

## COVID SYMPTOM STUDY BIOBANK VOLUNTEER INFORMATION SHEET

### WHY AM I BEING INVITED TO TAKE PART IN COVID SYMPTOM STUDY BIOBANK?

You are being invited to take part in COVID Symptom Study Biobank (CSS Biobank) as you were registered on the COVID Symptom Study app organised by ZOE Global Ltd and King's College London.

Please read the following information carefully. You can contact us using the details on our website [cssbiobank.com](https://cssbiobank.com), through our email [enquiries@cssbiobank.com](mailto:enquiries@cssbiobank.com), and at the end of this leaflet if you would like more information, have any queries or concerns, or would like to amend your participation level.

### WHAT IS THE COVID SYMPTOM STUDY BIOBANK?

The aim of the CSS Biobank is to understand the long-term impact and effects of COVID-19 and how these may be linked with health conditions and other genetic and environmental factors.

We want to collect clinical and questionnaire data, and samples such as blood, to understand how the body responded to the coronavirus that causes COVID-19, and how COVID-19 affects the body in the long-term.

The CSS Biobank is led by researchers from King's College London, and it is governed by the COVID Symptom Study (CSS) Management Group. The CSS Management Group consists of King's College London researchers, ZOE Global Ltd representatives and participant representatives.

### SUPPORTED BY



## WHERE WILL THE RESEARCH TAKE PLACE?

The research will primarily take place from the comfort of your own home. Questionnaires will be available to complete online or through an app. If we request samples, such as blood, stool or urine, we will send you sample collection kits with full instructions for you to complete at home and return to us in the post.

On some occasions, for example for specialised tests, we may invite you to come to our clinic at St Thomas' Hospital in London or satellite centres elsewhere in the UK. We may also arrange to visit you in your home.

## WHAT DOES TAKING PART IN THE COVID SYMPTOM BIOBANK INVOLVE?

We will invite you to take part in some or all of the following:

- Completing questionnaires
- Donating biological samples such as blood, hair, nail, stool, urine, and saliva
- Having clinical assessments and tests, such as physical measurements, fitness tests, skin assessments, dental and oral assessments, allergy testing eye tests, hearing tests, taste tests and other sensory tests, for example temperature checks
- Taking psychological tests and tests to understand brain function
- Using smart clinical devices or mobile phone apps to record, monitor and track health measures, diet, sleep, mood and exercise, to name a few
- Providing environmental samples such as drinking water, soil, or dust
- Making lifestyle or dietary changes that do not involve medicinal products, and do not involve changes to your medications that are routinely prescribed



We will provide full instructions for all tests and sample collections completed at home and for any preparation needed ahead of clinic visits.

We may also invite you to have a photograph taken to help with our publicity, for which we will ask your permission.

## IF I JOIN THE COVID SYMPTOM STUDY BIOBANK, DO I HAVE TO TAKE PART IN ALL THE TESTS?

You can choose whether or not to participate in any of the tests we invite you to take part in.

You can decide to take part in:

1. All of the tests on offer
2. Some of the tests on offer
3. None of the tests



You can make this choice at any time. To help you decide, we will provide detailed information about the research tests and what they involve on our website.

## WILL I BE GIVEN ANY MEDICATION TO TAKE?

Depending on the tests and sample collections you are doing, we may give you medication such as eye drops. We only use approved medications and do not ask volunteers to use any investigational medicines in any of our studies. We will not ask you to alter your current medications if you decide to take part. Please continue to take any regular medication as usual.

## ARE THERE ANY ADVANTAGES TO TAKING PART IN THE COVID SYMPTOM STUDY BIOBANK?

One benefit of taking part is that your involvement will contribute towards the advancement of long-term COVID-19 health research.

In addition, for some studies you may receive a set of clinically useful results which may help you and your GP identify health conditions.



## ARE THERE ANY DISADVANTAGES OR RISKS OF TAKING PART?

You should not experience any serious side effects whilst taking part in the CSS Biobank. However, you may experience the following minor side effects, depending on which tests you complete:

- You may feel slight discomfort when giving a blood sample.
- Some sensory tests may leave a small temporary area of reddening on the skin.

