Imperial College London

Royal Brompton and Harefield hospitals

Participant Information Sheet: Child Participant

The SMARTER-CM Study

Chief Investigator: Dr James Ware, Imperial College, London

Your child is being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish for your child to take part.

Thank you for taking the time to read this.

Introduction

Cardiomyopathies are diseases of the heart muscle. Known genetic factors may account for some cardiomyopathy cases but there is still much to understand about the genetic and environmental causes and how the disease progresses.

Treatments for cardiomyopathies include medicines, and sometimes surgical procedures to control symptoms, maintain health, and prevent complications.

Most cardiomyopathies have no cure. Finding new ways to diagnose and treat cardiomyopathies could improve the health and well-being of patients with these conditions.

What is the purpose of the study?

This study will collect data from individuals with cardiomyopathy or related heart muscle disease, or with a possible genetic predisposition to cardiomyopathy, and follow them over time to observe the progress of their heart and health.

The study is not evaluating a new test or treatment. The study does not involve any experimental medications or any other change to your child's medical care.

We will collect blood samples and detailed clinical & lifestyle information at the start of the study, health survey data during the course of the study and we will collect data during routine healthcare visits over time,

The study will help us;

- learn what causes cardiomyopathy, and therefore how to treat it
- understand why cardiomyopathy progresses differently in different people, so that we can improve our ability to recognise who will benefit from different treatments at different times.

Some of our participants will be included in the Sarcomeric Human Cardiomyopathy Registry (SHaRe). SHaRe is a collaboration involving sites across Europe, USA, South America, and Australia.

Data shared with the BWH will also be included in the Sarcomeric Human Cardiomyopathy Registry (SHaRe). SHaRe is a collaboration involving sites across Europe, USA, South America, and Australia.

We are also looking into the differences between people with African and white European ancestry who have thickened heart muscle, to help us better understand how ancestry affects disease, and whether disease management can be improved for some demographic groups.

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Why has my child been chosen?

Your child has been invited to join this study because either:

- they have been diagnosed with cardiomyopathy, or a related condition
- they carry a genetic variant that may predispose to cardiomyopathy, or a related condition

Does my child have to take part?

Participation in this research study is entirely voluntary. It is up to you to decide whether or not your child will take part. If you do decide that your child will take part you will be given this information sheet to keep and be asked to complete a consent form.

If you decide that your child will take part you are free to withdraw them at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you child receives from their doctors.

What will happen to my child if they take part?

If you decide that your child will join this research study, we won't change your child's clinical treatment, but we will ask:

- your child to provide a blood samples (or a saliva sample) when you next attend the hospital for an appointment You to complete health surveys annually on behalf of your child for as long as you are happy to/until your child is 16 years old and can decide whether they wish to carry on taking part as an adult
- Allow us access to your medical records to gather information until your child is 16 years old and can decide whether they wish to carry on taking part as an adult

What does my child have to do?

Providing biosamples

We will ask your child to provide a sample of blood (or saliva if a blood sample is not feasible).

If your child is having a blood test as part of their normal clinical care, we may be able to take these samples at the same time. If your child is unable to give a blood sample, we may collect a sample of their saliva instead.

These samples will be de-identified and labelled with a study code. Sample will be stored securely at the study site, and any samples being included in the SHaRe central research biorepository (storage) will also be sent to the Brigham and Women's Hospital, Boston, Massachusetts in the USA

Blood samples

We will collect some blood samples from your child to extract DNA for genetic analysis and to measure changes in the composition of the blood that can be useful to track heart health. We will not collect more than 50 ml (3.5 tablespoons) of blood from your child, and possibly less depending on age and weight.

OR

Saliva

Where it is not feasible or possible to collect a blood sample, a saliva sample may be collected instead. It is simple to provide a saliva sample and instructions will be available on the saliva kit. This will provide us similar genetic information that we would have obtained from the blood.

Tissue

If your child has provided a tissue sample as part of their clinical care in the past, or if they provide one in the future, we may wish to access leftover tissue to investigate their heart health and other genetic information.

Heart investigations

We would like to use data from your child's heart tests that you have during their usual clinical care. We will store de-identified copies of heart tests that your child has had in the past, or will have in the future, in our secure research database. We are particularly interested in digital images of the heart from cardiac MRI or ultrasound (echocardiogram), and digital heart rhythm traces (ECG / electrocardiogram).

