The ROYAL MARSDEN
NHS Foundation Trust

GI & Lymphoma Unit
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PATIENT INFORMATION SHEET

CARDS

Cancer: Rapid Diagnostics and Immune assessment for SARS-CoV-2 (COVID-19)

ARM B

We invite you to take part in a research study. Before deciding whether to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this carefully and discuss it with other people if you wish. Please ask your doctor or nurse if there is anything you do not understand or if you want more information. Please take your time to decide.

Why am I being invited to take part in this study?
COVID-19 is caused by a virus called SARS-CoV-2. Antibodies are molecules made by your immune system in response to infections such as COVID-19 and may indicate your immunity or past infection to COVID-19. Your doctor has invited you to take part in this study because we are studying Coronavirus (COVID-19) antibodies. We would like to be able to collect information on your medical condition, and collect additional blood to measure antibodies and other parts of your immune system during some of your visits to hospital. We would like to use your samples for our research project, which is described in detail below.

What is the purpose of this study?
Infection caused by COVID-19 has been responsible for a large number of deaths in the UK and around the world.

People who are receiving therapy for cancer sometimes have a lowered immune system. In this project, we want to study the effect of COVID-19 infection in people with cancer. We will study your body's immune system and its response to the COVID-19 virus.

You will be helping us to find out:

1. If we can develop a much quicker and accurate antibody test for the COVID-19 virus which would enable rapid identification of people who have been infected with the virus.
2. How cancer treatments affect immunity to COVID-19.

What will happen to me if I take part?

If you agree to take part in this study, any tests or treatment that your doctor recommends for you will not be affected by your participation in this study. We would like to collect blood every 28 days for 84 days (approximately 3 months). These visits will be incorporated into your pre-existing hospital appointments. We will contact you every month either by telephone or in person to ask you about any coronavirus symptoms. If you develop COVID-19 symptoms or have confirmed COVID-19, we may invite you to participate in Arm A of the study (confirmed or suspected COVID-19). We will provide you with a patient information sheet for Arm A and will request written informed consent prior to participation.

- We are asking for your permission to collect information about your medical history, cancer and previous treatments at the Royal Marsden Hospital (RM). We will collect this information from your medical records. We are also asking for your permission to contact your GP to obtain updated information. All of the information we collect will be anonymised at this stage so that researchers will not be able to identify you from the data collected. The majority of the work carried out on your samples will be conducted at the Royal Marsden Hospital and St George's Hospital but we may also on occasion share your anonymised information with other national or international institutions with whom we collaborate in ethically approved studies.

- We are asking for your permission to take additional blood samples. We would like to take a blood sample of no more than 30 mL (about six teaspoons).

- We are asking for your permission to perform research on the blood samples.

Once you have read this information sheet and signed the consent form, we will start collecting clinical information in an anonymised fashion and we will inform your GP. If you have given your consent, we will arrange for research blood to be taken. All samples will also be anonymised.

All of the anonymised samples will be collected at the Royal Marsden Hospital, and will be sent to and stored at St Georges Hospital where the appropriate analyses will be performed. These researchers will not be able to identify you. You should be aware that the scientists might not conduct all research immediately, but that your samples may be studied at a later point in time.

What will happen if I lose capacity to consent during the study or I don't want to carry on with the study?

If you decide to take part, and later change your mind, you are free to withdraw your permission. You do not have to give a reason for your decision and this will have no influence over your future medical care. After withdrawing consent no samples will be collected or any research procedure carried out. You will be given the option of whether further data can be collected and whether the samples you have already contributed can continue to be used in research. The

data collected about you up until the point of withdrawal of consent will still be used in the data analysis for the study.

What is capacity and loss of capacity? Capacity means the ability to use and understand information to make a decision, and communicate any decision made. A person lacks capacity if their mind is impaired or disturbed in some way, which means they're unable to make a decision at that time.

In the event that you lose capacity we will ask for further consent from your designated personal consultee. In the event that your personal consultee is unavailable or cannot be reached we will seek advice from a nominated consultee, who is a person independent of the project appointed in accordance with the Department of Health's guidance. When you regain capacity, we will ask for your consent again.

What are the possible risks and benefits of taking part?

