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

11 August 2023 via correspondence

Present:

Name	Role	Items
Dr Murat Soncul	Alternate Vice Chair	2a, 2b, 2c
Mr Anthony Kane	CAG Member	2c
Dr Harvey Marcovitch	CAG Member	2a, 2c
Professor Sara Randall	CAG Member	2a, 2b
Mr Marc Taylor	CAG Member	2b

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

There were no conflicts of interest declared.

2.New Precedent Set Review Applications

a. 23/CAG/0093 - Supervised consumption and drug related harm

Context

Purpose of application

This application from The University of Bristol set out the purpose of medical research, to determine and compare rates of drug related harm. This includes hospital admissions, non-fatal overdoses, self-harm, drug related deaths, suicide death and all-cause mortality. These outcomes are examined during supervised and unsupervised Opioid Agonist Treatment (OAT) (methadone or buprenorphine) and periods off OAT, before, during and after the COVID-19 pandemic. Applicants will also assess duration and retention on supervised compared with unsupervised OAT, before, during and after the COVID-19 pandemic.

Daily supervised prescription and consumption (DSC) for OAT medicines used to treat opioid dependence/opioid drug use disorders was the norm before COVID-19 lockdown for a substantial number of patients managed by community drug agencies (CDA). Although implemented to reduce drug related deaths (DRDs), evidence for intended benefits of DSC of OAT is limited, imposes additional costs on OAT delivery and patients often find DSC stigmatising and restrictive. The COVID-19 pandemic led to patients being supplied with weekly or fortnightly supplies of OAT. Face to face support has also stopped. Telephone appointments offer efficiency savings but may impact on patient experience. Evidence on the impact of lockdown on management of opioid use and drug related harm is emerging. In Scotland there was some evidence that uptake of harm reduction services declined and have not yet recovered to pre-pandemic levels. In North America drug related deaths increased. In UK changes to the delivery of OAT, including dispensing for up to 14 days for self-administration, has been well-received by patients. It's no longer possible to study DSC in a controlled trial. As the COVID-19 pandemic necessitated a shift away from DSC on DHSC advice, it has created a "natural experiment" allowing applicants to study the impact of DSC on fatal and non-fatal overdose and DRDs and wider impacts of changes to drug treatment on patients.

Applicants will use data about patients prescribed either methadone or buprenorphine, identified by Change, Grow, Live, a CDA. Date of birth, postcode and NHS number, alongside clinical data such as OAT prescription details, assessment information and

health and safety information, will be disclosed to NHS England, and linked with hospital episode statistics (HES) and mortality data, and an anonymous dataset provided to the University of Bristol for analysis.

A recommendation for class 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	Patients registered with Change, Grow, Live and prescribed opioid agonist treatment between 2015 and end of 2022. Approximately 6000
Data sources	1.Change, Grow, Live a. Clinical records 2.NHS England: a. Hospital Episode Statistics (HES) b. ONS mortality data
Identifiers required for linkage purposes.	1.Date of birth 2.Post code 3.NHS number
Identifiers required for analysis purposes.	1.N/A analysis will be undertaken on an anonymous dataset

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 application 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.

- **Feasibility of consent**

The applicant indicated that consent is impractical given the nature of the datasets (routinely collected data). The Sub-Committee were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage to NHS England datasets. The applicant stated that it was not possible to undertake linkage without identifiers. The Sub-Committee was content that using anonymous information was not 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 for display in Change Grow Live has been provided with an opt out option included. A privacy notice has also been provided. A study specific opt out option is available, and the National Data Opt-Out (NDOO) will be respected.

The Sub-Committee felt that although a study specific opt out option was available, the methods for opting out using the NDOO were too prominent. The Members therefore requested for a review of the poster to ensure that it is clear and explicit with regards to the options for raising objections using the study specific opt-out process, and merely state that the National Data Opt Out will be respected.

Secondly, the Members requested for clarity on exactly how, when and where the patient notification materials will be made available.

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 clarified that no patient and public involvement had yet been undertaken. As a response to queries, the applicant put together a Public and Patient Involvement group and are having their first meeting on the 08 August.

