Minutes of the meeting of the Confidentiality Advisory Group

10 March 2022 – held via Zoom

Present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG member
Dr Patrick Coyle	CAG vice-chair
Dr Sandra Duggan	CAG member
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Dr Katie Harron	CAG member
Dr Harvey Marcovitch	CAG member
Professor Sara Randall	CAG member
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Ms Emma Marshall	HRA Confidentiality Specialist
Mr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

Items 3a and 4a – Mr David Evans, CAG member, declared a conflict of interest. The CAG decided he would join for items 1 and 2, be absent for the discussion of items 3a and 4a, and then re-join the meeting from item 4b onwards.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **10 February 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **10 February 2022** meeting applications.

3. Consideration Item

a. 18/CAG/0146 - National Joint Registry – National Data Opt-Out (NDO) Deferral Request

The NJR (jointly controlled by HQIP and NHS England & Improvement) is the largest joint replacement register in the world with over 3 million records that collects, analyses and disseminates data on hip, knee, elbow, shoulder and ankle joint replacement surgery. It is a primarily consented registry and operates under a model where patient consent is recorded in three ways. The first is 'yes' where the patient has provided consent, the second is 'no' where the patient has not consented and anonymised surgical data is used, and the third is where patient consent status is 'unknown'.

Regulation 5 support relates only to the third category and provides a legal basis for patient identifiers to be uploaded to the NJR database by participating hospitals. Support also provides a legal basis to link HES, ONS and PROMS data from NHS Digital to that held in the NJR for this cohort of patients. It is for those patients where consent status is 'unknown' that a deferral request from the NDO is sought.

The National Data Opt-Out (NDO) enables patients to opt-out from the use of their confidential patient information for research and planning purposes where the data flows rely upon Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002.

It is a standard condition of support under Regulation 5 of the COPI Regulations 2002 that patient wishes are respected. In line with the National Data Opt-Out Operational Policy Guidance document (v4.0), the Confidentiality Advisory Group (CAG) may exceptionally advise the decision-maker that the NDO should not apply to a specific data flow supported under Regulation 5 of the COPI Regulations 2002.

Scope of NDO deferral request

Productive discussions prior to the CAG meeting had identified that the deferral request paper also referenced 19/CAG/0182. This is a linked research application that utilises non-research data collected under 18/CAG/0146 for research purposes. It was mutually agreed prior to the CAG meeting that the justifications given for NDO deferral did not have the same issues and weighting for the processing for research purposes and would therefore be excluded from the current request. The advice and decision set out below relate only to the non-research uses detailed in 18/CAG/0146.

Confidentiality Advisory Group advice

The National Joint Registry (NJR) collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales and has been operating under Regulation 5 support since 2006. It collects and monitors data about joint replacement surgery in order to provide an early warning of issues relating to patient safety, improve the quality of outcomes, and ensure the quality, and cost effectiveness of joint replacement surgery.

As part of the request, the applicant provided three core reasons why application of the NDO would impact the running of the NJR. CAG consideration of each point is summarised below each core issue.

1. Patient safety – loss of data will reduce the ability to detect signals of patient safety concerns

2. Introduction of bias – there are indications that the application of the National Data Opt Out is not random so impacts the integrity of the data

3. Technical impacts – the systems are not designed to apply the national data opt out on a direct entry system which will add workload to direct care teams to apply the national data opt out

1. Deferral rationale: patient safety

The paper set out a strong argument detailing the potential impacts on patient safety. This included how data is used to monitor performance of both individual surgeons and the Trust clinical services that deliver joint replacement surgery. The data is also used as a surveillance tool for orthopaedic medical devices to ensure that treatment decisions are safe, effective and evidence based. As such the NJR can be used to notify hospitals of relevant patients should a medical device be recalled, or a field safety notice issued.

