

Detailed information for people taking part



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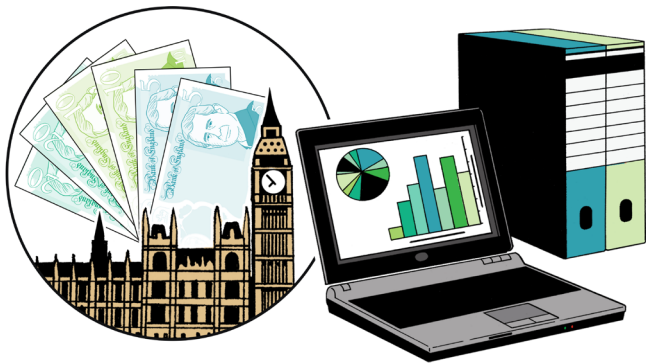
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About the VIVALDI Social Care Project



The VIVALDI Social Care Project is a national government funded research project. This means it was paid for by the government.

The project is led by:

The Outstanding Society

This is an organisation that shares information and support for social care providers.

Care England

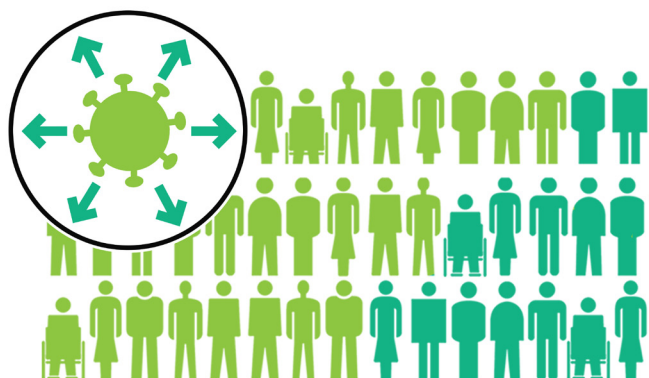
This is a charity that supports independent social care providers. This means social care that is not provided by the government.

University College London (UCL)

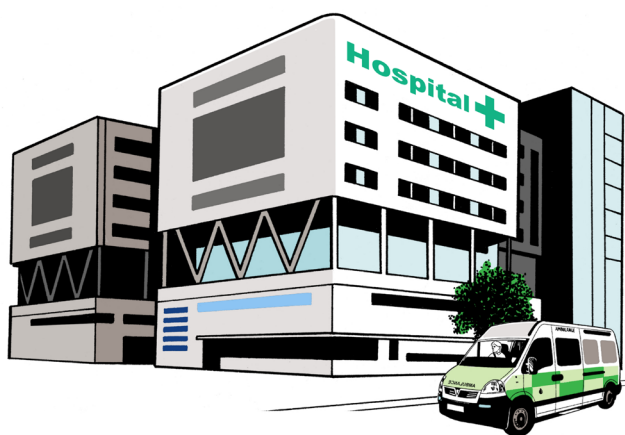
This is a research and teaching university in London.



Infections like flu, urine infections, diarrhoea and vomiting are really common in older people in care homes.



An **infection** is a health problem caused by germs. An **outbreak** is when lots of people get the same infection.



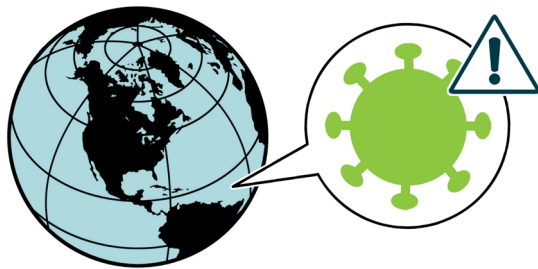
These infections can often cause severe illness that needs hospital treatment.



Outbreaks of infections like flu can spread fast. This sometimes means care homes have to close, and family members can not visit.



The COVID-19 **pandemic** showed that we need better ways to protect people who live and work in care homes from infection.



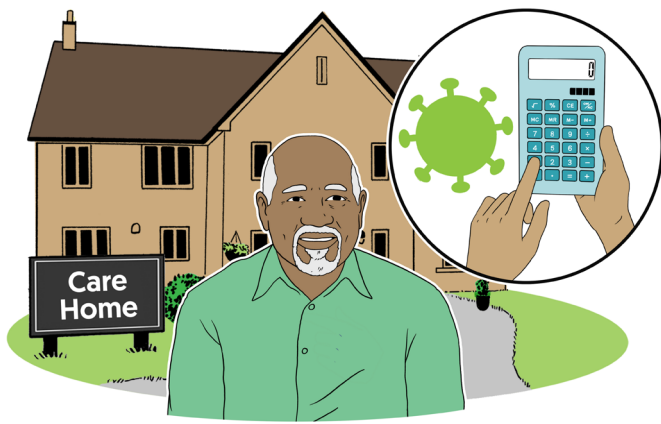
A **pandemic** is when an illness spreads across the world.



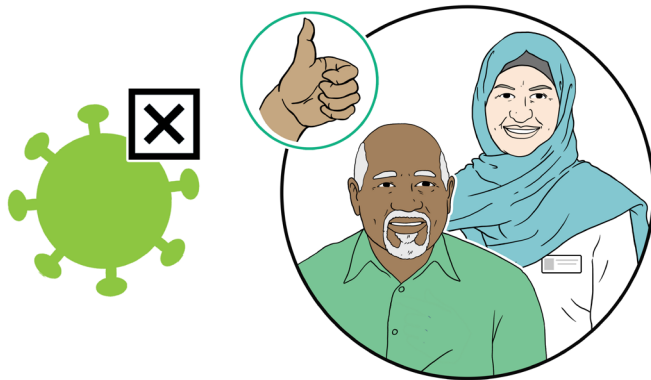
The VIVALDI Social Care Project aims to improve the way we protect people in care homes from infections and outbreaks.



We want to reduce infections, hospital treatment, and death in care homes.

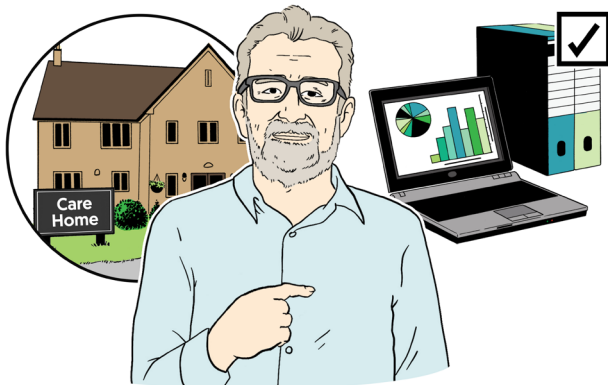


We plan to start doing this by measuring infections in care homes and how they affect **residents**. **Residents** are the people who live in care homes.



We will then do research to find new and better ways to stop infections happening and to protect people working and living in care homes.

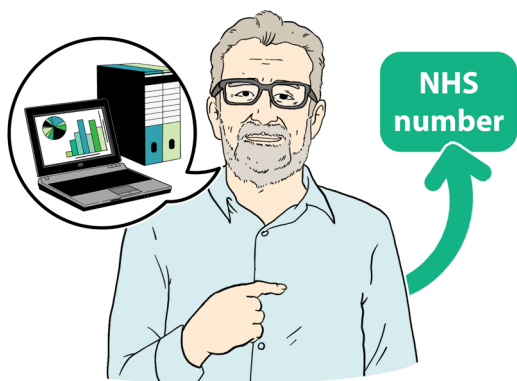
Invitation to take part



We are giving everyone who lives in your care home the chance to take part in this project.



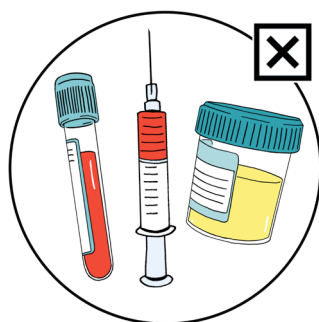
This includes people who are staying in your care home for a short time.



If you take part, we will collect your NHS number.

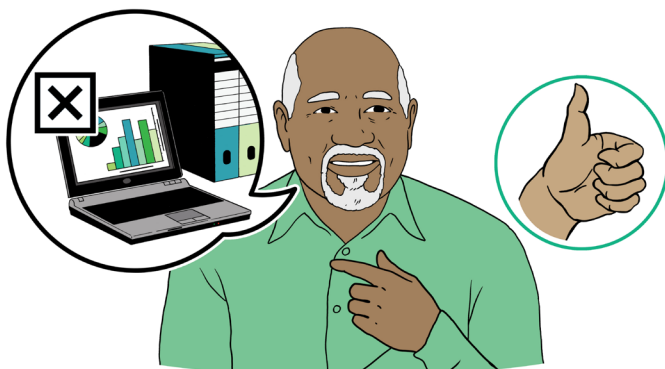


You do not need to do anything because we can get this number from your care home.

