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

23 April 2021

Present:

Name	Capacity	Items
Dr Murat Soncul	Alternate Vice-Chair	1a, 1b
Ms Sophie Brannan	CAG Member	1a, 1b
Dr Rachel Knowles	CAG Member	1a
Dr Simon Kolstoe	CAG Member	1b

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Caroline Watchurst	Confidentiality Advisor

1. New Precedent Set Review Applications – Research

a. 21/CAG/0049 - Do Safe and Well Visits delivered by the Fire and Rescue service reduce falls and improve quality of life among older people? A randomised controlled trial (FIREFLI)

Context

Purpose of application

This application from the University of York set out the purpose of medical research that seeks to determine whether the Safe and Well Visits delivered by the Fire and Rescue Service reduce the number of falls and improve the quality of life of people over 70 years of age.

The Fire and Rescue Service (FRS) routinely carry out approximately 670,000 Safe and Well Visits (SWV) each year. These visits take place in people's home and are aimed to reduce the risk of fire, as well as addressing wider issues related to health and wellbeing. This includes falls prevention, smoking cessation, winter warmth advice and social isolation. Falls can be a serious issue for older people. Around 1 in 10 people who have a fall suffer a serious injury as a result, costing the NHS £2.3 billion per year to treat. Some evidence exists that interventions to improve home safety are effective at reducing falls, however it is not known whether SWV delivered by the FRS reduce falls, improve quality of life or are good value for money.

The applicants will recruit 1156 people aged 70 years and over from lists held on FRS databases. All participants will receive a falls prevention leaflet from Age UK and usual care from their GP and/or other healthcare professionals. Participants will be randomised into two groups. Half will receive a SWV at the start of the study and half will receive a SWV after 12 months. All participants will complete a falls calendar and four postal questionnaires sent out over the 12-month period of the study. The applicants will also conduct interviews participants and members of the FRS to find out if the visits were acceptable to older people and the FRS.

The Humberside Fire and Rescue Service will submit an application to the NHS Primary Care Registration Management (PCRM) at NHS Digital to request a new 'cleansed' set of Exeter data, which is held by NHS England and Improvement, specifically for the study. The PCRM will then disclose a list of people aged 70 years and over, living in the catchment areas for Humberside FRS, to the Humberside FRS. The Fire Service will use this information to create a list of eligible patients. Confidential patient information from the Exeter dataset is routinely shared with Fire and Rescue Services in England to allow the Services to prioritise which households to target with their SWV, however the current data sharing agreement does not allow use of this data for research purposes; therefore the applicants are seeking support to use data from Exeter to identify and invite eligible people to take part in the study. FRS staff will

then remove those who have already received an SWV and send potential trial participants an invitation pack in the post, asking if they would like to take part in the study. The invitation pack will contain an invitation letter from Humberside Fire and Rescue Service (FRS), addressed to a named individual in the household. Participants who wish to take part in the study, will complete the consent and screening forms and return them to the York Trials Unit. Their participation will then be on a consented basis. The applicants advised that members of the research team based at the University of York, York Trials Unit (YTU) will not know which households have been mailed out to until the study documentation is returned to the University. However, the FRS may require help from the research team when undertaking the mailout of invitation packs and the researchers may be exposed to confidential patient information when assisting.

A recommendation for class 2, 3 and 6 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.

Cohort	Those aged 70 years and over, living in the catchment areas for Humberside Fire and Rescue Service who have not previous received an SWV. 1156 patients will be included.
Data sources	1. Exeter database at NHS England and Improvement 2. Primary Care Registration Management at NHS Digital
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Postcode – unit level 4. Gender
Identifiers required for analysis purposes	Analysis will be undertaken after participants have consented to the research.

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 CAG agreed that the application had a medical purpose and was in the public interest.

Scope

The applicants will access the existing database that they hold in order to select individuals, therefore the CAG agreed that the numbers of records searched could not feasibly be reduced.