## WILL I RECEIVE TEST RESULTS?

No. The tests we use are purely for research purposes, and so your participation in the CSS Biobank is not like a health check with your doctor. The tests we do are useful for research but currently have no clear medical meaning. This means that neither we, nor a GP, can interpret the results reliably. Other tests are carried out in a research laboratory rather than a clinical laboratory therefore cannot be used to diagnose health-related issues. We may therefore not tell you the results of any of these tests. You will, however, be kept informed of any resultant findings and publications of the studies through our newsletter and website.

## HOW WILL YOU CONTACT ME?

We will contact you primarily via email and the CSS Biobank study website. We may also contact you via telephone or post, for example for participation in a postal study.



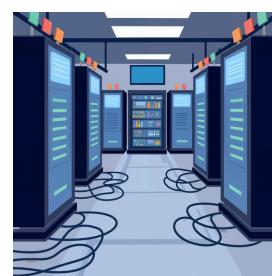
## HOW WILL YOU SECURE MY DATA SECURELY?

We will keep all information collected about you as part of CSS Biobank strictly confidential and we will store it according to the General Data Protection Regulation 2018 and the Data Protection Act 2018. We will store all your data using a unique participant ID study number. All personal information such as your name, address, exact date of birth and any contact information will be held on a separate secure database only accessible to authorised and approved King's College London personnel for administration purposes only. We will only share your pseudonymised data (i.e. data linked to your unique ID Number with no personal information), and your birth month and year with approved researchers. You cannot be personally identified using this data. Only the test results that we send to you will contain any personal information. participation in a postal study.

## WHAT WILL HAPPEN TO MY SAMPLES AND DATA?

We will store your clinical, genetic and questionnaire data in a secure electronic database for use in current and future projects. Your biological samples will be processed and stored at King's College London laboratories or in one of our approved partner labs and biorepositories. All the information we collect will be held securely in accordance with the General Data Protection Regulation 2018 and all samples will be stored in accordance with the Human Tissue Act 2004.

Researchers outside of King's College London may request to use data or samples held within the CSS Biobank. Our CSS Management Group strictly controls and manages access to data and samples by external researchers or organisations in the UK or abroad. Data includes photographs, images, scans, x-rays, genetic information, geographical information and data derived from biological samples collected for research purposes. Intellectual property relating to your participation will always reside within King's College London. You will not have claim to either the material that we collected or the data arising from the study.



## WILL YOU NEED ANY OTHER INFORMATION ABOUT ME?

We will ask your permission to link to your data collected via the COVID Symptom Study app. This includes your symptom data and other information you may have logged, such as time spent outdoors. This is essential for us to understand the long-term impact of COVID-19 when studied in conjunction with your samples collected as part of the CSS Biobank.

We will also ask your permission to request additional information about your health, education and environment through linkage to your official records held by the NHS and other organisations.

For further information about how we link to your app data, health, education and environmental records, please go to page 6 of this leaflet.

## WHO ORGANISES AND FUNDS THE COVID SYMPTOM STUDY BIOBANK?

The Co-Principal Investigators of the CSS Biobank are Professor Emma Duncan, Professor Claire Steves and Professor Sebastien Ourselin, of King's College London. The main funding body supporting the CSS Biobank is the Chronic Disease Research Foundation (CDRF).

The CSS Management Group will oversee all of the activities of the CSS Biobank. The CSS Management Group consists of King's College London researchers, ZOE Global Ltd representatives and participant representatives.

KCL sometimes has contracts with commercial organisations. These organisations are allowed to access, view and use the COVID Symptom Study Biobank database; access is controlled and monitored, and data are anonymised. The contracts with these organisations may lead to income or profit to KCL. The Vice President of KCL (Finance) will determine how this income is used.

KCL will never sell any of the samples you donate. However, we may share your anonymised data, stored on the COVID Symptom Study Biobank database, with research collaborators or commercial organisations. If we send data to commercial organisations, we will have an agreement in place with them. Agreements with commercial organisations may mean that other organisations might not be able to use COVID Symptom Study Biobank data in some situations.