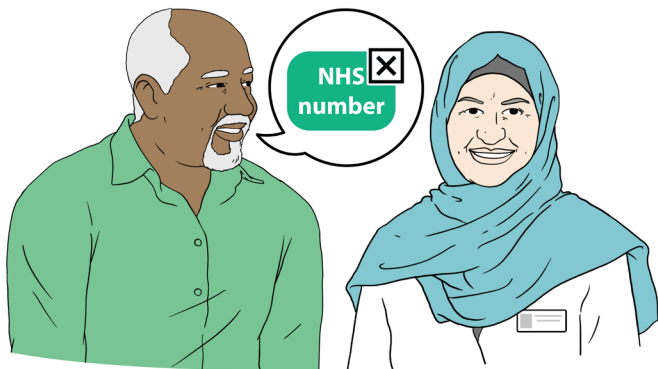


We will not ask you any questions, or collect any blood or other samples from you in this study.

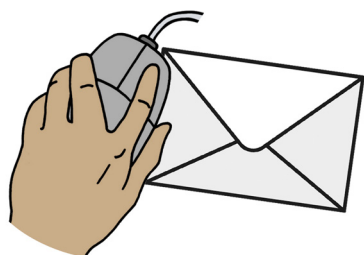
Do I have to take part?



You do not have to take part in this project if you do not want to. You can **opt out**, this means you will not take part.

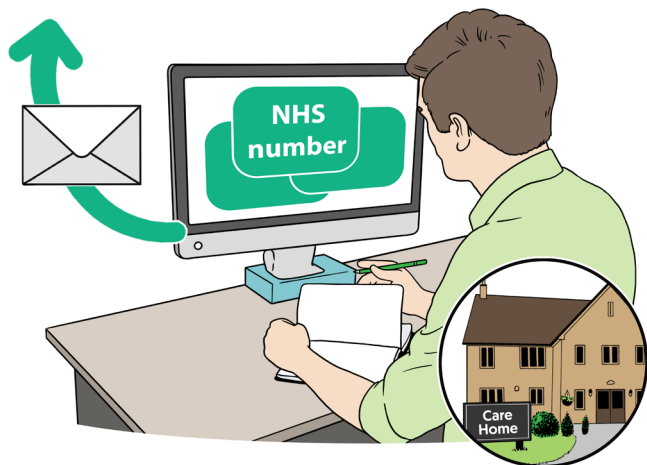


If you want to opt out, please tell someone who works in your care home. They will make sure your details are removed from the list.

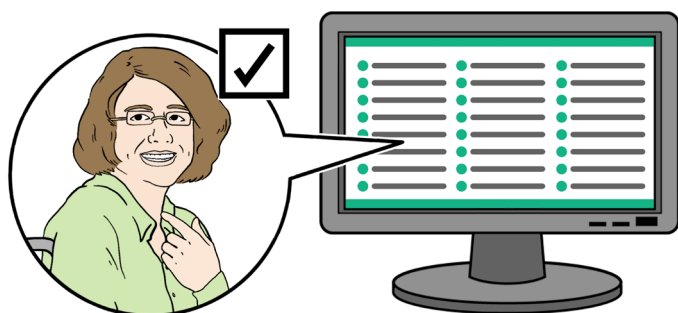


Or you can email:

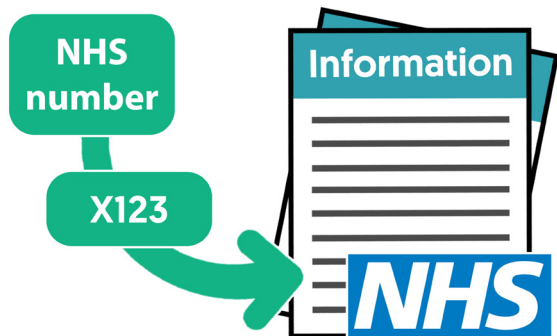
What will happen if I agree to take part?



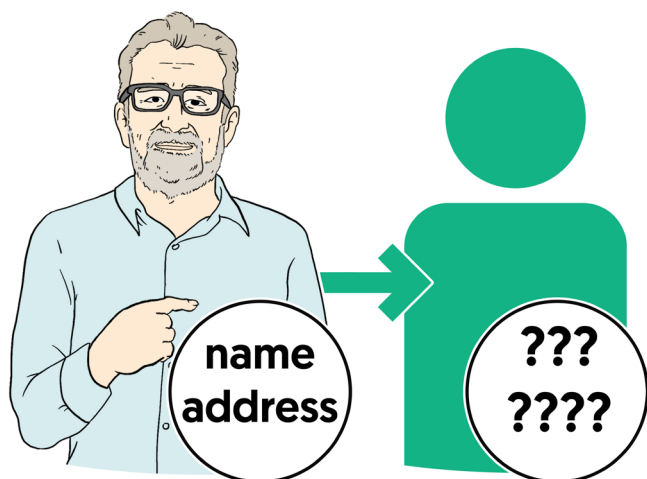
The company that does electronic care records for your care home will send the list of NHS numbers to **NHS England (NHSE)**. **NHSE** is the part of the NHS run in England.



If you take part your number will be on that list.



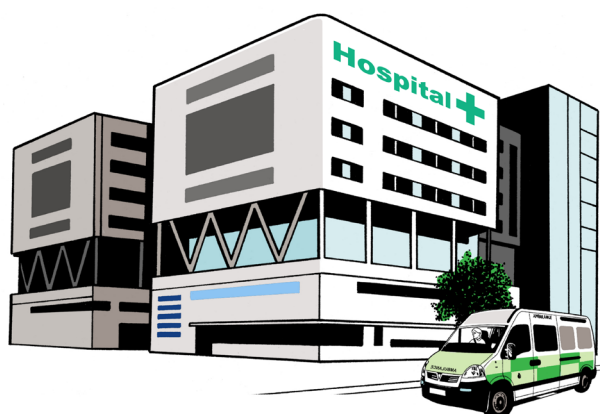
NHS England will change the NHS numbers into codes that can be linked to other data already held by the NHS.



They will then delete your NHS numbers and remove any personal information like your name or address.



NHS England will follow laws about how to keep your information safe. These are called the General Data Protection Regulations (**GDPR**).



The data that we will link your NHS number to includes:

- **Hospital admission**
The dates and the reason for going to the hospital.



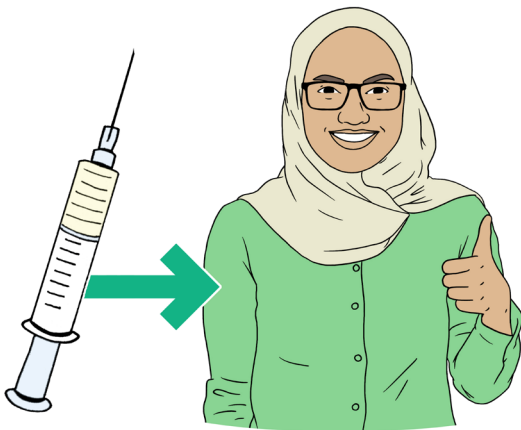
- **A&E attendance**

The dates and the reason for going to accident and emergency (A&E).



- **Vaccination records**

The dates and the type of **vaccine**.



A **vaccine** is medicine that helps keep you safe from an illness.



- **Death records**

The date and cause of death.



- **Lab test results for infection**

The dates, the type of test and what the test said.



- **Antibiotic prescriptions**

The dates and the type of antibiotic. An **antibiotic** is a type of medicine that helps fight infection.



No other data will be accessed and all information that links to you, like your name, will be removed before it is shared with the project team.

What we will use the data for



We will use the data we collect for 2 purposes.

1. Project research



The research team, public health experts, care providers and people who live and work in care homes will work together to agree on the best way to use the data to measure infections and outbreaks.