Several staff from the FRS will be involved in searching the records and staff from the University of York Trials Unit will be involved in searching the records and labelling envelopes. The CAG noted that the application does not describe how many staff from the Trials Unit will be involved. Members asked that the applicant provide the number of staff who will be involved in this process, and their job titles, so that it is clear who support will cover. Those undertaking this activity should also have received relevant and adequate training. The CAG noted that this will be checked as part of the DSPT assessment.

The CAG noted that the use of data for research is not covered in the data sharing agreement between the FRS and the NHS, and queried whether support was needed to amend the data sharing agreement to permit access for research purposes.

Data flow

The CAG noted that the Fire and Rescue Service will receive data from the NHS PCRM and use this data to create the list of eligible participants to be invited to take part in the research. Members noted that the FRS already holds the data which would determine eligibility and queried whether this list was the same as the list supplied by the NHS PCRM, meaning that 2 lists are sent by PCRM. The CAG also queried whether the list sent by the PCRM would list those who have received a Safe and Well visit in the previous 3 years.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Minimising flows of identifiable information**

The FRS already held year of birth, gender and unique property reference, although they do not hold patient names. The identifiers required to identify suitable participants are listed as; full name, date of birth, address, gender. The information given in the IRAS explained that the FRS hold year of birth, therefore the CAG agreed that the full date of birth was not needed as the FRS could use year of birth of identify those over 70 years of age. The CAG was unclear on why the PCRM would return the addresses, date of birth and gender to the FRS, as the FRS already held these details.

The CAG was also unclear why patients gender was needed for participants identification and the mail-out, and queried whether this data item was needed.

Members suggested that the data flow was revised as follows, as this would reduce the flow of confidential patient information as only patient name will be disclosed:

1. FRS search the data they already hold to identify the eligible group.
2. FRS send the unique property reference of eligible people to NHS Digital (support under Regulation 5 is not needed for this step as this identifier is not confidential patient information).
3. The PCRM at NHS Digital use the property reference to identify the correct addresses and send names only to FRS - minus the opted-out people (support under Regulation 5 is needed for this stage)

- **Feasibility of consent**

The applicants explained that it was not feasible to seek consent in advance of the sending of recruitment packs due to the large number of households covered by the FRS. The applicants also noted that not all eligible households would routinely receive an SWV, and approaching potential participants may mean that some people would be disappointed if they were not selected for an SWV.

The CAG agreed that the number of patients involved in the screening process meant that consent was not feasible. Members noted that up to 30,000 mailouts would be sent to recruit 1,156 patients and asked for details on the calculation that had been done to determine that 30,000 patients needed to be contacted in order to meet the recruitment target.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required so that the FRS can make contact with potential participants and invite them to take part in the study.

‘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 websites for Humberside Fire and Rescue Service will include information about the study and explain that households in the area may be sent an invitation pack in the post. Contact details will be given to allow any member of the public living in these areas, to inform the FRS that they do not wish to receive an invitation.

Eligible patients will be sent a recruitment pack in the post.

The applicant provided the text to be used on the Fire Service website. This included a link to information about the study and a freephone telephone number to opt-out.

The information for any patients who had opted-out of the use of their data in research would be removed from the Exeter dataset before it is released by NHS E&I. If a participant was approached who then wanted to dissent from the use of their Exeter data in research, they would not be included in the study. They would be directed to the appropriate NHS website to register dissent to any future use of their data in research.

The website for Humberside Fire and Rescue Service will include information about the study and explain that households in the area may be sent an invitation pack in the post. Contact details will be given to allow any member of the public living in these areas to inform the FRS that they do not wish to receive an invitation.

The CAG requested that further details were provided on the opt-out process. Members queried whether there would be a lead-in time, in which patients could register dissent before the data was processed.

Members noted that people were unlikely to check the FRS websites and queried whether further patient notification could be undertaken. The website text also needed to explain that the FRS already receive data from the NHS in order to offer the Safe and Well Visits, to prevent patients from wondering how the FRS had access to their 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.

