Data Privacy Notice

Version 1.2, 29-APR-2021

Keele University is committed to looking after your data. This ancillary privacy notice details the specific data processing activities which will be undertaken in relation to the **Bioimpedance Spectroscopy To maintain Renal Output (BISTRO)** trial.

The Trial is funded by the National Institute for Health Research, the research funding arm of the NHS.

The trial aims to test whether taking regular measurements with a bioimpedance device (a bedside measurement giving information about body composition, specifically how much excess fluid is present), improves outcomes for people who have newly started haemodialysis treatment for kidney failure.

1. **The purposes of the processing**

The **BioImpedance Spectroscopy To maintain Renal Output: the BISTRO Trial** is a randomised controlled trial funded by the National Institute for Health Research, the research funding arm of the NHS.

Most patients who develop kidney failure choose unit-based haemodialysis treatment. Dialysis removes waste products and excess fluid from the blood when the kidneys stop working properly. Haemodialysis involves diverting blood to a machine to be cleaned.

One of the main functions of dialysis is to control the amount of fluid in the body. Too much fluid can lead to raised blood pressure that damages the heart and increases the risk of stroke, and may cause fluid to collect in the lungs leading to breathing difficulties. Too little fluid causes dehydration, cramps and low blood pressure and more rapid or complete loss of any remaining kidney function. Bioimpedance is a simple, bedside measurement giving information about body composition, specifically how much excess fluid is present. Clinicians can use this to guide how much fluid should be removed from the body with the normal clinical assessment of the amount of fluid in the body, but it is not known if this results in better decisions and outcomes for patients.

This trial aims to test whether taking regular measurements with a bioimpedance device, which gives information about body composition, improves outcomes for people who have newly started haemodialysis treatment for kidney failure. In particular, the trial aims to see if this helps patients maintain their remaining kidney function, as this is associated with improved survival, fewer symptoms of kidney failure, fewer side effects of dialysis treatment and a better quality of life including confidence in managing their health, and cost benefit analysis.

People starting haemodialysis as an outpatient with some remaining kidney function will be invited to participate in a clinical trial that compares current best practice with the same but additionally guided by regular bioimpedance measurements. The study will intend to randomise 516 patients from about 30 dialysis units across the UK.
If you are deemed clinically suitable to participate in the BISTRO trial, for the purpose of this document you are defined as a trial participant.

Data collected will allow us to randomly allocate participants into two groups. Other than allocation of the intervention under investigation (which participants have given informed consent to be allocated through randomisation), there will be no decision making based solely on automated means.

2. 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.

The lawful basis for processing personal data for the BISTRO trial is therefore Articles 6(1)(e) and 9(2)(j) of the General Data Protection Regulation (2016).

2. A Categories of personal data to be processed

Name; NHS number or equivalent; date of birth

We will comply with data protection law.

We will only use your personal information when the law allows us to, as below:

Article 6(1)(e) - Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller. As a higher education establishment, the University conduct research to improve health care and services.

2. B Categories of sensitive personal data to be processed

Health data; Ethnicity

We will comply with data protection law.

This data is processed on the additional condition of: Article 9(2)(j) – Processing is necessary for archiving purposes in the public interest, scientific or historical research purposes.
3. How is your personal information collected?

Personal data will be collected from a number of sources. This will include identifiable data and information about your social and medical history.

The personal data to be processed is retrieved from research questionnaires completed by you and research data specific for the trial conduct, as well as, clinical data that is routinely collected by the NHS and stored in their health databases including; UK Renal Registry, Hospital Episode Statistic and the Office for National Statistics (and their equivalent bodies in Wales, Scotland and Northern Ireland).

4. How we will use information about you

The information will be used as part of the clinical trial that compares current best practice against best practice with the additional guidance of regular bioimpedance measurements. The study intends to consider 516 patients from about 30 dialysis units across the UK.

5. Data Sharing

The above personal data will be used by researchers at Keele University and their local research trial team (delivering the trial at the treatment site).

Data controller is Keele University who will be processing the data alongside our study collaborators including University of Warwick and Leeds Teaching Hospitals NHS Trust.

We will share your personal data with Hospital Episode Statistics, Civil Registration Data and other relevant health databases for long term follow up during and until the end of the trial. We require third parties to respect the security of your data and to treat it in accordance with the law.

NHS and academic researchers at other organisations will be able to apply for access to anonymised clinical data. This will include researchers in third party countries, so long as they meet information security and data protection standards. All such requests will be considered and if deemed suitable will be approved by Keele University.

For all the above, we require third parties to respect the security of your data and to treat it in accordance with the law.

This trial uses the encrypted NHSmail email system and the trial data is held and backed up in the University’s local servers.

6. Your Rights

You have a number of rights with regards to how we process your information including access, correction and restriction.

Full details of these rights and how to exercise them can be found at: www.keele.ac.uk/informationgovernance/yourdata-yourrights/.
A participant’s right to access their data

Participants have the right to see or have a copy of their personal information held at Keele University without any charge. If a participant wants to access their information held at Keele, they should make a written request to Keele University. Information will normally be provided within one month of receiving all the information needed to respond to a request.

A participant’s right to rectify their data

Participants have the right to have their personal information amended. If a participant wants to amend their information at Keele, they should make a written request to Keele University. Response to requests for rectification will be provided within one month or, in the case of a complex request, up to three months.

7. Data Retention

Your data will be processed for the duration of the trial and will retained for 10 years.

8. Data Protection Officer

We have appointed a Data Protection Officer (DPO) to oversee compliance with this privacy notice. If you have any questions about this privacy notice or how we handle your personal information, please contact the DPO. You have the right to make a complaint at any time to the Information Commissioner’s Office (ICO), the UK supervisory authority for data protection issues.

DPO contact details: dpo@keele.ac.uk

ICO contact details: www.ico.org.uk

Contact us

Enquiries about trial participation, please contact us. Our contact details can be found on the BISTRO study website: https://www.keele.ac.uk/bistro/contactus/.

Participants can withdraw from trial participation at any time. If a participant withdraws then the information collected up to the date of withdrawal cannot be erased and this information may still be used in the trial analysis.

9. Changes to this Privacy Notice

We reserve the right to update this privacy notice at any time, and we will provide you with a new privacy notice when we make any substantial updates. We may also notify you in other ways from time to time about the processing of your personal information.