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

30 September 2022

Present:

Name	Role	Items
Dr Tony Calland MBE	CAG Chair	2a, 2b, 2c, 2d
Dr Sandra Duggan	CAG Member	2b, 2d
Professor Lorna Fraser	CAG Member	2a, 2c
Dr Harvey Marcovitch	CAG Member	2b, 2d
Mr Andrew Melville	CAG Member	2a, 2c

Also in attendance:

Name	Position (or reason for attending)
Mr Will Lyse	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Expressions of interest

Regarding item 2a, Professor William Bernal, the applicant, is also a CAG alternate Vice-Chair. He did not participate in the development of the recommendation provided by the CAG.

2.New Precedent Set Review Applications – Research

a. 22/CAG/0125 - Management of Patients with Chronic Liver Disease Admitted to Hospital as an Emergency: Link MAP-CLD

Context

Purpose of application

This application from King's College Hospital NHS Foundation Trust with London School of Hygiene and Tropical Medicine as joint data controller, set out the purpose of medical research of linking together data from NHS Digital, Intensive Care National Audit & Research Centre (ICNARC), and NHS Blood and Transplant (NHSBT) about 100,000 patients with Chronic Liver Disease (CLD). London School of Hygiene and Tropical Medicine (LSHTM) will retain a linked dataset for analysis, which will contain full date of death and therefore require 's251' support. The research group includes researchers from the Institute of Liver Studies at King's College Hospital, LSHTM, the University of Exeter and King's College London, and is funded by the National Institute for Health Research. The overall aim is to identify which characteristics of treatments and services for acutely ill people with CLD impact on care processes and outcomes, in order to improve the national organisation and delivery of care for all people acutely ill with chronic liver disease. 's251' support is only required for the linkage element of this study, work package2.

Liver disease is a serious and increasing health problem in the UK, responsible for many preventable deaths. However, people with liver disease often do not know that they are affected until they need to be admitted to hospital as an emergency. These people are often very ill, and a quarter die within two months of coming into hospital. The care received in hospital, and post discharge, varies greatly across the country. This variation in care has major effects on survival. This study aims to understand what

clinical practices have the best results and will aim to make recommendations about how the services for patients with CLD can be made safer and more effective.

NHS Digital will identify the eligible cohort using Hospital Episode Statistics and ONS Mortality Datasets. This will include patients with CLD admitted with a first emergency hospital admission between 1 April 2009 and 31 March 2022. Confidential patient information, alongside a pseudonym (HES ID) will be disclosed to ICNARC, who will link to their Case Mix Programme data. NHSBT will send confidential patient information, alongside a pseudonym (UKT ID) on UK Transplant Registry patients with chronic liver disease who underwent transplantation, including recipient and donor characteristics and waiting list data, to NHS Digital, which will be linked to the HES/ONS cohort. All 3 organisations will send clinical data linked to a pseudo ID to LSHTM, in order for LSHTM to link the 3 datasets together. 's251' support required until full date of death is deleted.

A recommendation for class 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 patients older than 18 years with chronic liver disease (CLD) who were admitted with a first emergency hospital admission between 1 April 2009 and 31 March 2022. However NHSBT also identify patients planned for or undergoing a liver transplant in England between one year before the study period to one year after the study period. Approximately 100,000 people.

Data sources	1. NHS Digital – Hospital Episodes Statistics (HES) data (inpatient, outpatient data, A&E attendances and linked ONS mortality data) 2. NHS Blood and Transplant (NHSBT) - UK Transplant Registry 3. The Intensive Care National Audit and Research Centre (ICNARC) Case Mix Programme (ICNARC-CMP) database
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Sex 4. Postcodes
Identifiers required for analysis purposes	1. Date of death 2. Ethnicity 3. Sex

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 were agreed that this activity was in the public interest.

