





Adult Participant (Age 16+) Information Sheet V8 03.10.20

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

Part 1

What is involved?

Study 1) Online reporting of illnesses and other information

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 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.

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, previous contact with someone with COVID-19, previous symptoms that could have been COVID-19 and behaviours such as social distancing and hand hygiene. This will take around 20 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.

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 (we will provide a diary to help with this). This will take less than five minutes for each day that someone is 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 and 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. These questions will take around ten minutes to complete for each person who is ill.

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 social distancing, whether you have been asked to self-isolate following contact with a confirmed or suspected case, whether you are using an NHS app on your phone for contact tracing, whether you have been tested for COVID or for COVID antibodies. There will be questions about your employment to see how COVID advice is affecting you. This questionnaire will take around 15 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 write down a question that you would like us to try and answer, we will ask you again each month. We will read through your responses and allow you to vote each month for a question to be included in our monthly survey based on participant suggestions. 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 produce a regular newsletter that tries to answer common questions posed by the Virus Watch participants.

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 since January 2020, during the course of the study and for the 5 years after the study has finished. This is because COVID-19 may circulate for many years and we wish to understand whether infection this year 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. NHS Digital holds the data on hospital visits and admissions (called Hospital Episode Statistics data) and deaths, and Public Health England holds routinely collected virological testing data carried out by the NHS. We also want to be able to link to data on the Test and Trace programme including any positive results arising from this. We will provide NHS Digital and Public Health England (PHE) with names, dates of birth, sex, addresses, and, where available, NHS numbers of Virus Watch Participants. NHS Digital and PHE will return information on any hospital visits, admissions or deaths in the household. 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.

Study 3 - Swabbing study to tell if people have caught COVID-19

Your household **may be selected** to be part of a smaller group of Virus Watch participants that we study to find out whether you have been infected with COVID-19 (or a different kind of respiratory infection) when you experience a respiratory illness. We do this through testing your **nose and throat swabs.** If we invite you to take part, we will need everyone in the household to agree to submit nose/throat swabs. At the beginning of the study, we will send you a **household pack** containing some nose and throat swabs. Because swabs are in short supply we may send some more of these later. Please keep these in a cool dry place until you are ready to use them. They will come with instructions- you can take the swab yourself or have a family member do it for you. Taking a sample is straight forward and does not hurt. We will provide all the packaging you need to send it back to us free post ideally on the day or the next day after you take the sample. We will send you replacement swabs so that you always have some at home for the duration of the study.

Your household may be asked to join one of the following three groups:

GROUP 1: Submit a nose/throat swab anytime you experience 2 days in a row of any of the following symptoms: fever, or cough, or loss/change in sense of smell or taste, shortness of breath, or earache, or sore throat, or sneezing, or blocked nose, or runny nose, or wheeze.

This group will allow us to track how frequently people are developing COVID -19.

GROUP 2: Submit a nose/throat swab anytime you experience a new illness that includes:

 Either - two days in a row of respiratory symptoms (e.g. cough, shortness of breath, sore throat, runny nose, nasal congestion, sneezing, loss of or altered sense of taste or sense of smell).

- OR two days in a row of gastrointestinal symptoms (e.g. diarrhoea/loose stools, abdominal pain, nausea or vomiting, loss of appetite).
- OR two days in a row of general infection symptoms (e.g. feeling feverish, having a high temperature, feelings of severe unexplained tiredness, generalised muscle or joint aches)

This group will allow us to find out if national case definitions are picking up the majority of cases or if other symptoms need to be included.

GROUP 3: Submit a nose/throat swab anytime you experience 2 days in a row of fever OR cough OR loss/change in sense of smell or taste. We would also like that the whole household take swab that same day. If you or a member of your household receive a positive test result, we would like you all to swab the day of the result and 7 days later. This will give us important information on the spread of COVID-19 before symptoms occur, as well as any asymptomatic infection.

This group will allow us to understand how easily COVID-19 spreads to others in the household, the importance of infection without symptoms and the development of antibodies following infection or exposure to infection.

What happens to the samples and test results?

