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

22 April 2022

Present:

Name	Capacity	Items
Dr Tony Calland, MBE	CAG Chair	1a, 1b
Dr Martin Andrew	CAG Member	1a, 1b
Mr Andrew Melville	CAG Member	1a, 1b

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 22/CAG/0064 – Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries (BE SURE)

Context

Purpose of application

This application from Swansea University set out the purpose of medical research which aims to understand how people from minority ethnic backgrounds present to Emergency Ambulance Services and Emergency Departments with injuries, the care they receive and what happens to them, compared to the White British population. The applicant aims for the research to inform policy to address any differences in care, morbidity and mortality.

Injuries are a major public health problem which can lead to disability or death. In the United Kingdom (UK) six million Emergency Department (ED) visits a year are the result of accidental injuries. However, little is known about the incidence, management and outcomes related to injuries among people from ethnic minority groups in the UK. Studies from several countries have indicated that people from ethnic minority groups have poor experience of accessing care and poor satisfaction with care compared to their White counterparts. Poor experiences have been attributed to communication, cultural barriers, feeling excluded from vital decisions related to their care and perceived limited choice of care provision. The applicant aims for this research to support ambulance service and emergency departments to improve care and outcomes for ethnic minority people who experience injuries and inform injury surveillance resources where they exist, and to include ethnicity dimension in the reporting of injury.

This mixed methods study encompasses 5 work packages; 's251' support is not sought for WP1, WP4 or WP5. The retrospective linkage element, WP2 does require 's251' support. A questionnaire element (WP3), also requires 's251' support for the linkage element. Invitation letters are sent out by direct care team, inviting the patient to consent to a questionnaire, but stating that linkage will be undertaken using 's251'. WP2 comprises of a split file design, where ambulance services disclose clinical data alongside a pseudonym to SAIL, and an identifiable data file alongside the pseudonym to NHS Digital, in order for NHS Digital to link with Hospital Episode Statistics (HES), emergency care data (ECDS), and Office for National Statistics (ONS) mortality data (for 6 months post presentation), and send a dataset to SAIL. This data set will include full date of death, however it is unclear if unit level postcode is also disclosed in this flow. SAIL can then link the 2 files together. There is also a flow of Scottish data described for WP2, however this is out of scope for 's251' support.

A recommendation for class 1, 4, 5 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	**WP2**: patients for whom a 999 call was made for an injury, recorded in ambulance dispatch data, from participating Ambulance services, between 1 August 2016 and 31 July 2021. (People of all ages; coded with injury; who contacted or were attended by the emergency ambulance service (including those not conveyed) or attended ED; who were located within the nominated ED area; classified as belonging to an ethnic minority group (using the 2011 ONS census classification, covering White minority Gypsy, Roma and Traveller groups) or classified as White British.) Estimated cohort size: n=550,000 **WP3**: Any adult (18 plus); coded with injury; who contacted the emergency ambulance service or were attended by emergency ambulance (including those not conveyed) or attended ED; who were located within the nominated ED area; classified as belonging to an ethnic minority group (as in WP2, above) or classified as White British, between 1 April 2022 – and 30 September 2022. Estimated cohort = 800
Data sources	1. **NHS Digital** –

	• Office for National Statistics (ONS) Civil Registration (Deaths) • Emergency Care Data Set (ECDS) • Hospital Episode Statistics (HES): Admitted Patient Care, Critical Care and Outpatient Care **Ambulance dispatch data from;** 2. East Midlands Ambulance Services 3. South East Coast Ambulance Service 4. Yorkshire Ambulance Service **A+E data from:** 5. Leicester Royal Infirmary – (University Hospitals of Leicester NHS Trust) 6. East Surrey Hospital, Redhill (Surrey and Sussex Healthcare NHS Trust) 7. Northern General Hospital, (Sheffield Teaching Hospitals NHS Foundation Trust)
Identifiers required for linkage purposes	1. Pseudonymous Study ID 2. Name 3. NHS number 4. Date of Birth 5. Postcode (unit level) 6. Gender 7. Ethnicity
Identifiers required for analysis purposes	1. Date of death – applicant states this is not modified 2. Gender 3. Ethnicity 4. Date of birth – modified to week of birth by NHS Digital 5. Unit level post code – Applicant has stated this is not modified for analysis