Benefits

Information that we will obtain from your samples will not affect the way you will be treated, and you will not be informed of the results. There will be no direct benefit to you from your participation in this study. We are asking for your permission to study and store your samples now and in the future (indefinitely) at the Royal Marsden Hospital, St Georges Hospital, and other approved offsite facilities. These samples may be used in other ethically approved COVID-19 studies. The analysis of the samples you provide during this study may help us develop understanding and tests that will improve the treatment of people with cancer in the future.

Risks associated with taking blood

Risks associated with taking blood from a vein in your arm include pain, bruising, light-headedness and on rare occasions, infection.

Sometimes these types of samples can help to establish products that could be patented and licensed. Your samples would be considered a donation, and you would not benefit financially. Research carried out at our Institution is not for commercial purposes, but to help us understand how to improve the clinical management of COVID-19 infection in people with cancer.

If you have private medical insurance, please check with the company before agreeing to take part to ensure that your medical insurance will not be affected. Neither you nor your doctor will be told of the results of the additional research tests.

Will I be reimbursed for participating in this study?

We would be extremely grateful for your participation in this study. As these research blood tests will be taken when you have your routine blood tests, there will not be any extra visits to hospital as part of this study. You will not receive any payment for participating in this study. Similarly, other costs of transport (e.g. fuel, public transport) will not be reimbursed.

What if something goes wrong?
If you have any concerns about this study you should speak to your research doctor/nurse who will do their best to answer your questions. If you are harmed by taking part in this research project, there are no special compensation arrangements. Healthcare professionals working on clinical trials are covered by NHS Indemnity and if you are harmed due to someone else's negligence, you may have grounds for legal action but you may have to pay for it. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the National Health Service complaints mechanisms will be available to you. Concerns should be raised by speaking to a member of staff at your hospital or by talking to the local Patient Advice and Liaison Service (PALS) which has been established in every NHS trust. Contact details can be found towards the end of this patient information sheet.

Will my taking part in this study be kept confidential?
All the information which is collected about you will be kept strictly confidential. Your blood samples for research will be anonymised so that researchers will not be able to identify you. A unique subject identifier will be allocated to you which will be used to label your data and samples which is only accessible to the research team at the Royal Marsden Hospital. Regulatory authorities, monitors and auditors may have access to personal identifiable data. Any information about you or about the result of the research tests will be kept confidential and will not be included in your medical records.

In this research study we will use information from you, your medical records and possibly your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

What will happen to the results of the research study?
The results are likely to be published in a medical journal or presented at a medical conference. However, you will not be identified in any report or publication produced from this study. When the study is completed, we aim to make the results available to view on a clinical trials database (https://clinicaltrials.gov). If you do not have access to a computer and would like to know the results, please get in touch with the trial team who can arrange to send you or your family a copy.

Who is organising the research?
This research is sponsored by the Royal Marsden NHS Trust. Your doctor will not receive any personal financial payment if you take part.

Who reviewed the study?
This study has been approved by a Committee for Clinical Research (CCR), Health Research Authority (HRA) and Research Ethics Committee (REC) on behalf of hospitals throughout the UK.

What happens now?

Your doctor or nurse will be happy to answer any questions you may have regarding the study. Once you have read and understood the information contained in this patient information sheet and your questions have been answered you will be asked to decide whether you want to participate in this study. Additional research samples will be obtained at the same time as your routine blood test(s). Once you have reached your decision, please inform your doctor or nurse.

General Data Protection Regulation (GDPR) Transparency Statement

How will we use information about you?

We will need to use information from you, your medical records and possibly your GP for this research project.
This information will include your

- Name/Initials
- Date of birth
- Hospital number
- NHS Number
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. RM will keep identifiable information about you for at least 5 years after the study has finished, in line with local policies and legal requirements. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from the Royal Marsden Hospital and your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- the leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team (see phone numbers below)
- by sending an email to the Data Protection Officer at RM. Email: dpo@rmh.nhs.uk.