The Sub-Committee requested for the applicant to provide an outline of the patient and public involvement activities and feedback the discussions held, in relation to the use of confidential patient information without consent.

Exit strategy

Support is only required until NHS England have completed the linkage and deleted the Change, grow, Live data (and linkage key). The estimated timepoint for this is 18 months after receipt of data.

The application does not clearly state which organisation modifies the post code into deprivation index. Is this done by NHS England or by the applicant? The Sub-Committee requested on who modifies the postcode, and at what time point, thereby seeking clarity on the duration the postcode will be retained in identifiable format.

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. Amend the following within the patient poster:
   a. Review the patient notification material to ensure that it is clear and explicit.
   b. Clearly explain the options for raising objections, ensuring the study specific opt out is prominent, and the NDOO is merely stated as respected.

2. Clarify how, when and where the patient notification material will be made available.

3. Provide an outline of the patient and public involvement activities undertaken and feedback the discussions held in relation to the use of confidential patient information without consent.

4. Clarify who modifies the postcode, and at what time point, and confirm the duration the postcode will be retained in identifiable format.

5. Please provide the NHS England **22/23** DSPT review for Change, Grow, Live, as per standard condition of support.

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 21 August 2023.**

2. Confirmation provided from the DSPT Team at NHS England 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 England **22/23** DSPT review for **NHS England** was confirmed as Standards Met on the NHS England DSPT Tracker **22 August 2023**.

   The NHS England **22/23** DSPT review for **Change, Grow, Live** is pending

b. 23/CAG/0099 - Defining delirium and its impact in Parkinson's Disease (DELIRIUM-PD)

Context

Purpose of application

This research application from Newcastle University set out the purpose of medical research which aims to find out how well and how accurately a new Parkinson's-specific delirium tool (developed in the DELIRIUM-PD study - 18/CAG/0207), can identify delirium in people with Parkinson's in hospital compared to a detailed examination by an expert. Applicants will also identify if the tool can improve the care of people with Parkinson's while in hospital and shorten their length of stay. The applicants aim to make this new tool freely available, as raising awareness and correctly identifying delirium in Parkinson's will lead to better care and could improve patient outcomes.

18/CAG/0207 had 's251' support for access to confidential patient information for the purposes of identifying potential participants to approach for informed consent. Recruitment closed in January 2022 to the original study, and therefore 's251' support expired. The applicant has since received additional funding to validate the tool that was developed as per the original study aims. The sponsor has agreed that this should

be a Substantial Amendment to the original study as it is a direct continuation and will include the same participants and identical protocols, however as the 's251' support expired, a new application to CAG was required.

All patients with Parkinson's who attend movement disorder services in Newcastle upon Tyne will receive a letter and information sheet about the study which will explain that, should they be admitted to hospital, they will be approached by a researcher about the study. An electronic alert; a system already in use by the hospitals (Recurring Admission Patient Alerts or RAPA), will notify researchers of their admission. Applicant's will visit participants who consent to participate over consecutive days whilst in hospital and will complete a delirium assessment.

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	Patient with a diagnosis of Parkinson's disease or Parkinson's disease dementia according to UK Brain Bank Criteria made by a movement disorder specialist, that have attended the Newcastle Newcastle-upon-Tyne Hospital (NuTH) Foundation NHS Trust movement disorder clinics for the management of their Parkinson's within 18 months of the start of the study. Applicant will recruit/consent 100 more patients, however - Approximately 1,100 letters will be sent, and approximately 1,600 patient records screened for eligibility.
Data sources	1.Newcastle Newcastle-upon-Tyne Hospital (NuTH) Foundation NHS Trust movement disorder clinics medical records
Identifiers required for facilitating invitation process	1.Name 2.Address including postcode 3.Hospital number
Identifiers required for analysis purposes	1.N/A analysis is undertaken with consent as the legal basis under common law

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 application 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.