The applicants had consulted with the Patient and Public Involvement Group from the NIHR OTIS falls prevention study. The group members were positive about the Fire and Rescue Service delivering the Safe and Well Visits and would be willing to talk to the Fire and Rescue Service staff about falls risks around their home.

Opinions were sought from a PPI group at Involve York, which comprised of 5 members of the community over the age of 70, and also from members of the community/Older peoples forums in Kent (5 people), around the use of a list of households provided by the NHS to identify suitable patients and send an invitation to take part in the study. They saw no problem with the FRS using the data for the purpose of inviting householders to take part in the study.

The feedback given by the participants during the meeting was that they all felt it was acceptable to use the FRS data to invite people in this way. They were not concerned about

the use of their data by the FRS in this way as they felt that they could choose not to open the pack/or respond, as no further contact would be made if they did not respond. They were very keen that as many people as possible, including the most vulnerable groups such as those with dementia, were invited to take part in the research.

If required, the group will be contacted after the ethics submission, to provide assistance to responding to comments the ethics committee raises. A further two meetings will be held throughout the study at points where input from the group is needed most. A member of the group has agreed to join the Trial Steering/Data Monitoring and Ethics Committee. Humberside FRS plan to set up a user group of older people who have received a Safe and Well Visit and Kent FRS plan to set up a customer representation group.

The applicants arranged another virtual meeting via zoom with a group of people in Kent. This group of people were identified by Engage Kent and Older People's Forums in the area. The applicants had asked that those aged over 70 were invited, so they were similar in age to the participants in the research. A group of four people over the age of 70, two male, two female, and from different areas within the county took part. The meeting took a similar format to the previous meeting. The participants gave feedback during the session and saw no problem about the use of FRS data in this way for research purposes. No members of the group expressed any concern about how the FRS would use their data for the purposes of the study. However, it was strongly expressed in both groups that safeguards had to be in place to avoid the study and particularly the visits being mistaken for a scam. The group agreed that the suggested strategies in the protocol were acceptable to address this point.

Exit strategy

Once participants have consented to take part, their participation will proceed on a consented basis and support will no longer be required.

The applicants explained that information for those who did not consent would be retained until recruitment to the study was complete, to ensure that patients were not re-contacted. Once recruitment has completed, the contact details of those who did not respond to the study invitation or did not consent.

The applicants will also retain the list of Trial ID numbers, which will be allocated to the recruitment packs sent out, CONSORT diagram when reporting the findings of the study, we will retain the list of Trial ID numbers allocated to recruitment packs sent out, in order to record the total number of potential participants approached for this trial.

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, the applicant was required to respond back to all of the requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Clarify whether support is needed to amend the data sharing agreement between the FRS and the NHS to permit access to the Exeter database for research purposes.

2. Further clarification is needed on the identifiers that will be disclosed between the FRS and NHS Digital PCRM:

    a. Clarification needs to be provided on why the PCRM would return the addresses, date of birth and gender to the FRS, as the FRS already held these details.
    b. If the above details are not required, then the identifiers need to be revised to remove these data items.

3. The CAG suggest that the data flow is revised as below. If this cannot be implemented, please provide justification as to why not:

    a. FRS search the data they already hold to identify the eligible group.
    b. FRS send the unique property reference of eligible people to NHS Digital (support under Regulation 5 is not needed for this step as this identifier is not confidential patient information).
    c. The PCRM at NHS Digital use the property reference to identify the correct addresses and send names only to FRS - minus the opted-out people (support under Regulation 5 is needed for this stage)

4. Clarify whether the list that the FRS receive from the NHS PCRM will contain the same information as the information already held by the FRS to determine eligibility and whether the NHS PCRM will send two lists to the FRS.

5. Clarify whether the list sent by the PCRM will list those who have received a Safe and Well visit in the previous 3 years.

6. Provide the number of staff who will be involved in this process and their job titles.

7. Changes are to be made to the patient notification and dissent mechanism as follows:

    a. Consider whether other methods of patient notification could be undertaken, in addition to the website notification, and provide information on the further notification.

    b. The website text needs to explain that the FRS already receive data from the NHS in order to offer the Safe and Well Visits.

