Virus Watch

VACCINE WATCH (A Virus Watch Sub-study)

Adult Participant (Age 18+) Information Sheet
Version 2 24.09.21

This information sheet is divided into two parts. Part 1 details what is involved in the study and how we will use information and samples collected. Part 2 outlines Frequently Asked Questions

Virus Watch recruits whole households and follows them up to ask about illnesses that could be COVID-19 related and behaviours relevant to the pandemic. The Vaccine Watch part of the study monitors immunity to COVID-19 using finger prick blood samples to measure COVID-19 antibody levels. Adult members of Virus Watch are asked to take part in Vaccine Watch but this part of the study is not open to children under 18 years of age.

We are very interested in understanding how many people have been infected with COVID-19 and how effective COVID-19 vaccines are in preventing future infection and disease. This is particularly important as new variants of Covid-19 emerge. We are also keen to find out whether our immune response to COVID-19 vaccines diminishes over time and if this differs in people who suffer with chronic illness.

Part 1

What is involved?

Study 1) Online reporting of illnesses and other information

1a) The first step is to complete an **online registration and consent survey** that allows all adults in the family to confirm that they are happy to take part in Virus Watch and that they are happy for children in their care to take part. Children who are old enough to decide will also be asked to show that they agree. If there are children in the house please go through the relevant children's information sheet with them. Completing the registration and consent survey will take about 5 minutes for everyone in the household. Please make sure that you have the name and address of everybody's GP practice available before taking the survey and, if you can find it, everybody's NHS number. The NHS number is on most letters from the NHS.

1b) Immediately after the registration survey is completed, the Virus Watch lead householder will help household members complete **online baseline questionnaires** covering questions about age, gender, ethnicity, country of birth, employment, finances, chronic medical conditions, medications, and previous positive COVID-19 test results. This will take around 10-15 minutes for each household member. Please make sure that you have a record of adult's height and weight if you know it. If you don't know this please use the images at the end of the Frequently Asked Questions to select your body shape category and make a note of this.

1c) Weekly recording of all illnesses - Whenever anyone in your house is ill with coughs and colds or a range of other symptoms that could be COVID, they will need to write down their symptoms (including their temperature if you have a thermometer) every day that they are ill. The Virus Watch household lead will get an e-mail each week asking them to say whether or not anyone was ill. If the answer is "no" that is the end of the questionnaire, so most of the time this will only take less than a minute to respond each week. If the answer is yes, the Virus Watch household lead will be asked to record symptoms of anybody who was ill in an online survey, whether they were treated for this illness, what was done in the house to prevent infection from spreading and a few questions about what adult members of the household did in the week before the illness. We also ask if anyone in the household was self-isolating in the past week and, if yes, for what reason. We will also ask whether you have been tested for COVID-19 or for COVID-19 antibodies and whether you have been vaccinated (first and second doses and any boosters). This information will help us to understand whether antibodies produced as a result of previous infection or vaccination can reduce the chances of you getting symptomatic COVID-19 infection. These questions will take around ten minutes to complete for each person who is ill.

1d) Monthly survey of behaviours and impact of COVID-19 restrictions

We would like to understand how people respond to government advice about COVID-19 and how this advice is affecting their lives. As this advice will change through the study, we plan a monthly online survey to assess this. This will ask about whether any surveys were missed, whether anybody has been in hospital, questions about recent activities, and whether you caught COVID-19. If you have caught COVID-19, where you believe you acquired the infection. Some questionnaires will include questions about your employment and your social contacts to see how COVID-19 measures are affecting you. This questionnaire will take around 15-20 minutes per household member.

We want Virus Watch Participants to tell us what questions are important to them. With the help of tens of thousands of your fellow participants, we can help to answer these questions. Please email us on viruswatch@ucl.ac.uk any questions that you would like us to try and answer. We will read through your responses and select questions that are raised by participants repeatedly to be included in our monthly or weekly surveys. These can include anything you think is important e.g. if you think some things may affect your risk of COVID-19 or protect you from it or if you are worried about the impact of control measures we can use the surveys to try to find out

more. We won't be able to answer all the questions but we do our best! We will also put our latest findings on our website and update these regularly.