UCLH and the Health Services Laboratory is collaborating with the Francis Crick Institute to expand testing capacity, and samples will be processed through this collaboration. We will test the samples from swabs for COVID-19 as soon as we can and let you know your results. However, it is important to recognise that the results will not be available as quickly as swabs taken for clinical or public health purposes. Also, swabs taken by participants may be slightly less accurate than swabs taken by healthcare workers - so may miss some infections. For these reasons it is very important to understand Virus Watch Swabs do not replace swabs offered to you by the NHS. Please follow normal clinical (NHS) or public health advice for testing in addition to any swabs provided for the Virus Watch study.

Results will be returned to you by text message and/or email. You can refer to standard up to date information on our website which will explain what the test result means and provide the latest advice on what you should do. We are under a legal duty to notify Public Health England of positive COVID-19 test results. This will be done through the same automatic process that is used to notify positive samples processed in the NHS.

When COVID-19 is identified in a swab, we will undertake genetic sequencing of the virus. This allows us to see the entire genetic code of the virus which will be important for understanding whether some strains of the virus make people more ill. When more than one person in a household becomes ill with COVID-19 this virus genetic testing will help us to understand whether one person infected the other or whether the infections were transmitted from outside of the household. We will not feed these

results back to you as the findings can be difficult to interpret and would not alter your care.

In addition to testing samples for COVID-19, samples will be stored for later analysis of other respiratory infections that cause colds and flu like illness including Rhinovirus, seasonal coronavirus and influenza. As these will not be tested until the end of the study we will not feedback these results.

Study 4 - Immunity Study to find out if people have developed immunity to COVID-19

If your household has been selected to take part in any of the three swabbing study groups detailed above, we would also like you to take part in a study of immunity to COVID-19 and other common respiratory infections. 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. To do this we need to take small volumes of blood (similar to when your doctor asks you to have a blood test). This blood is tested for antibodies to COVID-19 and also for other aspects of the immune response.

During the autumn of 2020 and spring/summer of 2021 we will invite participants to attend a local clinic where a trained nurse, doctor or phlebotomist (a professional who specialises in taking blood) will take blood samples from adults and from children who agree.

How much blood?

Adults (age 16 years and older) - 30 mls (2 x 5ml, 2 x 10ml tubes equivalent to about 6 teaspoons),

Children aged 15 years and younger we will take 15 mls (1 x 5 ml, 1 x 10 ml tubes – equivalent to 3 teaspoons).

Those taking blood from children will be trained and experienced in doing this. We will offer to provide local anaesthetic cream to help numb the area to minimise any discomfort.

We would like all members of the household to attend and have their blood taken at the same time (if possible) and we will provide you with an online voucher to compensate you for your travel costs (please email viruswatch@ucl.ac.uk). Children aged 15 years or less are encouraged to provide a blood sample but can take part in the study even if they do not want to have a blood sample taken. We will also offer finger prick antibody tests to children who do not want to provide a blood sample or if their blood taking clinic does not have a staff member trained in taking children's bloods. This collects a drop of blood onto a bit of paper in the testing cassette. Tests done using this method may not be as accurate as a full blood sample but will still provide valuable information. Finger prick antibody tests will also be offered to any adult from whom we are unable to draw a blood sample.

If you are in any of the groups listed below a trained nurse, doctor or phlebotomist (a professional who specialises in taking blood) will offer to come to your house to take blood samples. If you prefer you can also opt to drive to the clinic and we can make sure that you do not have to have any contact with anyone other than the person taking the blood sample during the visit. The person taking the blood sample will not have any symptoms of COVID-19 and will wear Personal Protective Equipment including a face mask to ensure that you remain protected.

- aged 70 or older (regardless of medical conditions)
- under 70 with an underlying health condition listed below (i.e. anyone instructed to get a flu jab as an adult each year on medical grounds):
- chronic (long-term) mild to moderate respiratory diseases, such as asthma, chronic obstructive pulmonary disease (COPD), emphysema or bronchitis
- chronic heart disease, such as heart failure
- chronic kidney disease
- chronic liver disease, such as hepatitis
- chronic neurological conditions, such as Parkinson's disease, motor neurone disease, multiple sclerosis (MS), a learning disability or cerebral palsy
- diabetes
- a weakened immune system as the result of conditions such as HIV and AIDS, or medicines such as steroid tablets
- being seriously overweight (a body mass index (BMI) of 40 or above)
- those who are pregnant

If you are in one of the following categories, you should have received a GP letter telling you that you are **extremely vulnerable** to COVID-19 and asking you to stay shielded to prevent infection. If you are in this group, **we will not request to take a blood sample**, but we may ask you to provide a finger-prick antibody test.