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. Favourable opinion from a Research Ethics Committee. **Confirmed 27 April 2021**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

    Confirmed: The NHS Digital **2019/20** DSPT review for **the University of York** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (14 April 2021)

    Pending: The NHS Digital 2019/20 DSPT review for the Humberside Fire and Rescue Service is pending.

b. 21/CAG/0058- Evaluation of Homeless Health Peer Advocacy: an analysis of secondary data. Short title: HHPA evaluation: Secondary analyses of Hospital Episodes Statistics

Context

Purpose of application

This application from the London School of Hygiene & Tropical Medicine & University College London (as joint data controllers) sets out the purpose of medical research that seeks to explore how the homeless health peer advocacy (HHPA) intervention affects homeless peoples' use of health services. The applicants are proposing using a retrospective cohort of homeless adults who used an NHS hospital in London, and comparing the frequency of hospital use over 12 months between HHPA clients and controls. The research team has an ongoing mixed-methods consented research project (IRAS 271312) to evaluate the effect of HHPA, however Covid-19 related restrictions have caused the consented study to be halted. Applicants therefore propose this alternative design in order to meet the evaluations objectives.

People experiencing homelessness suffer extreme health inequalities. The health care costs of people who are homeless are estimated to be 8 times higher than the general population. Groundswell, a third sector organisation, have pioneered HHPA among homeless populations in London, a model that is being adapted by others. Peer advocates who themselves have experience of homelessness provide one-to-one support to attend health care appointments, which could be an acceptable, effective and cost-efficient intervention. However there is limited evidence showing the impact of HHPA on health service utilisation and other health and social outcomes. Further evidence would facilitate development and scale-up of the intervention among homeless and other vulnerable populations in London and elsewhere.

Groundswell's HHPA data manager will identify the last 150 new clients who received support from a peer advocate to attend an outpatient appointment prior to 1st March 2019 as intervention participants. Their confidential patient information will be collected (Name, NHS number, hospital ID, Date of birth, postcode (district level), sex, Nationality and ethnicity), alongside their HHPA start date. A Unique ID number is assigned by Groundswell's HHPA data manager, and the identifiable dataset is disclosed to NHS Digital in order for NHS Digital to link the details with the Personal Demographic Service (PDS) to locate any outstanding NHS numbers. NHS Digital will then undertake linkage of the intervention cohort to Hospital Episode Statistics (HES) records for the 12 months prior to and after their HHPA start date. NHS Digital then removes identifiers and discloses the linked dataset alongside the Unique ID back to applicants at UCL Data Safe Haven (DSH). Groundswell will also disclose a pseudonymised dataset linked to Unique ID to the UCL DSH in order for the applicants to be able to link this to the pseudonymised HES-linked dataset that is returned by NHS Digital, using the Unique ID.

For comparison participants, applicants will request NHS Digital to identify from the HES database 1000 adults aged 25 or more who had hospital-based care in London between March 2018 and March 2019 and who are likely to be homeless. People who have opted out or those who are HPPA clients are excluded, and other exclusions are listed in the application. The comparison participants HES records are requested for the 12 months prior to their first hospital visit in this time span, and for 12 months after. Identifiers are removed from this dataset by NHS Digital, and disclosed to the applicants at UCL.

A recommendation for class 1, 4 & 6 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.