Contact numbers:

GI

Royal Marsden NHS Foundation Trust, Sutton, Surrey

Professor Cunningham	(Consultant)	020 8661 3156
Dr Ian Chau	(Consultant)	020 8661 3582
Dr Sheela Rao	(Consultant)	020 8661 3159
Dr David Watkins	(Consultant)	020 8661 3158
Specialist Registrar		020 8642 6011
Kennaway Ward		020 8661 3128
West Wing		020 8661 6669
On Call Registrar	(24 hours)	020 8642 6011

Research Nurse Name……..

Contact Telephone No (9am – 5pm Mon – Fri) ……

Royal Marsden NHS Foundation Trust, Fulham Road, London

Professor Cunningham	(Consultant)	020 7808 2123
Dr Ian Chau	(Consultant)	020 8661 3582
Dr Naureen Starling	(Consultant)	020 7808 2123
Senior Registrar		020 7352 8171
Burdett Coutts Ward	(24 hours)	020 7808 2370
On Call Registrar	(24 hours)	020 7352 8171

Research Nurse Name……..

Contact Telephone No (9am – 5pm Mon – Fri) ……

Lymphoma

Royal Marsden NHS Foundation Trust, Sutton, Surrey

Professor Cunningham	(Consultant)	020 8661 3156
Dr Ian Chau	(Consultant)	020 8661 3582
Specialist Registrar		020 8642 6011
Bud Flanagan West		020 8661 3144
On Call Registrar	(24 hours)	020 8642 6011
West Wing		020 8661 6669

Research Nurse Name …….

Contact Telephone No (9am – 5pm Mon – Fri)……..

Royal Marsden NHS Foundation Trust, Fulham Road, London

Professor Cunningham	(Consultant)	020 7808 2123
Dr Ian Chau	(Consultant)	020 8661 3582
Specialist Registrar		020 7352 8171
Wilson Ward		020 7808 2378
On Call Registrar	(24 hours)	020 7352 8171

Research Nurse Name …….

Contact Telephone No (9am – 5pm Mon – Fri)……..

Patient Advice and Liaison Service (PALS)
Telephone: 0800 783 7176
Address: Royal Marsden NHS Foundation Trust, Downs Road, Sutton, SM2 5PT

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PATIENT CONSENT FORM (Page 1 of 2)

Cancer: Rapid Diagnostics and Immune assessment for SARS-CoV-2 (COVID-19)
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Name of researcher: *Dr Sheela Rao, Consultant Medical Oncologist.*

Please initial each box to agree and sign at the bottom of the form.

1. I confirm that I have read and understood the information sheet (CARDS ARM B v1.0 Dated: 10/07/2020) for this study and have had an opportunity to ask questions which have been answered to my satisfaction. ☐
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 or legal rights being affected. ☐
3. I agree that relevant sections of any medical notes and data collected during the study may be looked at by responsible individuals at the Royal Marsden Hospital, the trial sponsor, and the regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I give my permission to transfer information relative to my medical history to be analysed in other ethically approved studies and/or collaborations. ☐
5. I agree to researchers using my samples for the purposes listed in the information sheet. I understand that I am giving biological samples as a donation for research. ☐
6. I agree to have blood samples taken for research purposes as described in the patient information sheet. ☐

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PATIENT CONSENT FORM (Page 2 of 2)

Cancer: Rapid Diagnostics and Immune assessment for SARS-CoV-2 (COVID-19) ARM B

7. I give permission for my blood samples that have been collected during the CARDS study which will be stored indefinitely on behalf of the Royal Marsden NHS Foundation Trust or St Georges Hospital for use in future approved COVID-19 research projects. ☐

8. I understand that the samples retained for future COVID-19 research may be stored, processed and/or analysed by researchers at external storage facilities, other institutions, or laboratories including commercial companies or health and research organisations. This will be on the understanding that the samples are anonymised. ☐

9. I agree to my general practitioner being informed of my entry into this study. ☐

10. I agree for the research team to contact my GP to obtain updated clinical information. ☐

11. If I lose capacity, I am happy for a personal or nominated consultee to give consent on my behalf for me to continue in the study. **Optional.**

	YES	NO
	☐	☐

12. I agree to take part in the above study. ☐

Name of PATIENT	**Date**	**Signature**

Name of person taking consent	**Date**	**Signature**

When completed, 1 copy for patient, 1 original for researcher, 1 copy to be kept with case notes.