Study 2 - Analysis of Medical Records

We would like to review your medical records to identify any hospital visits that might be related to respiratory viruses and any deaths in the household during the course of the study and for up to 5 years after the study has finished. This is because COVID-19 may circulate for many years and we wish to understand how well infection and vaccination protects against illnesses in future years. It may also be that COVID-19 produces unexpected long-term illnesses and we want to be able to find out if that happens.

We will link your records to NHS Digital and Office for National Statistics (ONS) who hold the data on hospital visits and admissions (called Hospital Episode Statistics data) and deaths.

We will also link to NHS Digital, ONS and/or Public Health England (PHE) to collect information on dates of any COVID-19 vaccination you have received, the type of vaccine, and the batch number. We will use these data from the National COVID-19 Vaccination Register to ensure we have accurate information on the timing and type of any vaccinations received.

We will work with PHE and ONS who hold routinely collected virological testing data including data from the NHS Test and Trace programme and the COVID-19 Genomics UK Consortium (COG-UK) to organise genetic sequencing of virus from any positive COVID-19 swab tests you have taken as part of the Test and Trace programme. This will allow us to understand which strain of SARS-CoV-2 you were infected with. This information will not be fed back to you.

In summary, we will provide NHS Digital, Office for National Statistics (ONS) and Public Health England (PHE) with names, dates of birth, sex, home addresses, and, where available, NHS numbers of Virus Watch Participants. NHS Digital, ONS and/or PHE will return information on any COVID-19 vaccinations received, any hospital visits, admissions or deaths in the household. We will also receive any positive results arising from the Test and Trace programme, and we may organise further genetic tests on virus from these positive swab samples. These data will be linked to the Virus Watch Dataset before removal of identifiers so that people analysing the data will not be able to identify participants. These data will be used for statistical and research purposes only.

Study 3 - Finger prick testing every other month for COVID-19 antibodies

It is very important that we understand how many people have been infected with COVID-19 and whether infection leads to protective immunity that can stop people getting infected again. We are also interested in understanding how effective COVID-19 vaccines are in preventing future infection and disease, particularly as new variants

emerge, and whether our immune response to COVID-19 vaccines may diminish over time and differ in people who suffer with chronic illness.

The Vaccine watch sub study of the Virus Watch cohort will offer finger prick antibody tests every other month to all adults aged 18 years and over, August 2021-June 2022. After you provide consent, individual test kits will be posted to your home by Thriva, the company providing these tests. The test involves pricking your finger once and dropping 600 microlitres (about 10 drops of blood) into a small tube. You can take a look at the video on the following webpage: www.gov.uk/taking-antibody-blood-sample to see how the test is completed. After collecting the sample, you will need to post it back to the laboratory on the same day using the pre-paid envelope provided, using your nearest **priority post box**. Please do not post your sample on a Saturday as it might sit in the post too long.

The sample you provide will be tested at an accredited laboratory for antibodies against SARS-CoV-2, the virus that causes COVID-19. The tests detect antibodies that develop as a result of natural infection, as well as antibodies that develop as a result of vaccination.

Any residual blood sample will be stored for further detailed testing of your immune response during the study and after the study ends by our partner laboratories. These tests will look at immune response and vulnerability to other variants of COVID-19 and common respiratory infections (including Rhinovirus, seasonal coronavirus and influenza). Samples will not be used to test for infections other than those causing respiratory illness. The results of these additional tests will not be fed back to you.

What happens to the test results?

After you give your consent, we will securely share your name, address, and study number with a printing company and a logistics company for the purpose of posting your Virus Watch study number out to you. Your results will be sent via email by Thriva within 7 days of you posting the test kit. The results will be given under your Virus Watch study number, rather than your name, to ensure your privacy.

We would like to trial sending your results via SMS using the mobile telephone number you provided on registration into the study via a company called Janet txt. (part of PageOne Communications). The information we would send them is your mobile telephone, your study ID and your test result.

Please note that at present we do not have sufficient information to understand whether antibodies from these tests indicate you are immune – but they do give us a good indication of whether or not you have been previously infected or vaccinated. You should continue to follow national COVID-19 guidelines and recommendations whether or not your test is positive.