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 agreed that the medical purpose is clear, and the public interest in this application was very high, noting that there is evidence of inequalities in care and access to care from other studies, and the applicants seek to explore this further for populations in the areas involved in the study.

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**

The applicants reason it is not operationally feasible to seek consent from all eligible patients, given the expected volume of patients (550,000 in WP2) and the timescales involved.

For WP3, consent is not requested for linkage, as the applicants wish to be able to link to outcome data from NHS Digital regarding non responding patients. Therefore consent is not formally asked for, because if no response to consent, these non-responding patients would then have to be formally classed as dissenters, as per ICO guidance, and their information would not be allowed to be used. There will be a question on the questionnaire for people to opt out of having their data linked. However, not everyone may return the questionnaire and CAG support is required to link health data without consent for those who do not respond.

The CAG accepted that consent is not a practicable alternative for WP2 because of the large numbers of patients involved. For WP3, the Sub-Committee agreed that the applicant has a reasonable case for not consenting and wanting information on the whole cohort, as there may be significant bias in response rates particularly for people whose first language is not English. If the non-responders were excluded from the linkage element regarding this vulnerable cohort, then the value of the research would be significantly reduced.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage from ambulance service and emergency department data to NHS Digital outcome data, and it is not possible to undertake linkage without some form of identifier. The applicant is minimising flows of data where possible, although it is currently not clear why unit level postcode will not be modified, and this is explored further below.

Justification of identifiers

The Members noted the use of multiple fields for data linkage, and agreed this appears acceptable because paramedics may only be able to collect some information fields at the time, and this will increase the validity of the linkage.

The Members were very supportive in principle of the application, but required clarification surrounding the long term storage of identifiers. There is reference to the use and retention of full Date of Birth, full Date of Death and full Unit Postcode in the SAIL databank. The Members noted that some of the documentation is contradictory, and felt that there may not be an intention to use these identifiers in full format. Therefore the Sub-Committee required simple clarification regarding the use of identifiers, at what level and justification for the use.

Regarding full date of birth, the applicant has stated in the response to queries, *'Date of Birth will be modified by NHS Digital. They usually provide week of death which is good enough for the purpose of analysis'*. It is not clear if this means that Date of birth will be modified to week of birth, or if date of birth will be modified to something else. The CAG requested this be clarified. Because of the area being studied, the CAG assume that age in months and years would be sufficient, but this is not clear.

Regarding full date of death, as the subject covered is trauma, deaths from trauma often do receive media coverage so retaining full date of death could allow potential reidentification of an individual fairly easily with a Google search. It is not clear if the query response above means that NHS Digital disclose full date of death to SAIL, or if NHS Digital disclose week of death to SAIL. The CAG requested this be clarified.

Regarding unit level postcode, this is currently listed as not modified for analysis. It is not clear if this is received from NHS Digital, or in the 'pseudonymous' clinical dataset from the ambulance services. No justification has been provided for retaining full postcode. It is not clear if this is the intention of the applicant. This is required to be clarified.

'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.

As a response to queries, the applicant agreed to separate the notification strategies for WP2 and WP3, as the cohorts are different individuals.

WP2: The provided patient notification for WP2 will be displayed in the ambulance and ED Trusts, and the SAIL website. The applicant has stated these will also be displayed on social media sites run by 3rd Sector partners. The linkage for WP2 will take place 3 months after HRA approval. This will leave enough time for dissenting. There is a study opt out option available.