We will use tests carried out as part of your child's routine clinical care. Your child will not have to have any extra tests.

We may also upload these to other study sites based outside the UK in a de-identified manner, using a unique Study ID to label your child's scan and removing their personal details (name, date of birth).

The cardiac imaging repository will allow researchers to look more deeply into the structure and function of the heart by using the digital data available for research.

Follow Up

We would like you to complete short annual questionnaires about your child's health via the post or on the telephone/video call with one of the study team for as long as you are willing to. We currently have funding to cover the first five years of the study. If we secure further research funding, we will apply to extend length of the study and so we are asking for permission to follow up your child's medical health over their lifetime from their health records.

When your child reaches 16 years old, we will ask them if they would like to continue answering health surveys and allow us to access their health information and records. A member of the study team will be available to help with the questionnaires if required.

We may collect information relating to their heart condition from their GP and from any hospitals that they have been treated at. Information about your child's health is collected routinely by the NHS for national registries such as the Office for National Statistics and Hospital Episodes Statistics. We would like to collect and store information about your child's health from these registries. This data is managed by NHS England (formally NHS Digital); more information can be found at https://digital.nhs.uk. This would not require any direct contact with you. We will collect information about your child's health, whether they have experienced any cardiac problems or complications, had any procedures or investigations related to their heart. We will collect information about your child's medications and treatments related to their heart from their hospital records, and where available GP records and digital records.

The research team may also ask you if your child would like to take part in other related research studies. Your child's participation in any other research studies would be voluntary. You and your child would be given detailed information about these to help you decide whether you want to take part in these studies

Who will have access to my child's samples & information?

We want to combine the information we gather in this study with data in other international studies to help us maximise the power of our investigations. This includes the international Sarcomeric Human Cardiomyopathy Registry (SHaRe) involving multiple sites across Europe, USA, South America, and Australia, and the GoDCM study, a national multi-centre study also led by Imperial College.

Some participants who meet certain diagnostic requirements will be included in the SHaRe biorepository, and contribute to a research tissue bank. The research biorepository (storage) is located at Brigham and Women's Hospital, Boston, Massachusetts in the USA. The more samples and health information that we can collect, the more useful the biorepository will be for research. We will send samples and data to the SHaRe biorepository with a study code and will not include your child's name, date of birth, or contact details.

What are the possible benefits of taking part?

We are aiming to improve genetic diagnosis in cardiomyopathy or related heart muscle disease. Whilst we cannot promise the study will help your child, the information we get might help improve the diagnosis and management of people with inherited cardiac conditions.

What are the possible disadvantages and risks of taking part?

The study primarily uses data collected during routine healthcare, with relatively few additional risks. Data protection measures to protect your child's privacy are discussed below. We will assign your child a study ID number and will not use their name, address or date of birth to label their samples or data. Your child's genetic data will also be labelled with their study ID. As your child's genetic data is unique to you there is a small risk that it could be used to identify them, but there are many safeguards in place to protect your data. Researchers will not attempt to identify your child

We will collect additional blood samples. The physical risks of this are minimal. It is possible that your child might experience some discomfort, bleeding or bruising following the collection of blood samples for the study. These effects are generally mild and short lived.

Analyses of genetic data are not expected to generate results that will be useful to the care of individual participants (since genetic testing is already available through the NHS where helpful), and so genetic results will not be returned to participants. There is therefore no risk of harm from unexpected genetic secondary findings.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If your child experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If your child is harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you or your child has been treated during the course of this study then you should immediately inform the Principal Investigator (Dr Upasana Tayal, U.Tayal@rbht.nhs.uk. The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team

What will happen to my child's samples?

Your child's blood/saliva, optional tissue and DNA will be stored in a secure location in the Imperial study site and/or the at the Brigham and Women's Hospital in the USA, sample storage will only be accessible to approved researcher. Your child's samples may be used for genetic analyses. Your child's samples and DNA may be processed outside of the United Kingdom, but no additional personally identifiable information will be shared.

Your child's blood/saliva samples and results from tests on your child's samples may be shared with other researchers, including those based outside of the United Kingdom. Any research that uses your child's samples will need to be ethically approved.

