It is hereby agreed as follows:

1. In this Agreement:
 - (a) the term "Data" means fully anonymized datasets;
 - (b) the term "Research" includes the results and publication (if any) of the results of the Research by the Recipient Institution in accordance with clause 12.
 - (c) "personal data", "Data Controller", "Data Processor" have the meanings given to them in the Data protection Laws, as specified in clause 8.

2. In consideration of the obligations accepted by the Recipient Institution under this Agreement, the Provider Institution and Sponsor grants to the Recipient Institution for the term of this Agreement set out in clause 16 a non-exclusive, personal and non-transferable license to use the Data for the Research. The Provider Institution shall use reasonable endeavours to ensure that it does not share or provide access to any Data under this license (a) in breach of any legal or contractual obligation or restriction that it is subject to or (b) contrary to its Institutional Review Board (IRB) approval.
3. The Recipient Institution undertakes to the Provider Institution and Sponsor:
 - (a) to use the Data solely for the Research;
 - (b) to restrict access to the Data to the Recipient Scientists and those staff and students comprising the Recipient Scientist's research team, and to ensure that those staff and students are aware of and comply with the terms of this Agreement;
 - (c) to keep the Data confidential and not sub-license, transfer, disclose or otherwise make available the Data in whole or part to any third party, except as permitted by this Agreement, without specific prior written consent from the Provider Institution and Sponsor;
 - (d) to keep the Data secure by implementing organisational and technological measures appropriate to the nature and sensitivity of the data to prevent the unauthorised or accidental access, use or disclosure of the Data, including (without limitation) the measures set out in clause 5;
 - (e) to notify the Provider Institution and Sponsor as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the Data, and to reasonably co-operate with any investigation made by the Provider Institution and/or Sponsor in connection with the unauthorised or accidental access, use or disclosure of the Data; and
 - (f) to delete all copies of the Data from its hard drives and movable media and destroy all physical copies of the Data as soon as reasonably practicable on completion of the Research or on termination of this Agreement (if earlier) except to the extent the Recipient Institution is required by law to store the Data and for the purposes of research integrity and verification. This obligation does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of the Recipient Institution's information systems procedures, provided that the Recipient Institution makes no further use of those copies.
4. Where anonymised data is transferred to the Recipient Institution under this Agreement, no effort will be made to de-anonymise the data set; no attempt will be made to learn the identify of, or other identifying information about the patients who provided data and no effort will be made to re-identify data that are de-identified.
5. In particular (and without limiting the generality of the preceding wording) the Recipient Institution shall not make physical or electronic copies of the Data except to the extent reasonably necessary for the Research and shall ensure that, if applicable, any copy of the Data stored on movable media (including laptops) is password-protected and that any copy of the Data stored on networked or non-networked hard drives is properly protected with firewall and controlled access permissions.
6. The Data is supplied by the Provider Institution in pseudonymised form without the pseudonymisation key or other means for the Recipient Institution to re-identify individuals

from the Data. The Parties anticipate that the Data is likely to be personal data in respect of the Provider Institution's processing but not likely to be personal data in respect of the Recipient Institution's processing, but that this is a question of fact determined by the nature of the Data, the arrangements between the Parties, and any other means available to the Recipient Institution (whether publicly available or otherwise) to re-identify individuals from the Data. In the event that the Data is or becomes personal data when held or processed by the Recipient Institution, the Recipient Institution shall notify the Provider Institution and the Sponsor immediately and shall comply with any reasonable instructions of the Provider Institution and/or Sponsor. The Parties agree that further terms will be agreed in relation to such personal data where appropriate.