WP3: This will be sent via the post to all eligible individuals by the direct care team, and was provided to CAG part way though the review. Applicants are making it clear on WP3 notification that the consent requested is for the questionnaire, and no consent is requested for linkage, as this will be done under 's251' if patients do not opt out. A question on the questionnaire gives people the option to opt out of data linkage. Those who do not return the questionnaire will be provided with a contact number or email of the local clinical care team to enable them to opt out of having their data linked if they wish. Linkage for WP3 will take place 3 months after applicants begin data collection – this should leave enough time for dissenting.

The national Data opt out will be respected, and a study specific opt out is also in operation. If patients notify the study team directly that they dissent from the use of their records for research purposes then study team will request that NHS Digital ensure their data is excluded, or patients can contact study sites directly before the point of disclosure to NHS Digital.

The CAG were content that the opt out methods were sufficient.

The Members were content with the methodology described for notification for WP2, noting the use of websites is as expected, however the mentioned social media and 3rd sector organisations will be more visible. The CAG would like some examples of the 3rd sector organisations who will display the WP2 notification. The Members were also content with the described methodology for notification for WP3, which is by direct mail to the participants with the questionnaire.

Posters are mentioned, but these have not been provided for CAG review.

Despite the Members being content with the proposed notification methods, they were not content with the content of either the WP2 or WP3 notifications. The CAG commented that the notifications are too long and complex and not easy to follow, and seemed to be a mixture of notification and privacy notice, and suggested a more layered approach. The Members suggested something short and simple for each work package, with a link to get more detail and clarity if required.

The Members also mentioned that the notification needs to be more accurate in the descriptions of what is happening regarding the data flows, as the notifications currently seem to imply that SAIL will not receive any identifiable data, and it does appear currently that full date of death and unit level postcode will be received by SAIL The CAG felt the wording is ambiguous and could imply that applicants want details of people treated without consent. The Members also noted that it appears the notifications are only offered in English, which seems a weakness as half of the cohort is specifically recruited from ethnic minorities. There is mention of QR codes, could you have QR links to a range of languages?

The CAG noted that in one area of the notification, CAG approval is referred to. That explanation of the function of CAG is not accurate, as the CAG is not a decision-making group and instead provides recommendations to the decision maker, the Health Research Authority in this case. This statement should be amended to include correct reference to the decision-making element. For example, *'The Health Research Authority, on advice from the Confidentiality Advisory Group, has supported the use of confidential patient information without consent under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('Section 251 support').*

Overall, the CAG members felt the WP2 and WP3 notifications required rewriting with lay review.

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.

Two 'Patient and Public Involvement members' are part of the BE SURE research management group. One is a member of the SAIL Consumer Panel with experience in research based on data linkage, and one was a peer researcher on a related study in Wales. Both individuals have been through the asylum process and now have refugee status. Both have been peer researchers in previous research. Their experiences have helped applicants understand the perspectives of participants from ethnic minority groups. Two further members of the public also sit on the Study Steering Committee; and the applicant notes they plan to recruit 'peer researchers' within each of the 4 study regions.

The two 'Patient and Public Involvement members' of the research management group support the use of anonymised data without consent, recognising that this approach enables us to capture as many outcomes as possible for this important patient group.

The applicant confirmed that the two Patient and Public Involvement advisors are representative of the part of the cohort who are ethnic minorities. In addition, one Patient and Public Involvement member has had direct experience of calling the 999 service for injury and using the emergency services to address a family members need, and therefore they do understand and have experienced some of the challenges with accessing healthcare when a person is not familiar with the system or when language is a barrier.

The applicants plan to hold an online consultation with 10 Patient and Public Involvement members to ensure they capture a range of views regarding the use of CPI without consent.

The CAG agreed that Patient and Public Involvement has been detailed, but with a very small number of people. It is positive that assistance has been given by individuals with some direct experience of the issues and study design has been influenced accordingly. The CAG felt that the use of peer researchers to assist participants is also positive, and commended the applicant for this.