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 CAG noted that it may be possible to reduce the flows of confidential patient information with regards to the linkage with ICNARC. It currently appears that the all patient identifier about the entire cohort are being shared with ICNARC from NHS Digital, to link with what CAG assume is only a part of the cohort who have had an ICU admission. The Members queried if it was possible to reduce the flow of identifiable data by asking ICNARC to identify those with liver disease and sending those identifiers to NHS Digital, as this would mean much smaller flows of confidential patient information.

- **Feasibility of consent**

The number of patients is so large, (100,000) and many will since have died, therefore the applicant reasons it is not practicable to ask each person for their permission to use their information. The members accepted this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to link between clinical datasets. Date of death is required for the primary outcomes in the research and ethnic group to understand the determinants of variation in care and outcomes for patients with chronic liver disease. Use of month of death alone would provide insufficient granularity for the analysis. The members accepted this reasoning.

'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 provided a layered approach website notification linking to more detailed privacy notice. The notification materials will be displayed on the 'Research at Kings' pages on the Kings College Hospital website (Research - King's College Hospital NHS Foundation Trust), and the British Liver Trust website (British Liver Trust -

Pioneering Liver Health) is shortly to launch a research section where the link will be provided.

Originally, no study specific opt out was provided, and the privacy notice points patients only to the National Data opt out, which CAG do not usually advise. The applicants requested CAG advice on best way to apply a study specific opt out mechanism, stating that NHS Digital have confirmed that they would not be able to manage an opt out mechanism directly on behalf of this study. The applicant has suggested that during a 6 month time period, the applicant could provide additional patient facing materials though planned communication channels to enable study-specific opt-out facilitated by the research team, to include a postal and email address for those who wished to opt-out, to provide details that could then be forwarded to NHS Digital who would ensure that they are excluded from the de-identified dataset that is provided to the research team. Once the dataset has been prepared, the patient facing materials would then need to be revised to remove mention of the opportunity for study-specific opt-out.

ICNARC have an opt out option and this will be respected. The National Data opt out (NDO) will also be applied.

The members were content with the notifications and methodology. The Sub-Committee were agreed that the study specific opt out method should be applied as the applicant had proposed. The members noted that it is a large and significant study, and patients should be able to opt out without necessarily invoking the NDO. It was also noted that one or two of those involved in the Patient and Public Involvement were not sure about the use of their data, and this adds weight to the argument that individuals should have that choice.

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.

Patient and public involvement has been undertaken and patients are clearly supportive of this study. An online survey of 58 people was undertaken, 50 with liver disease and

8 family members, to understand in more detail their attitudes to the goals and basic research methods under consideration.33 of the respondents volunteered to continue to contribute to the planning process of this study and to be engaged as a consultative group as the project developed.

In December 2019, a face to face focus group was conducted at Kings College Hospital through the auspices of the 'Listen' Patient Group. The slides used as a basis for the structured discussion are provided for review. The focus group comprised 19 people of mean age 62 years, 18 of whom had previously had severe liver disease and undergone liver transplantation –many of whom had experienced emergency hospital admissions through complications of liver disease.

A letter of support from British Liver Trust has been supplied. Applicants confirm that the use of confidential patient information without consent was discussed with both the patient and public involvement groups and the charity regarding linkage and date of death being retained, and both were supportive of this.

The CAG were content with the patient and public involvement undertaken, and noted they hoped consultation would continue.

Exit strategy

Exit strategy is anonymisation by deletion of full date of death. Data access will be required by the analysis team until 3 years after the end of contract until 1 September 2027 to allow for all analyses to be completed, any corrections to analyses to be made, and queries about analyses to be answered.

Data retention will be for a further 2 years after analysts have stopped having access. The data retained will include full date of death. Therefore 'S251' support is required until 1 September 2029, at which time point the date of death will be deleted. The members 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. Please consider if it is possible to reduce the flow of identifiable data by asking ICNARC to identify those with liver disease and sending those identifiers to NHS Digital for linkage. If this is not possible please provide justification.

2. Please confirm the study specific opt out will be applied as suggested, and provide CAG with any updates to patient facing material in light of this.