They may measure:

- how many residents had a urine infection



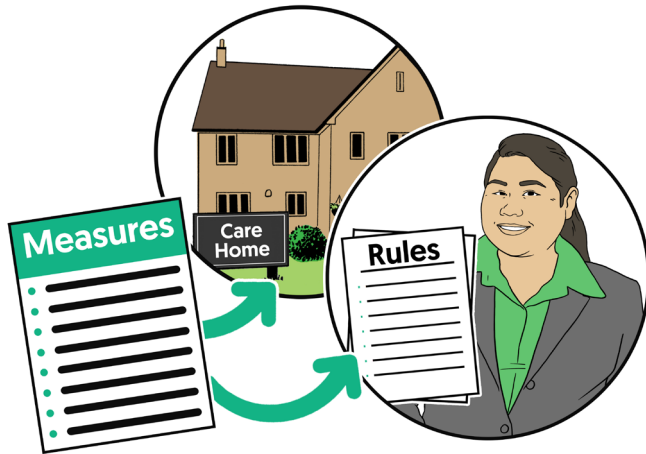
- how well vaccines are protecting residents from serious illness



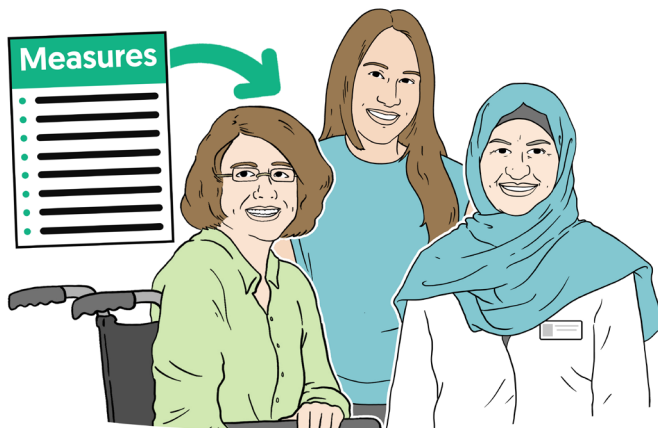
- the number of outbreaks in each care home.



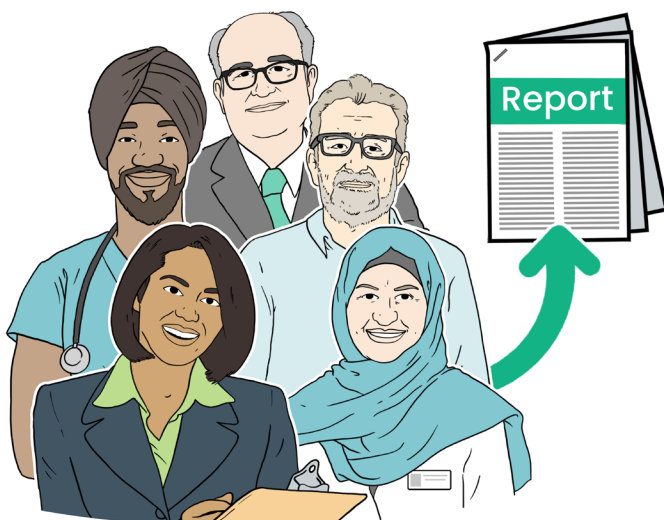
We want to have 10 different measures. We also want to make sure the measures we use are fair to all the care homes taking part.



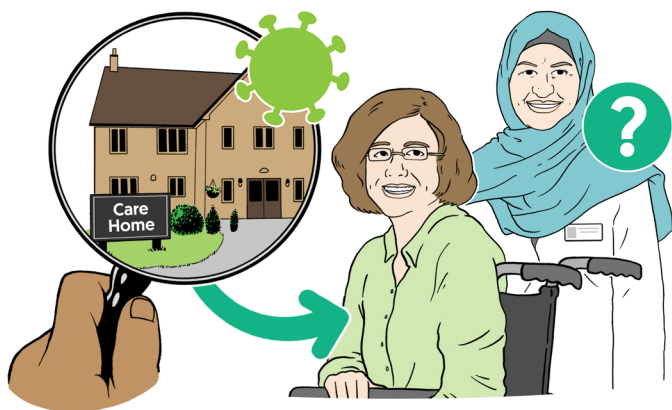
Once we have chosen the measures, we will share them with care providers and people who make rules and guidelines for social care.



We will also share them with people who live and work in care homes, and the public.



The research team, public health experts, care providers and people who live and work in care homes will work together to create a report about infections and outbreaks in care homes.

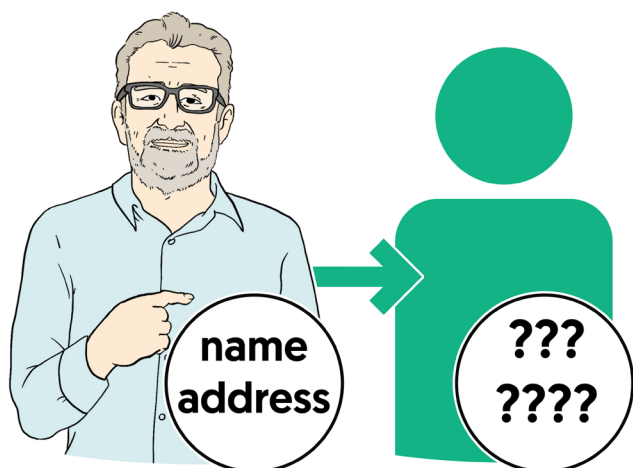


The goal is to look at infections and outbreaks in care homes and find out how they affect people living and working in care homes.

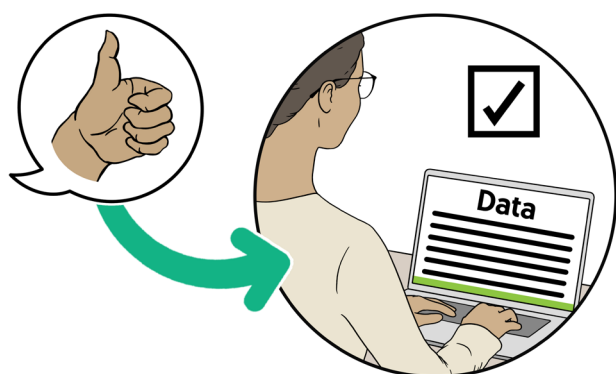
2. Research database



We will use the data we collect to make a research database that can be used by other researchers to find new ways to protect people living, working, and visiting care homes.



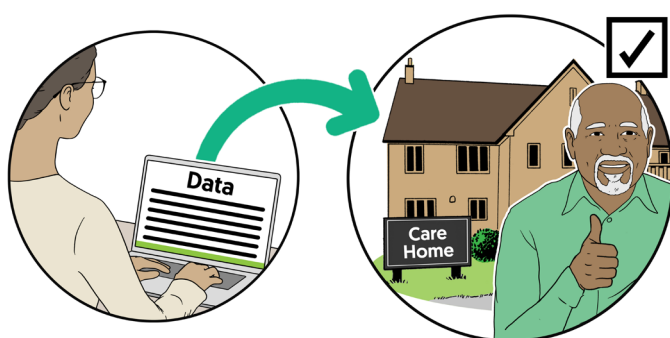
The data will be **anonymised** this means it will not show anything that links back to you, like your name or address.



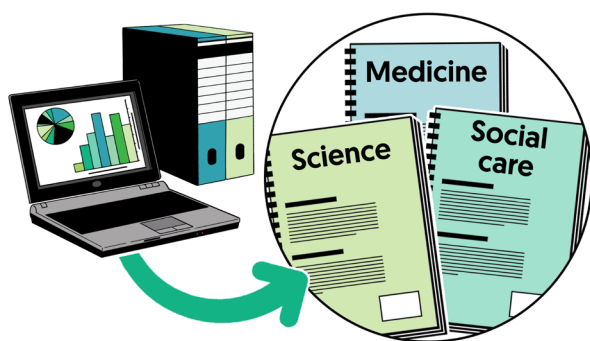
If a researcher wants to use the database, they will have to ask the **study data access committee**.



The **study data access committee** is a group of people that include people who live and work in care homes, family members, care providers, and people who make rules and guidelines for social care.



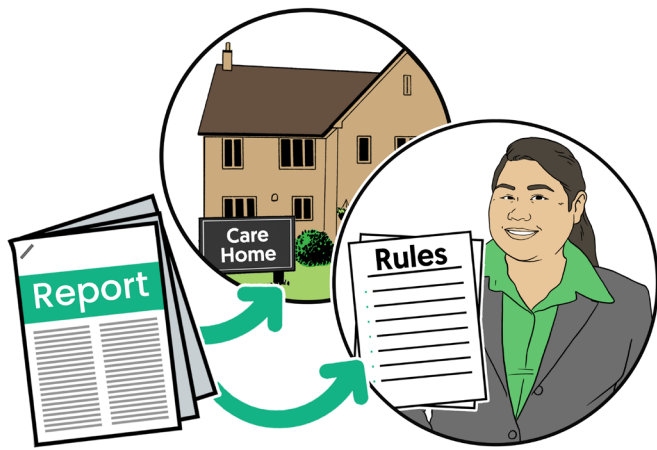
The committee will make sure that the database is only used for research that will help people who live in care homes.