## WHO HAS REVIEWED AND APPROVED THE COVID SYMPTOM STUDY BIOBANK?

The CSS Biobank was reviewed and approved by REC REF numbers 25/YH/0160

## CAN I LEAVE THE COVID SYMPTOM STUDY BIOBANK?

You are free to change the way you interact with the CSS Biobank at any time without giving any reason, and without your medical care or legal rights being affected. You may change your participation status regarding any of the following:

- Whether and how we may contact you
- Whether we may invite you to participate in studies
- Whether you are happy for us to link to your health, education and environmental records

You can contact us at any time via our email [enquiries@cssbiobank.com](mailto:enquiries@cssbiobank.com) about any changes you wish to make regarding your participation.

You are also free to withdraw from the CSS Biobank at any time without giving any reason or affecting your rights. Withdrawal means that we will no longer keep your personal details or be able to contact you about news or events involving the biobank. If you decide you would like to withdraw, you should email [enquiries@cssbiobank.com](mailto:enquiries@cssbiobank.com). You will then be sent a link to an online questionnaire, which will ask you to make a decision about whether we can continue to use your previously donated samples and data. If you do not want us to continue using your data and/or samples, we will destroy the data and/or samples that we hold. It may not be possible to trace and confirm the destruction of all remnants of anonymised data and samples sent externally, but these are governed by strict agreements on how they are used and how long they are stored. Once we have actioned your withdrawal on our databases, we will send you an email to confirm this has been completed.

## FURTHER INFORMATION ABOUT DATA LINKAGE

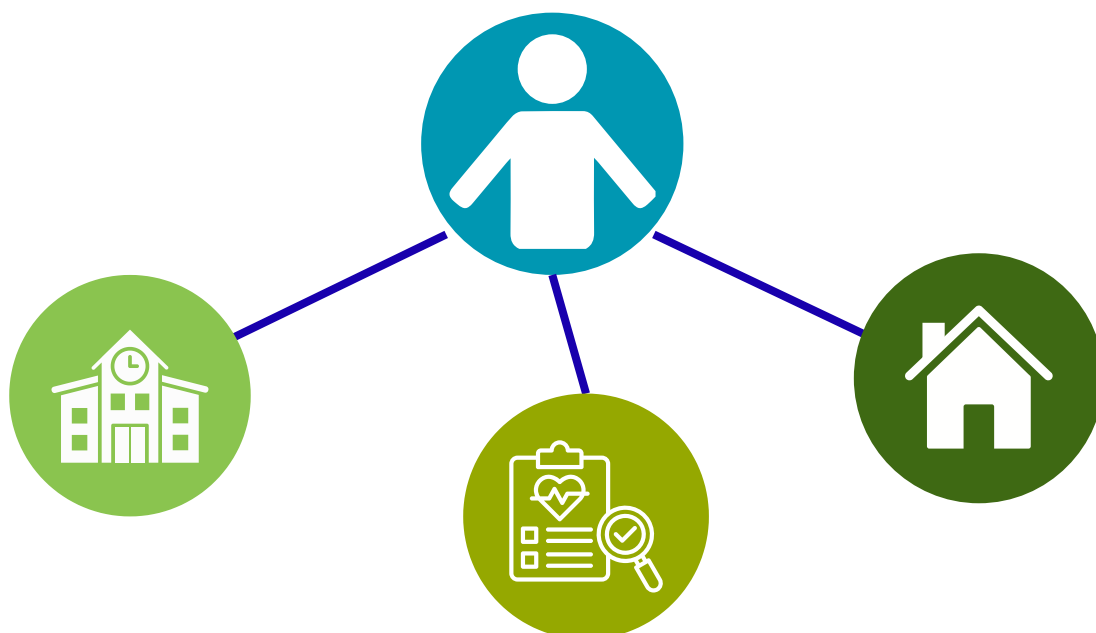
The following pages contain important information about how the COVID Symptom Study Biobank plans to link to your previous app data, health, education and environmental records, with your permission. Please read through the following pages and get in touch with us if you have any questions using the contact details at the end of the leaflet.