3. Please provide evidence of NHS Digital review of The NHS Digital **21/22** DSPT for **London School of Hygiene and Tropical Medicine** to evidence to CAG that 'standards are met', as per standard condition of support, below.

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 (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 23 September 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. **Pending:**

The NHS Digital **21/22** DSPT reviews for **Intensive Care National Audit & Research Centre, NHS Blood and Transplant and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 04 October 2022)

The NHS Digital **21/22** DSPT review for **London School of Hygiene and Tropical Medicine** was pending review.

b. 22/CAG/0131 - STandardising pAthways for diagnosing hypeRtension using routine healLthcare data: an InvestiGation of the Health and economic ouTcomes: STARLIGHT, Version 1.0

Context

Purpose of application

This application from The University of Oxford set out the purpose of medical research of a retrospective cohort study, to assess the value of implementing a diagnostic prediction model for identifying previously undetected hypertension among hospital inpatients, as part of a standardised care pathway that integrates patient information between secondary and primary care. A hypertension diagnostic prediction model will be used against a linked GP/Hospital admission dataset, to differentiate between those patients whose in-hospital data predict them to have undiagnosed hypertension and those whose data do not. The study is being undertaken as part of a PhD.

Hypertension is a leading risk factor for death globally with 12.8% of deaths annually attributed. In England, 1 in 8 adults has undiagnosed hypertension. These people are at risk of serious health problems. More needs to be done in the NHS to identify people with hypertension, on top of existing checks for hypertension. Presently, the only dedicated system for checking people for hypertension is the 'NHS Health Check', which misses a wide range of undiagnosed hypertension cases. Evidence suggests that patients with elevated blood pressure recordings in hospital frequently remain hypertensive in the community, however this likelihood is often dismissed for various reasons. Untreated hypertension is associated with a progressive increase in blood pressure that can become treatment resistant. Therefore, hospital detection and timely management of hypertension offer an important intervention opportunity to address this major cause of morbidity and mortality. This project will investigate the impact and value of implementing a standardised diagnostic pathway for identifying undiagnosed

hypertension in patients, using routinely collected blood pressure data obtained during hospital admissions. The aim of this, is to reduce the prevalence of undiagnosed hypertension.

This study will use data collected from patients registered with any GP Surgery in Oxfordshire, Berkshire, Northamptonshire and Buckinghamshire which contributes to the Oxford-Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) Database, alongside data collected routinely during an admission to Oxford University Hospitals NHS Foundation Trust for the same patients. ORCHID will use a hashing algorithm to code patient NHS numbers creating a pseudonymised dataset. ORCHID will send their dataset, along with the hashing algorithm code to Oxford University Hospitals NHS Foundation Trust, permitting patient matching between data sources and amalgamation of both ORCHID and OUHNHSFT datasets for all patients who are eligible. 's251' support is required for this linkage, as despite being transferred in pseudonymous format, both parties have access to the hashing algorithm and can re-identify. Once linkage has been undertaken, the dataset will be effectively anonymised and disclosed to the applicants at Nuffield Department of Primary Care Health Sciences, University of Oxford, in order for them to undertake analysis on this effectively anonymised dataset.

A recommendation for class 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 registered with a GP surgery in Oxfordshire, Berkshire, Northamptonshire and Buckinghamshire which contributes to the ORCHID database, for whom there is no coded diagnosis of hypertension recorded prior to June 2016

	Applicant is unsure how many individuals this will be - 19,744 is the statistical calculation for the minimum required data.
Data sources	1. The Oxford-Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) Database, Retained at University of Oxford (Nuffield Department of Primary Care Health Sciences). 2. Oxford University Hospitals NHS Foundation Trust – medical records
Identifiers required for linkage purposes	1. NHS number (hashed for transfer between organisations)
Identifiers required for analysis purposes	1. Ethnicity 2. Indices of Multiple Deprivation for the GP surgery at which the patient is registered The data will be effectively anonymous to applicants for analysis, as they will not have the means to re-identify

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 this application was strongly in the public interest.

