

RESTART Privacy Notice

The University of Edinburgh is registered as a Data Controller under the Data Protection Act 2018 (the “2018 Act”). The University of Edinburgh upholds the relevant data protection principles and processes all personally identifiable information about you (“personal data”) in accordance with the 2018 Act and other relevant legislation. The RESTART trial abides by the University of Edinburgh privacy policy. To view this policy which describes the information we collect about you, our security agreement and your rights, click here:

<https://www.ed.ac.uk/about/website/privacy>

This notice describes how the REstart or STop Antithrombotics Randomised Trial (RESTART) processes your data, including data about hospital admissions and deaths from NHS Scotland (approved by the Public Benefit Privacy Panel) and Hospital Episode Statistics from England and Wales (approved by NHS Digital) for the purposes of RESTART in accordance with University Policy.

Background

More than one third of the adults with a stroke due to bleeding into the brain – known as brain haemorrhage – are taking drugs to prevent clotting when they have a brain haemorrhage. These patients had previously suffered illnesses like angina, heart attack, or stroke due to blood vessel blockage, which is why they are treated with drugs to prevent further clots occurring. These drugs are usually stopped when the brain haemorrhage occurs. But when patients recover from brain haemorrhage, they and their doctors are often uncertain about whether to restart these drugs to prevent further clots occurring, or whether to avoid them in case they increase the risk of brain haemorrhage happening again.

RESTART is studying the potentially beneficial effects of antiplatelet drugs such as aspirin on the risks of heart attack, stroke and other clotting problems as well as their effect on the risk of a brain haemorrhage happening again. This information will help us to decide whether antiplatelet drugs are a promising treatment.

An MRI sub-study is also studying whether the presence of brain microbleeds modify the effects of antiplatelet drugs.

Recruitment to the trial closed on the 31st May 2018. 537 participants were recruited to the trial from 103 recruiting sites in NHS hospitals throughout the UK. Accurate information about the risks of brain haemorrhage, heart attack, stroke and other clotting problems is essential to determining the effects of antiplatelet drugs. This means we need to use as many sources of information as possible about these risks. We follow patients’ progress by sending them and their GP an annual questionnaire. Data on death registrations and hospital admissions (from the data sources mentioned above) are an important secondary source of information, to double-check the information provided in questionnaires. The final patient and GP follow-ups for the patients recruited on the 30th May 2018 are due by 1st December 2018.

What legal basis do we have to process this information?

RESTART required ethically approved voluntary explicit written consent to participate. Information given to the participants, family member or carer in RESTART is included within the relevant participant information sheets, consent forms, and other project-specific documentation created and supplied by those running the trial. Processing your information for the trial is necessary for the performance of a task carried out in the public interest (GDPR Article 6(1)(e)) and under Article 9(2)(j) necessary for archiving purposes in the public interest, scientific or historical research purposes in accordance with Article 89 (1).

Where are the data collected from?

The information we process may come from a variety of sources following consent from participants or their closest relative or carer for us to do so. This may have been provided by participants, a carer, a family member, from hospital medical records, from GP records and other approved third parties. The information we collect is restricted to only what is necessary for the conduct of the study.

What we do with the information

The RESTART trial team take our responsibility for looking after your information seriously. We take every step available to keep all data confidential in line with legal rules and guidelines. As RESTART is researching the potentially beneficial effects of antiplatelet drugs on the risks of heart attack, stroke and other clotting problems as well as their effect on the risk of a brain haemorrhage happening again we are interested to find out what happens. For this reason all participants in the UK will be followed up with NHS Digital in England and Wales (<https://digital.nhs.uk/>) and the Public Benefit Privacy Panel (PBPP) for Healthy and Social Care (in Scotland) (<http://www.isdscotland.org/index.asp>) at the end of the follow-up period of the trial. This will allow us to find out your vital status and if you have been admitted to hospital (Hospital Episodes Statistics [HES]) within the period of the trial and why you were admitted. We provide identifiable information (NHS/CHI number, name and date of birth) to NHS Digital or PBPP. Both NHS Digital and PBPP have datasets which they can link to individual participants in the study. NHS Digital and PBPP are subject to strict regulatory standards to make sure care information is looked after in line with good practice and the law.

The data received from NHS Scotland and HES will be imported into a securely accessed folder within the Edinburgh University 'Safe Haven' and used solely for the purposes of this research by the RESTART study team. We will augment our RESTART database with any new information provided by HES/PBPP.

Whilst the information received is specific to each study participant, no individual person will be identifiable in any publication arising from this work. Anonymous results of the study may be made available to collaborators with the appropriate agreements/approvals.

If study participants decide they no longer want their study data to be linked in this way they can withdraw from this follow-up, without affecting their current medical care in any way, by contacting Professor Rustam Al-Shahi Salman, RESTART Chief Investigator, University of Edinburgh, Centre for Clinical Brain Sciences (CCBS), University of Edinburgh, Chancellor's Building, 49 Little France Crescent, Edinburgh, EH16 4SB. Email: Restart.trial@ed.ac.uk Tel: 0131 242 7994.

Under Article 17 of the GDPR individuals have the right to have personal data erased. This is also known as the 'right to be forgotten'. The right is not absolute and only applies in certain circumstances.

Individuals have the right to have their personal data erased if:

- a) the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;
 - b) the data subject withdraws consent on which the processing is based according to point (a) of [Article 6\(1\)](#), or point (a) of [Article 9\(2\)](#), and where there is no other legal ground for the processing;
 - c) the data subject objects to the processing pursuant to [Article 21\(1\)](#) and there are no overriding legitimate grounds for the processing, or the data subject objects to the processing pursuant to [Article 21\(2\)](#);
 - d) the personal data have been unlawfully processed;
 - e) the personal data have to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject;
 - f) the personal data have been collected in relation to the offer of information society services referred to in [Article 8\(1\)](#).
2. Where the controller has made the personal data public and is obliged pursuant to paragraph 1 to erase the personal data, the controller, taking account of available technology and the cost of implementation, shall take reasonable steps, including technical measures, to inform controllers which are processing the personal data that the data subject has requested the erasure by such controllers of any links to, or copy or replication of, those personal data.
3. Paragraphs 1 and 2 shall not apply to the extent that processing is necessary:
- a) for exercising the right of freedom of expression and information;
 - b. for compliance with a legal obligation which requires processing by Union or Member State law to which the controller is subject or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

- c. for reasons of public interest in the area of public health in accordance with points (h) and (i) of [Article 9\(2\)](#) as well as [Article 9\(3\)](#);
- d. for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with [Article 89\(1\)](#) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing; or
- e. for the establishment, exercise or defence of legal claims.

As contractually required, HES data are not kept for longer than necessary and will then be securely destroyed in accordance with the contract. All trial data (research data) will be archived for 15 years after the end of the trial when your data will be disposed of securely in accordance with sponsor policy.

Data Protection Officer

If you have any questions, comments or complaints about how your information is handled in this study, or wish to obtain a copy of the Standard Data Protection Clauses, you should contact the Data Protection Officer (DPO) either via email at dpo@ed.ac.uk or via post to Data Protection Officer, Governance and Strategic Planning, University of Edinburgh, Old College, Edinburgh, EH8 9YL

Right to complain

You have the right to complain to the Information Commissioner's Office, you can use this link <https://ico.org.uk/global/contact-us>

There are National Offices for Scotland, Northern Ireland and Wales (see ICO website).