# Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

**3 December 2021**

## Present:

| Name | Capacity | Items |
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| Ms Clare Sanderson | Alternate Vice-Chair | 1a |
| Dr Martin Andrew | CAG member | 1a |
| Professor Lorna Fraser | CAG member | 1a |

## Also in attendance:

| Name | Position (or reason for attending) |
|---|---|
| Mr Michael Pate | Confidentiality advisor |

## 1. New Precedent Set Review Applications – Research

### a. 21/CAG/0156 - Understanding SARS-CoV-2 infection, immunity and its duration in care home staff and residents in the UK (VIVALDI STUDY)

## Context

### Purpose of application

This application from University College London (with the controller for the activity confirmed to be University College London) set out the purpose of medical research which aims to find how many care home staff and residents have been infected with COVID-19, to inform decisions around the best approach to COVID-19 testing in the future.

By testing around 6500 staff and 5000 residents across >100 care homes in England, the study will estimate the proportion who have been infected with COVID-19 in the past and have antibodies, and the proportion who are infected now. These tests will be repeated over time to learn how COVID-19 spreads in care homes and how long the antibody response lasts and whether this helps to prevent re-infection with the virus. In those who are currently infected, information will also be collected on who is experiencing symptoms to help to understand how this affects spread of infection within care homes. Information about how infection spreads between care homes, the community and hospitals will be sought by linking the information collected to national data on hospital admissions and deaths.

Support is requested to allow the disclosure of confidential patient information for care home data managers to upload lists of residents, participating care home staff, and data on symptoms to the NHS Azure system held by NHS England. This is only for care homes where the research team cannot retrieve pseudonymised data directly from surveillance datasets that are already held in NHS Foundry.

A recommendation for class 4 and 5 support was requested to cover access to the relevant unconsented activities as described in the application.

### Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

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| **Cohort** | Residents and staff in nursing and residential homes in England aged 18 yrs to 110 yrs who have not consented via the blood sampling element of the study. This will comprise of approximately 60,000 individuals until April 2023. Between April 2023 and April 2024, the applicants plan to continue data linkage for those individuals who are already taking part in the study. Data will be collected from 230 for-profit and 100 not-for-profit care homes. The researchers anticipate that there will be 40,000 participants from for-profit and 20,000 from not-for-profit care homes. |
| **Data sources** | 1. Care homes<br><br>- Care home records<br>- Care home dataset (capacity tracker)<br><br>2. NHS Digital<br><br>- Care home testing dataset (Pillar 2)<br><br>- Hospital Episode Statistics (Admitted Patient Care)<br><br>– Hospital Episode Statistics (Accident & Emergency)<br><br>– ONS Death Certificates<br><br>– National Immunisation Dataset<br><br>3. UK Health Security Agency<br><br>- National Covid-19 testing database (Pillar 1)<br>- Second Generation Surveillance System (SGSS)<br>- Care Home outbreak dataset |
| **Identifiers required for linkage purposes** | 1. Name<br>2. Date of Birth<br>3. NHS number<br>4. Address |

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| **Identifiers required for analysis purposes** | 1. None |
| **Additional information** | Wherever possible NHS numbers are used to create the pseudo-identifier enabling linkage between datasets. However, many care homes do not hold NHS numbers for their residents which means a substantial proportion of blood test results and PCR test results cannot be matched using this method. A further challenge is that NHS records are often not updated when residents move into a care home which means demographic details such as resident address may not be accurate.<br><br>The applicants state that because of the challenges of obtaining NHS numbers, they are using a wide range of other personal identifiers to try to match care home staff and residents to their NHS number. The combination of identifiers increases the likelihood that NHSE can achieve a deterministic match to NHS number using their linkage algorithm. This minimises the amount of data that is lost from the study. |

**Confidentiality Advisory Group advice**

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

## Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Committee also agreed that the research was in the public interest.

## Scope

The CAG noted that the application is currently relying on an alternative legal basis to process confidential patient information without consent, under the 'COPI notice' and that this will continue for its duration. The group therefore considered the elements of the project that are expected to be continuing following the planned expiry of the 'COPI notice', and which require support under regulation 5.

Confidential patient information is required to flow from care homes to NHS Azure (held by NHS England). The CPI is replaced by a pseudo ID based on a combination of name, date of birth, NHS-ID, address including postcode, and CQC-ID and after this, data is linked to external datasets held by NHS Digital, the UK Health Security Agency and care homes via the pseudo ID.

The only breach is therefore from care homes to NHS England to allow for pseudonymisation and linkage to national datasets via the pseudo ID.

For those who consent to blood sampling, care home staff transfer this personal identifiable information securely to the Doctors Laboratory (TDL) who process the blood samples and report the results directly to the individual participants. TDL securely transfer the NHS number, name, date of birth, CQC ID and blood test result directly to NHS Azure (NHS England are the data processors). NHSE allocate each individual a common pseudo-identifier based on their NHS number which is then used to link the blood test results to the other datasets. The residual samples will be anonymised and stored at TDL. Consent is the legal basis for transfer and sharing of this identifiable information.