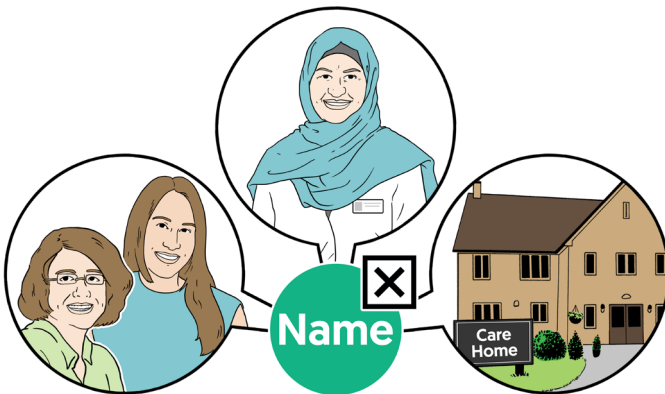
Results from research will be published in scientific, medical, and social care journals.



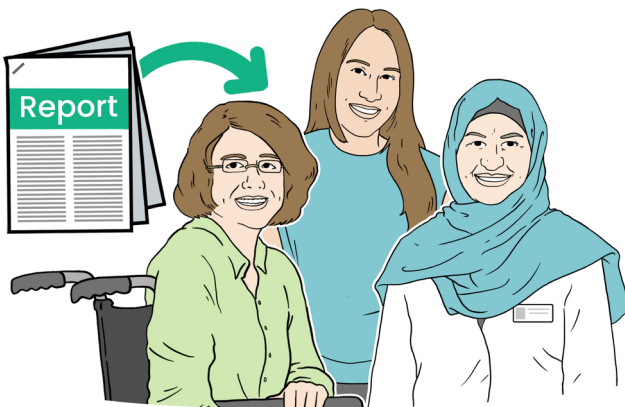
They will be presented at conferences for professionals.



Reports will be shared with care homes and people who make rules and guidelines for social care.



No resident, family member, staff member or care home will be named.

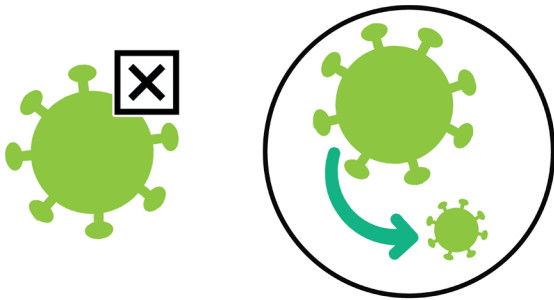


We will also share the results with residents and their families, as well as the staff working in the care homes.



We will try to share the results in an accessible way. This may be by using simple text, videos, or easy read.

What are the benefits of taking part?



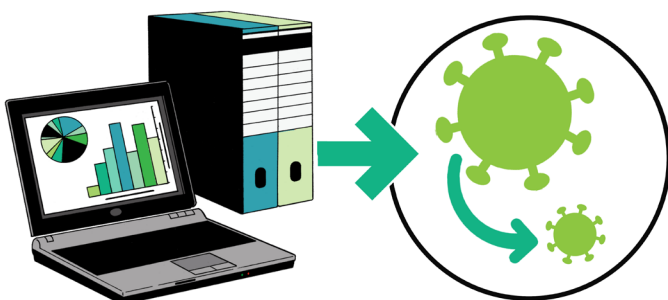
By taking part, you can help us stop or reduce infections that are common in residents and can be serious, sometimes needing hospital treatment.



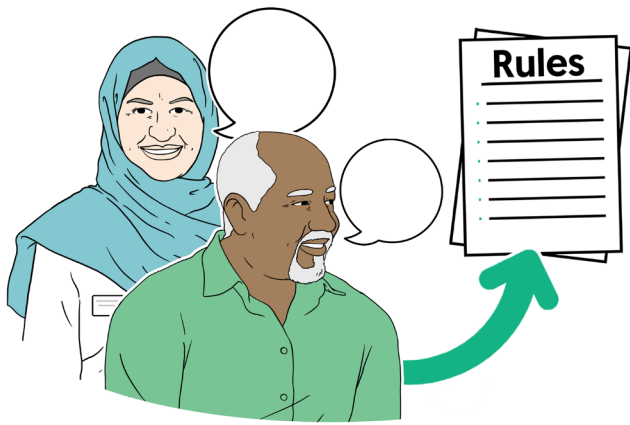
When there is an outbreak many care homes must close. This stops family members from visiting.



Care homes also can not take in new residents while they are closed because of an outbreak.



We believe this project will reduce the amount of outbreaks and the amount of care homes that close.

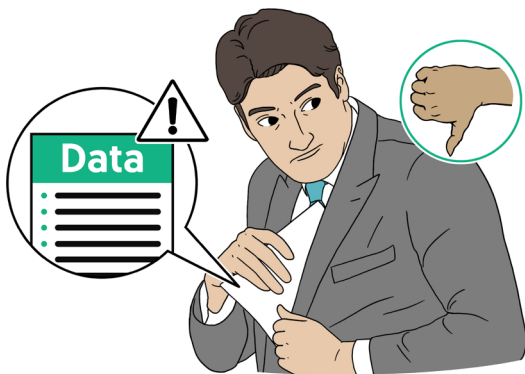


This project will give people who live and work in care homes the chance to have their say in rules and guidelines that affect them.



They will be able to share their ideas and opinions with academics and people who make rules and guidelines for social care.

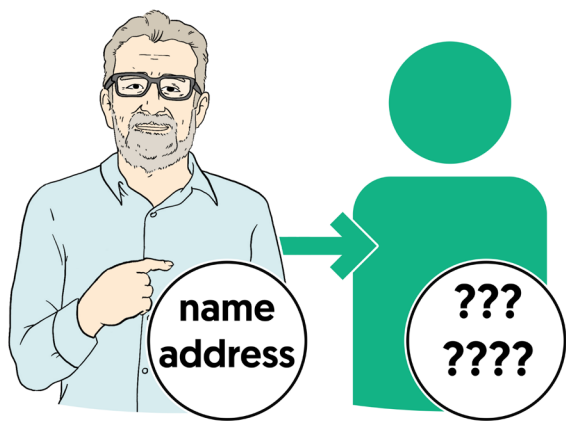
What are the risks of taking part?



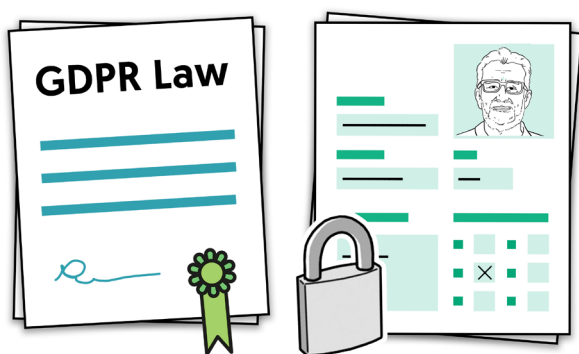
The only risk is that someone who does not have permission is able to see your data.



This risk is very low because we are only collecting one piece of information that links to you, your NHS number.



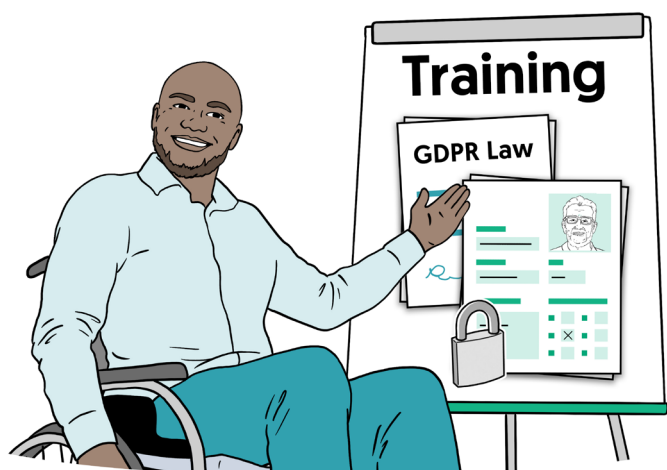
The NHS will be in charge of linking your NHS number with your data. They will remove any information linking back to you, like your name or address, before it is shared with the project team.



