**A close up of a sign

Description automatically generatedA drawing of a face

Description automatically generatedBristol Children’s Vaccine Centre**

**<add NHS Trust logo>**

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**Avon Community Acquired Pneumonia Study (Avon CAP):**

**A Pan-Pandemic Acute Lower Respiratory Tract Disease Surveillance Study**

**Invitation**

We are inviting adults with possible respiratory infection (pneumonia, lower respiratory tract infection and/or heart failure) to take part in a research study to gain a better understanding of how these diseases affect them, especially during the COVID-19 pandemic. The study is coordinated by the Bristol Children’s Vaccine Centre (University of Bristol) and is funded by Pfizer. It is approved by the Health Research Authority. We hope to enrol over 10,000 participants a year, and this study is taking place at several hospitals in the Avon area.

**Why am I being invited to participate?**

Your doctors think you may have an infection in your lungs – this is sometimes called pneumonia or a lower respiratory tract infection. These lung infections can be caused by many germs including viruses like SARS-CoV-2 which causes COVID19, respiratory syncytial virus (RSV), and bacteria like pneumococcus. We are inviting you to take part because we want to better understand the nature of these infections and the disease-burden they cause.

**What is the aim of the study?**

We are recording how many adults are admitted to hospital each year due to respiratory illness. We want to find out more about which bacteria and viruses cause disease and if patients with underlying medical conditions are at increased risk of certain causes of infection.

We urgently need to know how respiratory disease may change due to the COVID-19 pandemic, including whether it makes other lung infections more or less likely. Alongside COVID-19, we are particularly interested in pneumococcus and RSV, as both cause a lot of disease and all three infections may be prevented by new vaccines which are in development.

**What will happen to me in this study?**

With your permission, we will record the results of all the hospital tests routinely done to find out which infection is responsible for your current illness. The study will collect information (mainly from your medical notes) about you, your illness and what happens during your hospital stay. We may need to ask you some extra questions, such as whether you’ve ever smoked in the past, work outside the home and follow social distancing guidance.

We will ask your permission to take a respiratory sample (normally a nose or throat swab) if this hasn’t already been done by the doctors looking after you. We will ask for a urine sample and to take a blood sample, for additional tests for respiratory infection. These additional tests are for research purposes and won’t affect your medical care in any way. You can still take part in the study if you only want to provide some, but not all, of these samples. We also want to use any leftovers from samples already taken by your medical team as part of your care.

If you have been discharged from hospital, we may ask you to return in 1-2 months’ time to have an additional blood test, and sometimes an additional respiratory sample. Reasonable travel costs of this clinic visit will be reimbursed (please keep your receipt). You can still take part in the study if you are not able to attend this clinic visit.

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| --- | --- | --- |
|  | **Initial visit**  **(Day 0)** | **Follow up visit**  **(Day 22-60)** |
| **Patient Tests** | Urine sample  Blood test  Nose/Throat Swab  Questionnaire | Blood test  Nose/Throat swab |
| **Duration (weeks)** | 0 | 6-8 |

We may use any excess sample to run additional tests for respiratory infection. These tests are solely for research and will not affect your medical care in any way. We may also use the samples to perform tests to determine things like which strain of a virus you have been infected with (e.g. the variant of SARS-CoV-2) or to see how your immune system has responded to the infection. We will not be able to provide you with the results of these tests as they are not necessarily performed at the time of your illness and may be performed using research only techniques.

**Do I have to take part in the study?**

No, it is up to you to decide whether you want to participate in this study. Please take the time you need to consider the study and ask any questions you have. You may also wish to discuss this with other people including family or friends. If you choose not to take part, you don’t have to give a reason, and your routine medical care and legal rights won’t be affected.

If you decide to take part but later change your mind you are free to withdraw at any time, without giving a reason. A decision to not take part, or to withdraw, will not affect your legal rights or your future medical care outside of the study. If you do withdraw from the study, you can also withdraw your consent for the further use of your samples that have not yet been processed or other information about you, if you wish and ask us specifically.

**What are the potential benefits of taking part?**

This study will not directly benefit you beyond your normal clinical care. Your participation in this study will contribute to our understanding of your condition. We hope this may benefit other patients like you in the future.

**What are the potential disadvantages and risks of taking part?**

Taking blood samples can be briefly uncomfortable and can result in slight bleeding or bruising under the skin. Taking nose and throat samples can also be a little uncomfortable and can rarely cause a mild nosebleed. There are no other risks involved in taking part.