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 that the research questions require data from a large number of patients who have been admitted to hospital over the last 7 years and so it would not be practical or possible to ask every patient for consent. The Members agreed with the justification provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link between the hospital and primary care databases and is not required for data analysis. The applicants appear to be undertaking linkage using the least identifiable method possible. The Sub-Committee agreed that using anonymised data alone would not be a practicable alternative.

'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 the four hospitals of OUHNHSFT, and the same text will be used on the university website. This has a study specific opt out. The Orchid database has applied the NDO, and the Trust will also apply the NDO, in order to ensure anybody who has opted out since being included in ORCHID will not be included in this study.

The CAG stated that the patient notification leaflet is too dense, and not in accessible language. As an example, the following sentence should be re-written to ensure it is accessible to patients. This could be undertaken in conjunction with a patient group.

'The study will also look at the primary care data for those patients who aren't predicted to have hypertension using their hospital data, to help us know what proportion of people our diagnostic rule-set might be missing and whether these people are experiencing health problems caused by hypertension.'

The sentence about opt-out may mislead those who scan rather than read carefully, as it states; *'If you would like your health data to not be included in this study....'* . The Members therefore stated that this should be re-written to ensure clarity, and suggested; 'If you do not want your health data to be used in this study....' . The CAG noted that this section on opt out should be closer to the top of the page rather than a final sentence.

The Members also mentioned that the leaflet fails to emphasise the significance of not seeking consent, and the legal basis with which the linkage will be undertaken.

Therefore the applicant is required to provide the CAG with an updated patient notification which gives a brief and plain language explanation of the project, explains why consent is not possible, and explain the legal basis under which the linkage is being undertaken, including the role of CAG, and consider changing the placement of the opt out text, and the clarity of the descriptions regarding it.

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.

A primary care patient participation group in West Oxfordshire reviewed the study proposal at its initial conception and helped refine the design. The applicant has confirmed that the use of confidential patient information without consent was explicitly discussed and very interestingly the group expressed surprise that their health data wasn't already being used to screen for diseases in this way and said they actually had an expectation that with technology having developed so much in recent decades that health interventions such as this would and should be occurring. Some individuals had personal experience of hypertension and secondary diseases from this and felt that the more that could be done to detect hypertension sooner the better.

Applicants have also consulted several patient groups, including 3 members of the National Association for Patient Participation, 12 members of Eynsham Medical Group's Patient Participation Group, and 2 members of the British Heart Foundation Heart Voices Group regarding the principles of screening for hypertension using routinely collected healthcare data without prior consent. Individuals were a mix of age and genders.

There was unanimous agreement amongst all patient groups that routine screening to detect chronic diseases such as hypertension should be performed and they expressed full support for the study's planned methods of accessing and using patient data without consent for the purposes of designing automated screening methods for the healthcare service and it's patients in the future.

The Members stated that the applicants have consulted patient groups and the reported feedback regarding the use of data without consent appears to be supportive. It was noted that the Patient and Public Involvement undertaken seems proportionate, however it is not clear if the consultations have included minority groups and in particular ethnic minority groups. The applicant has stated only that the cohort consulted were a mix of age and genders. This is not raised as a request for further information, or as any formal condition, however it should be noted by the applicant to inform any continuing Patient and Public Involvement undertaken.

Exit strategy

The exit strategy is anonymisation. It is not completely clear when the Trust will delete the data received from ORCHID, for both those that were linked and those that were not. The applicant has stated that data will be retained for 3 years, but the data provided to the applicants does not require 's251' it is only the timepoint at which the Trust deletes the data from ORCHID that matters with relation to 's251'. When queried on how long the linkage process is expected to take, the applicant has answered a matter of weeks. However it is not clear if this is also the timepoint that the data from ORCHID will be deleted by the Trust.

The applicant is required to confirm the length of time 's251' support is required, by confirming when the data from ORCHID will be deleted by the Trust. Is this directly after the linkage has happened after a matter of weeks?