- **Feasibility of consent**

The applicant is seeking support to enable an approach for consent to be made. It would not be practicable to seek consent for up to 1,100 patients. As some participants are only seen annually, it would take over a year to approach all patients in clinic, which would significantly limit the time restrictions of this study.

The applicant also reasons that the direct care team would not have the capacity to send letters to over 1,100 patients in the period required, or alert the research team of an admission, due to the demands on their time as part of their care of patients. The recruitment method has also been proven to be successful in a previous pilot study (17/CAG/0191), and the main trial (18/CAG/0207).

The Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to facilitate the invitation process, that could not be otherwise achieved. The invitation process was piloted in the previous study and found to be successful.

The applicant clarified that the invitation process could not be achieved without access to confidential patient information.

The Sub-Committee were content that using anonymous information was not 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.

An introductory letter is sent to patient prior to hospital admission explaining the study, alongside a participant information sheet. All written information given to the participants have been reviewed by the patient & public involvement & engagement panel. The information letter and sheet provide an opt-out facility to enable an objection to be raised around an approach to participate if admitted to hospital.

The National Data Opt-Out will be applied prior to the research team screening any identifiable data.

There is currently no patient notification or opt out method prior to the actual breach of confidentiality, ie. prior to sending the patient the introductory letter, however this methodology is the same as supported for the previous iteration of the study. As a response to queries, the applicant responded that this is something they did consider previously as part of 18/CAG/0207. As many patients are only seen by movement disorder services annually or every six months, posters in the clinics would only capture a very small proportion of patients prior to sending out the information letters. Applicants are happy to develop posters if CAG would like.

The Sub-committee considered the approach to patient notification appears proportionate, and agree with the reasons given in the application not to put up posters in clinics. It would therefore be preferable for patient notification, including the scope for opting out, to appear on a web site that Parkinsons patients are likely to see. Although Parkinsons UK may have the best opportunity to explain the circumstances for potential patients, their website seems not to be designed to help people with Parkinsons or their families to understand any of their rights when taking part in research. The Sub-Committee therefore would advise the applicant not to bury this information in a long list of projects which may not draw proper attention to it. The applicant is to therefore identify a suitable online resource to help make notification materials available to patients and the public.

The Members felt that the limitation to raise objections within 7 days of receiving a letter is not reasonable, given postal times and the chance of people being on holiday. The Sub-Committee therefore requested the applicant to extend the period during which patients can raise objections to 6 weeks after a letter was received. Furthermore, the members requested for the objections process to provide an email and postal address alongside a phone number.

The letter to participants should specify that 'section 251 support' facilitates identification of suitable participants, so that they can be approached for their explicit consent to be part of the study. This should make clear that the patient's doctor has permission from the HRA (on advice from CAG), to use health records to approach the patient for consent to take part and in the section of the Participant Information Sheet which says the study has been reviewed by a REC it should add that the HRA has authorised the research team, following review by CAG, to use confidential information to identify and approach potential participants.

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 conducted significant Public, Patient Involvement and Engagement (PPIE) since the start of the original study. This includes a DELIRIUM-PD advisory group which has met regularly since 18/CAG/0207 began. An online survey was undertaken with 72 responses. Focus groups were undertaken, and feedback from patients agreed that the proposed methods would be acceptable to people with Parkinson's.

The applicants have already used these methods successfully as part of the initial phase of recruitment to 18/CAG/0207, out of 1,081 patients receiving a letter, 26 people (2.4%) contacted the team to decline involvement. In 17/CAG/0191, out of 926 patients receiving a letter, 44 declined involvement (4.7%). No patients in either study stated they were unhappy at being contacted or complained about the process. During the recruitment period for both studies, applicants did not receive any feedback from participants, potential participants or their families/carers about the method of recruitment being unacceptable.

The Sub-Committee was satisfied with the volume of patient and public involvement undertaken by the research team, noting it was substantial, appropriate and sufficient to reassure CAG that the proposed methods have proven acceptable in practice during the earlier phase.

Exit strategy

The exit strategy is patient consent to participate. Confidential patient information on any patient who declines to be approached to participate will be retained for the 18-month recruitment period, to ensure these individuals are not inadvertently approached to participate.

