

Participant Information Sheet

Scottish COVID CAncer iMmunity Prevalence (SCCAMP) study

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Since the outbreak of COVID-19, we have worried that patients with cancer may be at greater risk from COVID-19. It's also important that we continue to treat patients with cancer as safely as possible during the pandemic. We therefore need to understand more about how patients with cancer are affected by COVID-19 and how they develop immunity. Antibody tests for COVID-19 can confirm whether someone has had COVID-19 in the past and may suggest they are immune - but we do not know how many people with cancer have antibodies against COVID-19 and whether the antibody response is affected by treatment.

The SCCAMP study is testing a series of blood samples from patients with cancer for COVID-19 antibodies. We are aiming to understand how many people with cancer have had COVID-19, and how their immune system has responded.

Why have I been invited to take part?

You are currently undergoing care or follow-up for cancer. We are looking to understand more about patients like you who have been living through the COVID-19 pandemic.

Do I have to take part?

No, it is up to you to decide whether to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

This study requires you to do the following five times over the course of a year around the times outlined in the table below, noting there is room for flexibility:

- give extra blood samples
- answer some questions about your symptoms

	The day you give your first blood sample	+ 6 weeks	+ 12 weeks	+ 6 months	+ 1 year
Blood tests	x	x	x	x	x
Symptom checklist				x	x

How your visits are planned:

- Scheduling these visits will require a member of our team to review your appointment schedule because we will aim to take your blood tests at times **when you are already scheduled to attend the cancer centre (for example, for treatment or an outpatient clinic appointment)** – as such, the dates in the table above are just a guide. It could mean an extra blood sample on some occasions, or an extra visit to the hospital to provide blood samples purely for the study. If an extra visit is needed, we would invite you to attend our cancer trials area.
- If government guidance recommends attending hospital for only essential care, we would contact you and advise you not to attend. Even if you consent to this, you can say no at any time.

What our study team will do with your information and samples:

- We would also like to use some information from your medical notes, such as your diagnosis, treatment, symptoms and any hospital admissions. This means individuals trained in research and patient confidentiality will access to your medical records solely for the purposes of this study.
- We will test the samples you provide for the COVID-19 antibody and may perform further tests on the blood tests you provide to understand more about COVID19.

You may have already contributed blood tests to a Biobank during the pandemic. If this is the case then we may use these for this study alongside the blood tests outlined above. These previous samples may replace some of the five samples required by the study.

Is there anything I need to do or avoid?

There is no specific action required by you before, during or after the study.

What are the possible benefits of taking part?

You will be helping us to understand how COVID-19 affects patients with cancer, although it is possible that you will not personally benefit from the research. As we do not know enough about the accuracy and relevance of COVID-19 antibody response, and this is not currently standard of care, we will not be able to tell you your COVID-19 antibody result. However, if evidence emerges that will have an impact on your clinical care, or it becomes standard practice across the NHS, the clinical care team looking after you in the hospital will be made aware of this and they may explain the information to you.

What are the possible disadvantages of taking part?

The only risks to you would be the possibility of some pain or bruising from giving extra blood samples. As outlined previously, we plan to keep any extra visits to a minimum and would not invite you to attend for an extra visit to give a sample if government advice was against non-urgent visits. We will cover your travel expenses if any study visits do not coincide with a routine clinical visit.

What if there are any problems?

If you have a concern about any aspect of this study, please contact Heather McVicar (Lead Research Nurse) who will do their best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

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

It is entirely up to you whether you want to participate. We will not put you under any pressure, and you do not have to give a reason. Please be assured that your decision will not affect your healthcare.

You can also change your mind at any time. You can request no further involvement and you can also request that all your information and samples are removed from the study, including ones that have already been taken. If you change your mind later, some of your samples and depersonalised patient data collected for the research may already have been used. It would be too late for us to stop this, but we would dispose of any tissue that had not been used yet. We would also dispose of any information collected and stored about you for the study but would keep a small amount of data about your wishes to withdraw consent. This would be a copy of your consent form with “consent withdrawn” written on it and a copy of any letters we may send you confirming withdrawal.

If you decide to withdraw consent, you can tell a member of your healthcare team, or contact us on the telephone number or email address in the “Further Information” section.

If you lose the ability to consent, or cannot carry on with the study, we will use any data or samples provided up until that point, but will not use further samples or data after the point at which this becomes the case.

What happens when the study is finished?

When the study is finished, any samples left over will be destroyed unless you have consented to storage and future use of your samples, which is separate to SCCAMP. Your anonymised clinical information will be stored securely for longer in case it needs to re-analysed for this study as additional evidence emerges.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. For details on what data will be held about you and who will hold and store this information please refer to the Data Protection Information Sheet.

What will happen to the results of the study?

There is a website about the study which you can access to find out more about the study as it progresses: <https://cancer-data.ecrc.ed.ac.uk/sccamp/>. We ultimately plan to publish and present this work so others might learn from our findings and will place this on the website. You will not be identifiable from any published results.

Who is organising and funding the research?

This study has been organised by Dr Peter Hall and Dr Karin Purshouse, and sponsored by the University of Edinburgh.

The study is being funded by the Edinburgh Experimental Cancer Medicine Centres (ECMC) and NHS Lothian Endowment fund, and the Edinburgh and Lothian Health Foundation (ELHF).

Who has reviewed the study?

The study proposal has been reviewed by a team of cancer doctors and nurses, and specialists in COVID-19. This is listed in the protocol, and can be made available to you if you would like to know who has been involved.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from SESREC 2. NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact Dr Peter Hall - on telephone 0131 537 2196

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Professor Charlie Gourley – 0131 651 8510

Complaints

If you believe that you have been harmed in any way by taking part in this study, speak to the clinical team or contact the BioResource in the first instance. If you are still unhappy, you have the right to pursue a complaint and seek any resulting compensation through NHS Lothian which is acting as the research sponsor. Also as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Experience Team, Waverley Gate, 2nd Floor, 2-4 Waterloo Place, Edinburgh, EH1 3EG. Telephone 0131 536 3370 or email feedback@nhslothian.scot.nhs.uk. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Lothian, but you may have to pay your legal costs.

If you think of anything else later, you can contact us at 0131 465 5456, Public Health Office, NHS Lothian, Waverley Gate, Edinburgh, or email rie.tissuegovernance@luht.scot.nhs.uk

Participant ID:

CONSENT FORM

Scottish COVID CAncer iMmunity Prevalence (SCCAMP) study

Please **initial** box to all joints to which consent is given

- | | |
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| <p>1. I confirm that I have read and understand the information sheet (13th Nov 2020 and V2.2) and the Data Protection Information Sheet (13th Nov 2020 and Version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |
| <p>2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected.</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |
| <p>3. I give permission for the research team to access my medical records for the purposes of this research study.</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |
| <p>4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records.</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |
| <p>5. I give permission for my personal information (including name, address, date of birth, telephone number, Community Health Index (CHI) number/hospital number and consent form) to be passed to the University of Edinburgh and NHS Lothian for administration of the study.</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |
| <p>6. I agree to my General Practitioner being informed of my participation in the study.</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |
| <p>7. I agree to give blood samples for this study</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |
| <p>8. I agree to take part in the above study.</p> | <input style="width: 40px; height: 30px; border: 1px solid black;" type="checkbox"/> |

Name of Person Giving Consent	Date	Signature
Name of Person Receiving Consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record