However, the Sub-Committee requested that the Patient and Public Involvement should be wider, including more individuals, and also should include the views of non ethnic minority patients whose data will also be accessed without consent. The Members noted that paradoxically, because applicants have rightly focused on getting ethnic minority representation in the peer researchers, that the non ethnic minority cohort may not have their views addressed and these may be different.

The CAG noted the intention to hold an online consultation with 10 Patient and Public Involvement members, and requested further information about what this will involve and how individuals will be identified, noting that it is not clear if this is a one-off or ongoing and where this fits into the structure of the study. The Members also noted that 10 people does not seem ambitions, as online surveys are relatively easy to conduct. However if by online consultation, applicants mean more of a focus group methodology, then 10 people would be more acceptable. The CAG noted that applicants should aim to recruit a representative sample of the whole population. As mentioned in the notification section, there should be a lay review of the patient notification materials.

Exit Strategy

The applicants originally stated they will analyse an effectively anonymous dataset. Applicants estimate linkage will be completed by June 2023. However as part of query responses it seems unit level post code and full date of death are retained by SAIL for a number of years. This is to be clarified by the applicant.

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 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, within one month.

Request for further information

1. Please provide clarification regarding the use of the identifiers – Date of birth, date of death, and full post code. Please clarify if these are disclosed to SAIL, or if they are modified prior to this disclosure. If they are not modified, please confirm how long they are retained, and the justification for the use of the full data items.

2. Please provide some information about which 3rd sector organisations will host the WP2 notification on their websites/social media.

3. Please provide any notification posters for CAG review.

4. Please provide updated versions of the patient notification materials for WP2 and WP3. These should take into account the advice provided in this letter, and should be reviewed by lay individuals.

5. Please undertake further patient and public involvement with at least 10 more individuals, who are representative of the cohort (general population). Please focus on the use of confidential patient information without consent, and the content of the patient notification, and feedback to CAG.

6. The exit strategy for 's251' support is to be clarified, and this will be aided by the response to point 1, above.

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, a final support outcome will be issued.

Specific conditions of support (provisional)

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 5th April 2022**

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.**

   Due to the number of organisations involved it is the responsibility of University of Swansea, as controller for this application, to ensure that organisations processing confidential patient

information without consent for the purposes of this application, meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

The relevant organisations are;

1. NHS Digital
2. SAIL (8WG95)

English Ambulance services

3. East Midlands Ambulance Services
4. South East Coast Ambulance Service
5. Yorkshire Ambulance Service

English Trusts

6. Leicester Royal Infirmary – (University Hospitals of Leicester NHS Trust)
7. East Surrey Hospital, Redhill (Surrey and Sussex Healthcare NHS Trust)
8. Northern General Hospital, (Sheffield Teaching Hospitals NHS Foundation Trust)

b. 22/CAG/0065 – Comorbidities and outcomes of patients with chronic pancreatitis: a single centre cohort study

Context

Purpose of application

This application from Nottingham University Hospitals NHS Trust set out the purpose of medical research which aims to predict the risk of death and developing pancreatic cancer in patients with chronic pancreatitis (CP). By identifying prevalent comorbidities and associated risk factors, recommendations for potential interventions can be made.

CP is an inflammatory condition characterized by scarring and inflammation of the pancreas in individuals with genetic, environmental, and other risk factors such as excess alcohol intake or hypertriglyceridemia. Life expectancy is reduced, and survival affected by complications of CP, and adverse effects of alcoholism, smoking, and diabetes. Studies indicate an increased risk of pancreatic cancer, and an increased prevalence of osteoporosis, cardiovascular events and inflammatory bowel disease in patient with CP. However, up to date data is lacking for the UK population. In addition, little is known about the prevalence of other comorbidities.