If you sign up to take part in the CSS Biobank, you will need to indicate on your consent form which, if any, types of data you would be happy for us to link to.

We will always respect your decision, and you may contact us at any time to change which of your data we link to.

## WHAT IS DATA LINKAGE?

'Data linkage' is when an organisation accurately and confidentially collects information from your official records. In the context of health research, data linkage is an efficient way of improving the quality and volume of the data we use in our research.



## WHY IS THE COVID SYMPTOM STUDY BIOBANK LINKING DATA FROM OFFICIAL RECORDS?

COVID-19 is a viral infection that has shown to be severe and even fatal. While some individuals experienced minimal symptoms, others experienced symptoms for weeks or even months after infection.

We want to understand the impact and effects of COVID-19 long-term and how these may be linked with health conditions and other genetic and environmental factors.

Linking to data held in official records is important as good research needs the highest quality data possible. Data linkage allows us to access large volumes of high-quality data for long-term COVID-19 research, with minimal burden on participants.

## WHAT ARE THE BENEFITS?

- 1 Some participants may find it difficult to take part in projects and studies at the CSS Biobank that require collecting samples. Data linkage is an easier, effortless way to be involved in vital research.
- 2 For participants who are able to provide samples, data linkage allows us to get the maximum possible benefit from your samples.
- 3 Some of the most important information about us is not something we necessarily know or remember, for example the precise type and dose of vaccinations you may have received in the past. Data linkage helps to collect this information.
- 4 When small amounts of data from individuals are linked up and pooled together, researchers can look for patterns in the data. This helps researchers continue to monitor the long-term effects of COVID-19, improve care for those with ongoing symptoms, and enhance our understanding of the virus.
- 5 Data linkage enables you to play an important part in long-term COVID-19 research.

The next pages feature case studies of how data linkage can be used to carry out health research and examples of how the CSS Biobank would benefit from data linkage.



## CASE STUDY

### Reducing participant burden and improving research methods



Mrs Jones is a participant in the CSS Biobank. One morning she receives an email asking her to complete an online questionnaire from the CSS Biobank about previous vaccinations she has received throughout her life, so that researchers can investigate the effect of vaccination history and COVID-19 experience. Like most people, Mrs Jones had not kept notes on her vaccinations throughout her life.

With data linkage, we would be able to see when exactly Mrs Jones received vaccinations through the NHS much more easily and accurately. This would give us better quality data for our research study, and without needing to disturb Mrs Jones.

## CASE STUDY

### Linking COVID-19 symptoms and hospital records to understand outcomes



We know that COVID-19 affected people very differently. While some individuals experienced mild or no symptoms at all, others became very ill and required hospital treatment.

By linking individuals' historical COVID-19 symptom data with hospital records of their treatment and outcomes, researchers can build a clearer understanding of the long-term impacts of the virus and identify factors associated with severe cases.

This knowledge can help improve care for those at higher risk of complications and support early intervention strategies in the event of future outbreaks.

## CASE STUDY

### Linking to environmental data for COVID-19 research



We know that COVID-19 affected the lungs. In severe cases, individuals required invasive treatment in hospital to support their breathing, while other people who caught COVID-19 experienced breathing difficulties and other respiratory issues for weeks and even months after infection.

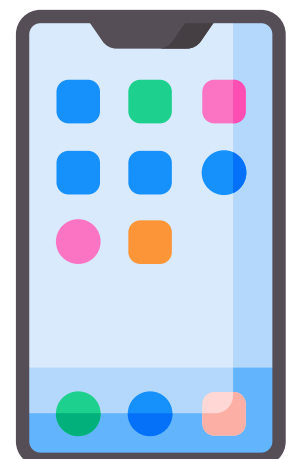
One factor that could have affected how an individual's lungs respond to COVID-19 could be exposure to local air pollution levels. By linking individuals' COVID-19 experience and outcomes with local air pollution levels, researchers could understand if there is a connection between the two and work out how to mitigate any increased risk in future

## YOUR COVID SYMPTOM STUDY APP RECORDS

You have been invited to take part in the CSS Biobank as you were registered on the COVID Symptom Study app. In order for us to maximise COVID-19 research, we would like to ask your permission to link to your COVID Symptom Study app records.