**What will happen to all the samples in and after the end of the study?**

All the samples we collect will be used to test for germs causing respiratory infection. These samples will be processed at University of Bristol and/or shared with, Pfizer Inc. in the United States for testing. Samples will be anonymised before sharing with any collaborator, including Pfizer. Samples sent to Pfizer will be stored for up to 15 years and used for additional vaccine-related research (no genetic research), after which they will be destroyed.

If there are any samples left over, and only if you agree, we would like to keep them in the Bristol Biobank (run by the University of Bristol), so they can be used in further future research. This future research, which would need ethical approval, could be related to vaccines or infectious diseases, and might involve testing human genetic material (DNA). Any such tests would be anonymous so no one could identify you or your family. If you don’t want us to keep the samples or to do DNA tests, you can say so on the consent form and you can still participate in the study.

**What patient data will you use?**

Patient data include information about your health problems, any tests or treatments that you have and information like whether you have smoked. When information about your healthcare joins with information that can show who you are (e.g. your name or NHS number) it is called identifiable patient information. It’s important that identifiable patient information is kept confidential and there are rules to ensure that this information is kept safe and secure. The research team will be looking at some of your health records, using some data from your GP, hospital, or central NHS records. The information that is collected from the health records by the research team is called research data.

**What happens to my patient data in the study?**

The research team will enter your patient data into a research database, which is held on a password protected encrypted system compliant with GDPR (see below). Your information will be entered under a code number, so that it is not possible to identify you from this database (pseudonymised data). These data can be matched up with any patient identifiable data using the code number. These data will be held for 15 years.

Only the minimum number of research staff necessary will have access to any patient identifiable data. The wider research team and collaborators, including Pfizer, Inc, will only have access to anonymised data. Monitors on behalf of the sponsor may access your records to check the quality of the research. We may also provide the results from this study to bodies like Public Health England and regulators like the Medicines and Healthcare products Regulatory Agency (MHRA). Regulators would only have access to anonymised data. Any reports about the findings from this study will be written in a way that no-one can work out that you took part in the study. The pseudonymised data may be used for future research related to infectious disease prevention and vaccine development and may be shared with other researchers.

### Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow GDPR rules under the Data Protection Act 2018. All research using patient data must follow UK laws and rules. Universities, NHS organisations and companies may use patient data to do research to make health and care better. Researchers must show that their research takes account of the views of patients and ordinary members of the public. Researchers must also protect the privacy of people who take part. An NHS research ethics committee checks this before the research starts. This process makes sure that researching using patient data does so as part of ‘a task in the public interest’, and only data needed for the research is used.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a ‘legitimate interest’ in using patient data.

**What if something goes wrong or I want to complain?**

This study involves gathering information already collected through your clinical care. We may ask some additional questions (e.g. whether you’ve smoked) and will also ask to perform a few extra tests (i.e. blood and urine samples, nose/throat swabs), which are considered minimally invasive. We don’t expect anyone to be harmed by taking part. There is no automatic insurance protection to compensate you if you are injured, but you can still make a legal claim (e.g. if you think someone has done something wrong), and the University has Public Liability Insurance that covers its legal liability in relation to study participation.

If you have any concerns that you would like to discuss or if you would like to make a complaint, please contact the study team (contact details on page 1). If it is an emergency, you should first seek appropriate help (GP, A&E) and then contact us when convenient. For complaints about the study team conduct, you should contact the local Patient Advisory Liaison Service (PALS) team at the hospital site <Insert PALS details for NHS Trust here>

If you’re unhappy about the use of your data in this study, you can complain to the research team. If you are not happy with the response or believe we are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner’s Office (ICO) (www.ico.org.uk or 0303 123 1113).

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

It is important to share the results of this study with other scientists and healthcare organisations. We will publish what we learn from this study in scientific journals. We will also publish results at national and international research and health service delivery meetings.

**Who is organising and funding this study?**

The University of Bristol is sponsoring this study. The research is funded by Pfizer, Inc.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by [insert name] Research Ethics Committee.

**What do I need to do now?**

After reading this information sheet, if you would like to take part, we will ask you to sign a consent form (or a witness on your behalf), either on paper or electronically. You can receive a copy of the signed consent form for your records if you would like this.

We will ask your permission to contact you with information about future research studies that you may be eligible to participate in, but you don’t have to participate in these studies.

Thank you for taking the time to read this information

Professor Adam Finn