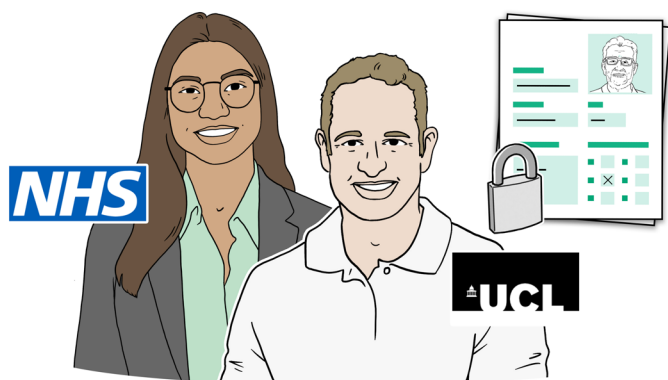
NHS England will follow laws about how to keep information safe. These are called the General Data Protection Regulations [**GDPR**].



Only organisations that already have access to residents NHS numbers will be able to see the information in this project.



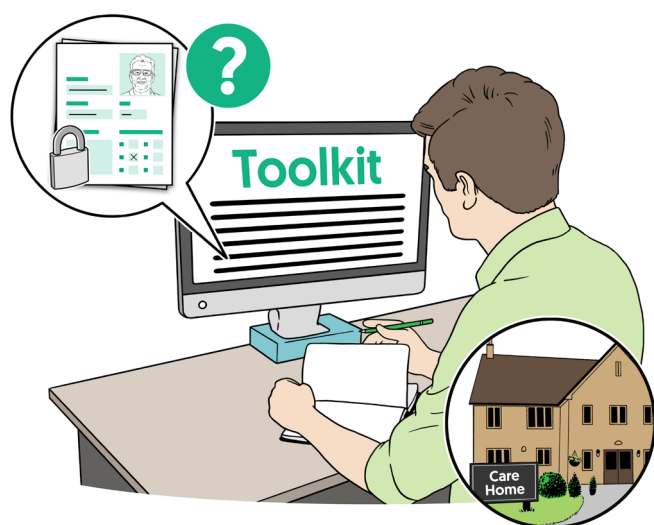
All members of the research and project teams have been trained in the GDPR rules and how to keep your information safe.



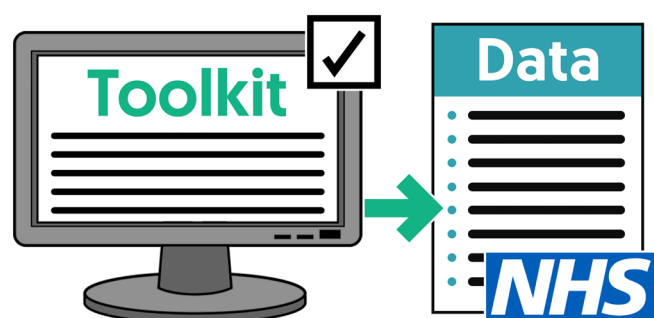
The project is **overseen** by experts in keeping information safe at NHS England and University College London.



This means they will watch over the project to make sure everything is being done properly and safely.



All care homes have to use the **The Data Security and Protection Toolkit**. This is an online tool that helps them check that they are doing everything they can to keep information safe.

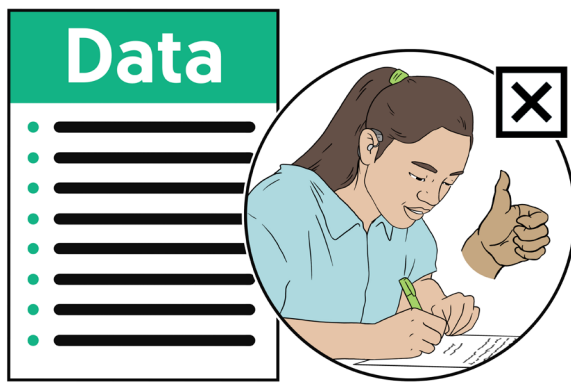


All organisations that have access to NHS patient data and systems must use this toolkit to show that they are keeping information safe.

Consent in this research project



Normally in research studies people **consent** to take part and sign a form. **Consent** means that you have said it is ok.

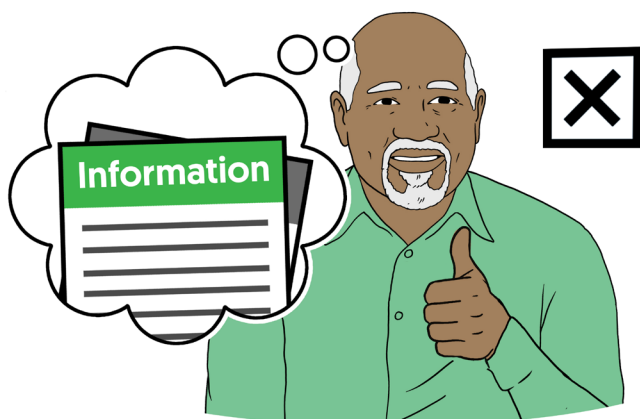


However, there are some special cases where it is ok to collect data without consent.

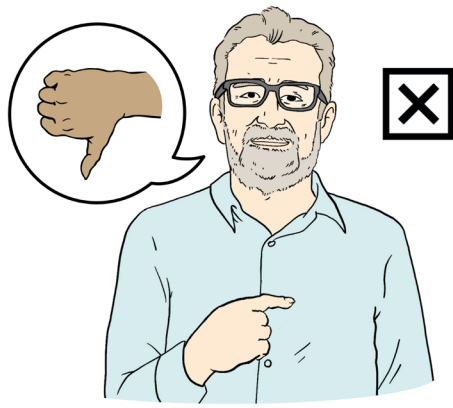


To be a special case a project must meet these 3 guidelines:

1. There must be more benefits from collecting the data than any possible harms.



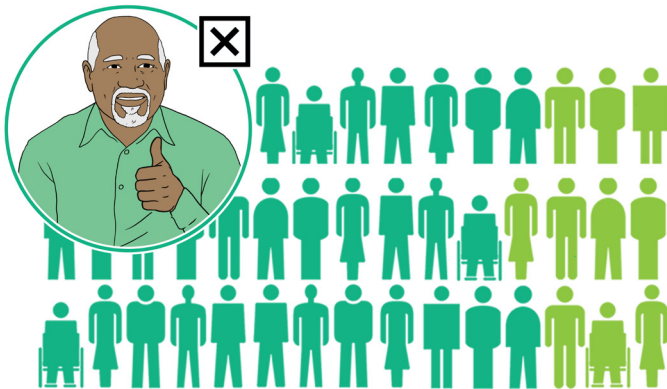
2. It is not possible to get **informed consent**. This means someone understands all the information and consents.



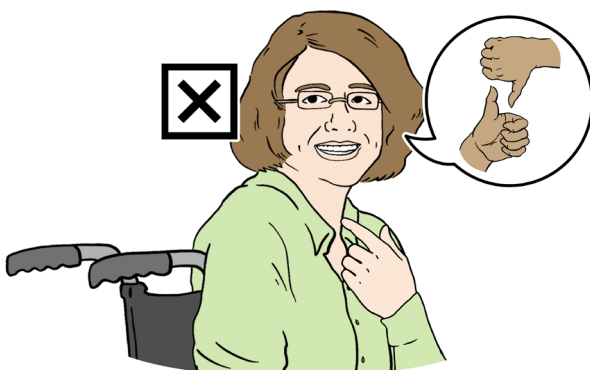
3. The people whose data is being used do not strongly **object**. This means saying they do not want to take part.



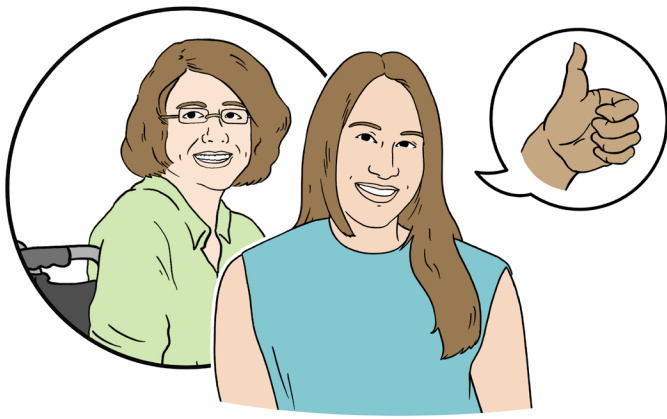
We have worked with people who live and work in care homes and done research in care homes in the COVID-19 pandemic.