Protocol

The Members noted that on page 22 of the protocol there is a sentence which is confusing, stating; '*The study period is June 2016 to August 2021*'. This may have been

left in inadvertently from an earlier draft. This is a point to note for the applicants to correct if required, but not required as a formal response or condition.

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 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 an updated patient notification which gives a brief and plain language explanation of the project, explains why consent is not possible, and explain the legal basis under which the linkage is being undertaken, including the role of CAG, and consider changing the placement of the opt out text, and the clarity of the descriptions regarding it, as per advice in this letter.

2. Please confirm the length of time ‘s251’ support is required, by confirming when the data received from ORCHID will be deleted by the Trust.

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 20 September 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:**

   The NHS Digital **21/22** DSPT reviews for **University of Oxford (Nuffield Department of Primary Care Health Sciences) - EE133863-MSD-NDPCHS (regarding ORCHID) and Oxford University Hospitals' NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 18 October 2022)

c. 22/CAG/0135 - UK Genetic Prostate Cancer Study

Context

Purpose of application

This application from The Institute of Cancer Research sets out the purpose of medical research that seeks to find genetic changes which are associated with prostate cancer risk. The UK Genetic Prostate Cancer Study (UKGPCS) was first established in 1993 and is the largest prostate cancer study of its kind in the UK, involving nearly 200 hospitals. Individuals are included with consent. If applicants can find alterations in genes that increase the chances of getting prostate cancer, it may be possible to screen family members to see if they are also at a higher risk of developing prostate cancer, and to develop new prostate cancer treatments in the future.

An amendment in 2008 included the collection of survival data through the Office of National Statistics, and this was updated on consent forms from v5 onwards. From 2011, the applicant received the cause and date of death for participants consented to UKGPCS from the Health and Social Care Information Centre (HSCIC) (the predecessor to NHS Digital). Applicants have been receiving quarterly updates on date of death and cause of death for participants on the study until recently. NHS Digital has now concluded that for participants consented prior to 2008, on forms v1-v4, the consent forms are insufficient to meet the common law duty of confidentiality. Therefore, for those participants consented prior to 2008, NHS Digital has asked the study team to apply to CAG.

A recommendation for class 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	Prostate cancer patients consented into the UK GENETIC PROSTATE CANCER STUDY prior to 2008, on consent form 1-4. The number of cases flagged on Consent form V1 to V4 total 8720 (out of which 4280 have died). Therefore 's251' support will be relevant to these 8720 individuals
Data sources	1. UK GENETIC PROSTATE CANCER STUDY Dataset retained at The Institute of Cancer Research 2. NHS Digital ONS mortality dataset
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode
Identifiers required for analysis purposes	1. Date of death 2. Cause of death (not directly identifiable)
Additional information	Quarterly updates of mortality outcomes are provided to the applicant from NHS Digital.

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 activity was clearly in the public interest.

Scope

As requested by the applicant, this application provides ‘s251’ support for only the cohort consented prior to 2008. The Members wish to emphasise that if ‘s251’ support is required for any of the other patients consented, post 2008, the applicant will need to submit an amendment.

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 patients have been consented, but NHS Digital do not consider this consent to be valid if consented on consent form 1-4. It is not practicable for the applicants to recontact so many individuals to reconsent, as this is an historic cohort, and many have died. The members agreed with the justification provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for flagging/linkage, and full date of death is required to be disclosed back to the applicant. It is not possible to link with NHS Digital outcomes without identifiable information, and date of death is required for analysis. The Members were content that this could not be undertaken with anonymous information.

‘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.

There is currently no notification for CAG purposes. The applicant has advised that a notification, including an activity specific opt out option, is added to their website, but not provided a copy of any website text. The National Data Opt Out will apply to data received back from NHS Digital.

The CAG noted that they could not find any notification of this on the relevant website, and requested that the applicant provide a website text patient notification, that includes an opportunity for individuals to opt out, for CAG 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.

