REVEAL Data Privacy Notice for Participants

Introduction to participant data privacy

The University of Oxford has substantial experience of ensuring that information is stored safely for studies like the REVEAL study. Information held about participants is only used for medical research purposes and for routine regulatory and audit purposes.

Where the University of Oxford is using information for research purposes, it will only process personal data as necessary for the performance of such research being carried out in the public interest. This is known under data protection law as our "legal basis" for processing personal data.

The University of Oxford is the "data controller" for this study. This means that we decide how to use data and are responsible for looking after it in accordance with the GDPR. For more information you can read the University Policy on Data Protection.

What data do we hold about participants?

Personal data that directly identifies participants - such as name, address, or date of birth - can be accessed by the REVEAL doctors and nurses who are running the study at local hospitals. Health regulators (such as the UK Medicine and Healthcare Regulatory Agency and U.S. Food and Drug Administration) and auditors from Merck could access these data if they were to visit a local hospital to check that the study is being carried out properly. Appropriate staff at the University of Oxford may also have access to these data for the purpose of carrying out the day-to-day running of the study. These people are all bound by a duty of confidentiality.

In the UK, name, date of birth, NHS number (or CHI number in Scotland) and postcode will be stored securely by the University of Oxford to link participants with data held by NHS Digital (or other central NHS bodies). Oxford University will not send these personal identifiers to anyone else (including Merck).

What data will we collect about UK participants from other sources?

If participants have given consent, then during and after the study the coordinating centre in Oxford will ask for information about participant health from UK participants' doctors, registries (e.g. the UK Renal Registry), and NHS Digital (or other central NHS bodies). The REVEAL team would send names, dates of birth, NHS numbers (or CHI numbers in Scotland) and postcodes to NHS Digital (or other central NHS body) who can link this information to individual participants in the study. For participants living in England and Wales, NHS Digital provides information about any cancer on behalf of Public Health England. NHS Digital and other central NHS bodies together provide information about admissions to hospital (called Hospital Episode Statistics) and development of cancer. In addition, they provide information about people who have died, including the date and cause of death supplied on behalf of the Office for National Statistics. Similar information will be requested from the relevant bodies for participants living in Scotland.

If people have requested that their NHS data is not used for research and planning then their details will not be transferred to the University of Oxford for this study. You can find out more about how the NHS uses your data - including how to opt in or out of research and planning - by visiting: https://www.nhs.uk/your-nhs-data-matters/.

De-identified data

To help keep information confidential, information recorded about participants in this study as well as any samples collected are "de-identified". De-identified means that health information and blood/urine samples are labelled with unique numbers linked inside a computer and not by name.

It would be very difficult for anyone to re-identify participants after de-identification as we use special measures to protect data, but it remains theoretically possible.

How do we use participant data?

De-identified data will be used for the following purposes: analysis of study results to learn more about how anacetrapib works in the body, to do future research, to write scientific articles, and to help design and conduct future studies.

Who will we share participant data with?

The University of Oxford will provide Merck with copies of the study database containing de-identified data only. It may be necessary for copies of the de-identified database to be shared with health regulators and ethics committees, and it may be shared with other bone fide medical researchers.

The University of Oxford and Merck may process and combine data from this study with data from other sources (always using appropriate safeguards) and may carry out these activities alone or in collaboration with public or commercial private partnerships (i.e. third parties) in the areas of research described above.

Some of the above mentioned parties who receive data will be located outside the UK. If any foreign country to which de-identified data is transferred does not have equivalent data protection standards to those required in the UK, appropriate safeguards will be adopted to protect and maintain the confidentiality of data and blood/urine samples (including using standard data protection clauses adopted by the European Commission, where relevant). Should participants require any information about these safeguards, they may contact us at: data.protection@admin.ox.ac.uk

The University of Oxford will safely keep the study data and Merck will safely keep a copy of the de-identified database for at least 25 years after the end of the study, and perhaps longer if required by the law or other research needs.

How does a participant opt out of data being collected about them?

If a participant decides they do not want any new information about them to be collected and used for the study they can inform us using the details at the bottom of this document. They do not have to give a reason and their decision will not affect their usual medical care in any way. All information that has already been collected (including analysis results from blood and urine samples), will still be kept and used for the study.

If a participant has previously given consent for us to use leftover blood and urine samples and related information which had been collected in the study, they may also separately withdraw their

permission for this optional part of the study at any point in time, without affecting their participation in the main part of the study. Any samples that they no longer wish for us to store or use will be destroyed.

How does a participant find out what data is held about them?

Participants have the right to know what personal data the University of Oxford and Merck hold about them and to have a copy of that data. The central coordinating team in Oxford can provide this (see contact details below). However, please note that in order to ensure the study's scientific integrity, participants may not be able to review some aspects of these data until after the study has been completed.

Participants also have the right to correct wrong or outdated personal data and request the deletion of their data. However, the study site and Merck may be obliged by law to keep data to ensure consistency and reproducibility of the results and we cannot delete data that has already been used in analyses (note that analyses are run regularly throughout the study).

Participants also have the right to restrict or object to what we do with their data, or to request that their data be transferred elsewhere. However, sometimes the data controller may not be able to (or have grounds not to) follow a request, for example, if we consider that deleting data would seriously harm the research.

Who to contact for further information about data privacy

Any participant wishing to exercise any of their rights can contact us. The data protection officer for the University of Oxford can be contacted by email at: data.protection@admin.ox.ac.uk.

If a participant is not happy with the way we have handled their data, they have the right to lodge a complaint with the Information Commissioner's Office (telephone 0303 123 1113 or ico.org.uk).

REVEAL study contact details

Post:

REVEAL,
Clinical Trial Service Unit (CTSU),
Richard Doll Building,
University of Oxford,
Roosevelt Drive,
OXFORD,
OX3 7LF

E-mail: reveal@ndph.ox.ac.uk

Telephone: 0800 585 323