7. Except to the extent prohibited by law, the Recipient Institution assumes all direct liability for damages which may arise from its receipt, use, storage or disposal of the Data. The Provider Institution will not be liable to the Recipient Institution for any use made of the Data, including any loss, claim or demand made by the Recipient Institution or made against the Recipient Institution by a third party, due to or arising from the use, storage or destruction of the Data by the Recipient Institution, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the Provider Institution.
8. The Provider Institution shall use all reasonable endeavours to ensure that the Data transferred to the Recipient Institution under this Agreement are fully anonymized under the Data Protection Act 2018, Directive 95/46/EU and the General Data Protection 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, as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 ("UK GDPR").
9. The Provider Institution warrants that it has complied with applicable law and where required has secured all necessary approvals from the appropriate regulatory bodies, including ethical approval from a competent national or local ethics committee before the collection and/or use of the Data as intended under this Agreement. With the exception of the foregoing, the Provider Institution provides the Data 'as is' and makes no representation and gives no warranty of any kind, either express or implied, including but not limited to warranties of accuracy or fitness for a particular purpose, or that the use of the Data will not infringe any patent, copyright, trademark or other proprietary rights. The Provider Institution will not be liable to the Recipient Institution for any loss, damage, claim or liability arising from any reliance placed on the Data by the Recipient Institution.
10. Nothing in this Agreement limits or excludes a Party's liability for (a) death or personal injury resulting from negligence; or (b) any fraud or for any sort of other liability which, by law, cannot be limited or excluded.
11. The liability of any Party for any breach of this Agreement or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business, or profit, or to any indirect or consequential damages or losses.
12. The Data is provided, and the Research is undertaken in pursuit of the primary charitable objectives of the Parties; that is the advancement of education through research and teaching. The Sponsor acknowledges that the results of the Research shall belong to the Recipient Institution (except that the Sponsor retains ownership of the Data to the extent incorporated or included within the results) and that the Recipient Institution may seek to publish the results of the Research. The Recipient Institution shall procure that in relation to any publication reporting on the results of the Research, the Recipient Scientist acknowledges the Provider Institution and/or Sponsor as the source of the Data in the publication. If the Provider Institution and/or Sponsor requests, the Recipient Institution shall

provide a copy of such publication to the Provider Institution and Sponsor thirty (30) days in advance of submission for publication. The Provider Institution and Sponsor agrees not to disclose any results contained in such advance copy to any third party until published by the Recipient Institution. The Recipient Institution shall not publish any confidential or proprietary information belonging to the Provider Institution and Sponsor without its prior written consent, including the Data in whole or in part. Confidential and proprietary information shall be deemed to include information which was marked as either "confidential" or "proprietary", or was described as such at the point of disclosure and confirmed as such in writing within fifteen (15) days of disclosure. The confidentiality obligations in this clause shall not apply where the confidential or proprietary information:

- a) has become public knowledge, other than through an unauthorised disclosure by the Recipient Institution;
 - b) was already known to the Recipient Institution, prior to disclosure by the Provider Institution;
 - c) was disclosed to the Recipient Institution or the Recipient Scientists by a third party, whom to the Recipient Institution's knowledge, was not under any obligation of confidence to the Provider Institution;
 - d) was released from confidential status by written authorisation of the Provider Institution and/or Sponsor as applicable; or
 - e) is required to be disclosed by law or by requirement of a regulatory body or court order.
13. Nothing in this Agreement grants the Recipient Institution any rights over the Data or under any patents, nor any right to use, or permit the use of, any products or processes containing the Data for any profit-making or commercial purposes ("Commercial Use"). Should the Recipient Institution wish to make Commercial Use of the Data and should the Provider Institution and Sponsor be willing and able to grant a license for such purposes, the Parties shall negotiate in good faith to agree an appropriate license or revenue sharing agreement on fair and reasonable terms.
14. Nothing in this Agreement shall prevent or impede the Provider Institution from being able to use the Data for any purpose, including but not limited to sharing and licensing of the Data to third parties, whether public, private or third sector, for any purpose.
15. The rights and obligations of the Parties are personal and may not be assigned at any time without the prior written consent of the other Parties which consent shall not be unreasonably withheld; provided that it shall be a requirement in all cases of assignation that the assignee undertakes to perform all outstanding obligations of the assignor as though the assignee had been an original party hereto.
16. This Agreement shall be effective from the date of last signature and shall continue in force until five (5) years from the effective date. The term of this Agreement may be extended by the mutual written agreement of the Parties signed by their authorised signatories in order to fully perform the Research.
17. The Provider Institution and/or Sponsor may terminate this Agreement if the Recipient Institution is in breach of any of the terms of this Agreement and, where the breach is capable of remedy, the Recipient Institution has failed to remedy the same within twenty-eight (28) calendar days of service of a written notice from the Provider Institution and/or Sponsor specifying the breach and requiring it to be remedied.
18. Any provision of this Agreement that expressly or by implication is intended to come into or continue in force on or after termination of this Agreement, including the Recipient Institution's obligations under sub-clause 3(f), shall remain in full force and effect.