The applicant has stated that although no Patient and Public Involvement has yet been undertaken, the applicant has commented that this is on the agenda for a Patient and Public Involvement group as part of their NIHR grant, on the steering committee meeting on 03 October 2022. However it was not clear to the CAG whether this would be a discussion with a group of patients who are representative of the cohort, regarding this use of confidential patient information, without their specific consent for this particular processing. Patient and Public Involvement to establish the acceptability of this application, with a representative group of patients should be undertaken, and comments and feedback provided to CAG for review, to help evidence the public interest in the activity being undertaken.

Exit strategy

The exit strategy will be anonymisation. NHS Digital data (date of death) will be kept for up to 5 years after the last follow-up date for all cases on the study. The study is currently open for recruitment until 31 December 2022, however applicants have recently applied for an extension of 5 years, and this would be until 31 December 2027. Therefore data retained until 31 december 2032. 's251' support required until this time.

's251' also required until NHS Digital delete the flag for those consented prior to 2008. NHS Digital retain the flagging for this cohort until 31 december 2032.

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 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 a website text patient notification, that includes an opt out, for CAG review.

2. Patient and Public Involvement to establish the acceptability of this application, with a representative group of patients should be undertaken, and feedback provided to CAG for review.

3. Please provide Favourable Opinion from a Research Ethics Committee for the submitted amendment regarding CAG input - AM2204-44.

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. **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. **Confirmed:**

   The NHS Digital **21/22** DSPT reviews for **The Institute of Cancer Research, and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 19 October 2022)

d. 22/CAG/0138 - James Lind Alliance Major Trauma Priority Setting Partnership

Context

Purpose of application

This application from The Major Trauma Priority Setting Partnership Steering Group, at Queen Mary University of London, set out the purpose of medical research of identifying uncertainties about the treatment and rehabilitation of patients suffering major trauma in collaboration with patients, carers, and clinicians, in order to inform future research questions.

This James Lind Alliance (JLA) Priority Setting Partnership (PSP) brings together all involved and affected by Major Trauma to prioritise the top 10 research uncertainties.

Major trauma is an injury or combination of injuries that are life-threatening and potentially life-changing, with significant risk of long-term disability. It has historically been the leading cause of death and disability in those under the age of 40, but its prevalence in the elderly population has increased as medical care advances result in patients living longer lives. Previous work has often focused on clinician-centred outcomes. Previous work looking specifically at elderly trauma has identified the need to identify preferred goals of trauma care, and there is a pressing need to identify priorities for patients, families, and their carers. This PSP will be the first to systematically investigate this topic and will be the first to incorporate the priorities of patients and carers.

The applicants plans to invite patients to complete a questionnaire. They are presenting a few different ways of undertaking this, which do not require ‘s251’ support, such as displaying informaiton online which a patient can complete without any breach of confidentiality if they happen across it. The direct care team will provide information directly during inpatient of clinic visits. The direct care team at participating sites will also search their local TARN database to identify eligible patients, and will then find the correct contact details using the electronic patient medical records at their Trust, the direct care team will then send out an invitation letter. None of this would represent a breach of confidentiality and would not require a CAG application. However the applicant is also requesting ‘s251’ support to allow the direct care team (usually also the local TARN coordinator) to disclose name and address information to the applicant at QMUL, in order for them to assist in sending invitation letters. This is in case the direct care team do not have capacity to undertake the invitation process.

The return of the questionnaire would be considered implied consent to take part, and no further processing of confidential patient information is required.

