UK Clinical Cohorts Trusted Research Environment (UK CliC) – Participant Notification Sheet

You are receiving this because you are taking part in, or have taken part in, a research study collecting valuable information from you and others to benefit patients and health services. The research team conducting the clinical cohort study would like to use the UK Clinical Cohorts (UK CliC) Trusted Research Environment (TRE) to store, link and analyse your data.

Cohort studies involve gathering a group of people who have the same illness or condition and tracking their health over time. By combining this information with their routine health records (like GP visits, hospital stays, and medications), researchers can better understand how the illness develops and how well treatments work. This helps them find useful answers more quickly, which can lead to better care for patients. We have developed the UK CliC TRE, which is a secure database (also called a Trusted Research Environment, TRE) where approved researchers can access and study data, to support such research breakthroughs. A list of the studies taking part in UK CliC are available on our website.

The purpose of this document is to tell you how UK CliC works to make sure your data is only used in the way you agreed, we will tell you about the process your data goes through to reach the UK CliC TRE, and we will make sure you know about your right to opt out and how to do this.

Who runs UK CliC?

UK CliC is run by the British Heart Foundation Data Science Centre (BHF DSC which is turn part of Health Data Research UK (HDR UK), who provide management and governance oversight of the TRE. The technical platform is provided by the Secure Anonymised Information Linkage (SAIL) Databank team at the University of Swansea, who have built and maintain the TRE platform, and whom we work in partnership with. The team, made up of individuals from the BHF Data Science Centre, HDR UK and SAIL, work closely with colleagues from the NHS and other custodians of health data to ensure data is handled and stored in a safe and secure way.

SAIL Databank works closely with the study team who collected your data to make sure they store, handle, process and destroy the data in the right way. The terms of this are set out in a contract. Through this contract, your study continues to control whose data is uploaded to the UK CliC TRE, what data are provided or linked to, and who can use which data and for what purposes.

The UK CliC TRE has a Patient and Public Involvement Group – and involves members of the public who actively review applications in line with the Caldicott principles (https://www.gov.uk/government/publications/the-caldicott-principles) which ensure people's information is kept confidential and used appropriately.

Your consent and permissions

A blank version of the consent form(s) you originally signed will be checked by the study team, the study sponsor, and the UK CliC team. This is to make sure you gave permission for your data to be used in future research and for it to be linked with information the NHS collects about you during your routine care. Where this is not clear, the study team may need to obtain further consent from you before any of your data can be added to the TRE. Where it is not possible to regain consent from participants (e.g. because participants may have moved, died etc), their information is still very valuble for research and the study that they originally consented to. In this circumstance approval from the NHS Confidentiality Advisory Group (CAG) may be obtained to lift the common law duty of confidentiality so that data can be included, where there is a clear public benefit in doing so and low risk to the individual. This is called Section 251 support (of the NHS Act 2006). In all cases, the study

team must be fully transparent and notify study participants of the plans to add their data to the TRE for research.

Can you opt out so your data is not used in UK CliC?

Yes, you can choose to opt out so your data is not used in UK CliC. Anyone taking part in the studies can opt out — for themselves, or on behalf of their child, or if consent was given on behalf of someone under the Mental Health Act. If you wish to opt out, you should contact your study team directly and let them know. If you choose to opt-out your study will manage this process according to their standard policies and procedures. You have the right to opt out at any time without needing to provide a reason. If you should withdraw, any of your data already collected by your cohort study team which has been added to the TRE will be used for analysis as part of UK CliC, however your data will be anonymised (contain no personally identifiable data).

Does the National Data Opt Out apply to this trusted research environment?

No, the National Data Opt-Out will not be applied. The National Data Opt Out (NDOO) applies to patients in England and any Welsh residents who may hold health records in England. The NDOO allows patients to make a decision to stop their Confidential Patient Information (CPI) being used for research and planning purposes.

For the UK CliC TRE, we will be working with many researchers, and due to technical limitations, NHS England cannot support any variation in the consent that has been gathered by each individual cohort. As each cohort that wants to use UK CliC has slightly differing consent terms (e.g the type of data that can be linked to or dates in which consent to perform linkage was gathered). This means that participants from all cohorts will have their data linked with all datasets which are being provided for linkage from NHS England. In some cases, this may mean linking to datasets that have not been explicitly mentioned within participant consent materials, or within a timescale specified at the time of consent being taken.

It is important to note that while the data will be linked, the data which will be accessed by researchers will be managed so that they only access the data that the researchers have approval for, and any data will not be identifiable.

Where is the data stored?

The data will be stored on secure servers controlled by the University of Swansea who have built the UK CliC TRE. This system is tried and tested for this purpose. This system is ISO 27001 certified, which is a globally recognised standard for information security management systems, and is accredited by the UK Statistics Authority. This accreditation gives assurance on the legal, physical and technical controls in place to keep the data safe and secure across its lifetime.

Researchers cannot extract data from the TRE, the data stay within the secure environment and researchers have to come to the environment to carry out any analyses. Any research results being extracted from the TRE are checked to ensure they do not include any disclosive information (results cannot include any information that can be used to identify an individual).

The legal basis for the processing of data within UK CliC is under UK General Data Protection Regulation (GDPR): Performance of a task carried out in the public interest (Article 6(1)(e) in the

GDPR); and, where sensitive personal information is involved: processing for scientific research purposes (Article 9(2)(j).

To perform linkage to your NHS health records, your study team will send a small set of data used to identify you (name, address, date of birth, gender, NHS/CHI number) to Digital Health and Care Wales (DHCW). DHCW send these records to the relevant NHS body who will locate and link these data to your medical records and then send a de-identified version of these data to the TRE. The data used to identify you for linkage are then deleted. Only anonymised data about you will ever be held in the TRE. The processing of the data is not outsourced to a commercial company.

How are data accessed?

Only a small number of staff with data management responsibilities can access the data. Researchers wishing to access the data must:

1. Submit a research project application detailing; the research question(s), the data required to answer the research question(s), and an explanation of how their research is in the public interest.

2. Complete relevant training that covers researcher responsibilities in handling individual level data, how to work in a safe research setting (TRE) and how to generate safe research outputs.

Applications to access data are reviewed by an independent panel to ensure that the research being proposed is appropriate and in the public interest, and the panel is made up by representatives from various organisations and includes members of the public. More information on this panel can be found here: https://saildatabank.com/governance/approvals-public-engagement/information-governance/

Once their application is approved and they have completed the necessary training, researchers are then granted access to use the data in UK CliC.

Your rights

UK CliC aims to meet the highest standards when handling personal information. We encourage people to tell us if they think that our use of information is unfair, misleading or inappropriate. We would also welcome any suggestions for improving the way we handle your personal details. You can contact us via email us at ukclic@hdruk.ac.uk and find out more information about UK CliC at: https://bhfdatasciencecentre.org/areas/enhancing-cohorts/.

The General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018 provides individuals with rights over how their data is used. UK CliC supports these rights.

If you have any questions about the content within this document and would like to contact a team member at UK CliC you can email ukclic@hdruk.ac.uk.