

CIPHER
STUDY

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Sponsor: Royal Devon University Healthcare NHS Foundation Trust

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Privacy Notice

This notice explains how we collect, process, transfer and store health data for the CIPHER study. It forms part of our duty of accountability and transparency under the General Data Protection Regulation (GDPR) and Data Protection Act (2018) (DPA). These laws require us to tell our study participants how we will use health data and to give them the opportunity to tell us not to use their data in that way.

What data have we collected?

Between January 2018 and June 2021, the CIPHER study consented 2,500 patient participants from 78 UK hospitals, who were due to have an ileostomy or colostomy formed. Out of these 2,500 patients, 2,342 had an ileostomy or colostomy and continued with the study.

The CIPHER study collected direct identifiers and study data (surgery and health data and questionnaire data). Direct identifiers included name, date of birth, address, NHS number, postcode, telephone number, email address and demography.

All CIPHER participants were 'followed-up' during their hospital stay and for at least 1 year after surgery. The last study patient completed their follow-up in September 2022. During follow-up we collected more study data. This included information about patient health and recovery via site and questionnaire follow up.

Who controls the use of CIPHER data?

The University of Bristol and Royal Devon University Healthcare NHS Foundation Trust are joint Data Controllers for the CIPHER study. A Data Controller is an organisation who determines why and how personal data are processed. This is defined in the Data Protection Act (2018).

The University of Bristol can be contacted at:

Data Protection Officer
University of Bristol
Beacon House
Queens Road
Bristol BS8 1QU, UK

Email: data-protection@bristol.ac.uk

Royal Devon University Healthcare NHS Foundation Trust can be contacted at:

Information Governance Office
Devonshire House
Riverside Road
Barnstaple
EX31 1SW

Email: ndht.dpo@nhs.net

Consent

All the patients taking part in CIPHER were given written information about the study before deciding to take part. This included information about what data we would collect, how it would be stored and used. Patients had the chance to ask questions and made their decision about taking part freely without pressure. All gave their agreement (consent) to take part voluntarily and in writing. For English patients this included consent for the CIPHER study research team to send their identifiable data to NHS Digital (NHS number and date of birth).

What will the CIPHER study use data for?

The primary aims of CIPHER are to establish the incidence of symptomatic and radiologically confirmed parastomal hernia (PSH) during a minimum of 2 years follow up; and to evaluate the effects of key technical surgical steps when a stoma is created on the risk of developing a PSH.

These study aims require the linkage of personal (health) data collected during the study (study data) to routinely collected NHS health data (routine data). This will enable the study team to determine which of the study participants developed a PSH within the study follow up period. Linkage of study data to routine data is also required for completion of a health economics analysis as part of the study. This will look at the resource use of patients who develop a PSH and enable the study team to estimate the cost effectiveness of modifying surgical techniques during stoma formation.

How will CIPHER study use data?

NHS Digital will create a Secure Electronic File Transfer (SEFT) account for the CIPHER research team. Data will be transferred from University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) to NHS Digital by a member of the CIPHER team who is a substantive employee of the University of Bristol (UoB) with an honorary contract at UHBW. The data will consist of identifying details (specifically NHS Number, Date of Birth, start and end dates, and a unique person ID) for the cohort to be linked with NHS Digital data. The start and end dates are for the period that patients have consented for the CIPHER study team to access their data.

NHS Digital will use the identifiable data to extract the routine data about hospital healthcare use (hospital episodes, diagnostic imaging and mortality data). The data will contain directly identifying data items including NHS Number and Date of Birth which are required to ensure effective linkage of the data at record level with study data already held.

