

# FAQs for VIVALDI Study Care Homes

## 1. Why is this study important?

The COVID-19 pandemic has severely affected care homes and many residents have died from the infection, but we still lack information about what care homes can do to stop infections. We also need to monitor how well vaccines are working in residents and staff. The VIVALDI study is working to answer these questions. Our research results are regularly fed back to the government and to public health agencies so that they can make the best decisions about how to protect care homes from infection. To make sure that the study can produce the best quality evidence, it is important to collect information about everyone in the care home. Without this information, it is difficult to measure how well vaccines are working or to work out how COVID-19 spreads between people (because lots of people will be missing from our dataset).

In an ideal world, we would get written consent from everybody in the care home to use data. Unfortunately, this is not possible because 1) lots of residents can't consent to share their data (because of conditions like dementia) and 2) there are lots of new staff and residents joining/leaving the care home, so we would have to keep consenting every few weeks. This just isn't possible in care homes during the pandemic because getting consent takes a lot of time. This is why we are asking people to share their data without getting their consent first. This approach is sometimes used in research studies, but these studies must be approved by a Government appointed group called the Health Research Authority (HRA).

For more information visit the VIVALDI study website: <https://www.ucl.ac.uk/health-informatics/research/vivaldi-study>

## 2. What information will you collect?

We will be collecting information that is already being collected by the government National Testing Programme and by the NHS. This includes your COVID-19 swab test results, COVID-19 vaccinations, any A&E attendances or hospital admissions, and month and cause of death for any residents who have died. Until June 30th 2022, we are able to access this information under the COPI Notice (Control of Patient Information), which was introduced by the Government during the pandemic to support the public health response. COPI allows confidential patient information to be shared between health organisations and appropriate research bodies, to help monitor and manage the COVID-19 outbreak.

However, the COPI notice expires on June 30<sup>th</sup> 2022, which means we need a new set of permissions if we want to keep collecting and analysing data from care homes without consent. As the pandemic is not yet over, and COVID-19 infections are still common in care homes, we think it is important to continue the research study. We have applied to the Health Research Authority Confidentiality Advisory Group to get permission to keep using data from care homes for 12 months to support the pandemic response.

Importantly, the research team does NOT have access to your personal information such as name, NHS number, date of birth and address. We are also collecting information about your care home such as the number of staff and residents, the number of beds, whether it is closed to visitors, and the total number of COVID-19 deaths.

### **3. What will you do with my information?**

We will use your information in a form where it will NOT be possible for the study team to identify you. We will combine your information with information from other people in the care home to answer important questions about COVID-19. Some of the questions we will answer are: How many people are getting infected with COVID-19? How many infected people have been vaccinated? Are new types (variants) of COVID-19 spreading in care homes? How long does protection against infection last following vaccination? Why do some care homes get outbreaks and others do not?

### **4. Who will be able to see my personal information such as my name, date of birth and address?**

Your personal information will NOT be visible to the VIVALDI researchers as these details will be removed and replaced with an ID number that links your records together. This linkage and removal of personal information is carried out by NHS England as part of their routine processing of swab results and vaccination records and is performed in line with the General Data Protection Regulations (GDPR) 2018.

For example:

Original information	Information visible to researchers:
Sally Llewelyn	<i>ID 123456</i>
06/10/1964	<i>Age 57</i>
32 Cherry Drive, Liverpool	<i>Region: North West England</i>

### **5. Is it possible for my personal information to be passed on or sold to third parties such as commercial companies outside of the NHS and public health bodies who already have access to this information?**

No, this is NOT legally allowed under the General Data Protection Regulations (GDPR) 2018 which the study team and organisations that process your data must comply with.

This is also NOT allowed under the ethical approvals that allow the study team to use your data.

For more information about GDPR follow this link: <https://www.gov.uk/data-protection>

For more information about how the VIVALDI study will use your data follow this link to see the privacy notice: <https://www.gov.uk/government/publications/vivaldi-study-privacy-notice/vivaldi-study-privacy-notice>

## **6. Who has approved the use of my information for this study?**

The ways in which the VIVALDI study will use your information has been reviewed by the Confidentiality Advisory Group (CAG) which is a part of the Health Research Authority (HRA). CAG are responsible for reviewing the plans for studies in health and social care that use data they have been collected without consent. They make sure these studies are ethical and protect and promote the interests of the patients and public.

For more information about CAG, follow this link: <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/>

For more information about the HRA, follow this link: <https://www.hra.nhs.uk/>

## **7. Have you asked people in the care homes what they think of your study?**

We have visited a few of the care homes that are taking part in our study and have spoken to some of the staff, residents and their relatives. We have also spoken to members of the public who are interested in research in care homes and are working with us on the VIVALDI study. These individuals were interested in the results of the study and could see the benefits of allowing us to use their information to lower the risk from COVID-19 for people who live and work in care homes. We will continue to talk to residents, families and care home staff during the study and get their views on our study and how we are using their data.