Members reflected on the uniqueness of the NJR and understood that the ability to identify instances of joint failure and identify and communicate with patients who needed to have their joint replaced was an important safety issue. In particular, it was noted that when patients actively decline consent, they will be counselled on the implications of this before consent is declined. However, this would not be possible for patients whose data is processed under Regulation 5 support and who have opted out via the NDO. Members were concerned that this group of patients would be unaware of this safety implication when registering their objection preference.

In considering the patient safety arguments, CAG noted the issue of particular weighting here was around joint failures and the subsequent danger to patients in this instance. It would be critical for the NJR to be able to recognise where joint

failure occurred and the need to follow-up. While some of the other rationales proposed by the NJR could be considered applicable to any other activity, CAG strongly agreed that the patient safety issue around devices was not generalisable in the way other justifications were, and the fact that a faulty device could cause active harm was the primary factor that led to CAG advising that the NDO should not be applied to this activity. Members also noted a specific issue related to bias that links to patient safety concerns as set out below.

2. Deferral rationale: Introduction of bias

The paper acknowledged that due to the large size of the NJR it was potentially resilient to the general impacts of opt-outs and currently around 1.5% of patients actively object. However, the paper focused concern around the non-random nature of existing objections based upon NHS Digital statistics. The paper indicated that excluding patients that have registered against the NDO would introduce a biased sampling frame due to non-random opt-out patterns. In particular, it was noted that around 4% of practices have at least double the current national average of 5.35% and a small number of practices have recorded rates of over 30% objections. It was stated that it was not possible to model the impacts of these non-random objections due to not having access to equivalent comparison data without opt-outs applied.

Accepting the limitations around providing evidence to support the issue of bias, members noted that Regulation 5 support applied only to a sub-cohort of patients and from this sub-cohort approximately 5% would object using the NDO, therefore numbers of impact appeared initially relatively minimal. However, members were supportive of the point that in terms of analyses examining the outcomes of named clinicians and specific devices, the absence of a small number of cases could be the difference between an outlier finding or not. The paper confirmed this to be a safety risk if the NJR's ability to detect signals of concern are compromised and could equally risk reputational damage to surgeons and implant manufacturers if a false positive outlier finding was made when relying upon a biased set of data.

3. Deferral rationale: technical impacts

The applicants noted that NJR data is entered by the majority of hospitals into a secure web-portal on a case by case basis. The paper indicated that as the screening mechanism maintained by NHS Digital for applying the NDO is built upon the basis of screening an uploaded file of records, this creates challenges for the NJR as it uses a direct data entry method. It was indicated that applying the NDO would generate additional workload for hospital teams with potential for delayed entry of data into the NJR for all cases, or potential non-compliance by overwhelmed clinical teams.

Whilst the CAG noted the potential technical challenges articulated in the paper, it was also noted there had been a significant period for implementation of the NDO. CAG understood that the NHS has been under considerable pressure during the last years due to COVID-19 and there has been necessary focus on other matters. However, members were clear that practical difficulties around the NDO implementation would have to be very clear with evidence and not just statements of potential negative impact. Requests for deferral from the NDO from the CAG should be exceptional and based primarily on reasons other than that of system process issues. Members were therefore not persuaded that this specific reason in isolation provided sufficient reasonable justification to disapply the NDO.

Informing the patient population

In order to ensure that the relevant patient population are informed that the NDO would not be applied CAG agreed that it would be critical, as a general principle, for clear communication methods around the deferral to be established. CAG noted that a notification and local dissent mechanism is already in place for those patients whose data is processed under Regulation 5 support, and it is expected that this will continue.

Members noted there was limited information in the paper on how the NJR would communicate to patients that the NDO would not be applied while the local objection mechanism would still be applicable. It was identified that thinking was ongoing and would include a website update and potentially using relevant networks. Members highlighted the importance of transparency and taking all reasonable steps to inform the relevant population the NDO would extend to in order to ensure the principle of 'no surprises' would be achieved. Members also advised that the NJR should seek advice from the National Data Guardian in terms of appropriate communications around the NDO

Members noted that appropriate communications would be critical to support and maintain public trust in the appropriate use of data. It was also noted that patients who had registered via the NDO would expect their data not to be used, therefore the principle of 'no surprises' was considered critical. It was agreed that final support should not be issued until the applicant had provided a proportionate, credible and relevant communications strategy/plan, setting out proposed content and intended dissemination routes for review.