A recommendation for class 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	Major trauma patients enrolled into the Trauma and Audit Research Network (TARN) database, with a discharge date range between 1 July 2020 and 1 July 2022. There is no age limit and will include children. 's251' support only required for that data which is disclosed to QMUL, not for those patients who are contacted by direct care team. Applicant estimates around 2,000 and 5,000 patients requiring CAG support, but it is not possible to know until further down the line, as it is not yet known which sites may struggle with capacity to undertake this activity.
Data sources	Participating Trusts, where direct care team cannot undertake the proposed activity: • Local Trauma and Audit Research Network (TARN) databases at participating Trusts • Electronic patient records in order to identify contact details 14 total Participating sites in England:

	University Hospitals Birmingham, UK Addenbrookes Hospital, Cambridge, UK University Hospitals Coventry & Warwickshire NHS Trust, UK Oxford University Hospitals Trust, UK University of Bristol Hospitals, UK University Hospitals of Leicester, UK Salford Royal Hospitals NHS Trust, UK Sheffield Teaching Hospital, UK South Tees Hospitals NHS Trust, UK Newcastle Upon Tyne Hospitals, UK Royal Manchester Infirmary, UK Leeds Teaching Hospitals NHS Trust Newcastle Upon Tyne Hospitals, UK Barts and the London NHS Trust And 1 participating site in Wales: Swansea Hospital
Identifiers required for sending invitation purposes	• Name • postal address • email address if available
Identifiers required for analysis purposes	1. N/A Any data collected will be with implied consent

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 Members agreed that the application was in the public interest.

Scope

The CAG commented that the scope of the application was unclear, due to a comment made by the applicant as part of a response to queries; '*at some sites this will be undertaken by research nurses. Does this constitute the "direct clinical care team" by your definition?',* and *'If CAG are able to confirm that local research nurses are classified as part of the direct care team, this will hopefully reduce the instances where CPI will have to flow via QMUL.'.* It is the responsibility of the data controller of the data processed, so in this case each individual participating Trust, to determine if they are satisfied whether or not there is any breach in confidentiality that may require a CAG application. In this application, this hinges on whether or not research nurses would be considered direct care team. It is not within CAG remit to decide this, as CAG do not have all the local details, and this should therefore be discussed by the applicant with the Caldicott Guardians at each participating Trust to establish whether the research nurses at each Trust are considered direct care team or not. Please read the information in the CAG pre-application flow chart to see a definition provided by the National Data Guardian. CAG_pre-application_checklist.pdf

Once the applicant has established which participating sites are processing confidential patient information without consent, undertaken by individuals who are not considered direct care team, the CAG will need to be informed of which sites these are, and provide 's251' support for this processing, whether this is identifying eligible patients from TARN lists, and/or sending invitation letters – the processes requiring 's251' support will need to be defined.

It is not clear why, if local research nurses were defined as direct care team, this would reduce the data flow to QMUL. 's251' support could be requested for research nurses to send invitation letters, instead of direct care team if direct care team did not have capacity, rather than send any confidential patient information to QMUL, which would be a less disclosive design. Of course, if neither direct care team, nor any non-direct

care team individuals at each Trust have capacity to send invites, if the only option was to then send identifiable information to QMUL, then CAG would be supportive of this. Both situations are a breach of confidentiality, and disclosing data to QMUL would be more disclosive than local research nurses sending invites, whether or not they are considered direct care team.

Members felt the scope of 's251' support needs to be more clearly defined as to which process will be happening at which site, which would also provide a clearer indication of how many individuals data might be processed under 's251' support, as part of the CAG application.

If the applicant requires any further explanation around this point, they are encouraged to talk to the Confidentiality Advice Team (CAT) in the first instance.

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**

It is not possible to consent patients for the approach to consent, however a breach of confidentiality would be avoided if the direct care team sent the invites. The applicant has justified why this is not possible, stating that wherever possible, these duties will be undertaken by the direct clinical care team and confidential patient information will not leave the local hospital. However, in some cases, due to lack of clinician time, the direct care team will be unable to process the data and post the surveys to individuals. The CAG felt this was reasonable, but that the role if research nurses needed to be clarified.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for the purposes of inviting patients to take part in a questionnaire, and the Members agreed that It is not possible to send invitation letters if name and address are not used.

‘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.

