

The CHAMPION Study Privacy Notice



What is the CHAMPION Study?

CHAMPION (Congenital Heart Audit: Measuring Progress In Outcomes Nationally) is a research study based at the Clinical Operational Research Unit (CORU), University College London. It is funded by the UK National Institute for Health Research Policy Research Programme (NIHR PRP Ref: PR-R20-0318-23001). The Chief Investigators are Dr Sonya Crowe and Professor Christina Pagel and the study sponsor is University College London (UCL).

The CHAMPION Study respects your privacy and is committed to protecting your personal data. Please read this privacy notice carefully – it describes the data that each data source will provide to us and information about your rights. The CHAMPION Study will not receive **any** personal information such as names, NHS number or date of birth.

What information is being used?

We are not collecting any new data as part of the study. We are using data already collected routinely across England and Wales to understand better the quality of services that the NHS provides to people born with Congenital Heart Disease (CHD). Most of the data we are using for CHAMPION is already held at a secure location at University College London for use in another study (called LAUNCHES) that is also being led by Dr Sonya Crowe and Professor Christina Pagel: <https://www.ucl.ac.uk/clinical-operational-research-unit/research-domains/congenital-heart-disease-children-and-adults>

The National Congenital Heart Disease Audit (NCHDA) has collected information on every heart procedure performed on children and adults with congenital heart disease in the UK since 2000. We will use the NCHDA database (source National Institute for Cardiovascular Outcomes Research (NICOR), data controller Healthcare Quality Improvement Partnership (HQIP)) to understand better what happens to adult patients after operations and what happens to patients in the longer term. We will also look for NCHDA patients treated in England that appear in four other national, routinely collected, datasets (together these five datasets make up the LAUNCHES dataset):

1. The Paediatric Intensive Care Audit Network (PICANet) (contains data on children's stays in intensive care), data source PICANet, data controller HQIP.
2. The Intensive Care National Audit and Research Centre Case Mix Programme (ICNARC-CMP) (contains data on adults' stays in intensive care), data source and data controller: ICNARC.
3. Hospital Episode Statistics (HES) (contains data on A&E visits, general hospital stays and specialist outpatient appointments), data source and data controller: NHS Digital.
4. Office of National Statistics Death Registrations (ONS) (lets us know if someone has died), data source and data controller: NHS Digital.

We are also asking for data from two other national sources:

- The National Adult Cardiac Surgical Audit (NACSA) (contains data on all major heart operations, data source NICOR, data controller HQIP) so that we can understand differences in the data collected primarily for adult onset heart disease (NACSA) compare to data collected for congenital heart disease (NCHDA). We will be applying for all records held in the NACSA dataset and will also link to NCHDA to add matching records to the larger dataset.
- The National Congenital Anomaly and Rare Disease Registration Service (NCARDRS), which currently holds one year of national data of children born in 2017/18 who were diagnosed antenatally with CHD, and is collecting data for 2018/19 (data source and data controller: Public Health England (PHE). This data will not be linked to any other dataset.
- A pseudonymised clinician derived dataset from Barts Health NHS Trust (data controller Barts Health NHS Trust)). This data will not be linked to any other dataset.

We will also be working with three national charities (The Children's Heart Foundation, Little Heart's Matter and The Somerville Foundation) to develop online forums to elicit patient and family perspectives. The charities themselves will set up and oversee these forums and the CHAMPION Study team will receive anonymised transcripts from the forums.

UCL researchers will receive clinical data for included patients from each data source with personal information stripped out and replaced with a Study ID number. This is known as pseudonymised data. That means that UCL CHAMPION Study Privacy Notice

v2 dated: 31st March 2020

researchers will not have access to names, addresses, dates of birth or treatment, or any hospital or NHS numbers. This clinical data is held at University College London's secure Data Environment, Gower Street, London WC1E 6BT. University College London are the data controller for this research dataset.

Why are we using this data?

About 5,600 babies are born with Congenital Heart Disease every year in England. It is a complex, lifelong condition and many problems cannot be fully cured. Every year about 7,500 procedures are performed on children and 3,000 on adults. All hospitals submit data on each procedure that they undertake to a central NHS audit database. Currently, the NHS carefully monitors the proportion of people surviving at least 30 days following surgery for CHD. Survival for at least 30 days is very high (over 97%) and we know that there are many other aspects of quality that the NHS could measure and report. The NHS has commissioned the CHAMPION study to develop new ways for measuring quality of services for congenital heart services for both children and adults. This includes developing fair ways of measuring survival after surgery in adults and developing ways of reporting longer term outcomes for people treated for CHD.

How will this data be stored, for how long and who has access to it?

The data will be stored in UCL's bespoke "Data Safe Haven" which has been certified to meet all NHS information security and governance standards. This will prevent your data from being accidentally lost, used or accessed in an unauthorized way, altered or disclosed. We have established procedures to deal with any suspected data breach and you and any applicable regulator will be notified of a breach where we are legally required to do so.