Section 251 support is required until 28th February 2025, which is when recruitment ends. On this date, applicants will stop recruitment/screening, will remove themselves from the RAPA system and permanently destroy all confidential patient information.

The Sub-Committee was content with the exit strategy provided.

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 provide the Caldicott letter of support, as per standard requirement for applications to CAG.

2. Please identify a suitable online resource/website to make notification materials clearly available to patients and the public, and provide these details to CAG.

3. Please amend the following within the invitation letter and associated materials:

    a. Ensure the objections process provides an email and postal address alongside a phone number.
    b. Extend the period in which patients can raise objections, from 7 day to 6 weeks.
    c. Specify within the introductory letter to participants that section 251 support facilitates identification of suitable participants, so that they can be approached for their explicit consent to be part of the study.
    d. Include that the HRA has approved (on advice from CAG) in the section of the PIS where the REC review is detailed.

4. Please provide a favourable opinion from the Research Ethics Committee regarding the amendment, as per standard condition of support.

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 regarding amendment 18/YH/0486/AM11**

2. Confirmation provided from the DSPT Team at NHS England 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 England **22/23** DSPT review for **Newcastle upon Tyne Hospitals NHS Foundation Trust** was confirmed as Standards Met on the NHS England DSPT Tracker (checked 22 August 2023).

c. 23/CAG/0107 - Emergency Surgery Or noT for common Vascular conditions in the periods before and during COVID-19 (the ESORT-V study)

Context

Purpose of application

This non-research application from London School of Hygiene & Tropical Medicine set out the purpose of aiming to investigate how effective and cost-effective urgent surgery is compared to elective surgery for patients with common vascular conditions. The study will generate evidence about which patient subgroups benefit most from urgent surgery, those in whom elective surgery may be more cost-effective, and those for whom there is sufficient uncertainty around the relative risks and benefits of urgent intervention. The results will inform service design for vascular surgery, National Institute for Health and Care Excellence (NICE) clinical guidelines, Getting It Right First Time (GIRFT) and commissioning guides for acute services.

Patients require surgery on their blood vessels to help prevent the likes of stroke, limb removal and death. Some patients require urgent surgery, but others may benefit from receiving treatment or attending exercise classes first, before undergoing surgery. There is little evidence currently available on the benefits of having surgery sooner or later. Covid-19 has reduced the ability of the NHS to meet recommended waiting times for patients receiving surgery. Waiting lists for planned surgery are approaching 10 million patients and advice is urgently required on how to sort patients into those who will benefit from receiving surgery soon versus those who would benefit from surgery at a later date.

Eligible patients will be identified within the National Vascular Registry (NVR), which is commissioned by the Healthcare Quality Improvement Partnership (HQIP). Patients undergoing elective surgery are included in NVR via consent. For patients undergoing emergency surgery, support under Regulation 5 is in place via application CAG 5-07(f)/2013. The NVR will disclose confidential patient information, together with a study specific ID, to NHS England to facilitate linkage with HES and ONS. Wider clinical information from the NVR will be released to the applicant with the same study-specific ID attached. NHS England will undertake linkage to HES and ONS and release this information to the applicant with the study-specific ID attached. ‘s251’ support will be required for the flow back, as the applicant will receive full date of death. The applicant will link the two datasets together using the pseudo-ID, and date of death will be modified for analysis.

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	Patients who undergo one of the vascular surgical procedures of interest on an urgent or elective basis from 01 January 2016 up to the most recent available data. The populations and procedures of interest are: • Patients with non-ruptured AAA undergoing AAA repair • Patients undergoing carotid endarterectomy (CE) after stroke/transient ischaemic attack (TIA) • Patients with peripheral arterial disease (PAD) undergoing lower limb revascularisation/amputation. Approximately 51,000 (however 's251' support only covers those patients who are not consented into NVR)
Data sources	1. National Vascular Registry (NVR) data, retained by the Royal College of Surgeons of England 2. NHS England – a. HES b. ONS
Identifiers required for linkage purposes	1.First name 2.Surname 3.Date of birth 4.Postcode 5.Gender 6.NHS number 7.Pseudonymous study ID
Identifiers required for analysis purposes	1.Full date of death received, but modified for analysis 2.Age 3.Ethnicity 4.LSOA 5.Gender

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care

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 application 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.