National public health regulations require UCL to report all SARS-CoV-2 antibody test results to Public Health England (or equivalent bodies in the devolved nations).

Antibody results are shared along with identifiable details, including name, NHS number (where available), date of birth, and home address. Identifiable information is required in order to link test results with the national COVID-19 vaccination register. These data will be used by Public Health England (or equivalent bodies in the devolved nations) for national COVID-19 infection surveillance and vaccine evaluation. These data will be shared securely by the Virus Watch team for the purposes outlined above.

How long will the study go on for?
The study, will run until June 2022.

Thank you for reading Part 1.

The next section outlines Frequently Asked Questions.

Adult Participant Information Sheet Part 2

Frequently Asked Questions

Who is conducting the study? It is funded by the Medical Research Council and the National Institute of Health Research. The study sponsor is UCL. UCL is the data controller (meaning it owns and is responsible for all of the data generated by this study). This includes surveys, blood samples and laboratory data generated at Thriva. UCL are data processors of the linked medical records data. Partner laboratories that are collaborating with UCL will be the data processors for laboratory results arising from additional testing of your immune response.

- **Who has reviewed the study?** Before any research can be done it has to be reviewed by an Ethics Committee, they make sure that the study is well planned and fair to those taking part. They look at it from the point of view of the public and ensure that researchers have complied with the appropriate rules and regulations. As this is a national study it has been reviewed and approved by the Hampstead Research Ethics Committee– 20/HRA/2320

- **Why have I been chosen?** The study group needs to include all types of people. This study is being conducted in all 9 regions of England and Wales. We would like everyone in your household to take part.

- **Do I have to take part?** No. It is up to you to decide whether to take part or not. We appreciate that some people will not want to be involved in this research.

- **Why does everyone in the house need to take part?** This is important because we need to see how COVID-19 and other respiratory viruses spread between people in the house.

- **What if I don't mind but someone else in house does not want to do it?** Unfortunately we need whole households, so you will not be able to take part.

- **What if I live alone?** You can still take part.

- **What if there are more than 6 people living in my household?** Unfortunately you will not be able to take part. The maximum household size for this study is six. A household refers to a group of people (not necessarily related) sharing the same kitchen, or living/sitting room, or dining area, whose usual residence (4 days/week or more) is at the same address.

- **Why do I need internet access at home or on a smartphone?** Most of our information collection will be through secure online surveys that will be emailed to a nominated adult in the household (the Lead Householder). This will allow us to know what is happening in "real time/live" and is easier and more efficient than using paper based questionnaires. The questionnaires can be completed on a smartphone but may be easier to complete on a computer.

- **What if I have an internet connection at work but not at home?** We will need to collect information from you when you are ill and not at work. That is why you need a home or mobile phone internet connection.

- **What if I am pregnant?** We hope to include some pregnant people in this study.

- **What if I have been vaccinated to COVID-19?** You are very welcome to take part in finger prick antibody testing. We are interested in how long immunity to COVID-19 lasts following vaccination.

- **What if I am taking part in a booster vaccine COVID-19 trail?** You are very welcome to take part in finger prick antibody testing. We are interested in how long immunity to COVID-19 lasts following booster vaccinations.

- **What if I think I have already had COVID-19?** You can still take part. We are interested in how long immunity to COVID-19 lasts and how other respiratory viruses are spreading.

- **Will being involved in the study help me get a test for COVID-19 or a vaccine for COVID-19 more quickly?** No – this study will not affect your medical treatment in any way.

- **What if I go on holiday?** If you are away on holiday, please continue to complete your surveys as best you can and send us your finger prick blood sample as soon as you can.

- **Will my taking part in the study be kept confidential?** All the information that you enter into our surveys will go directly into secure computers at UCL (Data Safe

Haven). Access to personal data that could be used to identify you will be strictly limited to a small number of trained researchers at UCL. The identifying information (such as NHS numbers and names) are kept in a separate database, away from the data about your health, test results, or any other information collected via the survey. All staff working on this project have a legal duty of confidentiality to protect personal information about individuals. All staff working with the data have had special training in keeping data confidential and secure.