Only researchers agreed with national bodies (HQIP, NHSD, PHE), named on legal data sharing agreements and with a legitimate need to see it for the purpose of carrying out their job, will have access to the data. All results from the research data will be published only in aggregated and anonymised form.

The CHAMPION study runs until April 2022 and the research data will be stored at UCL for a further 3 years to give the researcher's time to make the overall results public, before being securely deleted.

We will not transfer any personal data outside of the European Economic Area (EEA).

What is our legal basis for using your data?

Data Protection Legislation requires that we meet certain conditions before we are allowed to use your data in the way described in this notice. Our agreed basis is known as 'Public Task', where the use of your data is necessary for the performance of a task carried out in the public interest.

As the CHAMPION study will be analysing health data from routinely collected audits, we have obtained 'section 251 approval' from the health research authority, which checks that we have the capability to process confidential patient information and that we are using that information appropriately (because we're not able to obtain consent directly from each of the patients represented within the audits).

What if I don't want information about me or the child I care for to be used for the CHAMPION study?

If you do not want information relating to you or the child you care for to be included in the CHAMPION research data, please contact NICOR and Public Health England by telephone or email (details provided below) and we will ensure that your information is removed from the CHAMPION study data (Each data controller will let UCL know which data they need to delete). If you took part in our online forums and would like your responses removed from the study please contact the charity you took part through (please note we do not hold any of your personal identifiers so will not be able to remove any of the discussion without the charity's input) (details below). You are free to request this at any time and any decision to request removal of your or your child's identifiers will not alter the care you receive in any hospital. You also have the right to request access to, and to request to rectify information held about you or the child you care for.

You can find further information about your rights in UCL's privacy notice: https://www.ucl.ac.uk/legal-services/sites/legal-services/files/ucl_general_research_participant_privacy_notice_v1.pdf

Listed below are several contacts who can help you remove your data from the study should you wish to do so. The CHAMPION study is based at University College London. Please note that the data we will hold will not include the patient identifiers name, address, date of birth or postcode (it will be pseudonymised).

If you would like to discuss any of your data rights or are unsure who to contact to remove your data from the study, please contact Sonya Crowe who is the Principal Investigator (lead researcher) on the study. Please note that as we do not hold your identifying information we will redirect you to the appropriate data controller.

Principal Investigator for CHAMPION

Dr Sonya Crowe
Clinical Operational Research Unit
University College London
4 Taviton Street
London
Tel: 0207 679 4953
Sonya.crowe@ucl.ac.uk

Data Protection Officer University College London

Data Protection & Freedom of Information Officer
University College London
Gower Street
London
WC1E 6BT
Data-protection@ucl.ac.uk

If you would like your or your child's data removed from the CHAMPION study (NACSA and NCHDA data which may be linked to PICANet, ICNARC, HES and ONS data), please contact:

NICOR Chief Operating Officer
James Chal
National Institute for Cardiovascular Outcomes Research (NICOR)
Barts Health NHS Trust
2nd Floor, 1 St Martin's Le Grand
LONDON EC1A 4AS
Tel: 0203 765 8539
j.chal@nhs.net

If you believe that your or your child's data would be held in the NCARDRS audit and would like it removed from the CHAMPION study, please contact: (Please note that the data we will hold will not include the patient identifiers name, address, date of birth or postcode (it will be pseudonymised)).

For NCARDRS data

PHE Director of corporate affairs
Public Health England
Wellington House
133-135 Waterloo Road
London
SE1 8UG

If you believe your data would be held in the clinical audit of congenital heart treatment performed at Barts NHS Health Trust or the Heart Hospital, and would like it removed from the CHAMPION study, please contact: (Please note that the data we will hold will not include the patient identifiers name, address, date of birth or postcode (it will be pseudonymised)).

Barts Health NHS Trust

Data Protection Officer

Barts Health NHS Trust
The Royal London Hospital
3rd Floor, 9 Prescot Street
London
E1 8PR
dpo.bartshealth@nhs.net

If you took part in one of the online forums for this project and you have decided you would like to remove your anonymised responses from the study, or any data the charity may hold on you, please contact the charity you completed the forum with.

Little Hearts Matter
75 Harborne Road,
4th Floor
Edgbaston
Birmingham
B15 3BU
0121 455 8982
info@lhm.org.uk

Childrens Heart Federation
Suite 12,
The Centre
Lakes Industrial Park
Braintree
CM7 3RU
info@chfed.org.uk

The Somerville Foundation
Saracens House
25 St Margaret's Green
Ipswich
IP4 2BN
01473 252 007
admin@thesf.org.uk

You also have the right to lodge a complaint with the Information Commissioner's Office (**ICO**) (the UK data protection regulator). For further information on your rights and how to complain to the ICO, please refer to the [ICO website](#).