With consent, the University of Birmingham will also receive a blood sample to undertake immunity assays. The results are pseudonymised and provided to the UCL Safe Haven. TDL share antibody test results linked to identifiable data with Birmingham (these results inform decisions about which tests Birmingham need to undertake). Support is not required here because consent is the legal basis.

Once data has been inputted into NHS Azure by care home data managers, it is stripped of all identifiers by an algorithm held by NHS England. The identifiers are replaced by a pseudo ID based on NHS number, which is used to directly link the data held in NHS Azure with those held in national datasets held by NHS Digital, the UK Health Security Agency and Health Care Providers. These national datasets are stored in the NHS Foundry, As no identifiers flow to link these datasets, support for linkage is not required.

Linked, pseudonymised datasets flow from NHS Foundry to the UCL Data Safe Haven, but this flow is outside of scope, as no identifiers flow from NHS Foundry.

The CAG are clear that support is only for research relating to Covid-19. The data cannot be used for any other disease outbreaks under this support.

The CAG noted that new members will be added to the cohort until March 2023 and the researchers wish to link their data for a further 12 months. The CAG considered that the rationale for continuing to collect and link data beyond the end of the COPI period was unclear and requested a justification. A rationale was also required about how the research team would remove the data of patients and staff who leave the care home setting during the research period – as their data would no longer be relevant but this could skew the research.

## Practicable alternatives

- **Feasibility of consent**

6000 staff and residents have consented to the study. However, this required funding for a project manager at each site, and only captured about 10-30% of the total care home population.

Without obtaining data from all staff and patients in each care home, the results of the study would be of limited use in answering future questions about the epidemiology of COVID-19 in care homes. Resident and staff turnover in care homes is high, and this would mean consenting at regular intervals.

The CAG accepted that consenting 6000 staff and residents would not be possible but wished to highlight to the applicant that lack of capacity in care homes was not a justifiable reason for seeking section 251 support.

The CAG believes that staff should be treated separately with respect to consent. Even if there is a high turnover of staff, a simple consent process at staff induction might be possible as a practical alternative to support. The CAG requests justification if a consent process like this would not be possible.

- **Use of anonymised/pseudonymised data**

Care homes need to provide identifiers to NHS England in order for a pseudo ID to be created that can link to the same pseudo ID contained in national datasets. Without the identifiers, the correct patient cannot be identified.

The CAG accepted the proposed use of pseudonymised data.

## Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

Some PPI has been undertaken with care home resident relatives and a limited amount with care home staff (who are a significant part of this cohort). The CAG felt that staff might have strong views about the use of their data without consent and, as there are already heightened feelings over compulsory vaccination for care home staff, using data without consent needs to be handled carefully and properly consulted on. Staff recruitment and retention in homes is already a problem and if there is mistrust over the handling of CPI it has potential for exacerbating the situation. As a result, the CAG believe that further consultation should be conducted in the planned visits to homes and this must involve staff having some protected time to hear what is being planned (especially the use of CPI) and what is already happening.

## Patient 'Notification' and Mechanism for Managing Dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The CAG reviewed the poster provided with the application and understood that this would be amended as a result of future Patient and Public Involvement and Engagement. The CAG did not consider the poster to be suitable for notifying staff of the proposed activity. A separate poster for staff should be created, being clear about how confidential participant information (CPI) has been used thus far under the COPI Notice, as well as future data capture. The poster should contain a link to the FAQ document provided with the application. Leaflets, containing the same information, should be given to all current staff and new staff, when they commence employment, and a separate leaflet provided to residents and family. The patient and staff information should contain cohort-specific details about the National Data Opt-Out and a local opt-out mechanism.

## Exit Strategy

Once the pseudo ID has been created by the algorithm held by NHS England, support is no longer required.

The CAG were content with this exit strategy

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

## Request for further information

1. To provide a justification for continuing to collect and link data beyond the end of the COPI Notice period.

2. To provide confirmation that staff consent to take part in the study would be taken at induction, and if not, to provide a justification why not.

3. To create a separate poster for staff to being clear about how confidential participant information (CPI) has been used thus far under the COPI Notice, as well as future data capture.

4. To add a link to the FAQ document in the poster.

5. To confirm that leaflets, containing the same information as the poster, will be given to all current staff and new staff, when they commence employment, and a separate leaflet provided to residents and family.

6. To amend the patient and staff information to contain cohort-specific details about the National Data Opt-Out and a local opt-out mechanism.

7. With respect to PPI, further consultation should be conducted in the planned visits to homes and this must involve staff having some protected time to hear what is being planned (especially the use of CPI) and what is already happening.

8. To provide a rationale as to how data from staff and patients who leave the care home during the study period would be removed, so as not to skew the results of the research.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

## Specific conditions of support

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Support is only for research relating to Covid-19. The data cannot be used for any other disease outbreaks under this support.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 29 May 2020**

Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information i.e. care homes, NHS Digital and the UK Health Security Agency is in place once support under Regulation 5 is active.**

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| Mrs Clare Sanderson | 5 January 2022 |
| Signed – Officers of CAG | Date |
| Mr Michael Pate | 23 December 2021 |
| Signed – Confidentiality Advice Team | Date |