# 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 H4RT Study. Their contact information is as follows:

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| Research and Innovation,<br>Southmead Hospital,<br>North Bristol NHS Trust,<br>Westbury-on-Trym,<br>Bristol, BS10 5NB<br>United Kingdom | Bristol Trials Centre (BTC)<br>Bristol Medical School<br>University of Bristol<br>1-5 Whiteladies Road<br>Bristol, BS8 1NU<br>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 sole data processor.

### 2. The purposes of the processing

The High-volume Haemodiafiltration versus High-flux Haemodialysis Registry Trial (H4RT) is a randomised controlled trial funded by the National Institute for Health Research, the research funding arm of the NHS.

The trial aims to see whether there is any difference between high-volume haemodiafiltration and high-flux haemodialysis in terms of longer term survival and hospitalisation from heart disease or infections in people with kidney failure. Effects on quality of life, admission to hospital, symptoms, infection rates and costs will also be examined.

A secondary aim is to understand how people make decisions about participating in clinical studies like H4RT. Currently we know little about how people make decisions about whether or not to take part in clinical studies. One way to improve our knowledge is to audio-record the conversations patients have with hospital staff about their possible participation in the H4RT study. This will help us to understand better how the information about the H4RT study is presented to patients, and how we could improve the way we discuss the study with patients in the future. Interviewing patients after they have made their decision about

whether or not to take part in H4RT will also help us to understand how they came to their decision.

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 be not decision making based solely on automated means.

**3. Data processing activities**

For H4RT participants, the University of Bristol will send a file containing identifiable data to NHS Digital for linkage to HES Outpatients, Critical Care, Admitted Patient Care and Mortality data. (Equivalent data will be requested from the equivalent national databases in other participating UK countries.) The identifying information shared will be NHS number, date of birth, and gender. No special category data, specifically no health data, will be sent from University of Bristol.

Once the records of H4RT participants have been identified by NHS Digital, all identifying data will be removed and a pseudonymised file containing the pseudonym study ID and health data will then be returned to the University of Bristol to be linked using the pseudonym study ID to the other trial data.

Health data from NHS Digital (or their equivalent in other UK countries) will be added to other health data in the clinical database using the pseudonym study ID for linkage. For patients in England, such other health data includes data from the trial case report forms, patient questionnaires, UK Renal Registry and Public Health England. The University of Bristol will store the identifying details of H4RT 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.

The lawful basis for processing personal data for H4RT 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 Digital (Hospital Episode Statistics and Civil Registration) and Public Health England/UK Health Security Agency (UKHSA) in England, Information Services Division in Scotland, NHS Wales Informatics Service, 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 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 anonymised 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 H4RT trial management group.

**7. The retention periods for the personal data**

Personal data will be stored for up to 15 years. 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.


**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 H4RT, participants have the right to see or have a copy of their personal information at the BRTC without any charge. If a participant wants to access their information at the BRTC, they should make a written request to the BRTC – see the section below on 'Contacting the BRTC'. 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 H4RT, participants have the right to have their information amended. If a participant wants to amend their information at the BRTC, they should make a written request to the BRTC – see the section below on 'Contacting the BRTC'. 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/

**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 H4RT they should contact their local H4RT 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 H4RT 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

www.informationcommissioner.gov.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


**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.