**Group C: Volunteer Patient Information Sheet**

**CAPTURE** - Cancer and COVID-19 antiviral response study

**A sub-study within TRACERx Renal** (**TRA**cking Renal **C**ell Carcinoma **E**volution Through Therapy (**Rx**)

*RMH Protocol No.3723*

**Introduction**

The coronavirus pandemic of 2020 has created an urgent need for further investigation into the virus, how it affects patients and how it can be contained. We are asking you to participate in this research project specifically aimed at capturing the effects of COVID-19 in patients with a history of cancer.

We are asking three groups of patients to participate in this research:

**Group A**: Individuals with a history of cancer and confirmed or suspected COVID-19 infection

**Group B**: Individuals with a history of cancer *without* COVID-19 infection

**Group C**: Healthy volunteers with *or* without a history of COVID-19 infection

You are being asked to participate (consent) as an **Arm C** *volunteer* to enable comparison with the patients who are recruited with a history of cancer.

Consent is a freely given agreement, based on a full understanding of what is to happen. Researchers can only use the samples after their research has been approved by independent researchers and by an independent Research and Ethics Committee consisting of researchers, academics, clinicians and patients representatives. This is to make sure that the research is in the interest of patients and is carried out safely.

**What is the purpose of the study?**

We, as researchers at The Royal Marsden NHS Foundation Trust, are looking to improve our understanding of COVID 19 in patients with cancer.

We are looking to investigate the consequences of COVID-19 infection in patients with cancer and understand which patients are particularly vulnerable. We also aim to understand how this virus affects cancer patients and how specific cancer treatments, such as immunotherapy, change the course of the disease. Some of these findings might help with the development of new drugs and vaccines in the future.

You are being asked to participate as a healthy volunteer to become part of a control group which is necessary for scientific analysis.

**What will happen to me if I take part?**

If you decide to participate in the study you will be asked to sign the attached consent form.

If you agree to participate (consent) you will be asked to:

* complete questionnaires about symptoms and risk factors for COVID-19. We will ask you to complete questionnaires at 10 time points over a 12 month period.
* provide information regarding your medical history
* have blood samples and throat swabs to look at genetic material (DNA) and proteins related to the virus in the blood.
	+ blood samples will be conducted / obtained at baseline and will be repeated every 4 weeks for 12 weeks, and every 3 months until the end of the 12 month trial period.
	+ Throat swabs will be taken at Baseline, 2 weekly for 3 months, and every 3 months until the end of the 12 month trial period.

You are free to refuse to give these samples and/or to withdraw from the study at any time.

**Where will my samples be kept and who will have access to it?**

Any samples you donate may be stored, processed and/ or analysed at The Royal Marsden NHS Foundation Trust or the following laboratories, including but not limited to: University College London (UCL), The Francis Crick Institute, Royal Marsden Hospital Centre for Molecular Pathology (CMP) and Institute of Cancer Research. Samples may also be sent to other collaborators such as commercial companies, after approval from The Royal Marsden NHS Foundation Trust (RM). These collaborators may not be located in the United Kingdom, please note data protection guidelines may differ outside of the UK. In each laboratory where tissue is stored, there is a named individual who is responsible for the tissue samples. This is normally a senior person in the laboratory or a medical consultant. The Chief Executive of the Trust has overall responsibility for the tissue.

We would also like to collect samples to be used for future research by researchers interested in COVID 19 and coronavirus. The projects would need to be approved by The Royal Marsden NHS Foundation Trust including the Chief Investigator of this study, and a Research Ethics Committee. The samples would not include any personal information therefore researchers will not be able to identify you from your samples. These projects may be carried out by researchers at other institutions other than The Royal Marsden NHS Foundation Trust or laboratories listed above, including researchers working for commercial companies outside of the UK.

**What will happen to the samples taken for this study?**

The blood tests will be examined to investigate your immune system. This includes looking at antibodies and other markers of immunity, including some genetic markers.

We are hoping to detect patterns in the genetic profiles, antibodies and inflammatory markers that will help us understand how the virus causes disease and how this is changed by cancer treatment.