All information will be collected and stored in accordance with data protection legislation. UCL policy is to store data for a minimum of 10 years. We will need to share some information about you with Thriva, the company providing the antibody kits and testing, in order to send the finger prick test kits to you and to return your results. This information includes your **name** and **address** so that your test kits can be posted out to you, and your **email address** and Virus Watch **study number** so that your results can be shared with you. No other information about you will be shared with Thriva.

We are working with partner laboratories on this study (they will be processing your blood samples) and we will also need to share some data about you. This information will be pseudonymised so that researchers will not be able to identify you. These data transfers will be conducted in line with data security policies at both UCL and our partner laboratories.

In order to share your test results with you securely, we will issue you with a study number printed onto a fridge magnet. We will share your name, home address, and study number with a logistics company and a printing company, for the purposes of sending you your study number.

We would like to send you your results via SMS as an alternative to email. UCL will share your mobile telephone number, study number, and results with a company called Janet txt. (part of PageOne Communications) in order to facilitate this.

We will provide NHS Digital, Office for National Statistics (ONS) and Public Health England (PHE) with names, dates of birth, sex, home addresses, and, where available, NHS numbers of Virus Watch Participants. NHS Digital, ONS and/or PHE will return information on any vaccinations, any hospital visits, admissions or deaths in the household. We will also receive any positive results arising from the Test and Trace programme, and we may organise further genetic tests on virus from these positive swab samples. These data will be linked to the Virus Watch Dataset before removal of identifiers so that people analysing the data will not be able to identify participants. These data will be used for statistical and research purposes only.

The Office for National Statistics may provide access to data shared with them to accredited researchers for accredited research purposes via accredited processing environments, where it is lawful and ethical to do so, and where the research is considered to be in the public good. It will not be possible to identify individuals from this data. Data will only be used for statistical research and analysis purposes and will not be shared with anyone else (other than access by accredited researchers).

We are also required by law to share some information about you with Public Health England (or equivalent bodies in the devolved nations), for the purposes of national COVID-19 surveillance and COVID-19 vaccine evaluation. This information includes your **SARS-CoV-2 antibody results** and identifiable information that will allow linkage to your vaccination records.

- **Local Data Protection Privacy Notice:**

  The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at dataprotection@ucl.ac.uk Further information on how UCL uses participant information for participants in health and care research studies, click https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

  The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices. The legal basis for processing personal data for this study at UCL falls under Article 6(1)(e) "public task" and Article 9(2)j "processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes". Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudo-anonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible.

  If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO) (https://ico.org.uk/concerns/handling/).

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 central NHS Digital records. 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/
- our study website www.ucl-virus-watch.net
- by asking one of the research team
- by sending an email to the study manager **viruswatch@ucl.ac.uk**

- **What if I change my mind about taking part?** Adults in your household are free to drop out of the finger prick antibody testing at any stage, without giving a reason, but we will keep information about your antibody test results and vaccination status that we already have. If one member of the household changes their mind, the rest of the household can continue finger prick antibody testing. This will not affect your household's participation in the online survey aspects of the study.

- **Are there any risks or disadvantages of taking part?** There are no major risks. Some people may find completing the questionnaires inconvenient – we have tried to make these as simple as possible. Taking your finger prick blood sample may involve minimal discomfort.

- **What are the possible benefits of taking part?** We cannot promise that the study will benefit you individually but the information that we get will be vital for planning future COVID-19 vaccines and their roll out. The finger prick tests will allow you to find out if you have been infected with COVID-19 and not had any symptoms.

- **What happens when the research study stops?** We will let you know what the study has found.

- **What if I still have questions?** Please e-mail **viruswatch@ucl.ac.uk** with any further questions you have.

