

Data Management Plan

Project title: The role of an implantable Doppler vascular monitoring device in kidney transplant patients: a feasibility randomised controlled trial with an embedded qualitative study.

Chief investigator: Dr. M Shahzar Malik

Project start date: April 2022 **Project end date:** April 2024

Sponsor: R& D department, University Hospitals Plymouth NHS Trust

Funder: Renal Department, University Hospitals Plymouth NHS Trust

Legal Basis: Task in public interest

Data Controller: University Hospitals Plymouth NHS Trust

Data asset owner/ Stewart: Chief investigator (Dr. Shahzar Malik)

Data storage duration: 10 years

Any data storage offsite (except Derriford Hospital University Hospitals Plymouth NHS Trust): No

The overall (highest of all components) security classification level for this research study is

- 1: Restricted
 - 2: Confidential
 - 3: Standard
 - 4: Public (open)
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A data management plan for this study was prepared under the University of Plymouth's information governance Policy, the General Data Protection Regulation (GDPR-2018), and Good Clinical Practice (GCP). It consisted of a complete plan for data protection, retention, and erasure after 10 years.

During the data collection, patient information in fRCT and embedded qualitative study will be pseudonymised and kept strictly confidential by the CI using a unique study code, ensuring it does not contain any patient identifiers.

In the fRCT, the renal database (Vital Data) will be used for the information extraction and is password protected present only on the Trust intranet. The patient's medical notes will be accessed by the CI who is a member of the staff at UHPNT. The notes will not be removed from the premises of the record room. The quantitative data will be logged in the Microsoft spread sheet. In the embedded qualitative study the interviews will be audio-recorded and transcribed verbatim. The pseudonymised transcripts will be noted in the NVivo software.

After transcription of the data, the restriction of access to the Microsoft spread sheet and NVivo software will be maintained by encryption. All data protection measures will be undertaken to maintain the confidentiality of the participants. The official NHS email address will be used for the transfer of any pseudonymised information if required. Data processing and analysis will be performed in the Microsoft Excel worksheet, IBM SPSS version 25.0, and NVivo software. It will be stored in a password secured drive on the Trust intranet.

If there is a requirement to share data with the University of Plymouth, the anonymised data file will be exported to the One Drive account of the CI (data asset steward) under the University of Plymouth license, once a data sharing agreement has been put in place.

Two copies of the duly signed written informed consent will be taken from the eligible participants. One copy will be attached in the patient's medical notes along with the routine consent for the kidney transplant surgery. The other copy will be given to the participant. The CI will scan the consent form and keep an electronic copy along with other research documents in a password secured drive on the Trust intranet.

The CI will be the custodian of the data and the R & D department UHP will be the data controller. There is no license or restrictions other than when the research is published. The study data will be backed up regularly with the R & D department UHP and this source will be used for data recovery in the event of a disaster.

In line with the R & D department UHP and University of Plymouth's policy, all data will be stored for 10 years. The essential study documents and data will archived in a password secured Trust drive in a dedicated archive area with very restricted access, on completion of the archive period all documents will be deleted. All the resources required to deliver the data management plan for this study are available.

Description of dataset	Level	Storage details (start date, end date and destruction method)	Justification	Storage location	Named persons with access to the data
Consent forms (fRCT and embedded qualitative study)	2	April 2022 – April 2024 plus secure storage for 10 years. Electronic file erasure will be under data asset owner and steward supervision	This involves consent forms of patients and participants involved in the research	Scanned documents will be stored in the password protected University Hospitals of Plymouth NHS Trust Secure Drive	As per R & D ethical committee policy UHP. It may be shared by the CI with the Steering group committee of the Renal department University Hospitals of Plymouth NHS Trust and the UoP.
Pseudonymised and Processed data in Microsoft Word and Excel Spread sheet analysed with descriptive and analytical statistics. Thematic analysis of qualitative data will be in NVivo software	3	April 2022 – April 2024 plus secure storage for 10 years. Electronic file erasure will be under data asset owner and steward supervision	This involves data not cleared for publication, like anonymised/ pseudonymised and processed data from research with human participants	Microsoft Word, Excel Spread sheet, and NVivo documents will be stored in the password protected University Hospitals Plymouth NHS Trust Secure Drive	As per R & D ethical committee policy UHP. It may be shared by the CI with the Steering group committee of the Renal department University Hospitals of Plymouth NHS Trust and the UoP
Ethical Committee Approval letter	3	April 2022 – April 2024 plus secure storage for 10 years. Electronic file erasure will be under data asset owner and steward supervision	This involves other associated research data and documentation with no value to external users	Word documents will be stored in the password protected University Hospitals Plymouth NHS Trust Secure Drive	As per R & D ethical committee policy UHP. It may be shared by the CI with the Steering group committee of the Renal department University Hospitals of Plymouth NHS Trust and the UoP.