

Division of Cardiovascular Medicine
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ORFAN Study

Long-term Follow-up Privacy Notice

The Oxford Heart Vessels & Fat (Ox-HVF) cohort consists of participants recruited into one of the four clinical sub-studies constituting the cohort: ART Vascular Study, Bypass Vascular Study, AdipoRedOx and ORFAN. Ox-HVF is designed to provide synergistic results allowing the deployment of a multi-level strategy to understand the mechanisms of cardiovascular disease (see www.oxhvf.com). As each one of the individual studies approaches the issue of cardiovascular disease pathogenesis from a different angle, the Ox-HVF cohort provides a unique and powerful platform that provides direct access to human tissue (vessels, myocardial and fat biopsies, DNA, plasma and others), in combination with extensive non-invasive cardiovascular phenotyping that includes cardiovascular computed tomography angiography, ultrasound and others.

You have previously consented to participate in the ORFAN study. The Oxford Risk Factors And Non Invasive Imaging (ORFAN) study aims to recruit individuals with risk factors but not advanced coronary artery disease, so as to investigate the predictive and prognostic value of metabolic risk biomarkers for early cardiovascular disease detection.

Participants in the study have given permission for the study investigators at the University of Oxford to access their records and to store them on a secure database linking their personal details, clinical notes and research findings. In order to keep our research records up to date throughout the duration of the study we will send identifying information including the unique Study ID number, NHS number, date of birth, postcode and date of surgery of the participants to [NHS Digital](https://www.nhs.uk) who will link it to Hospital Episode Statistics Outpatients, Critical Care, Admitted Patient Care and Accident and Emergency data. NHS Digital will send the hospital data back to the University of Oxford including the date of hospital admission and reason for admission for each individual participant, as well as civil registry mortality data including date of and cause of death.

The data that we receive and analyse from NHS Digital will be identified by a trial number only, and will not be identified by name, date of birth, NHS number or address. With the trial number, we will link to the original study database, and information collected during the earlier trial visits. The information received from NHS Digital will be imported into a database held securely by the University of Oxford and used solely for academic research purposes. Before analysing this complete dataset (including information already provided by trial participants with information from NHS Digital) personal identifiers will be removed. Importantly, whilst the information received is specific to each trial participant, no individual person will be identifiable in any publication arising from this work.

Research is a task that we perform in the public interest. The legal basis for the processing and storage of personal data for the ORFAN Study is that it is 'a task in the public interest' (article 6(1)(e)) and, that sensitive personal data is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (article 9(2)(j), based on Article 89(1)). The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum

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personally-identifiable information possible. The University of Oxford will keep identifiable information about you up to one year after the study (including follow-up) has finished. This excludes research documents with personal information, such as consent forms, which will be held for 5 years after the end of the study. If you agreed to your samples being used in further research, then your consent form will be held securely until the samples have been depleted or destroyed.

None of the study data, including any participant personal data, will be transferred or shared with any third parties, third countries or international organisations. No data will be used for automated decision making. If you would like to have this data withdrawn, please contact the study team using the details given below. We will continue to store the data we already hold about you in accordance with your consent to the ORFAN Study.

Participants in the study have additional rights under the General Data Protection Regulation and the Data Protection Act 2018, although such rights may be restricted in the context of academic research. These are:

- Be informed about the collection and use of your personal data
- Access the information we hold and process about you
- Request that we correct any inaccurate, out of date or incomplete information about you
- Request that we restrict the way that we use your personal data
- Object to the processing of your information
- Request that we erase the information that we hold about you

This study has been reviewed and approved by the South Central – Oxford C Research Ethics Committee (15/SC/0545), who can be contacted at oxfordc.rec@hra.nhs.uk. You can also lodge a complaint by contacting the study team via email at maria.lyasheva@cardiov.ox.ac.uk or by phoning +44(0)1865 228340 or by post at the following address: Charalambos Antoniadis, Level 6, West Wing, John Radcliffe Hospital, Oxford, OX3 9DU. In addition you may contact the Data Protection Officer (DPO) who is part of the University's Information Compliance Team at data.protection@admin.ox.ac.uk. The DPO is responsible for monitoring internal compliance with GDPR, advising on the University's data protection obligations. Furthermore, you can independently lodge a complaint with the Information Commissioner's Office (ICO) by visiting <https://ico.org.uk/global/contact-us/>, or by phoning 0303 123 1113 or at the following postal address: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

What to do next?

If you decide you do not want your study data to be linked in this way you can withdraw from this follow-up, without affecting your current medical care, by contacting the study team via email at maria.lyasheva@cardiov.ox.ac.uk or by phoning +44(0)1865 228340 or by post at the following address: Charalambos Antoniadis, Level 6, West Wing, John Radcliffe Hospital, Oxford, OX3 9DU. The study team will require your identifiers to then inform NHS Digital that you no longer wish to be part of the cohort. NHS Digital will then remove your identifiers from the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited

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in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at <https://compliance.web.ox.ac.uk/individual-rights> or by contacting the study team using the details above.

If you have further questions, please contact the study team using the details above. You may also contact the Data Protection Officer (DPO) who is part of the University's Information Compliance Team at data.protection@admin.ox.ac.uk.

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