Confidentiality Advisory Group advice conclusion

Following thorough review of the request rationales, members agreed that the patient safety rationale around devices and linked bias issue was particularly strong

and provided appropriate rationale for advising why the NDO should not be applied to this data flow.

However, CAG was very clear that any requests for deferral from the NDO must have in place a clear communications strategy as it would represent a significant deviation from published information. In particular, it was identified that there would be no transparency in introducing a major change to earlier information provided to the public through editing previous privacy information without considerable, detailed and wide notification. Taking into account the CAG's role in supporting public trust, members advised that the information to be given to the public when requesting a deferral from the NDO should be correct, understandable and available.

Taking the issue of communication into account, the CAG agreed that they were supportive, in this specific instance, of the request for the application of the National Data Opt-Out to be disapplied in relation to the non-research activities contained within 18/CAG/0146. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be provisionally approved. However, this recommendation was subject to an acceptable communications strategy and supporting text being clearly defined and in place before final support could be issued.

Request for further information

1. Set out clearly the various communication routes that will be used to inform the relevant patient population that the National Data Opt-Out will not be applied to the NJR audit activity for those patients whose consent status is recorded as 'unknown'. Dissemination/communication methods should be proportionate to the requested change with all relevant text provided for review. Final support will be issued if the response is satisfactory.

Specific conditions of support (provisional and may change in final support outcome):

1. The National Data Opt-Out does not apply to the non-research activities specified in 18/CAG/0146.

2. The National Data Opt-Out must be applied in relation to processing for research purposes and specifically in relation to 19/CAG/0182

3. A local patient objection mechanism must continue to be used in relation to 18/CAG/0146

4. Communication and notification - TBC

Declarations of Interest

Mr. David Evans declared a conflict of interest and was not present for the item discussion.

4. Resubmitted new applications – Research

a. 22/CAG/0045 - Patient Reported Experience Measure: a closer to ‘real time’ survey of patients’ experience of general practice

Context

Purpose of application

This application by NHS England, for the purpose of managing health and social care services, looks to introduce a new GP experience survey which will allow for a closer to ‘real time’ survey of patient’s experience of general practice in England. The survey is designed to capture patients’ experience of their most recent contact with their general practice, as well as gathering feedback on their experience of access to general practice overall.

The intention is that, following an appointment in general practice, a sample of patients will receive a text message which directs them to complete a web-based form containing a number of questions relating to their experience and whether or not this met their expectations and needs. They will also be asked to provide some basic demographic information (gender, ethnicity etc.). Response to the demographic questions is optional.

The results of the survey will be analysed and then published on a monthly basis, aggregated at Primary Care Network (PCN) level, and will be used to track trends in patient experience overall and in relation to different groups of patients (i.e. of certain ethnicities, ages etc.) to allow for monitoring of any inequalities in experience, improve access to general practice services and financially incentivise practices to improve their overall performance.

A recommendation for class 1, 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 at a general practice in England, aged 16 and over, who have had an appointment/contact with a general practice provider.
Data sources	General Practice Clinical Systems - Medical records
Identifiers required for linkage purposes	1. NHS number 2. Mobile phone number 3. Date of birth 4. Date of death
Identifiers required for analysis purposes	1. None
Additional information	Although this is a resubmission of a previous application, the methodology and data flows have changed; therefore, it is being treated as a new application.

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 the management of health and social care services 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 aim of the application was in the public interest but had concerns about the execution of the project.

The applicants sought to obtain the mobile telephone numbers of all patients attending GP appointments to avoid bias. However, this design introduced the risk of bias, as patients with no mobile telephone or no access to a smart phone would be excluded, which would not be a representative sample of the population. Those with visual impairments, language issues and those living rurally with no or insufficient internet access, did not seem to have been considered.