This includes your symptom data and other information you may have logged while using the app. For example, this may include answers to short questionnaires about time spent outdoors, medications used and the results of any COVID-19 tests.

Your COVID Symptom Study app records are essential for us to understand the impact of COVID-19 when studied in conjunction with any samples or additional data collected as part of the CSS Biobank.



# YOUR OFFICIAL HEALTH RECORDS

Unless you have opted out online or through your GP, your health records will already be being used to plan healthcare nationally and for healthcare research.

Much of the information that is most useful to health researchers is held in your official health records. Health records include those held by your general practitioner (GP) and hospital records, mental health data, cancer registrations and mortality data held by the NHS across the UK.

The UK Longitudinal Linkage Collaboration (UK LLC) is a national research resource that supports studies for the public good. It provides a secure and cost-effective way for researchers to work together and makes it easier for more people to be included in important health research. You can read about the UK LLC at [\[CSSBiobank web page – About the UK LLC\]](#) and at [ukllc.ac.uk](http://ukllc.ac.uk)

There are two sets of data that will be accessible to approved requestors via our partnership with UK LLC:

- The UK LLC will hold unlinked and de-identified CSS Biobank study data (such as questionnaire data) that can only be accessed by approved researchers for public interest research. Before any data from the CSS Biobank is made available to approved researchers, the CSS Biobank study team will carefully review each request and must approve or decline it. This ensures your data is used responsibly and in line with the study's purpose and values.
- CSS Biobank data that has been de-identified and been linked with electronic health record data will only be available to approved researchers via a Trusted Research Environment (TRE). A TRE is a secure computer system that holds the data. This is where researchers can access and study the data, but it can't be copied or removed from the system.

When using the UK LLC your data is:

- De-identified so researchers can't see your name or personal details
- Stored in a Trusted Research Environment (TRE) that prevents unauthorised access
- Audited and monitored to make sure it's used properly and ethically



Researchers will never be able to identify you from CSS Biobank study data or study data linked to your electronic health record information.

You can review or withdraw your consent for us to use your CSS Biobank data for health record linkage or withdraw from the CSS Biobank altogether by contacting us using the details at the end of this information sheet.

## YOUR EDUCATION RECORDS

Socioeconomic factors, including education and care you may have received, can tell us how your environment may affect your future. There is a strong link between educational attainment and health.

Linkage to education records is particularly relevant for long-term COVID-19 research in the context of school, college and university closures due to COVID-19.

Education records held by the Department for Education include:

- Your exam results
- Information about your attendance.
- Information about support and care you received e.g. if you have a special educational need.
- Information about whether you received free school meals.
- Specific information about you such as your ethnic group or the languages spoken in your home.



## YOUR ENVIRONMENTAL DATA - NEIGHBOURHOOD AND THE NATURAL ENVIRONMENT

Your surrounding environment can influence your health and wellbeing. Information about your neighbourhood and environment is derived from your postcode only, from organisations such as the Office of National Statistics. The CSS Biobank aims to understand how your neighbourhood and your environment impact on your health and wellbeing.

Natural environment and neighbourhood information includes:

- Information about your community, such as crime figures, house prices and employment figures.
- Information about houses in your neighbourhood, such as insulation levels, house age and house price.
- Information about pollution and the type of land around your neighbourhood and where you work.
- Information about services around you, such as distance to the nearest GP, parks, libraries and other facilities.



## HOW WILL THE COVID SYMPTOM STUDY BIOBANK LINK APP, HEALTH, EDUCATION, AND ENVIRONMENTAL DATA?

The CSS Biobank will follow strict guidelines when linking data, and our plans to link to participants' records have been approved by the Health Research Authority (HRA). The HRA ensures that research is ethically reviewed.



To accurately identify your records, we use information such as NHS ID numbers, date of birth, name and postcode to make an accurate link to your health, education and environmental records.