Cohort	All participants will be: • aged 25 years or older, and • Homeless, per UK government definition • Had hospital-based health care in London between March 2018 to March 2019. 150 intervention participants; The last 150 newly-enrolled HHPA clients who received support from a peer advocate to attend an outpatient appointment prior to 1st March 2019. (HES records linked 12 months prior and 12 months after start of HHPA enrolment) 1000 control participants identified by NHS Digital (HES records linked 12 months prior and 12 months after first hospital visit)
Data sources	3. Groundswells HHPA database 4. Personal Demographics Service (PDS) (to find any missing NHS numbers) - NHS Digital 5. Hospital Episode Statistics (HES) - NHS Digital

Identifiers required for linkage purposes	Data items sent by Groundswell to facilitate linkage with PDS: 1. Name 2. NHS number 3. hospital ID 4. Date of birth, 5. postcode (district level) 6. Nationality, 7. Ethnicity 8. Gender 9. Unique ID number (HHPA start date additionally sent) NHS Digital will then use the NHS number to link with the HES database.
Identifiers required for analysis purposes	1. Ethnicity 2. Nationality (converted to WHO region of birth) 3. Gender 4. Postcode (district level) 5. Age This dataset can be considered anonymous to the applicant

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 Sub-Committee were supportive of this application, and it was noted that they have presented a strong argument for the public interest of this medical purpose, in a population which is difficult to reach. It was noted this group is often ignored, and it is important to understand what interventions will work to address these health inequalities.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

Data collection for the consented parent project was halted in March 2020 since health service appointments were stopped and the homeless health peer advocacy (HHPA) intervention delivered by Groundswell halted. In the context of the on-going epidemic of COVID-19 and the likelihood for future interruptions to the provision of peer advocacy and hospital-based care, the applicants propose this new design to evaluate HHPA.

The applicants reason that It is difficult to consent for retrospective data collection for this target population, as they state the cohort is characterized by chaotic lives, geographical transience, and changing contact details. Groundswell advised that it will be possible to contact relatively few of their past clients and, further, that the accessible clients are not representative of all past clients.

The Members agreed with the justification provided and were content that consent is not a practicable alternative. It was commented that this application provides a pragmatic solution given the challenges of conducting research during COVID-19.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage from Groundswell data on HHPA clients to PDS and HES datasets held by NHS Digital, and to identify a control group. Data will be pseudonymised by NHS Digital for the return flow, and this can be considered as anonymous to the applicant as they will have no way of re-identifying.

The CAG agreed it is not possible to undertake these processes without identifiable information.

Justification of identifiers for linkage

It was noted by the Sub-Committee that there seem to be more than the usual amount of identifiers required by NHS Digital to identify the NHS numbers from the PDS service. The group commented that it is especially unusual to use gender and nationality for this linkage. It was commented that in the response to queries, the applicant has confirmed hospital ID as one of the identifiers required, however in the updated CAG form, hospital ID appears not to be required, but GP registration is additionally ticked.

The members therefore requested further clarity regarding which identifiers are definitely required for identifying the NHS number from the PDS service, and justification provided as to why so many different data items are required. The Members also requested confirmation on which identifying information would then be used to link to HES. This should be evidenced with communication from NHS Digital to confirm the identifiers required. The applicant has not yet submitted an application to DARS – they state they are awaiting CAG advice. However CAG advice is often contingent on what NHS Digital have confirmed following a DARS application. The Sub-Committee therefore additionally requested that support should only be provided once NHS Digital had confirmed they are able to undertake the proposed linkages and provide a control cohort.

'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 applicant has developed a dissent Information sheet that includes details of how to opt out. This will be displayed at a substantial number of hostels and day centres, and GP clinics in London. Staff at the hostels and day centres will also be provided with information about the study to enable discussion with potential participants, and they will refer participants with questions to the study team. The research team will translate the dissent information sheets and key policy briefs into the main languages spoken by the community – which is predominantly Polish. There is a project website: https://www.lshtm.ac.uk/research/centres-projects-groups/hhpa

There is a clear opt out process, and the CI will keep a record of the full names of individuals who opt out. This list will be included with the data request to NHS Digital, with instructions to exclude the relevant HES records. These names will be retained at Groundswell.

The applicant was queried surrounding if the national data opt out would apply, and responded; '*This is not relevant since the data requested is only for people living in London'*. This response is not relevant to the query, as the national data opt-out is a service that allows patients to opt out of their confidential patient information being used for research and planning, which would include any patient in london who had chosen to opt out via the national data opt out. https://digital.nhs.uk/services/national-data-opt-out However, as this will be applied by NHS Digital on the intervention dataset returned to UCL SLMS and on the control

cohort, the CAG were content to not provide any conditions or requests for further information surrounding this point.