The applicant anticipated a low response to the invitation to participate in the survey. This also limited the applicants' ability to gain a representative sample.

The third-party supplier, who would undertake the extraction of patient data from GP systems, had not yet been identified. The CAG noted that the system proposed was inefficient, as it required a third-party to extract data from GP surgeries which was already collected for the Patient Demographics Service at NHS Digital. As the breach of confidence occurs in transferring data to this third party it is essential that the identity of the third party, if it is needed, is known. The CAG advised that alternate ways of collecting patient contact details were explored.

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**

Data for a million patients per day would be transferred to the third-party supplier. The application referenced that a "statistically significant" percentage of these patients would be contacted. The CAG agreed that it had not been adequately explained why details of such a large number of patients needed to be collected when it had not been determined how many patients could be contacted each day.

- **Feasibility of consent**

All patients aged 16 years and over who are registered with a GP practice in England may be invited. Around 1 million GP appointments take place every day and it would be impracticable to seek consent from all patients. The applicants explained that asking clinical staff in the GP practices to seek consent before or when attending, as this would be burdensome to the practice staff. The applicants also noted that not every patient who consented would then be contacted and that it would be difficult to track whether consent had been given in every case.

The applicants noted that asking GP practices to consent patients may introduce bias as practices may 'self-select' the patients that they want to be surveyed.

- **Use of anonymised/pseudonymised data**

The third party supplier require access to confidential patient information in order to send the survey invitation to selected patients.

'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.

Patients will be informed about the survey, and their right to opt out should they wish, via a range of communications materials including posters for display in practice, information for patient information screens, information to be added to practice websites, a script and FAQs to be shared with practice teams which will help inform their conversations with patients about the survey. A full communications strategy was provided with the application. However, the applicants explained that the posters and other materials were not available at the time of the application, as further user engagement with patients and practices was required. The notification materials will also need to be amended to reflect the national data flow, once this is fully confirmed

A draft privacy notice had been created and would be shared with practices. Practices will be asked to update this with the practice details. The notification materials will be amended accordingly to reflect the national data flow once this is fully confirmed. As

mentioned in the application, the materials were developed to support initial testing of the process, which used a slightly different approach and data flow, hence why the information is slightly different. Further and comprehensive communications will be developed to support further testing and national rollout. Patients would be able to opt-out of any further survey requests by replying with the word 'STOP' when the text message is received. NHS BSA will maintain a list of all individuals who have opted out and this will be applied to the raw data during the sampling process. The National Data Opt-Out and Type 1 Opt-Out will be applied as a filter by the GP practice before identifiers start to flow.

The CAG noted that, although extensive patient notification was planned, none of the materials had been provided with the application. Should the applicants make a further submission, then the notification materials would need to be provided with the application.

Patient and Public Involvement and Engagement

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

The applicants explained that Deloitte and NHS Business Services Authority had consulted patients during the discovery phases of this project. IPSOS Mori also undertook cognitive testing of the survey questions with groups of patients covering a range of demographics. Patients were asked to give their views on whether they would have any issue with the NHS using their data in this way. No significant concerns were highlighted, and patients appeared to be comfortable with use of contact and other identifiable data to support improvement in the NHS. Further engagement was undertaken during the testing phase. This included engagement with a group of approximately 1000 users who responded to specific questions in relation to the survey. As a result of that engagement, the text message was changed to make 'NHS' more prominent in the messaging and create further trust in the process.

Engagement with practice participation groups was undertaken to understand their experience and any concerns in terms of the survey. As a result of this engagement, questions were made more relevant and duplication removed. It was noted that the groups had no issue with the NHS using their data in this way to support improvement in the NHS. A user experience survey was attached webform used throughout the testing period to capture feedback and/or concerns from patients. No issues were raised in relation to the use of patient data. Specific user experience expertise was planned to support the programme and is expected to be in place

from 1 April 2022 to support further user experience work throughout the next round of testing.