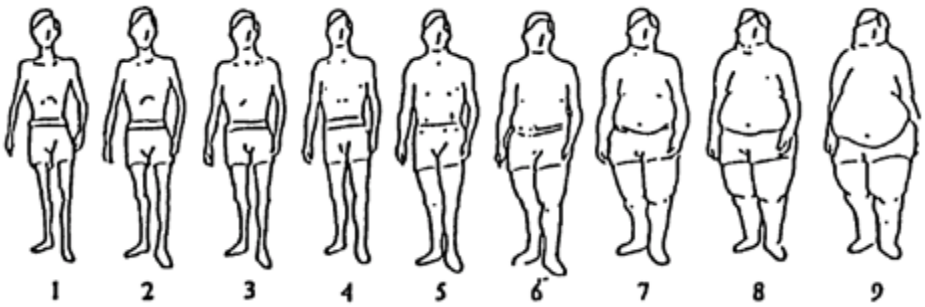
- **What if I am unhappy about the way the study is conducted?** We have tried to make the study as easy as possible for those taking part, if you have any complaint about the way you have been dealt with this will be addressed. If you wish to

complain about the conduct of the study please contact the study manager, at UCL Department of Epidemiology & Public Health, 1-19 Torrington Pl, Fitzrovia, London WC1E 7HB or email viruswatch@ucl.ac.uk. If you remain unhappy you can take up your complaint through the UCL Ethics Committee at: ethics@ucl.ac.uk and copy in the research-incidents@ucl.ac.uk.

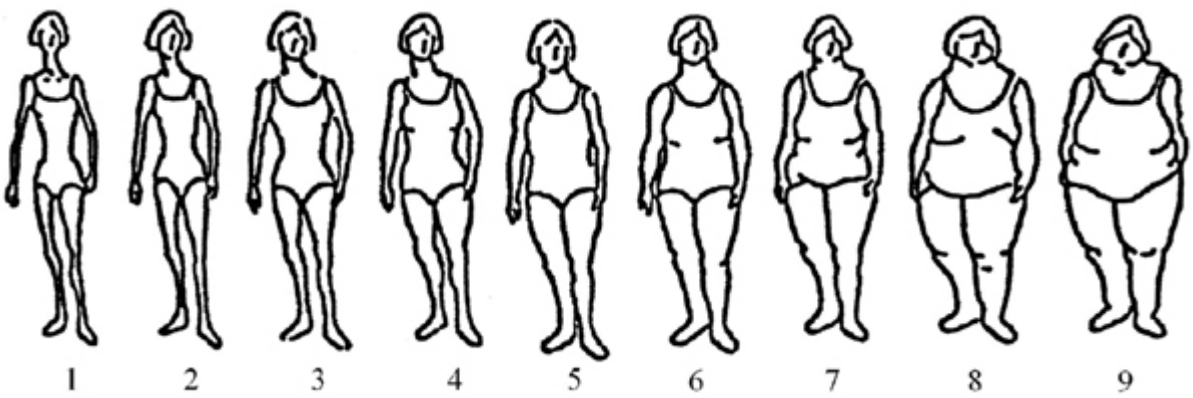
- **Harm:** In the unlikely event that you are injured by taking part, compensation may be available but you may have to pay your legal costs. If you suspect that the injury is the result of the Sponsor's (University College London) negligence, then you may be able to claim compensation. Please make the claim in writing to Professor Andrew Hayward who is the Chief Investigator for the clinical trial/ study and is based at UCL 1-19 Torrington Place. The Chief Investigator will then pass the claim to the Sponsor and on to Sponsor's Insurers. Also, the normal National Health Service complaints mechanisms will still be available to you (if appropriate).

- **What will happen to the results of the research study?** Any COVID-19 S&N antibody test results relating to samples you have sent us will be given back to you. We would also like to keep you updated with our study results via a regular newsletter. Study results will be shared with the NHS, Public Health England COVID-19 response teams and the Joint Committee on Vaccine and Immunisation to plan the current and any future response to pandemics. We will also make analyses of study results publicly available throughout the study in an online dashboard. The study results will be published in scientific journals and presented at scientific meetings. You will not be identifiable in any of these publications or websites.

- **How can I select my body shape category?** If you don't know your height and weight and don't have a tape measure and scales you can select your body shape using the chart below. Please take a note of this as you will need it for the baseline survey.



Men: Which shape looks most like you?



Women: Which shape looks most like you?

Thank you for considering taking part.