**How will I complete the questionnaires?**

We will be using an online questionnaire system called PROFILES. In order to administer the questionnaires, your name and contact information will be stored in the PROFILES system on servers owned and based at the Royal Marsden. Please note your answers will not be reviewed by the clinical team and any symptoms or issues that arise should be directed to your doctor. We will ask you to complete a questionnaire at 10 time points over 1 year. Completing the questionnaires should take between 10-20 minutes and can be completed at home. The only people who will have access to information that identifies you will be people who need to contact you about the questionnaires, the researchers working on the trial and the regulatory organisations. Your data will be stored in the PROFILES system indefinitely, unless you choose to withdraw your consent and request the data be deleted. If you have any questions regarding the PROFILES system please contact the team on ***CAPTURE@rmhs.nhs.uk***.

If the PROFILES system is unavailable you will be provided with paper questionnaires.

**How will this study benefit me?**

This research is done to help us understand the COVID-19 virus and how our immune system fights the disease. The research is not intended to benefit you but to help us treat the disease better in the future.

**What about confidentiality?**

Samples will be given a unique code so that only The Royal Marsden NHS Foundation Trust will know your name or any other personal details. Samples can only be traced back to the study participant, by the team managing this research. Tissue may be transferred to other external organisations. This will be done under written agreement, which guarantees the use and safe keeping of samples, which will be kept anonymous. This means that no information that could identify study participants will be sent outside the Trust. All staff must work with the Trust’s confidentiality policies and the data protection laws so all personal information is protected.

**If I agree, what do I have to do?**

We will ask you to sign a consent form agreeing to take part in this project.

**What if I do not wish to take part and change my mind?**

Before you decide whether 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 this information carefully and discuss it with others if you wish. Ask 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. You can still change your mind at any time, even after you have signed a consent form, this will not affect your legal rights.

**Who is organising and funding the research?**

This study is being organised by The Royal Marsden NHS Foundation Trust Renal Unit. You will not receive any reimbursement for participating in this research.

**How will my data be processed?**

The Royal Marsden NHS Foundation Trustwill be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Royal Marsden NHS Foundation Trust will keep identifiable information about you for at least 5 years after the study has finished, in line with local policies and legal requirements. 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.

The Royal Marsden NHS Foundation Trust will use your name and contact details you provide to contact you about the research study and oversee the quality of the study. Individuals from outside of The Royal Marsden NHS Foundation Trust, employed by the Royal Marsden, and regulatory organisations, may look at the information you provide and research records to check the accuracy of the research study.

When you agree to take part in a research study, the information you provide about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of healthcare research, and cannot be used to contact you.

You can find out more about how The Royal Marsden uses your information by contacting the Data Protection Officer at The Royal Marsden. Email: dpo@rmh.nhs.uk.

**What will happen to the results of the research study?**

The results of this clinical research study will be published in a scientific journal. Results may also be presented at scientific conferences. Results from an analysis of your tumour may be made available, in an anonymous format, for use by other researchers. No details of individual study participants will be presented in either publications or presentations of the results. A copy of the published results will be available to you or your family on request.

**Who has reviewed this study?**

This study has been reviewed and approved by a research ethics committee.

**Who do I contact if I have any questions?**

If you have any questions or you no longer want us to use your samples, please consult the research team:

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|  | **London** | **Sutton** |
| The Royal Marsden (switchboard) | 020 7352 8171 | 020 8642 6011 |
| Dr Samra TurajlicConsultant Medical Oncologist | 020 7811 8151 | - |
| Senior Registrars/Fellows | Cordless: 1912/1940 | Cordless: 1091/1453 |
| Research Nurses | Cordless: 2656/3650/1666/1550 | Cordless: 3650 |
| If you have questions about your rights as a research subject, you may contact: PALS/Patient Information OfficerLondon 020 7808 2083; Sutton 020 8661 3759Working hours (9am to 5pm):  |

Thank you for your time spent reading this information sheet and considering this clinical study.