The CAG noted that the feedback provided during the patient and public involvement cited that 20% of those consulted were unhappy with the proposed use of mobile telephone numbers. This was a significant percentage and should be taken into account in the application design.

Exit strategy

The applicants advised that the survey is expected to run for the foreseeable future. The applicants noted that the data source feeding the survey may be subject to change and, should an alternative data source such as GPDfPR or other data collection become available, the survey methodology may be revised.

Should those contacted opt-out via text, their numbers would be retained indefinitely by the third-party. The CAG recognised that this was to prevent the recontact of patients, but expressed concern over this retention.

The CAG agreed that they could not recommend support for this activity to continue indefinitely.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that the application should be rejected.

Further information required

The below points summarise the reasons for rejection by the CAG:

1. The proposed methodology was inefficient, as it required a third-party to extract data, specifically patient phone numbers, from GP surgeries when NHS Digital may already collect this data.
2. The need for the specified sampling approach is not sufficiently justified, given the proposed design will also introduce bias, as patients with no mobile telephone or no access to a smart phone would be excluded, which would not be a representative sample of the population. Those with visual impairments, language issues and those living rurally with no or insufficient internet access,

also did not seem to have been considered. Also, only those who responded to the survey invitation would provide their views. This also limited the applicants' ability to gain a representative sample.

3. The feedback provided during the patient and public involvement cited that 20% of those consulted were unhappy with the proposed use of mobile telephone numbers. This was a significant percentage and should be taken into account in the application design.
4. Patient notification materials must be made available for CAG to consider. It must contain a means of opting out before the breach of confidence has occurred as the STOP mechanism is only available after the breach has occurred.

Declarations of Interest

Mr. David Evans declared a conflict of interest and was not present for the item discussion.

b. 22/CAG/0042 - A long-term prospective cohort study on the effects of smoking and prophylactic aspirin on all cause mortality in male British doctors

Context

Purpose of application

This application from University of Oxford sets out the purpose of medical research that seeks to determine the effects of smoking and aspirin use on a cohort of British doctors started in 1951. The British Doctors study (BDS) started in response an increase in deaths from lung cancer in the British population between 1922 and 1947, to investigate the link to tobacco consumption. This application to CAG is for a final linkage to mortality data and cancer registrations for the cohort.

The applicant retains a database of 35,000 male doctors, from 1951. They originally were included in a questionnaire study on the basis of implied consent (return of questionnaire). Further questionnaires about changes in smoking habits were sent in 1957, 1966, 1971, 1978, 1991, 1998 and 2001. In 1978, some participants were additionally consented (by paper consent) to a randomised trial of prophylactic daily aspirin to prevent death from stroke, heart attack or other vascular conditions (British Doctors Aspirin Trial-BDAT). Previous linkages of the cohort to ONS mortality data and cancer registration data have been undertaken under references PIAG 3-06(i)/2004 and ONS ref MR181, however any data received from HSCIC/NHS Digital has confirmed to have been deleted, and analysis complete. Analysis of data to date has shown the extent of the reduction in risk when cigarette smoking is stopped at different ages and the effects of long term use of aspirin on the incidence of cancers. This new application for final long-term follow-up through data linkage with NHS Digital will complete the study as the majority of BDS participants are now deceased, and applicants plan to analyse the time to death, cause of death and any incidence of cancer during follow up.

BDS did not receive ethical approval prior to recruiting patient in 1951 because no relevant ethics committees existed at the time. Additionally, the legal basis under common law for the retention of confidential patient information regarding the BDS cohort at university of Oxford has been implied consent (due to return of questionnaires), and is now unclear. It has been held in the public interest until the present day. The applicant is therefore now requesting ‘s251’ support for the continued retention of this confidential patient information, in order to allow a final linkage with ONS mortality data, HES, and Cancer registration data from NHS Digital, before removing and separating the confidential patient information, and analysing a dataset contains date of death, but no other direct identifiers. Once analysis is complete, all confidential patient information will be deleted, which will be by March 2024.