This has shown us that it is not possible to get informed consent from most people in a care home.



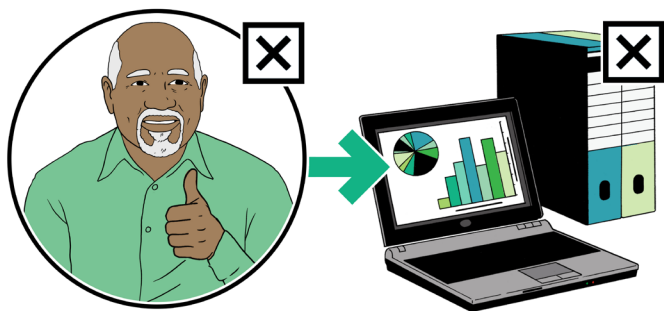
This is because many people in care homes **lack capacity**. This means they are someone who can not make decisions for themselves.



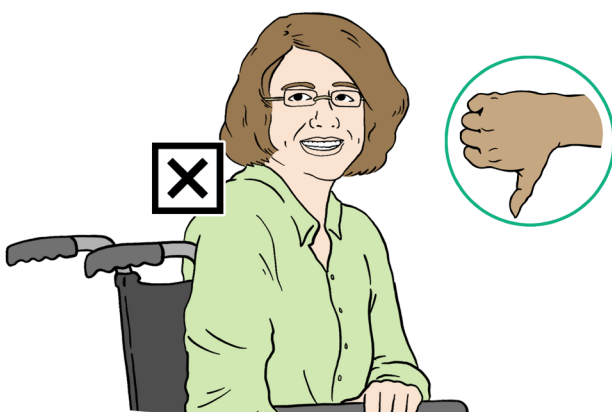
One way of including residents who can not consent is to get consent from their family.



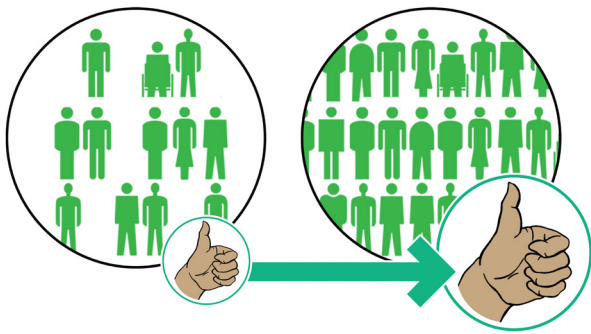
But this would be a lot of work for teams to phone every family to see if they are happy for their relative to take part.



Because of this, care home residents who cannot give informed consent are often left out of research studies.



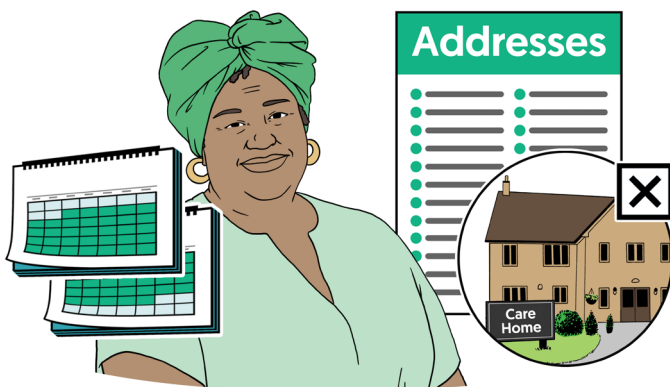
We think it is not fair to leave these residents out. And it may mean that what we learn in the study does not help them.



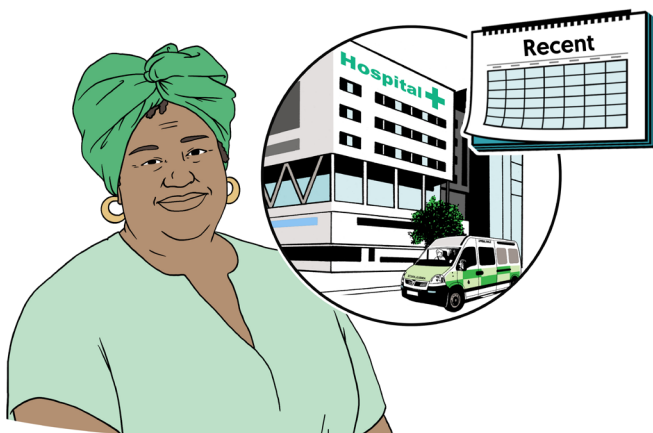
The more people we can include in our research the better. If everyone is included then they may all be helped by what we learn.



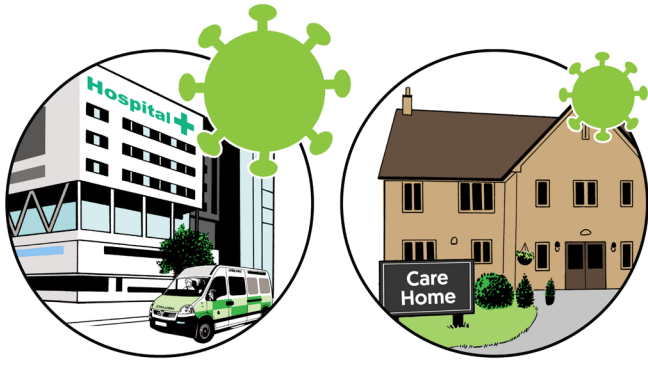
In the past people have tried to use people's addresses to find out who is and is not in a care home, by using things like doctors records.



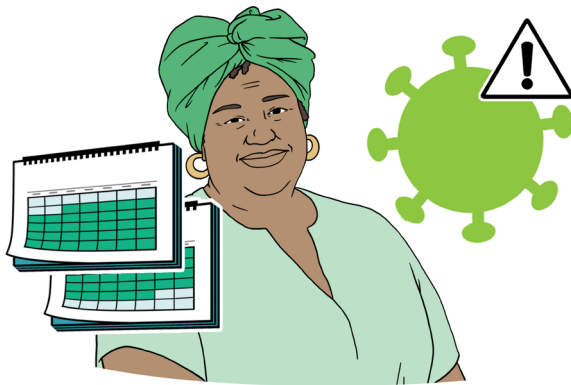
But often these records are out of date. And people only staying in a care home for a short time will have their home address on the record, not the care home.



It is important to include people only staying in a care home for a short time in research studies on infection. This is because many of them have recently been in hospital



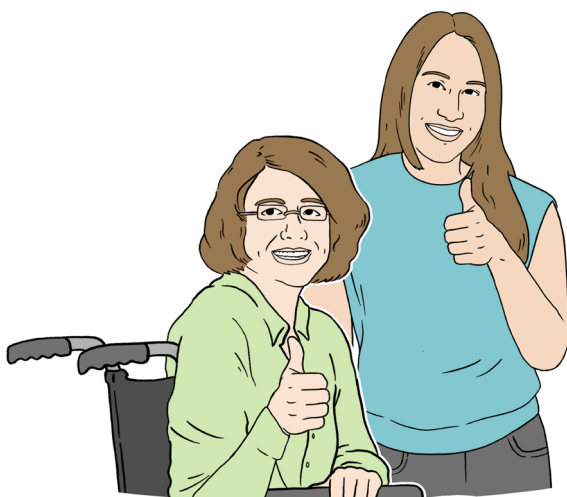
Hospitals usually have more infections than care homes.



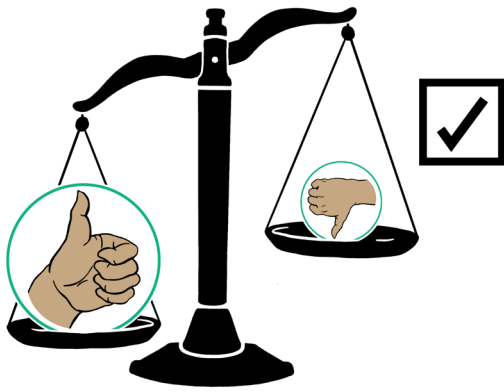
This means people staying at a care home for a short time are more likely to bring infection in to care homes than other residents.



We have talked with residents and their families and explained why we want to collect data without consent.



So far no one has said they are not happy with this way of collecting data.