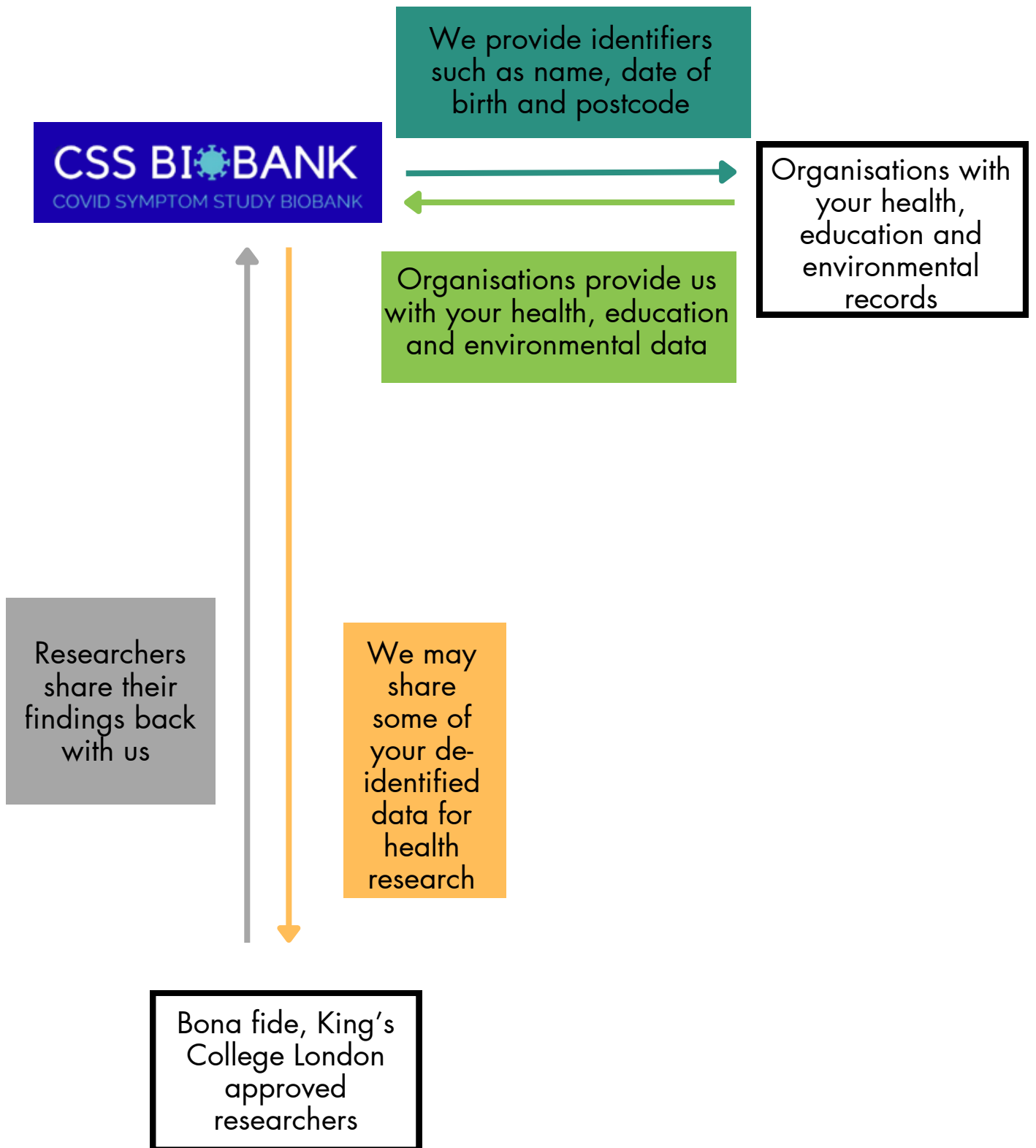
We will provide this information to organisations that hold your health, education and environmental data and they will provide us with the data they hold on your health, education and environmental records.



The data is imported into our database with any information that could directly identify you removed. The data is linked with your other CSS Biobank pseudonymised data using a unique, de-identified number. This de-identified data will be kept in a secure research environment controlled by King's College London.