To allow researchers to share test results, the National Institutes of Health (NIH) in the USA and other central repositories have developed special data (information) banks that analyse data and collect the results of whole genome studies. Your child's name or other directly identifiable information will not be given to central banks. Only fully anonymised data will be shared with NIH repositories.

At the end of the project if any of your child's samples remain, they will be stored by the research team. They may be used in other research projects. An ethics committee will review and approve any new projects that your child's samples may be used for. If your child's samples are not used for any other research projects, they may be disposed of according to applicable guidelines.

Will my child taking part in this study be kept confidential?

All information which is collected about your child during the course of the research will be kept strictly confidential. Everyone handling your child's personal and medical details will be bound by a professional duty to protect their privacy. When research studies are published from this project, they will not contain

your child's identifiable details (name, date of birth, etc) and it will not be possible for anyone else to identify who you are.

Why share data?

Cardiomyopathy is a rare disease with very limited treatments available.If we want to find new treatments and cures, it is incredibly important to have data from lots of individuals for research.

If we can combine data from lots of people across the world, we will have a powerful resource, and will work together with medical and scientific experts across the world to develop better healthcare.

Study staff will assign a study ID number to your child's samples and cardiac imaging files. Your child's blood samples and if available, your child's cardiac imaging will not be labelled with any information that could identify them. The staff will use the study ID number to connect your child's sample to their health information that is stored in a computer database. The computer database is protected with a password. Only study staff will know the password.

Only the UK research team members with appropriate permissions will have access to the key linking your child's study ID to their personal information. This will only be used when we need to update your child's information or contact you and your child. Researchers will not attempt to identify your child when analysing study data.

Your child's genetic and genomic results may be stored on secure computer systems at Imperial College and/or the central SHaRe facility or other collaborating research centres. These results will be labelled with your child's study code. This information will not include your child's identifiable information (name, date of birth, etc.).

With your permission we will inform your child's GP of their participation in this study and ask them to provide relevant information about your child's cardiovascular health to us.

Will my child receive any genetic results?

We will not provide feedback on the results of research on your child's blood or saliva samples.
If your child's clinical team requests access to your child's genetic results to inform their clinical care, we are happy to provide relevant data to them with the understanding that any results will need to be confirmed by a diagnostic laboratory., however, we will ask for your consent to do so. Requests in the first instance from your clinician may be made to smarter-cm@imperial.ac.uk

We will only be looking at genetic variants related to cardiovascular disease and will not be screening for other genetics results in different disease types. We will not report back any genetic results relating to other conditions.

What will happen to the results of the research study?

To increase the benefit from your child's participation in this study, we may share our genetic research findings with other researchers. Results from genetic research on your child's samples and health information may be published on controlled access databases. Controlled access databases mean that only researchers who apply for and get permission to use the information for a specific research project can access the information. Your child's genetic and health information would not be labelled with their name, date of birth, or other information that could be used to identify them. Researchers approved to access information in the database will agree not to attempt to identify your child.

Sharing research results on controlled access databases will allow researchers from other organisations to use your child's information to study genetic causes of diseases. These databases may be located in countries outside of the United Kingdom and European Union. Data protection laws in other countries may not offer the same level of privacy protection as those in the UK, but none of their identifiable information (name, date of birth, etc) will be included on these databases.

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At the end of the project all the research results will be gathered together and analysed. The researchers have a professional responsibility to publish their findings, however your child's identity will not be revealed. Most research is published in the medical press – if you are interested in knowing the overall results of the study, ask the research team about this.

Who is organising and funding the research?

The research project is being organised by the research team at Imperial College London and working with partner hospitals in collaboration with an international study team.

The research is being funded by the National Institute for Health (NIH) and the Sir Jules Thorn Award. Bristol Myers Squibb are providing a grant to support increasing the diversity of participants recruited at Kings College Hospital.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS (or private sector) by East of Scotland Research Ethics Service REC 2.

Contact for Further Information

Please contact the study team on the following contact details:

Email: smarter-cm@imperial.ac.uk

GDPR and Imperial College Privacy Notices

How will we use information about your child?
Imperial College London is the sponsor for this study and will act as the data controller for the SMARTER-CM Study.
This means that we are responsible for looking after your child's information and using it appropriately. Imperial College London will keep your child's personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is stated to finish in August 2027

We will need to use information from your child, your child's medical records and your child's GP for this research project.