A member of the CIPHER team who is a substantive employee of the UoB with an honorary contract at UHBW will remove the identifiable information (pseudonymise, linking by only by study id) from the NHS Digital dataset on the UHBW network and then download the dataset and store it to a UoB encapsulated virtual machine (eVM). This is a very secure method to store electronic data, eVMs

have been designed in conjunction with NHS Digital. Only a few members of the CIPHER study team (study statisticians, manager and health economist) will be able to access linked pseudonymised data on the eVM. Using the eVM, the CIPHER research team at the University of Bristol will join the NHS Digital dataset and the study data together. This 'linked' dataset will not contain any direct identifiable data, only study IDs.

We will only 'link' study data and NHS Digital data for patients from England

Where is CIPHER data stored?

We store both direct identifiers and study data (not NHS Digital data) on a study specific CIPHER study database against a study ID. Each CIPHER patient has a unique study ID. University Hospitals Bristol and Weston NHS Foundation Trust hosts the CIPHER study database. The UoB eVM (which stores pseudonymised data only) is located at the Slough Data Centre and is run by Virtus.

How long will CIPHER store the data?

The study data (including identifiable information) will be held securely on University Hospitals Bristol and Weston NHS Foundation Trust servers until the end of the study (April 2024). It will then be securely stored for a further 5 years to April 2029. The 'linked' pseudonymised data set will be stored on the EVM at the University of Bristol until April 2029.

Who will have access to my data?

Your local recruiting hospital will collect information from you and your medical records for this research study and will transfer it securely to the CIPHER research team at the University of Bristol. This data will be stored securely on a database on a University Hospitals Bristol and Weston NHS server.

Your local recruiting hospital and the University of Bristol will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Royal Devon University Healthcare NHS Foundation Trust and regulatory organisations may only look at your medical and research records to check the accuracy of the research study. They will not have access to patient level NHS Digital data. The only people at the University of Bristol who will have access to information that identifies you will be people who need to contact you as part of the CIPHER study, request NHS Digital (limited to those with honorary UHBW contract) or audit the data collection process. Your local recruiting hospital will keep identifiable information about you from this study for 5 years after the study has finished.

Our legal basis for processing personal data

The CIPHER study is conducting scientific research that aims to improve the public good and public health.

Our legal basis for using your information, under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is:

1. Performance of a task carried out in the public interest (Article 6(1)(e) in the GDPR); and, where sensitive personal information is involved:
2. Processing for a task in the public interest (Article 9(2)(i) in the GDPR)

The GDPR defines data concerning health as 'special category data'.

This legal basis within GDPR and the Data Protection Act 2018 is separate to, and in addition to, our seeking patient consent to take part in the CIPHER study, which we have used to help ensure our research is ethical and complies with other applicable laws.

Rights of the Individual

The GDPR provides rights for individuals; the right to be informed, the right of access, the right to rectification, the right to erasure, the right to restrict processing, the right to data portability, the right to object to processing and rights in relation to automated decision making and profiling. There is no automated decision making (making a decision solely by automated means without any human involvement) or profiling (automated processing of personal data to evaluate certain things about an individual) involved in this study. The rights available to you depend on the reasons why we are processing your data. In certain circumstances, you have the right to request the restriction of the processing of your personal data. This means that you can limit the way that an organisation involved in this study uses your data. You may contest the accuracy of your personal data, you may feel that your data has been unlawfully processed, you may wish for an organisation to keep your data for a longer period in relation to a legal claim, or you may object to the articles under which an organisation has processed your data.

These requests can be made in writing or verbally. You can contact the CIPHER study manager via email at cipher-study@bristol.ac.uk

What if I don't want to carry on with the study?

If you decide to not carry on with the study, you can withdraw at any time and without giving a reason by contacting the CIPHER study manager at cipher-study@bristol.ac.uk. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Complaints or queries

If you would like to complain about our handling of your data, please contact the Data Protection Officer at the University of Bristol: data-protection@bristol.ac.uk.

You may also contact the Information Governance team at Royal Devon University Healthcare NHS Foundation Trust: ndht.dpo@nhs.net

You may also complain to the Information Commissioner's Office. Their helpline number is 0303 123 1113 or website: <https://ico.org.uk/make-a-complaint/>.