Pre breach:

The applicant has agreed to including a notification and opt out mechanism text via the website and social media:

“*If you have previously been treated in hospital for a serious injury, we want to hear from you to help us set priorities for research to care for other people with serious injuries in the future. We may receive your contact details with the help of the Trauma Audit and Research Network and the Confidentiality Advisory Group, and use these to post you an optional survey. If you would like to opt out from this, please contact boneandjointhealth@qmul.ac.uk”.*

The National data opt out will be applied.

The CAG were content with the proposed notification mechanism, although commented that the phrasing; ‘*We may receive your contact details with the help of the Trauma Audit and Research Network and the Confidentiality Advisory Group’* was not technically correct, as CAG do not provide any data. The applicant should alter this phrase to something similar to; ‘*We may receive your contact details with the help of the Trauma Audit and Research Network, under ‘s251’ support from the Health Research Authority (HRA), following advice from the Confidentiality Advisory Group (CAG)’*

It may also be prudent to list the participating sites, so opt outs are not received from patients throughout the whole country.

Post breach:

The applicant has provided an updated information sheet (PIS), which is sent in the post.

The CAG considered that the post-breach letter is sufficient, except for the definition of CAG. The PIS states: '..*Other patients with serious injuries and the national Confidentially Advisory Group approved this use of your data'.* The applicant should alter this to state something similar to; '*..Other patients with serious injuries support this application, and the Health Research Authority (HRA), following advice from the Confidentiality Advisory Group (CAG), has provided 's251' support for this use of your 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 applicant responded to queries to state that the use of confidential patient information without consent has been discussed at several steering group meetings, all of which have had at least one PPI representative present. The PPI members felt this was a reasonable and acceptable use of identifiable data without consent and outside the direct care team. The applicants state they can provide minutes of the meetings, which lists the PPI members in attendance. They have also said they can re-discuss this at the next steering group meeting if required.

The CAG noted that although the entire study is about patient and public engagement in research, it lacks adequate PPI engagement in determining attitudes to the movement of personal data without consent, for which 's251' support is requested, as agreement provided by a steering committee is not usually accepted as such. The CAG request that the applicant undertakes a further round of Patient and Public Involvement, (aside from steering group meeting, as these individuals may not necessarily be considered lay, or representative of the cohort, and may be biased), focussed entirely on the use of confidential patient information without consent, for the purposes of this application.

Exit strategy

The invitation process by QMUL will take 6 months from receipt of the data. QMUL will delete name and address information as soon as the surveys have been posted. Exit strategy will be anonymisation by deleting of the data.

The CAG were content with the proposed 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 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 clarify the scope of support by establishing which of the participating sites require 's251' support for research nurses to send out invitation letters, and clarify if this changes the proposed study design of data flowing to QMUL.

2. Please provide an updated number of individuals whose data may be processed under 's251' support, once you are clearer on the scope of 's251' support, as above.

3. Please alter the pre-breach patient notification wording, and provide updated wording back to CAG.

4. Please update the PIS with correct definition of CAG and provide updated version back to CAG.

5. Please undertake further Patient and Public Involvement, (aside from steering group meeting), focussed entirely on the use of confidential patient information without consent, for the purposes of this application, and provide feedback to CAG.

6. Please provide confirmation from the IG Delivery Team at NHS Digital to the CAG that the **21/22** Data Security and Protection Toolkit (DSPT) submission for **Queen Mary University of London - Pragmatic Clinical Trials Unit (PCTU) - SMD (8HN69-PCTU)** has achieved the 'Standards Met' threshold, as per standard condition of support below.

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 12 September 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. **Pending:**

   The NHS Digital **21/22** DSPT review for **Queen Mary University of London - Pragmatic Clinical Trials Unit (PCTU) - SMD (8HN69-PCTU)** was pending

   Due to the number of participating organisations involved it is the responsibility of Queen Mary University of London, as controller, to ensure that participating sites 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 about a Trust.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Tony Calland, MBE, CAG Chair		*31 October 2022*
Signed – Confidentiality Advice Team		Date
Caroline Watchurst, HRA Confidentiality Advisor		*31 October 2022*