This information will include your child's:
NHS number

Name
Date of Birth
Contact details

People within the College and study team will use this information to do the research or to check your child's records and make sure that the research is being done properly and to check that the information held (such as contact) details is accurate

People who do not need to know who your child is will not be able to see your child's name or contact details. Your child's data will have a code number instead.

We will keep all information about your child safe and secure.

Some of your child's information will be sent to the USA. They must follow our rules about keeping your child's information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

Legal basis for data use
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 for your child to take part in a research study, we will use your child's data in the ways needed to conduct and analyse the research study. Our legal basis for using your child's information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"); 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

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes.

International transfers
There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner,

either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your child's personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your child's personal data is processed.

Sharing your child's information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your child's personal data with certain third parties.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your child's personal data for specified purposes and in accordance with our policies.
- The following Research Collaborators / Partners in the study
  - the Brigham and Women's Hospital, Boston, Massachusetts, USA as part of the SHaRe consortium. We will share data and samples with the Brigham and Women's Hospital, but it will be labelled with a code and will not contain participants names, addresses or date of birth.
  - Collaborators at Kings College London

Potential use of study data for future research

When you agree for your child to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify your child and will not be combined with other information in a way that could identify your child, used against them or used to make decisions about them.

Commercialisation

Samples or data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your child's name and any identifying details will NOT be given to these third parties, instead your child will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your child's data (in a way which does not identify your child individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your child's data will not be shared with a commercial organisation for marketing purposes.

What are your choices about how your child's information is used?

Your child can stop being part of the study at any time, without giving a reason. We will keep information about your child that we already have because some research using their data may have already taken place and this cannot be undone.

If you choose for your child to stop taking part in the study, we would like to continue collecting information about your child's health from central NHS records/ their hospital records. If you do not want this to happen, tell us and we will stop.

- If you choose for your child to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop. This will not affect any healthcare or support your child may be receiving separately
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child if this could affect the wider study or the accuracy of data collected.
- If you agree for your child to take part in this study, they will have the option to take part in future research using their data saved from this study.

The study is expected to finish in August 2027. We may extend the study further if we secure further funding and ethical approval.

For more information / confirmation regarding the end date please contact the study team, (smarter-cm@imperial.ac.uk; or via the study team at your primary hospital).

Where can you find out more about how your child's information is used?

You can find out more about how we use your child's information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to smarter-cm@imperial.ac.uk

Complaint

If you wish to raise a complaint about how we have handled your child's personal data, please contact the research team first by sending an email to **smarter-cm@imperial.ac.uk**

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via

post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your child's personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

Thank you for taking part in this study!

A copy of the written information and signed informed consent form will be given to the participant to keep.

Imperial College London

Royal Brompton and Harefield hospitals

Informed Consent Form for Parent/Legal Guardian/Representative of Minor

Child's Name:…….

Name of Principal Investigator: Dr Upasana Tayal

Full Title of Project: The SMARTER-CM Study - Genetics, Imaging and Artificial Intelligence for Precision Care in Cardiomyopathy

		Please initial box
1.	I confirm that I have read and understand the subject information sheet dated..... version ..... for the above study and have had the opportunity to ask questions which have been answered fully.	☐
2.	I understand that my child's participation is voluntary and I am free to withdraw at any time, without giving any reason and without my child's legal rights nor treatment / healthcare being affected.	☐
3.	I understand that sections of any of my child's medical notes may be looked at by responsible individuals from Imperial College, from NHS Trust or from regulatory authorities where it is relevant to my child taking part in this research.	☐
4.	I give consent for information collected about my child to be used to support other research or in the development of a new test, medication, medical device or by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).	☐
5.	I give consent for samples (human tissue) or DNA collected from my child to be used to support other research or in the development of a new test, medication, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).	☐
6.	I give permission for study team to access my child's records that are relevant to this research during my lifetime and after my death including local hospital records, GP record and national electronic records	☐
7.	I understand that my child's samples, DNA and data may be shared and analysed with other researchers including outside the UK and EEA. I understand that information from my samples and data will only be made available to researchers in a form that protects my child's identity.	☐
8.	I understand that my child's data will be securely archived in an access-controlled repository approved by Imperial College, to comply with our funders' requirements, and to protect this data for future research use. This will include genetic data. Other personal data will not be stored in the archive. Health data will be linked to my child only by a code that is stored separately and securely.	☐