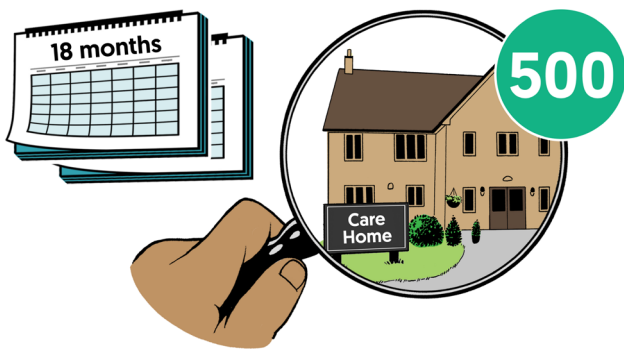


Overall, we think the benefits of having better data on infection in care homes are bigger than the possible harm of sharing data without consent.

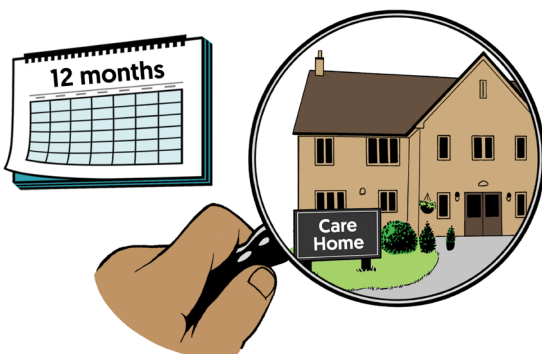


But we will keep reviewing this and talking to people who live and work in care homes about what they think throughout the project.

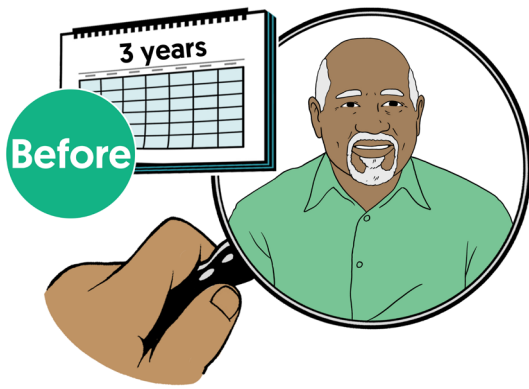
How long will the project last?



We are planning to collect data from around 500 care homes over 18 months.



We will only collect data from each care home for a maximum of 12 months.



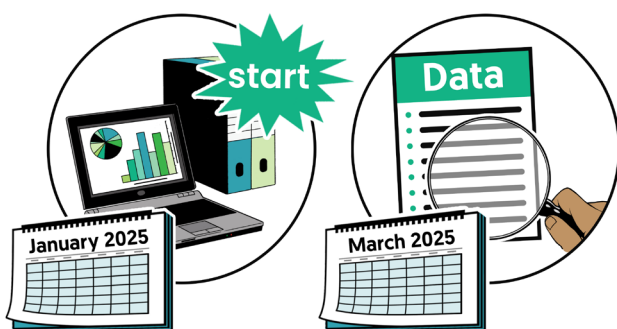
For residents taking part, we will also look at data about them from the three years before we start collecting data for this project.



This data will be things like when they have gone to hospital and why, and if they have been given medicine like antibiotics.



We collect this data so that we can see what has happened to residents before they came to the care home, and if they had any illnesses already.

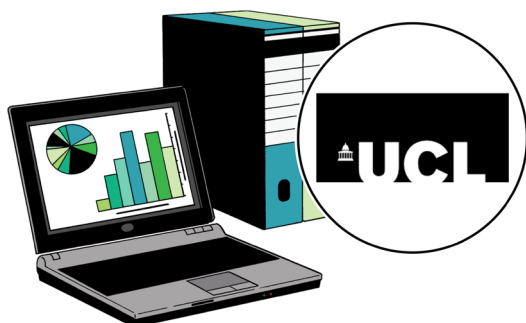


Our goal is to start the study in January 2025, and begin looking at the data from March 2025.

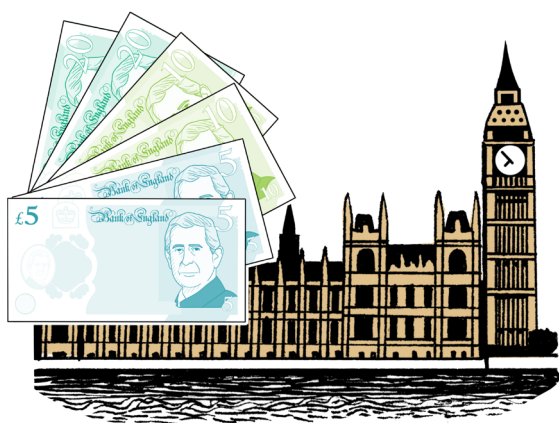
Who is involved in this research project?



This project is being led by 3 organisations working together. The Outstanding Society, Care England, and University College London (UCL).



The project is managed by UCL. The lead researcher is Professor Laura Shallcross.



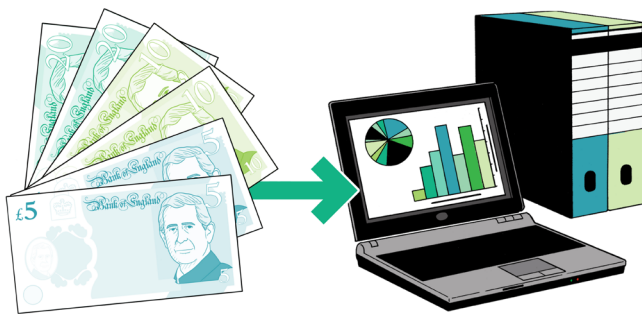
The study is funded by the **UK Health Security Agency (UKHSA)**. This means it was paid for by a government department.



The **UKHSA** is a government department in charge of protecting the public's health and protecting against infectious diseases.

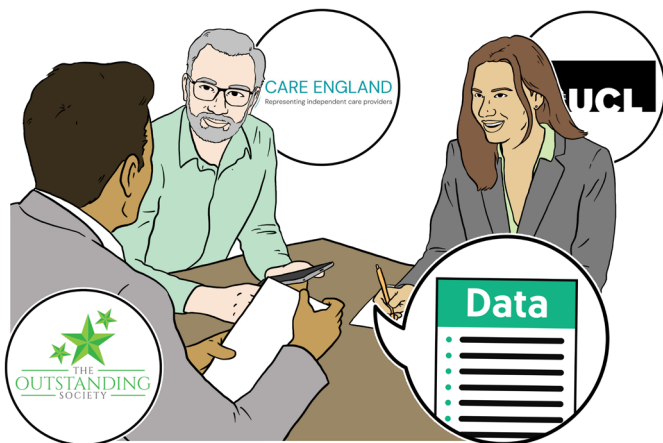


Members of the research team are paid for by the **National Institute for Health and Care Research (NIHR)**.

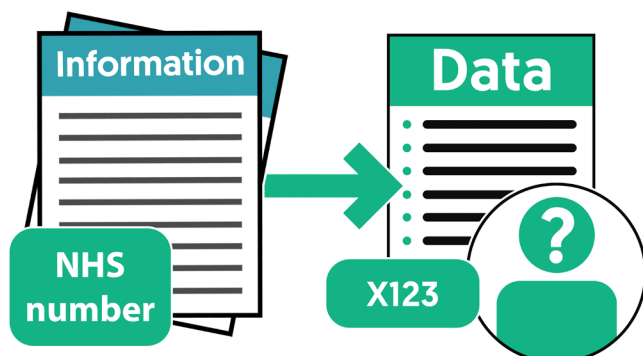


The **NIHR** is an organisation that funds important health and care research.

How will my data be kept safe?



The three organisations that are leading the project are joint **data controllers**. This means they decide why they are collecting data and how.



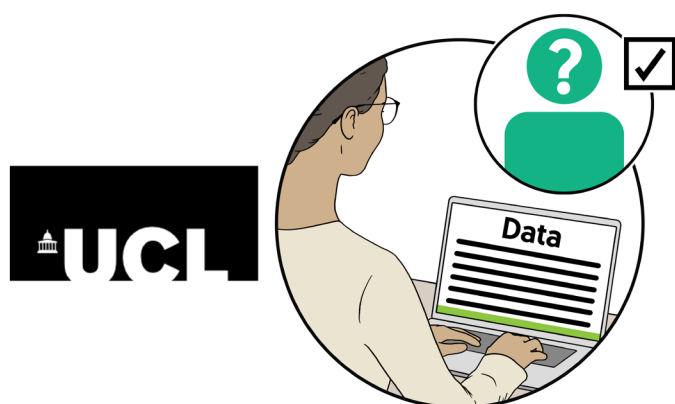
NHS England (NHSE) are in charge of linking NHS numbers to the data and then removing any information linking back to you, like your name or address.



