

CLARITY IBD Privacy Notice

Introduction

This privacy notice sets out ways in which personal data is managed by the Royal Devon University Healthcare NHS Foundation Trust for the purposes of the Impact of Biologic and Immunomodulatory Therapy on SARS-CoV-2 Infection and Immunity in Patients with Inflammatory Bowel Disease (CLARITY IBD) study. The Royal Devon University Healthcare NHS Foundation Trust is a UK hospital, located at Barrack Road, Exeter, EX2 5DW.

This notice specifically sets out how the Royal Devon University Healthcare NHS Foundation Trust will manage data received from NHS Digital for the purposes of the CLARITY IBD study. It is intended to supplement the existing Royal Devon University Healthcare NHS Foundation Trust [Data Protection Policy](#) and [privacy notices](#).

For the purposes of this privacy notice, Royal Devon University Healthcare NHS Foundation Trust is a Data Controller, as defined in the General Data Protection Regulation (GDPR) and the Data Protection Act 2018. Royal Devon University Healthcare NHS Foundation Trust is registered with the Information Commissioner's Office. Its registration number is ZB322774 and its entry on the ICO website is [here](#).

The CLARITY IBD study

The CLARITY IBD study is led by Prof Tariq Ahmad. [CLARITY IBD](#) (ISRCTN45176516) is badged as a UK National Institute of Health Research COVID-19 urgent public health study (1B) (<https://www.nihr.ac.uk/covid-studies/>). This study investigates the impact of specific drugs and shielding on COVID-19 infection and subsequent immunity following infection or vaccination.

The results of the study have and continues to inform public health policy decisions for patients with IBD as well as millions of other UK patients treated with immunosuppressive drugs.

The study comprises two workflows:

Workflow 1 is a non-consented retrospective study of SARS-CoV-2 seroprevalence across the UK using surplus serum samples. Patient identifiers such as date of birth, sex, postcode as well as the date of the serum sample, which biological medication they are being treated with (if applicable), and the name of the referring hospital were provided.

Workflow 2 is a consented prospective observational UK-wide study (6970 patients) of SARS-CoV-2 seroprevalence in IBD patients receiving infliximab or vedolizumab in UK infusion units

How do we get data for the CLARITY IBD study

We will receive data from NHS Digital, the nation's provider of information and data in health and social care. A Data Sharing Agreement is in place with NHS Digital to provide access to the data required for the purposes of this study.

What data will we use

We will use record-level, patient data, including National Health Service number (patient identifier) and COVID-19 vaccination data (including date of vaccine dose and brand).

The main dataset we will be working with relates to SARS-CoV-2 PCR testing results, obtained from UK Health Security Agency, for all patients recruited to the CLARITY IBD study between 09 February 2020 and 30 June 2022.

How long we will use the data

Data from the study will be kept for up to 5 years after the study end date (June 30th, 2022), but the identifiable information linking information to you will be removed 12 months after the study end date. Data will then be destroyed safely in accordance with the GDPR and the Data Protection Act 2018 and the NHS Digital requirements, as set out under The Royal Devon University Healthcare NHS Foundation Trust's Data Sharing Framework Contract and Data Sharing Agreement with NHS Digital.

Legal basis for processing this data

The Royal Devon University Healthcare NHS Foundation Trust will process this data for research purposed under Articles 6(1)(e) and 9(2)(j).

Protecting your interests

Data will only be accessed by individuals within the Royal Devon University Healthcare NHS Foundation Trust and Imperial College Healthcare NHS Trust who have authorisation to do so. One of the co-chief investigators of the study is at Imperial College London, and this investigator's team are conducting the T-cell experiments relating to vaccine response. They are completing this under instruction of Royal Devon University Healthcare NHS Foundation Trust. The data will not be shared with anyone else nor be linked to any other data.

We maintain a register of which individual needs access for each project and we restrict researchers' access to the data strictly on the grounds of the data required for their individual project. We will not use the NHS Digital data for anything else.

The data will be securely stored at the Royal Devon University Healthcare NHS Foundation Trust. The data security arrangements at the Royal Devon University Healthcare NHS Foundation Trust form part of the data sharing agreement with NHS Digital - these are documented in detail and regularly audited.

Data rights

Under the GDPR and the Data Protection Act 2018, you have a number of rights in relation to your personal data.

For patients consented into the study, you have the right to withdraw consent. You may withdraw your sent from having any further contact with the study. In addition, you may also ask for us to cease using any existing information we hold about you and remove it from our database.

For patients in the non-consented workflow, you may also ask for us to cease using any existing information we hold about you and remove it from our database.

We do know the identity of any individuals in the data that we receive from NHS Digital for the CLARITY IBD study, and can act on any data subject requests in relation to named individuals.

If you would prefer that your health data is not used for research and planning in the future, please look at the national data opt-out information at:

<https://digital.nhs.uk/services/national-data-opt-out-programme>. Please note that the national data opt-out does not apply to confidential patient information when an individual has given their explicit consent for it be used for a particular purpose.

Transferring data

We will not transfer the data to anyone outside Royal Devon University Healthcare NHS Foundation Trust, Imperial College Healthcare NHS Trust, and UK Health Security Agency.

Contact details

If you want further information about how the CLARITY IBD study uses personal information, please see <https://www.clarityibd.org/patient-information-sheets> or contact via email rde-tr.clarityibd@nhs.net or telephone (01392 406850).

If you have questions about the CLARITY IBD project, please contact Prof Tariq Ahmad at tariq.ahmad1@nhs.net

If you have any queries about the way your personal data has been processed, please contact the Data Protection Officer via email at ndht.dpo@nhs.net.

If you have concerns about the way we handle your personal information, you have the right to lodge a complaint with the Information Commissioner's Office:

<https://ico.org.uk/make-a-complaint/yourpersonal-information-concerns>