9.	I give consent to inform my child's GP of my participation in the SMARTER-CM study	☐
10.	I give permission for leftover tissue collected for diagnostic tests, or surplus samples collected during surgery to be used to obtain DNA, RNA, proteins, and other biomarkers for use in this study. I give permission for historically collected samples (collected prior to this study) to be used in this way. I give permission for such tissues to be retained for use in future approved research projects related to cardiovascular disease	☐
11.	I agree to be contacted by the research team for updates on my child's health, updates about the SMARTER-CM Study and to be invited to participate in future extra research tests or studies. I understand that my child does not have to participate in any future studies.	☐
12.	I agree to my child's tissue samples being used to undertake genetic research which may have the potential to generate data that can be tracked back to my child.	☐
13.	I consent/do not consent for my child to take part in the SMARTER-CM Study (delete as applicable)	☐

		Yes	No
14.	I understand that my child's data and samples will be shared with BWH in the United States for the BWH studies described in this form. I confirm that I have received a copy of the "Notice to SHaRe Registry, Biobank, and Imaging Repository Participants Regarding Personal Data Processing" (BWH Notice). By signing this form below, I am consenting to the processing of my child's Personal Data described in the BWH Notice which explains how Brigham and Women's Hospital will process my child's personal data as a separate data controller.	☐	☐

Name of Parent/Guardian/Legal Representative……

Signature……..

Date……

Name of person taking consent ……

Signature ……..

Date……..

1 copy for Principal Investigator; 1 copy to be provided to participant's guardian

Brigham and Women's Hospital
Founding Member, Mass General Brigham

Personal Data Processing Notice

MASS GENERAL BRIGHAM
NOTICE TO SHaRe REGISTRY, BIOBANK, AND
IMAGING REPOSITORY Participants
REGARDING PERSONAL DATA PROCESSING

Imperial is part of an international group of cardiovascular care providers and researchers studying genetic heart disease. This group is organized by Brigham and Women's Hospital in Boston, Massachusetts, USA. You are being provided with this Notice to SHaRe Registry, Biobank, and Imaging Repository Participants Regarding Personal Data Processing ("Notice") because you are being asked to have your Personal Data (as defined below) or the Personal Data of the individual for whom you are the legal representative transferred to the Sarcomeric Human Cardiomyopathy Registry ("SHaRe Registry"), a research database operated by investigators from Brigham and Women's Hospital (together, with its parent organization Mass General Brigham Incorporated, "Institution"). You may also be asked to have your Personal Data transferred to a biological sample repository ("Biobank") and an imaging repository ("Imaging Repository") related to the SHaRE Registry and operated by Institution. In the remainder of this Notice, Personal Data of the individual for whom you are the legal representative (if applicable) is referred to as your Personal Data.

The SHaRe Registry and the related Biobank and Imaging Repository follow patients with genetic heart disease and individuals at risk for such disease to enable research on how disease develops, how disease affects individuals and families, and how we can improve our treatment. In connection with the SHaRe Registry and, if applicable, the Biobank and Imaging Repository, your Personal Data may be processed (e.g., transferred, recorded, stored, used, disclosed, and destroyed, including by automated means) by (i) Institution and its affiliates and investigators; (ii) Institution's contractors and vendors; and (iii) Institution's research partners and others outside Institution, including research oversight authorities if required by law (such entities in clause (iii), "Third Parties"). This Notice is provided to you by Institution to explain the protections in place for the transfer of your Personal Data to Institution and for the storage, use, disclosure, and other processing of your Personal Data for the SHaRe Registry and, if applicable, for the Biobank and Imaging Repository, by Institution. This Notice is intended to comply with the General Data Protection Regulation (Regulation (EU) 2016/679) as applicable in the European Economic Area and The United Kingdom General Data Protection Regulation, as applicable in England, Wales, Scotland and Northern Ireland. This Notice provides details on how your Personal Data will be processed by Institution and the rights you have with respect to your Personal Data vis-à-vis Institution.

