

Prepare for Kidney Care

A research study comparing preparation for responsive management with preparation for renal dialysis

Data Protection Privacy Notice

1. The data controllers and how to contact them

North Bristol NHS Trust and the Bristol Trials Centre (University of Bristol) are joint data controllers for the Prepare for Kidney Care Study. Their contact information is as follows:

Research and Development, Southmead Hospital, North Bristol NHS Trust, Westbury-on-Trym, Bristol, BS10 5NB United Kingdom	Bristol Trials Centre (BTC) Bristol Medical School University of Bristol 1-5 Whiteladies Road Bristol, BS8 1NU United Kingdom
Tel: +44(0)117 414 9330	Tel: +44(0)117 455 1230
Email: ResearchSponsor@nbt.nhs.uk	Email: btc-mailbox@bristol.ac.uk

The University of Bristol is the data processor with the SAIL databank acting as a sub-processor.

2. The purposes of the processing

The Prepare for Kidney Care study is a clinical trial funded by the National Institute for Health Research, the research funding arm of the NHS.

The trial aims to compare length of life and quality of life of two pathways of care for managing chronic kidney disease, to which patients will be randomly allocated. In one pathway patients will have renal dialysis if their symptoms progress, and in the other they will have supportive treatment and care without dialysis.

Secondary aims of the study are to compare survival, days out of hospital, physical function, capability, quality of life, treatment burden, impact on carers, acceptability and cost of the two pathways.

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Alongside the main trial is a study in which patients choose the treatment they receive, rather than being randomly allocated to a treatment, and are followed up to allow comparison of length of life and quality of life with those in the main trial.

Data collected will not be used to create categories of participants (i.e., to profile participants). Other than allocation of the intervention under investigation (which participants have given informed consent to be allocated through randomisation), there will not be decision making based solely on automated means.

3. Data processing activities

For Prepare for Kidney Care participants, the University of Bristol will send a file containing identifiable data via Digital Health and Care Wales (DHCW) to the SAIL databank in Swansea for linkage to HES Outpatients, Critical Care, Admitted Patient Care (and the equivalent databases for other participating UK countries) and Mortality data. The identifying information shared may include system ID, NHS or CHI number, forename, surname, address, postcode, date of birth, and gender. No special category data, specifically no health data, will be sent from University of Bristol to SAIL.

Once the records of Prepare for Kidney Care participants have been identified by SAIL, all identifying data will be removed and a pseudonymised file containing the pseudonym study ID and health data will be stored on a secure database at SAIL for access by approved researchers.

The University of Bristol will store the identifying details of Prepare for Kidney Care participants linked with the pseudonym study ID in a separate database.

4. The lawful basis for the processing

As a University we use personally-identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

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The lawful basis for processing personal data for Prepare for Kidney Care is therefore Articles 6(1)(e) and 9(2)(j) of the General Data Protection Regulation (2018).

5. The categories of personal data obtained

Personal data such as identifying data and information about your social and medical history will be collected from a number of sources, including:

- A researcher will ask participants questions and complete some forms
- The participant will be asked to complete some questionnaires
- Clinical data that is routinely collected about the participant will be collected from other health and social care databases including: NHS England (Hospital Episode Statistics and Civil Registration) and UKHSA in England, Public Health Scotland Scotland, NHS Wales Informatics Service, the Department of Health Northern Ireland, the Office for National Statistics and the UK Renal Registry.

6. The recipients or categories of recipients of the personal data

Only the research team at the University of Bristol and essential staff at SAIL will have access to participants' personal identifiable data and clinical data. NHS and academic researchers at other organisations will be able to apply for access to pseudonymised clinical data. This will include researchers in third countries, so long as they meet information security and data protection standards. All such requests will be considered by and approved by the Prepare for Kidney Care trial management group.

7. The retention periods for the personal data

Personal data will be stored for up to 5 years after the end of the study. Participants are consenting for their trial data to be linked to Hospital Episode Statistics, Civil Registration Data and other health and social care databases for long term follow up during and beyond the end of the trial (for up to a further 5 years). This requires the retention of identifiable data for linkage. As for the clinical data, we have therefore proposed that personal data is held for up to 15 years. Data Sharing Agreements will remain in place with the organisations from whom participant information is collected for the full 15-year duration.

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8. The rights available to individuals in respect of the processing

The General Data Protection Regulation provides individuals with eight rights in respect of processing their personal data:

- i. **The right to be informed** – this provides individuals with the right to be informed about the collection and use of their personal data.
- ii. **The right of access** – this gives individuals the right to obtain a copy of their personal data as well as other supplementary information. It helps individuals to understand how and why you are using their data, and check you are doing it lawfully. In Prepare for Kidney Care, participants have the right to see or have a copy of their personal information at the BTC without any charge. If a participant wants to access their information at the BTC, they should make a written request to the BTC – see the section below on ‘Contacting the BTC’. We will normally provide their information within one month of receiving all the information we need to respond to their request.
- iii. **The right to rectification** – this gives individuals the right to have inaccurate personal data rectified, or completed if it is incomplete. In Prepare for Kidney Care, participants have the right to have their information amended. If a participant wants to amend their information at the BTC, they should make a written request to the BTC – see the section below on ‘Contacting the BTC’. We will normally be able to make these changes within one month of receiving all the information we need to respond to their request.
- iv. **The right to erasure** – also known as ‘the right to be forgotten’, this gives individuals the right to have personal data erased.
- v. **The right to restrict processing** – this gives individuals the right to request the restriction or suppression of their personal data.
- vi. **The right to data portability** – this allows individuals to obtain and reuse their personal data for their own purposes across different services
- vii. **The right to object** – this gives individuals the right to object to the processing of their personal data in certain circumstances.
- viii. **Rights in relation to automated decision making and profiling** – this gives individuals rights in relation to (a) automated individual decision-making (making a decision solely by automated means without any human involvement); and (b) profiling (automated processing of personal data to evaluate certain things about an individual).

For more details on these eight rights, see <https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/>

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9. The right to withdraw consent

Participants can withdraw consent for the data collected about them from any source to be used. If a participant wants to withdraw consent for their data at the BTC to be used for Prepare for Kidney Care they should contact their local Prepare for Kidney Care research nurse who will complete a 'change of permissions/ withdrawal' form and submit this to the BTC. If the participant is unsure how to contact their local Prepare for Kidney Care research nurse, they should contact the BTC (see Section 1: The data controllers and how to contact them).

10. The right to lodge a complaint with a supervisory authority

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer (see the section 'Contacting the University of Bristol Data Protection Officer') who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office.

Information Commissioner
Wycliffe house,
Water Lane
Wilmslow
Cheshire
SK9 5AF

Tel: 01625 545745

<https://ico.org.uk/>

11. Contacting the University of Bristol's data protection officer

Mr Henry Stuart,
Information Governance Manager and Data Protection Officer,
University Secretary's Office
University of Bristol
Beacon House
Queens Road
Bristol
BS8 1QU

Tel: +44(0)117 455 6325

Email: data-protection@bristol.ac.uk

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12. Changes to this notice

The data controllers listed within this agreement in Section 1 confirm that they will ensure that a GDPR compliant, publicly accessible transparency notice is maintained throughout the life of this agreement. If you are dissatisfied with any aspect of our privacy notice, please contact the data protection officer.