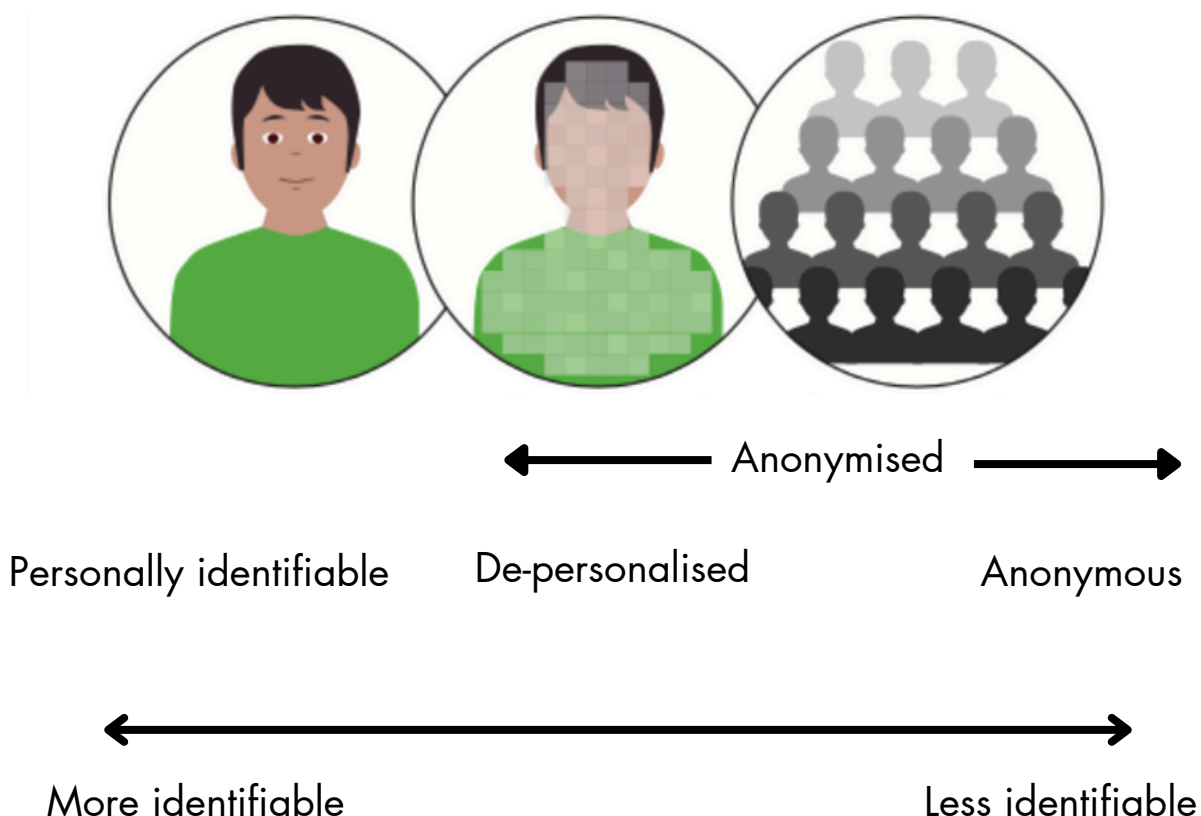


The CSS Biobank Management Group will review all applications from the wider research community to use this data and only bona fide researchers approved by King's College London working in the public interest will be granted access.



The figure above depicts how data flows between the CSS Biobank and other organisations and bona fide researchers.

## SPECTRUM OF IDENTIFIABILITY



De-identified data has had any information that could identify the individual to which it belongs removed. This includes information such as the individual's name, date of birth and address.

Pseudonymised data is anonymous to the people who hold or receive it (e.g. a research team) but contains information or codes that would allow others (e.g. those responsible for the individual's care) to identify an individual from it.

More information about how we link to health records can be found on the HRA website:

<https://www.hra.nhs.uk/information-about-patients/>

## HOW WILL THE COVID SYMPTOM STUDY BIOBANK PROTECT APP, HEALTH, EDUCATION AND ENVIRONMENTAL DATA?

We will keep all information collected about you as part of the CSS Biobank strictly confidential. We will also store it according to the General Data Protection Regulation 2018, and the UK Government's data security and protection standards for health and care organisations.