The UK Health Security Agency (UKHSA) will use the data to make reports on the results of our research.



The data will be kept in a safe place that is managed by NHS England.



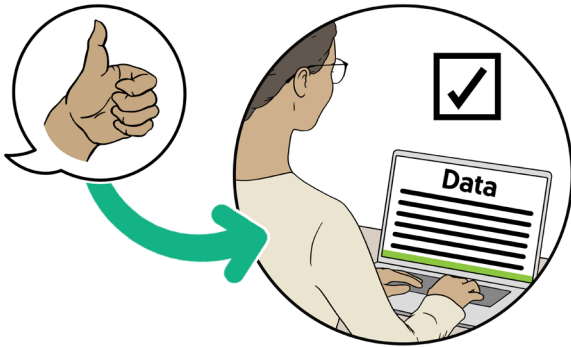
The research database will be kept at University College London (UCL). This will not have any names or information that links back to you.



Any information that links back to you can only be seen by people who already have access to this information.



Only certain members of the research team will have access to the data. These members are trained in how to keep information safe.



Only projects that have been approved by the study data access committee will be allowed to use the research database.

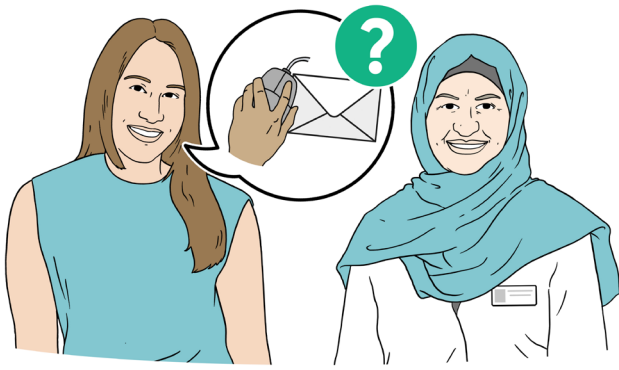


The programme that runs the research database regularly checks to see who has access to the database and if they are supposed to.

What if I do not want to take part any more?



Any time while we are collecting data, residents or their families can tell someone who works in the care home that they do not want to take part anymore.



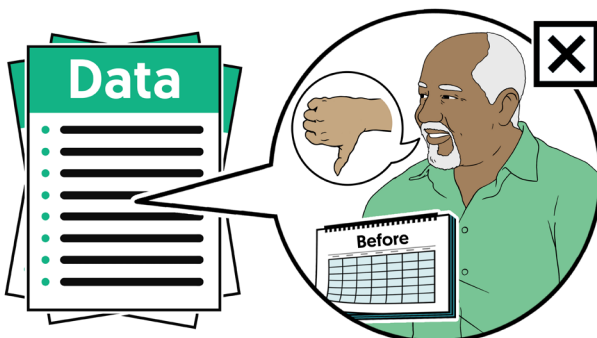
Or they can email their care home lead. Talk to someone in your care home to find out who this is.



If we have finished collecting data, it will not be possible to remove residents from the data.



This is because their NHS numbers will have already been removed and the information anonymised so it does not link back to them.

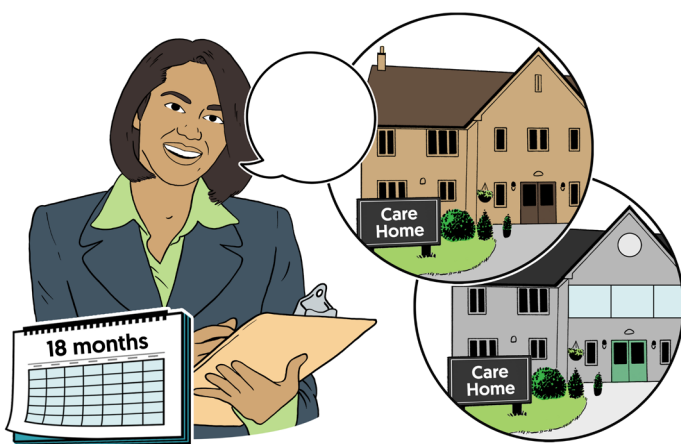


People who have already said they do not want to take part will not be included in the data.

Who has reviewed this project?



Reviewing the project means looking over the plan and how the project will work, and checking that it is safe and ok to do.



Over the last 18 months we have talked with residents, family, care home staff and care providers from different care homes to plan this project.



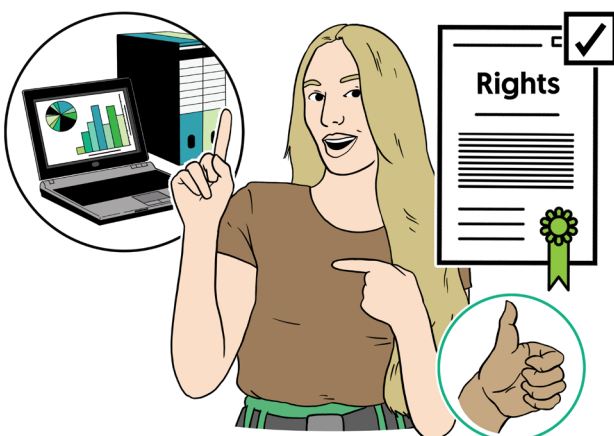
The project has been reviewed by:

- **The UK Health Security Agency**

A government department in charge of protecting the public's health and protecting against infectious diseases.

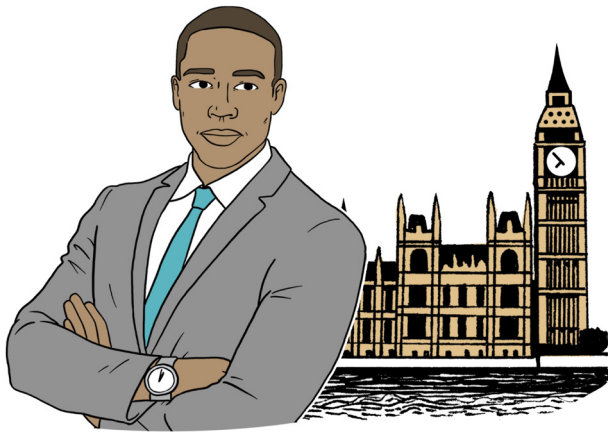
- **NHS Research Ethics Committee**

This is a group in charge of protecting the rights and safety of people taking part in research.





Health Research Authority



- **The Health Research Authority**

This is an organisation that protects patients and the public in health and social care research.

- **Secretary of State for Health and Social Care**

This is the person in charge of the government health and social care department.

- **Confidentiality Advisory Group**

This is an organisation that reviews plans for research in health and social care that use data that has been collected without consent.



The whole project will be overseen by the **Stakeholder Oversight and Governance Group**. This means they will make sure everything is being done safely.



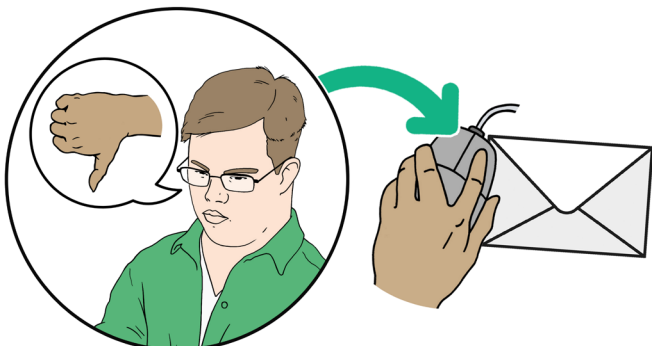
The **Stakeholder Oversight and Governance Group** is a group of people which includes residents, family, care home staff, care providers, experts, and people who make rules and guidelines for social care.

What if something goes wrong?



If you are unhappy about something that has happened in the research project and want to talk about it with the project team, please contact:

info@vivaldisocialcare.co.uk



If you want to make a complaint, please contact the UCL research complaints team:

research-incidents@ucl.ac.uk

More information and contact details



Thank you for reading. If you have any more questions about the VIVALDI Social Care project, email:

info@vivaldisocialcare.co.uk

To find out more about the project or the Outstanding Society visit their website:

www.theoutstandingsociety.co.uk

To find out more about Care England visit their website:

www.careengland.org.uk