The Sub-Committee were broadly content, commenting that the applicant has done a good job of trying to communicate with the population and provide an opt-out mechanism. However it was noted that the section on data linkage is misleading, stating: *"To carry out this 'data linkage' we would need to collect your: name, date of birth, gender, current or previous postcodes, nationality, ethnicity, and if known, your NHS number and local hospital number. The 'data linkage' will then be undertaken by NHS Digital."* However, Groundswell are not 'collecting' this – they already hold these data. The data flows should be explained clearly, as in the previous design, this identifying information was being collected by UCL, however in the updated design, groundswell send this information directly to NHS Digital.

It was also commented that throughout the application, it seems data on "sex" will be gathered/transferred but the data analysis switches to analysing "gender", and this slippage between the two also appears in the participant notification documents.

The members therefore requested an updated dissent information sheet that is clear and precise about the data flows, including making it clear that Groundswell already retain items of confidential patient information. It should be clear surrounding what will be linked, and the Sub-Committee suggested consistency of terms concerning sex/gender.

The CAG also suggested a poster is needed alongside the dissent information sheet, as this is more likely to catch attention unless a staff member physically hands out the info sheets. This is also in line with the layered approach suggested by the ICO.

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.

People with lived experience of homelessness have been consulted throughout the development of the study. The applicants have conducted public engagement work with representatives of the homeless population who are broadly supportive of the use of confidential patient information without consent for the purposes of the study; 12 people were interviewed, recruited via a range of services identified through our study steering group and ongoing research (Find & Treat, SHP, St Mungo's North London Women's Hostel, St Mungo's, Groundswell). This was via various communication methods, and asked the group

specifically about the acceptability of the use of confidential patient information without consent. Overall acceptance of the study was high, with participants recognising the importance of the question and appreciating that the aim was to improve services for people who are homeless. Some concerns were expressed which are described in the CAG application, and the applicant has addressed all concerns with further Patient and Public Involvement and changes to the study design.

The Members were content with the Patient and Public Involvement undertaken, noting that it had been well described in the application.

Exit strategy

Support is required for a time limited period to enable NHS Digital to undertake the requested linkage and provide a control cohort. Applicant confirmed this may take a timeframe of approximately 12 months, and request support until March 2022.

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, the applicant was required to respond back to the requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide further justification regarding which identifiers are definitely required for identifying the NHS number from the PDS service, and if it is the proposed amount, justification for why the higher amount of data items is required. Please also provide clarity on which items of confidential patient information NHS Digital will then use to link to HES, as detailed above.

2. Please provide supportive communications from NHS Digital to confirm they can undertake the processing activities as described in the application.

3. Please provide an updated dissent information sheet that is clear and precise about the data flows, including making it clear that Groundswell already retain items of confidential patient information. It should be clear surrounding what will be linked, and be consistent concerning sex/gender.

4. Please provide a notification poster which can be displayed on the locations listed in the application.

5. Please provide an NHS Digital reviewed DSPT for Groundswell when available, this is a condition of support as set out below.

6. Please provide a favourable opinion from the REC when available, this is a condition of support as set out below.

7. Please provide the final version (not DRAFT) of the signed CAG form, before final support is provided.

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 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. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending:**

   The NHS Digital **19/20** DSPT equivalent review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 10 May 2021)

   The NHS Digital **19/20** DSPT review for **Groundswell (8J114**) is pending, as the DSPT is not yet published. It is understood the applicant has requested Groundswell to submit a DSPT, and will then request a review via NHS Digital.

Minutes signed off as accurate by correspondence from Dr Murat Soncul, CAG Alternate Vice-Chair		*21 July 2021*
Signed – Officers of CAG		Date
Caroline Watchurst		21 July 2021
Signed – Confidentiality Advice Team		Date