- people with cancer who are undergoing active chemotherapy or radiotherapy
- people who have received an organ transplant and remain on ongoing immunosuppression medication
- people with cancers of the blood or bone marrow such as leukaemia who are at any stage of treatment
- people with severe chest conditions such as cystic fibrosis or severe asthma (requiring hospital admissions or courses of steroid tablets)
- people with severe diseases of body systems, such as severe kidney disease (dialysis)

Finger Prick Study of immunity to COVID-19 over time

We are also interested in understanding how our immunity to COVID-19 may diminish over time. A group of households that are not taking part in the swabbing study, will

be invited to take a finger prick antibody test at home in the autumn of 2020 and again in the spring of 2021.

If your household has been selected to take part in **swabbing study Group Three**, we will ask that all householders take a finger prick antibody test at the same time as having your blood taken (autumn 2020), and 14 days after anyone in your household receives a positive COVID-19 test result from their nasal/throat swab. Finger prick antibody test kits will be provided in your household packs with instructions and a link to a demonstration video. You will need to take a photo of your test and upload it to UCL through a secure web address that we will provide.

What happens to the blood samples and test results?

Blood samples will be analysed for immune response and vulnerability to COVID-19 by the Francis Crick Institute. One of the most important unknown questions at the moment is how many people have already been infected with COVID-19. Your samples will be important to us finding out the answer to this in different parts of the country and in different groups of people.

You may have heard about antibody tests for COVID-19 and how these might be used to issue "immunity" certificates to people. At the moment not enough is known about COVID-19 to be confident that a positive test means that you are protected from future infection. Similarly, people who have been infected with COVID-19 but have low levels of antibody may have a negative test. Work is still going on to assess which antibody tests are most accurate and your samples will help with this work. When your test results (from your whole blood sample) are available, we will feed these back to you along with information based on the best available evidence to help you interpret the findings.

Samples will be stored for later testing of the immune response and vulnerability to other common respiratory infections that cause colds and flu-like illness including Rhinovirus, seasonal coronavirus and influenza. Samples will not be used for infections other than those causing respiratory illness.

Our bodies make many thousands of proteins the patterns of which are determined by our genes and by our environment. Research shows that around 5000 of these proteins are related to whether or not people develop illnesses. Modern tests can use blood samples to test for all of these proteins. Understanding this can give clues as to how to protect people from diseases and develop new treatments. This type of research is called "Proteomics" research. One of the blood specimens will be stored for this type of research so it can be used to understand why some people develop severe disease when infected with COVID-19 and other people do not. The results from these tests **will not** be fed back to you.

Study 5) Movement Tracking- so that we can understand how people's movements outside the house affect their risk of catching COVID-19

We would like to study movement data as you go about your normal activities. Adult participants will be invited to download a free movement tracking App called "Tracker for ArcGIS" onto their phone. This app records the location of mobile phones and runs

in the background using the telephone's GPS sensor and proximity to wi-fi and bluetooth hot spots. It is designed to use minimal battery life and is configured to transfer data when you are attached to a wi-fi network so it does not use up data allowances on your telephone.

The data will allow us to get a good understanding of the extent to which social distancing advice is affecting people's movements. We will also use the data to understand how much people have been in public spaces in the week before infections compared to other times. This will allow us to understand what sort of activities (e.g. going to work, shopping, theatres, cinemas, large sporting venues, tourist attractions, pubs, clubs, cafes & restaurants, using public transport, or exercising) increase the risk of infection. The information will also help us understand if people who need to leave the house a lot for their work are more at risk of infection. We are also interested in looking at levels of exposure to pollution and climate variables. Finally, we are interested to see if people and their household contacts stay at home when they are ill.

To help us answer these questions we would like participants to leave the app "On" for the duration of the study (12 months), however, you will be able to control the on and off switch. At the end of the study, we will send you a reminder that you can delete it from your phone.