We take appropriate measures to ensure that the information disclosed to us is kept secure, accurate and up to date and kept only for so long as is necessary for the purposes for which it is used.



More information about how your data is kept are available here:

[www.gov.uk/government/publications/data-security-and-protection-for-health-and-care-organisations](https://www.gov.uk/government/publications/data-security-and-protection-for-health-and-care-organisations).

## WHO WILL HAVE ACCESS TO APP, HEALTH, EDUCATION AND ENVIRONMENTAL DATA?

The information from the app, health, education and environmental records can be used to help us understand more about COVID-19, in conjunction with the data and samples collected through participation in the CSS Biobank. But the CSS Biobank can't do all the data analysis on its own. We work in partnership with researchers from across the health research spectrum, including academic institutions, charities, health companies and regulators, provided the research is in the public interest and is governed by data sharing agreements.

Researchers from outside of the CSS Biobank may ask us for permission to use the data we hold. The CSS Management Group is responsible for the governance of the CSS Biobank, and they will review each and every one of these requests carefully. Only bona fide researchers approved by King's College London and working for the public good will be granted access. The CSS Biobank will never share your personal data such as name or date of birth.





# WHAT ARE THE RISKS OF DATA LINKAGE?

The way we keep your health, education and environmental data is regulated in order to make any risks as low as possible. Outlined below are the possible risks and the steps to reduce them.

## **Invasion of privacy, or personal information being revealed to others**

- All our data is held on secure servers. Your personal data (name, date of birth and address) is kept completely separately and is only ever accessible by a very small number of individuals in the core CSS Biobank team for the purpose of contacting you and recruiting you to studies.
- Research data DOES NOT include your name and contact details. Only a series of numbers and codes taken from a record is used in research.
- Research data can only be accessed by King's College London approved researchers with official credentials. There is a clear audit trail showing who has accessed the data and when.
- Only the minimum amount of information necessary is passed on to any researcher relevant for their specific research.
- We treat it as a potential criminal offence to misuse personal data, including trying to re-identify someone without permission.

## **Loss of control if data is passed outside the CSS Biobank:**

- Sharing of health records data must be in accordance with stipulations by NHS Digital and are subject to audit.
- The CSS Biobank will never share data linked with your personally identifiable data.
- Whoever the user, there are regulations to access your data. Researchers have to sign contracts setting out what they can and cannot do with the data, including limits on passing data to other third parties. Data must be stored securely, with controlled access and robust IT systems to keep data safe, and there are strong sanctions if data is misused.

# NATIONAL OPT OUT

If you have opted out of allowing your data to be used for research or planning through your GP surgery or online, we will not be able to access your health records even if you decide to agree to linkage through the CSS Biobank. You can find out more about the National Opt-out and set your permissions here:

[www.digital.nhs.uk/services/national-data-opt-out-programme](http://www.digital.nhs.uk/services/national-data-opt-out-programme)

## CONTACT US

If you have any further questions about the CSS Biobank or data linkage, please contact the team using the details below:



[enquiries@cssbiobank.com](mailto:enquiries@cssbiobank.com)



[cssbiobank.com/contact-us](https://cssbiobank.com/contact-us)

If you have any concerns or would like to make a complaint, please contact the CSS Biobank team using the details above in the first instance. If you remain unhappy and wish to take your complaint further, we will provide you with the contact details for the Chair of CSS Biobank Management Committee which provides oversight for the CSS Biobank and research studies.

If you feel this does not resolve your complaint sufficiently, you can escalate this to the King's College London Chair of Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittees (BDM RESC):

Chair of BDM RESC  
Research Ethics Office  
Room 4.16/ 4.16A Waterloo Bridge Wing  
Franklin Wilkins Building  
Waterloo Road  
London  
SE1 9NH  
020 7848 4070

**THANK YOU FOR TAKING THE TIME TO READ THIS  
INFORMATION SHEET**