Personal Data

"Personal Data" means any information, including publicly available information, that relates to you as an identified or identifiable person and that is transferred to Institution by your enrolling site in relation to the SHaRe Registry and, if applicable, the Biobank and Imaging Repository. Your Personal Data may include, among other information, pseudonymized (coded) data about your gender, age, country of residence, country of origin, race, ethnicity, health and health condition, genetic information, and treatment experience. Your Personal Data may also include clinical images of your heart and surrounding structures and data associated with your biological samples if such samples are transferred to Institution by your enrolling site. The Personal Data will be obtained from your enrolling site. Institution will not receive any information that could directly identify you. Your enrolling site will replace any directly identifying information with a numeric or alpha-numeric code before transferring any data or samples to Institution. Institution will use the code to associate your Personal Data in the SHaRe Registry with your samples and images in the Biobank and Imaging Repository, if applicable. Only your enrolling site and its vendors will be able to link your data, samples, or images to your name or other information that directly identifies you.

Purposes of Processing and Related Information

Institution and Third Parties may process your Personal Data for purposes of the conduct and oversight of the SHaRe Registry and, if applicable, the Biobank and Imaging Repository, as well as for specific research projects using these resources, for analysis of research results, for creation of anonymized data for distribution to other SHaRe sites and SHaRe Registry funders for use in research, and for purposes of quality control, public health and safety, and compliance with law. Institution's legal basis for processing your Personal Data for these purposes is your explicit consent. By signing the informed consent for the SMARTER-CM Study at your enrolling site describing the SHaRe Registry and, if applicable, the Biobank and Imaging Repository, you consent to the processing of your Personal Data as described in this Notice.

Given that Institution is established in the U.S. and that Institution's contractors and vendors and Third Parties may be established in the U.S. or other countries outside of the country in which you reside, your Personal Data will be transferred out of the country in which you reside to the U.S. and these other countries (if applicable) for processing, where less strict privacy protections may apply to your Personal Data than those in the country in which you reside. Institution and its contractors and vendors and Third Parties will put in place appropriate safeguards to protect your Personal Data that is transferred outside the country in which you reside.

Institution will retain a copy of your Personal Data until completion of the purposes listed in this Notice or for as long as reasonably necessary to comply with applicable laws and Institution's internal retention policies, which may be for at least seven years after completion of the aims of the SHaRe Registry, the Biobank, and the Imaging Repository.

Your Rights

You may withdraw consent to the processing of your Personal Data by Institution. To do so, you can contact smarter-cm@imperial.ac.uk or the Investigator at your hospital. If you withdraw consent, then Institution will not further process Personal Data that was already transferred to it except to comply with law and to maintain the reliability of the SHaRe Registry, the Biobank, and the Imaging Repository, consistent with public interest in the area of public health. On the basis of public interest in the area of public health, Institution may also anonymize your

Personal Data and continue to process the anonymized data for these limited purposes

You have the right to request access to, correction of, or erasure of your Personal Data. You may also request restrictions on or object to certain processing of your Personal Data, or request that your Personal Data be transferred to another person or entity. If you would like to make any such requests or would like more information about your rights related to your Personal Data, you can contact the Mass General Brigham Chief Information Security and Privacy Officer at cispo@partners.org. You can also contact Institution by mail at the following address: Mass General Brigham, Attn: Chief Information Security and Privacy Officer, 399 Revolution Drive, Somerville, MA 02145, United States. Lumis International GmbH and Lumis International Ltd are Institution's data protection representatives in the European Economic Area and in the United Kingdom, respectively; therefore, if you are in the European Economic Area or in the United Kingdom, you can also contact Lumis International GmbH, Giesebrechtstrasse 15, 1629 Berlin, Germany, contact person: Heike Schoen, e-mail: HS@Lumisinternational.com (EEA) or Lumis International Ltd, 483 Green Lanes, London, N13 4BS, UK, contact person: Heike Schoen, e-mail: HS@Lumisinternational.com (UK). You understand and agree that Institution's ability to comply with any requests you make regarding the processing of your Personal Data may be limited by the requirements of the SHaRe Registry and, as applicable, the Biobank and Imaging Repository and by applicable laws and regulatory requirements to which Institution is subject. You also have a right to lodge a complaint with your country's supervisory authority.