We recognise that movement data is highly confidential and, along with all the other data we collect from you will ensure the highest possible data protection safeguards. If you choose to participate in the movement tracking study, the UCL study team will upload your user profile information (first name, surname and email address) to an ArcGIS online subscription (hosted on a North American server) in order to set up your tracker app account. The UCL study team will then email you instructions on how to download and sign into the app. A small number of named ESRI employees (the company that runs the ArcGIS tracker app) may also have access to your user profile data for the sole purpose of supporting the UCL study team in the creation of your tracker app account. Once you begin using the app your geo-location data will be transferred from your phone to a secure EU Amazon server every 3 days and will then be deleted from your phone. Your data will be stored on the secure EU Amazon server for no more than thirty days, and the UCL study team will regularly download your data to its secure Data Safe Haven where it will be pseudonymised with access strictly limited to named researchers. Your geo-location data will only be analysed by highly specialist researchers from UCL and named ESRI employees who will not have access to your personal details. The data will not be used for any purposes other than research into the transmission of respiratory infections.

https://www.esriuk.com/en-gb/arcgis/products/tracker-for-arcgis/overview

https://trust.arcgis.com/en/

How long will the Virus Watch study go for?

This study will run until spring next year (2021).

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, geo-tracking data and the laboratory samples, laboratory data and linked medical records data.
- 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. Your name
 was chosen at random from a list of postcodes in your region. 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 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. If you choose to take part, you may be selected to send us nasal/throat swab samples when you are ill and have 2 blood samples taken. Swabs will be tested for all different types of circulating respiratory viruses including COVID-19 and your blood sample for antibodies to these viruses. The results of these test will be shared with you with advice about what these results mean.
- What if I go on holiday? If you are away on holiday, please continue to complete your surveys as best you can.
- Will my taking part in the study be kept confidential? Yes. 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. If your household is invited to participate in Studies 3 and 4, we may need to share some information about you. This information includes your name, address, date of birth, sex, mobile telephone number and email. The Health Services Laboratories needs this information so that they are able to identify and test your samples and feedback your test results to you. NHS research nurses/private phlebotomy company will need this information to organise blood taking

appointments and the logistics company will need this information to assemble and post your household a study kit pack. If you participate in the movement tracking study the UCL study team may need to share your name and email address with a small number of named ESRI employees who will assist the UCL study team in the creation of your tracker app account.

What information will you look at and analyse from the movement tracking app ArcGIS? The information we are interested in analysing includes the amount of time per day spent in the following locations and how they might predict risk of infection. Retail (shopping centres, supermarkets, shops, markets), Entertainment (e.g. theatres, cinemas), Social venues (e.g. pubs, bars), Food and drink venues (cafes restaurants), Work, Home, Public transport, Walking, running, cycling, Parks, Sports arenas or Music venues, and Tourist attractions.

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.

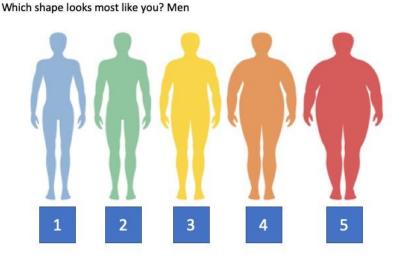
Where can you find out more about how your information is used?

You can find out more about how we use your information

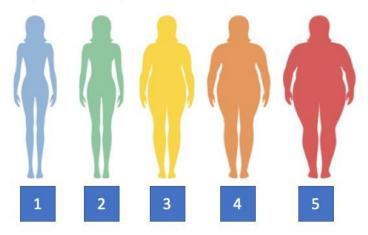
- at www.hra.nhs.uk/information-about-patients/
- our study website www.ucl-virus-watch.net
- by asking one of the research team
- by sending an email to the study manager viruswatch@ucl.ac.uk
- What if I change my mind about taking part? You are free to drop out of the study at any stage.
- Are there 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. Nose & throat swabs involve virtually no discomfort although some people may gag a little. Taking your blood sample may involve minimal discomfort and cause a small bruise in some people. We will use experienced health care professionals to take your blood.
- 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
 how to deal with the current COVID-19 and any future pandemics. If you are part
 of our swabbing study, we will let you know if you have been infected with COVID19. If you provide blood samples we will let you know the results of COVID-19
 antibody tests.
- 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 PI, Fitzrovia, London
 WC1E 7HB or email viruswatch@ucl.ac.uk.

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 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 NHS and Public Health England COVID-19 response teams to plan the current and any future response to pandemics. We will also make analyses of study results publicly available weekly throughout the study in an online dashboard hosted by ESRI ArcGIS. 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.



Which shape looks most like you? Women



Thank you for considering taking part in Virus Watch.