CANcer Diagnosis Decision rules Study (CANDID) GDPR Participants' Privacy Notice

Background

The University of Southampton is required to inform people about the ways in which we use their personal information. We need to tell you about the types of personal information we collect, the purposes we use it for, the legal reasons contained in the General Data Protection Regulation and Data Protection Act 2018 which allows us to use it in these ways, how long we retain the information for and how you can exercise your rights.

This requirement applies when dealing with "personal data". If data is considered personal then the GDPR places specific legal obligations on the controller of that data. If data is not personal (i.e. if it never related to a person or if it has since been anonymised) then the GDPR does not apply.

Data Controller

The University of Southampton is the Data Controller for the CANDID Study. This means that we will decide how your personal information, as a participant in the study, is created, collected, used, shared, archived and deleted (processed). When we do this we will ensure that we collect only what is necessary for the project. If any other organisation will make decisions about your information, this will be made clear in the participant information sheet (Primary Care PIS or Secondary Care PIS]) provided to you when you agreed to participate.

Access to patient data is vital for this study and we implement high security and governance standards to ensure patient confidentiality within our study. We obtain appropriate ethical and legal approvals for all research and ensures that it is strictly in the public interest when we use personal information. We do this by following the UK Policy Framework for Health and Social Care Research.

About the CANDID Study

In primary care the key areas of concern for both doctor and patients are delay in diagnosing cancer, getting high risk patients referred first, and keeping investigation to a minimum. There have been few valid studies to assist decision-making in primary care, either to get a patient referred quickly, or to assist in making sure an anxious patient is effectively reassured. This study seeks to work out which of the symptoms and examination findings are the most effective in predicting lung or colon cancer.

The study has two key parts:

1. We will interview patients and also get consensus from a group of experts.
2. We will recruit and follow over 5 years, 20,000 patients who consulted their GP with lung symptoms (for example cough) or bowel symptoms (for example loose stool).

The study has conducted interviews to build consensus between clinicians and researchers on potential diagnostic indicators (symptoms and signs) and tests considered crucial in the identification of patients presenting in primary care with symptoms indicating an increased risk of lung or colorectal cancer. This part of the study involved a sample of 10 lung cancer (LC) and 20 colorectal cancer (CC) patients, diagnosed in the previous 12 months. They were selected purposively from a respiratory

clinic and a colorectal cancer clinic respectively at the Leighton Hospital, North Staffordshire.
The study also recruited 20,000 patients who consult their GP - half with lung symptoms and the other half with low bowel symptoms – who will be followed over time. For each participant that enrols in this part of the CANDID study, their GP or hospital doctor will conduct a clinical examination and this information will be captured and shared with the study using standardised web based proformas. Participants will also be invited to provide additional measures (e.g. genetic, inflammatory and lifestyle information including smoking and alcohol status). The study has also asked participants for their consent to access data included in their health records to identify any diagnosis of colorectal or lung cancer within two years to five years of presentation though linkage to national cancer registries and GP records.

The clinical prediction 'rules' or decision aids developed from these studies will then be tested with a further 2000 patients for each condition for validity.

In this study, your personal information will only be used for the purpose of health and care research and cannot be used to affect your care. It will not be used to make decisions about future services available to you. All data used in publications will be completely anonymous.

What personal data do we process

We process personal information about you as a CANDID Study participant (which includes your name, postcode, date of birth and information about your health and treatment) from the following sources:

- Directly from you with your consent (Interviews, consent form, Baseline Questionnaire, optional Lifestyle Questionnaire, and optional Blood or saliva sample)
- From your doctors (from your GP or your referral letter if recruited during a hospital appointment)
- From third-party sources (e.g. NHS organisations, disease registries, other research institutions, NHS England and NHS Wales, Office for National Statistics) with your consent or, under exceptional circumstances (where consent is not possible), with relevant approval from the Health Research Authority to do so.

To understand whether study participants are diagnosed with cancer after enrolling in the study, we will securely send your NHS number and date of birth, as well as your study ID to the National Cancer Registration and Analysis Service, (which is part of NHS England) and from The Welsh Cancer Intelligence & Surveillance Unit (WCISU,). NCRAS and WCISU are national cancer registries that are responsible for recording information about every diagnosed with cancer, their diagnoses, treatment and outcomes.

NCRAS and WCISU will use the NHS numbers and dates of birth to identify if any study participants have a cancer diagnosis. If they identify a participant has been diagnosed with cancer, the cancer registry will securely share this back with the University of Southampton.

You can learn more about how the two cancer registries collects data here: https://www.ndrs.nhs.uk/ or https://phw.nhs.wales/services-and-teams/welsh-cancerintelligence-and-surveillance-unit-wcisu/about-us/

Legal basis to process your personal data for the study

Data protection law requires us to have a valid legal reason to process and use personal data about you. This is often called a 'legal basis'. GDPR requires us to be explicit with you about the legal basis upon which we rely in order to process information about you.

For research the legal reason is *"Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller" (Article 6 of GDPR)*

For sensitive information (called special category personal data) the legal reason is: "the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes… which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject". (Article 9 of GDPR)

Your rights

You have rights over your personal information by law;

- The right to object (to processing of the data)
- The right to correct (inaccurate or incomplete data)
- The right to erasure (also known as "the right to be forgotten")
- The right to restrict processing (e.g. while the accuracy of the data is contested)
- The right to portability (to have a copy of any data you have provided to us)
- The right to access (to have a copy of data we hold about you)
- The right to withdraw consent (if you have previously consented to take part)

These rights apply to information processed for research purposes, however there are some specific exemptions and 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. . Once the information has been irreversibly anonymised and becomes part of the research data set it will not be possible to access your personal information and uphold these rights.

If it is considered necessary to refuse to comply with any of your individual rights, you will be informed of the decision and you also have the right to complain about our decision to the Information Commissioner.

In addition to the legal requirements under GDPR, the study sought your consent. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. You can opt out by contacting Southampton Clinical Trials Unit:

e-mail: ctu@soton.ac.uk

If you ask us to withdraw you from the study, identifiable data or sample already collected with your consent would be retained and used in the study but no further data would be collected or linked.

Protecting your data

The University of Southampton stores all your data securely and to the highest industry and professional standards. We have the following safeguards:

- Policies and procedures that tell our staff and students how to collect and use your information safely.
- Training which ensures our staff understand the importance of data protection and how to protect your data.
- Security standards and technical measures that ensure your information is stored safely and securely.
- Our research involving personal data are scrutinised and approved by a research ethics committee.
- We carry out data protection impact assessments on high risk projects to ensure that your privacy, rights as an individual or freedoms are not affected.

Only the study team have access to your data with the personal identifiers (which is necessary in order to allow us to add more information about each participant as it becomes available).

Retention of Data

The University of Southampton will store your data for 10 years from the end of the study.

How to get in touch with the study or to withdraw your consent

Patients have the right to withdraw from the study at any time. To discuss withdrawal options, please contact Southampton Clinical Trials Unit by e-mailing ctu@soton.ac.uk.

Lodging a complaint

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your data, please data.protection@soton.ac.uk

If you are not happy with the way your Personal Information is being handled, or with the response received from us, you have the right to lodge a complaint with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, SK9 5AF (https://ico.org.uk/). The University's registration number with the Information Commissioner's Office is Z6801020