Applicants wish to link confidential patient information collected about a retrospective and a prospective cohort of CP patients from Nottingham University Hospitals NHS Trust, to routinely collected clinical outcome data, to establish long-term clinical outcome data and associated comorbidities for patients with CP. Applicants will link together outcome data from various local Trust datasets, and will also link with NHS Digital datasets; ONS Mortality data, and cancer registration data. Applicants will link back the received data from NHS digital to the local dataset using NHS number, and all identifying information will then be removed. Analysis will be undertaken on an anonymous dataset.

A recommendation for class 1, 2, 4 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	All adult patients (aged ≥18 years at the time of diagnosis) diagnosed with chronic pancreatitis at Nottingham University Hospitals NHS Trust between 01 January 2006 to 31 December 2025 (approximately 4000 total) • Retrospective: A derivation cohort will include approximately 2,500 patients diagnosed with chronic pancreatitis between 1 January 2006 and 31 December 2020 • Prospective: A validation cohort will include approximately 1,500 patients diagnosed with chronic

	pancreatitis between 1 January 2021 and 31 December 2025.
Data sources	**8. The Nottingham University Hospitals NHS Trust local clinical records, including:** • Medway, • Clinical Imaging from local PACS system, • Summary Care Records and • Local Hospital discharge summary data **9. NHS Digital –** • ONS Mortality data • Cancer registration data
Identifiers required for linkage purposes	For linkage with NHS Digital datasets: 8. NHS number 9. Date of Birth For linkage to local sources: 1. NHS number 2. Hospital number
Identifiers required for analysis purposes	6. Receiving date of death – not clear if this is modified or not. 7. Subsector level postcode (modified to deprivation score) 8. Gender 9. Ethnicity 10. Date of birth - will be converted to age at diagnosis, and time to outcome (e.g. death or cancer) will be calculated from the time of diagnosis rather than using date of birth Applicant states analysis will be on anonymous dataset.
Additional information	At least 5 years follow up data will be collected. NHS Digital data for the derivation cohort will be requested once in January 2026 and NHS Digital data for validation cohort will be requested once in January 2031. In addition, NHS Digital data will be requested for part of the derivation cohort (for those diagnosed with chronic

	pancreatitis between 1 January 2006 and 31 December 2015) as soon as support is in place, for preliminary analysis. Identifiers will not be held in the same database as the clinical data. Retention of key until data collection complete – confidential patient information is replaced by an unrelated sequence of characters. Secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media. Once data collection has been completed, the linking code will be destroyed.

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 agreed that the medical purpose is clear, and the public interest satisfied, as the study will add to the limited research in this disease area.

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**

Regarding the retrospective derivation cohort, consent will not be sought due to the high numbers of patients in the cohort, and this is not practicable for the applicant. Some of the cohort may also be deceased, and it will not be possible to consent the deceased.

The applicant has reasoned that they cannot take consent from the patients in the validation cohort who will be diagnosed prospectively until 2025, because although the validation cohort patients are currently in the future, applicants are not seeking to identify them prospectively. The patients who will be included in the validation cohort will be identified retrospectively, rather than prospectively, in the same way as the derivation cohort.

The applicant has further reasoned that consent would not be practicable because not all patients with chronic pancreatitis are referred to the clinical service. It is also not possible to periodically review in order to identify all patients with chronic pancreatitis prospectively. Including only those referred to the clinical service will result in only those with severe disease being included the validation cohort and lead to a biased data and skewed results.

The CAG were content to accept the applicants reasoning that consent was not practicable for both groups, as this may potentially affect the result if the recruitment methodology differed, and also accepted that the validation cohort would in fact also be recruited retrospectively.

