Privacy Notice for EMPA-KIDNEY Participants

The University of Oxford is a world-leader in developing systems to ensure that information is stored safely for studies like the EMPA-KIDNEY study. Information held about participants is only used for medical research purposes and for routine regulatory and audit purposes.

You can read the University's Data Privacy Notice in detail on the NDPH website.

What happens to participant information?

There are an increasing number of data protection regulations that we are required to follow. These laws require us to disclose participant rights and how we will use participant data.

The two parties involved in this study (the University of Oxford, whose full legal name is "The Chancellor, Masters and Scholars of the University of Oxford", and Boehringer Ingelheim International GmbH) will be responsible for deciding how any personal data collected during this study are processed and will ensure data protection laws are followed (i.e. they will be the "data controllers"). Both parties are bound by a duty of confidentiality. In an exception to this, only for data that Oxford receives from NHS England, the University of Oxford will be sole Data Controller.

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.

In this study personal data that directly identifies participants such as name, address, or date of birth (so-called personal identifiers) can be accessed by the EMPA-KIDNEY 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 Boehringer Ingelheim could also access these data if they were to ever perform an audit by visit to your local hospital or "virtually" (e.g. due to Covid-19 travel restrictions) to check that the study is being carried out properly. These people are also all bound by a duty of confidentiality.

During the study, a member of the University of Oxford or other EMPA-KIDNEY staff may ask permission to be present during a participant clinic appointment. This helps us ensure study procedures are being followed.

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

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.

As already explained above, 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.

The "de-identified" data in this study are to be used for the following purposes: analysis of the study results, to help learn more about how empagliflozin and other "gliflozins" work in the body, to do future research, to write scientific articles on kidney diseases and associated health problems, and to help design and conduct future studies.

Oxford will provide Boehringer Ingelheim with a copy 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 researchers.

Oxford and Boehringer Ingelheim[1] 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 Boehringer Ingelheim will safely keep the 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.

[1]Including Boehringer Ingelheim Group of Companies

How is information about participants collected?

During participation in the study, individuals will provide personal data about themselves, such as information on medical condition and medical history, to the study nurses at study visits (and relevant blood and urine test results held at local hospitals). These data will be entered into a computer system managed by the University of Oxford and stored securely.

The University of Oxford is a world-leader in developing systems to ensure that information is stored safely for studies such as EMPA-KIDNEY. Only staff with appropriate training and permission can access this computer system.

In addition, for participants based in the UK, the coordinating centre in Oxford will ask for information about participant health from participants' doctors, registries (e.g. the UK Renal Registry), and NHS England (or other central NHS bodies). The EMPA-KIDNEY team would send names, dates of birth, sex, NHS numbers (or CHI numbers in Scotland) and postcodes to NHS England (or other central NHS body) who can link this information to individual participants in the study. For participants living in England and Wales, NHS England provides information about any cancer on behalf of Public Health England. NHS England 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. Having this information will help to make sure that the study team does not make unnecessary contact and cause any distress to relatives, as this information includes 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.

Data protection rights for participants

If a participant stops taking the study pills and does not wish to have further blood samples to be collected at their study clinic, we would like to keep in touch by phone. However, they can also decline to be contacted again. In this case, we would like to continue to follow how they are getting on by contacting their local doctor or through national registries or other publically available sources of data.

If a participant decides they do not want any new information about them to be collected and used for the study (known as "withdrawal of consent"), we will ask them to sign a form and will not collect any further information from them. All information collected, including analysis results from blood and urine samples that have been already collected, 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.

Participants have the right to know what personal data the University of Oxford and Boehringer Ingelheim hold about them and to have a copy of that data. The local study nurse could provide this, however, to ensure the study's scientific integrity, participants may not be able to review such 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 Boehringer Ingelheim (as the study's sponsor) 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 controllers 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. Any participant wishing to exercise any of these 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 https://ico.org.uk/).

Contact Us

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