We also held a meeting in July 2021 with a group of care providers, researchers, and government policy-makers who also felt that the questions we are working on are important. They also thought that we should continue research in care homes to reduce the impact of infection overall (not just COVID-19). They thought it was particularly important that the research reflects the needs of the care homes and that care homes play a key role in deciding what questions are answered – this is something that we are taking forward in all of our future work. Over the coming year, we will visit more care homes to talk about our study and to discuss and explain how we are using data from staff and residents.

## **8. Do I need to have any extra tests because I live or work in a care home that is taking part in this study?**

No, you will NOT need to have any extra tests other than those that are already being carried out as part of the national testing programme or outbreak testing. The swab kits that you use will have a different barcode to the ones used in care homes that aren't part of the VIVALDI study. This will not affect the COVID-19 test or the ways in which and how quickly you receive the result. Your barcodes will start with the letters "VIV" which allows the labs to pick the samples out in case we need to do any extra tests on them. These tests can tell us about how infectious the virus is, the strain and the detailed genetic code, which can give us information on how the virus passes between people. Although some people who took part in the first stage of the study had blood samples taken from them, they all provided written consent for this, and we do not plan to continue blood sampling beyond April 2022.

## **9. What have been your results so far?**

Over the last 18 months, the VIVALDI study has published reports that show that:

- Paying sick pay and reducing movement of staff across care homes are likely to reduce the spread of infection and outbreaks.
- People who have been infected before have a very low risk of getting infected again in the next 15 months.
- One month after people have their first vaccine dose the chance of infection in care home residents is halved.
- People who have had COVID-19 before have bigger immune responses to one vaccine dose than people who have never been infected.
- Care home residents have strong antibody responses to vaccination.
- Over one-third of surviving care home residents and one-quarter of care home staff were infected with COVID-19 between March 2020 and May 2021.

For summaries of our results so far, which we designed in collaboration with members of the public, follow this link: <https://www.ucl.ac.uk/health-informatics/research/vivaldi-study/patient-and-public-involvement-ppi>

## **10. What will I get from this?**

Our goal is that results from the VIVALDI study will provide important information to prevent infections, hospital admissions and deaths from COVID-19 in care home residents and staff. We will use information from the current pandemic to make sure that lessons are learned in case of future waves of COVID-19 or other epidemics.

## **11. How long do you plan to do this for?**

We will continue to collect anonymised (names and all identifiers removed) information about staff and residents in care homes taking part in VIVALDI, including anyone who joins the care home, until April 2023. For one year after this (until April 2024), we will collect information on swab results, vaccination, hospital admissions and deaths only from people who were already in the care home in April 2023.

## **12. What if I leave the care home?**

If you leave a care home that is part of VIVALDI, we will keep any anonymised information that we have already collected about you while you were at the care home and use it in our analysis and reports. We will NOT be able to access any information about you after you have left the care home unless you move to another care home that is taking part in VIVALDI.

## **13. How long will you keep my information?**

We will keep the dataset that we create using your non-identifiable information for 10 years from the end of the study which is in keeping with UCL policy. This is stored securely within the UCL Data Safe Haven which has data security accreditation and is regularly maintained and monitored.

For more information on the UCL Data Safe Haven, follow this link:

<https://www.ucl.ac.uk/isd/services/file-storage-sharing/data-safe-haven-dsh>

## **14. What if I don't want you to use my information in your study?**

If you have read these FAQs and still don't want us to use your non-identifiable information, please speak to your care home manager. They will be able to give you a form that you will need to complete with your name, date of birth and NHS number. This will be sent to NHS England who process your information and will be able to remove your record from the VIVALDI dataset. Your treatment within the care home will NOT be affected in any way if you decide to opt-out of your information being used in the study.

For more information on how to opt-out of data sharing through NHS National Opt-Out, follow this link: <https://www.nhs.uk/using-the-nhs/about-the-nhs/opt-out-of-sharing-your-health-records/>

**15. I am next of kin to someone who lives in this care home, and I don't want their information to be used in this study. What should I do?**

In the first instance please speak to the manager of your care home. If your next of kin has the capacity to decide whether or not they would like their information to be included in the study, then you should speak to them about whether they want to take part. If they do not have the capacity to make this decision, then you should consider whether taking part in the study is something that is in line with their wishes. If you believe that it is not, then please follow the steps outlined in Q14.

**16. Who can I talk to if I have a complaint about the study?**

If you would like to make a complaint, please contact the UCL research complaints team: [research-incidents@ucl.ac.uk](mailto:research-incidents@ucl.ac.uk)