20. The Data is provided subject to the Recipient Institution paying the Sponsor an administrative fee of £3,000. Please refer to schedule 3.
21. The Parties shall procure that in carrying out their obligations under this Agreement, they will comply with all applicable laws, regulations and statutes, including those relating to modern slavery and anti-bribery and the Data Protection Laws. Non-compliance with this clause by a Party shall not be sufficient justification for another Party not to comply with its obligations under this Agreement.
22. A person who is not a party to this Agreement shall not have any rights under or in connection with it.
23. Notices

The Provider Institution's representative for the purpose of receiving notices shall until further notice be:

Director of Research,
Partnerships and Innovation
University of Sheffield
Level 4, Arts Tower
Western Bank
Sheffield S10 2TN
Email: ri-contracts@sheffield.ac.uk
Quoting Ref : DAT/0678

The Recipient Institution's representative for the purpose of receiving notices shall until further notice be:

Precision Cardiovascular (Rafael Cordero Alvarez), 2 Communications Road, Greenham
Business Park, Greenham, Thatcham, RG19 6AB

The Sponsor Institution's representative for the purpose of receiving notices shall until further notice be:

Clinical Research Director
Director of R&D
Clinical Research & Innovation Office
Royal Hallamshire Hospital
Glossop Road, S10 2JF
Email: Sth.researchadministration@nhs.net

24. This Agreement constitutes the entire agreement between the Parties in respect of its subject matter and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement.
25. This Agreement shall be governed and construed in accordance with the laws of England and Wales and the Parties agree to the exclusive jurisdiction of the English Courts.
26. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by e-mailed portable document format file or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

IN WITNESS WHEREOF this Agreement is executed as follows:

For and on behalf of University of Sheffield

Signed:
Signed by: *Kirsty Lindley*
2DE5B3B5E0EB445...
Print Name:.....
Kirsty Lindley

Date:.....
03/12/2025

Job Title:.....
Head of Research Operations

For and on behalf of the Sheffield Teaching Hospitals NHS Foundation Trust

Signed:
DocuSigned by: *Dipak Patel*
2580F085A387484...
Print Name:.....
Dipak Patel

Date:.....
28/11/2025

Job Title:.....
Associate Director Research & Innovation

For and on behalf of Precision Cardiovascular Ltd

Signed:
Signed by: *Mohamed Abou-Alam*
70B97BB6B34E464...
Print Name: Mohamed Abou-Alam

Date:.....
27/11/2025

Job Title: CEO

I, **Rafael Cordero Alvarez**, the Recipient Scientist, have read and understood the terms of this Agreement:

Signed:
Signed by: *Rafael Cordero Alvarez*
3B636D7186AD407...
Print Name: Rafael Cordero Alvarez

Date:.....
28/11/2025

Job Title: Head of Data Science

Schedule 1

The Research

The following application was made to the ASPIRE research database REC ref 22/EE/0011 and was approved by the Data Management Committee. The ASPIRE study reference is study 051, Chris McLeod. The Investigators also signed a copy of the ASPIRE terms and conditions for data usage.

Relevant documents are enclosed:



Application to ASPIRE (Study 051) – STH14169 Study
51_ASPIRE Registry /



Signed agreement for data use and disposal - STH14169 ASPIRE
Registry Agreement fr



ASPIRE outcome letter - STH14169 ASPIRE
Registry application o

Schedule 2

The Data

This project aims to use human clinical data from the ASPIRE registry to develop and validate algorithms for the estimation of cardiac output (CO) using the Pulmonary Artery Pressure (PAP) waveform, to improve early detection of clinical deterioration in heart failure patients.

The analysis will extract and characterise PAP waveform features in heart failure populations, establish their physiological ranges in diseased states, and correlate these with reference CO values to enable the development of a robust and accurate CO estimation model. This will inform the development of cardiac monitoring algorithms and support the performance verification of cardiac output estimation methods.

Data to be provided: Demographics, PAP measurements, CO values, hospitalisation records (presentation, visit duration, outcome).

The Provider Institution will fully anonymise the above Data prior to transferring to the Recipient Institution.

Justification: To correlate PAP/CO trends with hospitalisation events and establish reference ranges for algorithm development and validation.

Schedule 3

Financial Arrangements

	Area of Cost	Payment (£ Sterling)
1.	Administrative Fee	£3,000

Schedule of payments and details of payment arrangements

Payment to be made by cheque payable to:

Sheffield Teaching Hospitals NHS Foundation Trust

and remitted to:

Ian Brown, Research Accountant

Sheffield Teaching Hospitals NHS FT, Finance Department, Clock Tower, Northern General Hospital, Sheffield, S5 7AY

STH.Finance-Research@nhs.net

Or arrange BACS Transfer to: NatWest Bank PLC

Sort code: 60-70-80

Account: 10004025

And send the relevant paperwork to Ian Brown at the above address, quoting reference: **STH14169 ASPIRE Study 051**