- **Feasibility of consent**

The applicant reasons that seeking consent from patients is not practicable due to the need to obtain identifiable data and contact details to do this. The costs would also be prohibitive. The Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage, and the full date of death is required for calculations such as 'death at 90 days' or 'days alive and out of hospital (DAOH) at 90 days'. The applicant clarified that it is not possible to link without identifiers. The Sub-Committee was content that using anonymous information was not 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 patient notification document has been provided which is available on LSHTM's public website and provides details of how to opt-out of the National Vascular Registry. The applicant has provided information regarding dissenting from NVR only, rather than this application, and therefore no opt out is available for this application.

The Sub-Committee requested for the notification material to clearly explain what confidential patient information is processed, why, and at what stage confidential patient information will no longer be processed, including a clear option to raise objections for this study specifically.

Furthermore, the Sub-Committee requested for the revised notification to be reviewed as part of further patient and public involvement which is to be undertaken.

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 states that the protocol has been reviewed by clinicians and patient and public representatives. As a response to queries regarding the use of confidential patient information without consent specifically, the applicant stated they have had specific input from one of their patient and public co-applicants on the use of confidential patient information without consent. The co-applicant conveyed the need to avoid burdening people. Indeed, they recognised this as being part of the appeal of service evaluations like this, which use existing data in that it can provide very useful information to benefit future patients, without imposing a burden of requiring people to consent.

The Sub-Committee noted that one or two participants is insufficient for adequate patient and public involvement, and therefore the members requested for patient and public involvement to be undertaken with additional patients who represent the cohort. As stated in the section on notification, the further patient and public involvement should review the notification materials, and discussions should be specifically around the use of confidential patient information without consent.

Exit strategy

A common pseudonym, generated by NVR, will be applied across all datasets. This pseudoID will be provided with patient identifiers for data linkage from the NVR to NHS England, this study ID will then be utilised by all data sets to enable linkage of pseudonymised data. The NVR pseudoID is automatically generated and held by the NVR IT system. It is utilised for all NVR data projects, as such it will be maintained by the NVR and not deleted, however, the applicant does not have access to this key, and therefore Section 251 support only required until linkage undertaken by NHS England, and the CPI sent from NVR is deleted by NHS England – which will occur as soon as soon as linkage has been completed.

LSHTM will retain full date of death until outputs have completed peer review. Once applicants have derived outcomes under all main and sensitivity analysis options, date of death will be removed from the analysis datasets. Date of death will be retained in a separate dataset and will only be linked to the analysis datasets if applicants need to derive alternative outcomes in response to peer review comments. Date of death data will be securely destroyed once outputs are published.

The Sub-Committee are content with the exit strategy provided.

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 Secretary of State for Health and Social Care 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. Clearly explain within the patient notification material what confidential patient information is processed, for what purpose, and at what stage confidential patient information will no longer be processed, including options for dissent from this application specifically, and provide the updated documentation to CAG.

2. Please ensure the revised notification is reviewed by the patient and public involvement group and discuss the use of confidential patient information without consent.

3. Please undertake further patient and public involvement with additional individuals, specifically discussing the use of confidential patient information without consent.

4. Please provide the NHS England 22/23 DSPT review for **London School of Hygiene & Tropical Medicine**, as per standard condition of support.

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. Confirmation provided from the DSPT Team at NHS England 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 England 22/23 DSPT review for **NHS England** and **Royal College of Surgeons of England** was confirmed as Standards Met on the NHS England DSPT Tracker (checked 22 August 2023)

The NHS England 22/23 DSPT review for **London School of Hygiene & Tropical Medicine** was pending

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Murat Soncul, CAG Alternate Vice-Chair		28 August 2023
Signed – Confidentiality Advice Team		Date
Ms Caroline Watchurst		01 September 2023