However the Members did note the statement surrounding not all patients being referred to the clinical service. Are all the individuals in the cohort from one Trust? It is assumed that data will be collected from a single Trust for patients diagnosed with chronic pancreatitis, although these patients may not have been under the care of their hepatology service. The CAG discussed if the clinicians undertaking this data collection could be considered part of the direct care team. The applicant has confirmed in the advice form that no 's251' support is required for the collection of this confidential patient information, as the individuals would be considered direct care team. The CAG also noted that patients in this study would likely not be particularly surprised if one of the hepatology team was doing the identification rather than the hepatologist that they have seen from the same hospital. The CAG therefore accepted that the researcher could be considered a member of the direct care team for all the cohort.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage between Trust data and centralised outcome data. It is not possible to link without some items of confidential patient information. The applicant has confirmed with NHS Digital the minimum identifiers required for linkage, and has stated they will be analysing an effectively anonymous dataset.

Justification of identifiers

The Members noted that it is not entirely clear if full date of death is modified to a less identifiable format for analysis, and the full date of death deleted, either by NHS Digital prior to disclosure, or by the applicant after receipt. This has been implied, but not confirmed. The applicant is requested to clarify if the full date of death is modified for analysis before deletion, and, if not, the applicant needs to justify why it is required in full format, and at what time point it will be deleted.

'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.

A poster will be displayed in clinical areas in the Trust, and it contains a clear opt out option for this study specifically. The applicants will also respect Nottingham University Hospitals NHS Trust local opt out. The National data opt out will be applied prior to disclosing data to NHS digital in line with trust procedures.

The CAG considered this patient notification to be clear and simple, and noted it will be displayed in suitable areas. The Members agreed that opt out options have been adequately covered. However the Members requested that an email address should be added to the poster in addition to the current contact options. This is a condition of support. The CAG mentioned that a QR code link to a privacy notice on the trust website would produce an easy layered approach, however this is a suggestion rather than a condition of support.

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 have discussed the study with a patient representative group. Members of the Patient Advisory Group (PAG) of Nottingham NIHR Biomedical Research Centre will be involved in writing a range of "lay" literature to facilitate dissemination of results.

Applicants states that the use of confidential patient information without direct consent from patients was discussed with the PAG members. They agreed that sharing patient identifiable information with other relevant authorities such as NHS Digital would be the only reliable way of acquiring robust data and were satisfied with the approach of seeking 's251 support.

The Members noted that although the correct questions seemed to have been asked of the PAG, it was not clear how many individuals were in the PAG group, commenting that if this was any less than 5 individuals, then the applicant should undertake some further patient and public involvement, to ensure there was a public interest in this study.

Exit Strategy

Exit strategy is anonymisation, on deletion of the identifiable information and the key, once all linkages complete. 5 years follow up data will be collected. ‘s251’ support therefore required until 5 years after 31 December 2025, to allow 5 years follow up post last individual recruited from validation cohort. Applicant confirmed, this linkage is expected to be undertaken January 2031. Once this is returned to the applicant, and linked to local hospital data, and then anonymised, no ‘s251’ support required.

The CAG were content with the exit strategy, however noting this is years in the future, because of the timescales of data collection and linkage.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (conditional)

1. Please clarify if the full date of death is received from NHS Digital, if it is, is it modified for analysis by the applicant before deletion, and, if not, please justify why it is required in full format, and at what time point it will be deleted, within one month from the date of this letter.

2. Please update the poster with an email address for opt out, and consider the addition of a QR code linking to the Trust privacy notice. Please provide the updated poster within one month from the date of this letter.

3. Please confirm the numbers of individuals in the ‘Patient Advisory Group’. If this is less than 5, please undertake further patient and public involvement surrounding the use of confidential patient information without consent, and provide feedback to CAG within three months from the date of this letter.

4. Favourable opinion from a Research Ethics Committee. **Confirmed 24 March 2022.**

5. 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 **20/21** DSPT reviews for **Nottingham University Hospitals NHS Trust and NHS Digital** were confirmed as ‘**Standards Met’** on the NHS Digital DSPT Tracker (checked 04 May 2022)

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Tony Calland, MBE, CAG Chair		*06 May 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst		*06 May 2022*