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 registered medical doctors practising in the United Kingdom in October 1951 were invited to be included in the cohort. This application is specifically for 34,439 Male British doctors, which make up the British Doctors Study database
Data sources	1. The University of Oxford, Nuffield Dept of Population Health (NDPH) - The British Doctors Study (BDS) database 2. NHS Digital (for England and Wales) ○ National Cancer Registration and Analysis Service (NCRAS) ○ ONS Mortality data ○ Hospital Episode Statistics (HES)
Identifiers currently retained in BDS database	1. BDS Study ID 2. NHS Number 3. Date of Birth 4. Name 5. Postcode 6. Gender
Identifiers required for linkage purposes	1. BDS Study ID 2. NHS Number 3. Date of Birth 4. Name 5. Postcode 6. Gender

Identifiers required for analysis purposes	**Data received back from NHS Digital;** 1. Cause of death - Primary outcome for the study 2. Date of death 3. Diagnosis of cancer (cancer registration) 4. Date of registration of cancer (cancer registration) 5. Date of embarkation or other loss to follow-up 6. BDS ID 7. Date of birth – to ensure perfect match **Identifiers required for analysis;** • Date of birth – modified to month and year, in order to age at death/cancer and other disease diagnosis • Date of death – retained in full, in order to calculate age at death/cancer and other disease diagnosis Other identifiable information is retained in a separate location and is not required for analysis.
Additional information	One single extract requested

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.

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

- **Feasibility of consent**

Participants entered the study by returning the original questionnaire in 1951 and subsequently sent back a signed form for inclusion in BDAT in 1978. The majority of the participants are now deceased. This implied consent is not deemed sufficient for linkage, or for the ongoing retention of the confidential patient information in the database.

The applicants explained that it was not feasible to contact patients to seek consent as, when patients were recruited in 1951, the median age of the cohort was 42 years of age. The youngest patient in the cohort would now be 95 years of age. The applicants were aware that, by 2016, 90% of the patients in the cohort had died. Those still living were unlikely to still be resident at the addresses held from the last contact made by the applicants, which was in 2001 and may also be too unwell to respond to requests for consent. The CAG agreed that re-contacting patients to seek consent was not feasible.

- **Use of anonymised/pseudonymised data**

Require date of death back from NHS Digital, and linkage can't be undertaken with anonymised information. The CAG agreed that the application activity could not be undertaken in any other way.

'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.

NHS Digital will apply the national data opt out. The Privacy Notice contained information on how patients could request the withdrawal of their data from the study.

Patient and Public Involvement and Engagement

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

The applicants had discussed the use of confidential patient information with four members of their departmental patient data research group. This group were supportive of the use of confidential patient information based on the input the cohort had provided over the decades since the study was set up. The study also could not be repeated. The CAG agreed that it would be disappointing not to make the best use of the data that had been collected.

Exit strategy

Personal data will be retained in a separate file only accessed by named study personnel throughout the study, with the exception of date of death which is required for analysis.

The applicants advised that all items of confidential patient information will be destroyed by 31st March 2024, after linkage has been undertaken.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 15 September 2021**

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

   The NHS Digital **2020/21** DSPT reviews for University of Oxford – Medical Sciences Division – Nuffield Department of Population Health and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2022)

c. 22/CAG/0036 - Cardiovascular morbidity and mortality in Liothyronine-treated patients: a linked record cohort study

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research that seeks to determine whether patients treated with T3 (liothyronine) have a higher risk of death than those treated with T4 (levothyroxine).

Hypothyroidism or thyroid hormone deficiency affects 1-2 million people in the UK and untreated patients suffer significant ill-health. Levothyroxine (T4) is the conventional treatment for hypothyroidism and most patients who are treated with T4 respond well to treatment and enjoy a good quality of life. However, a small proportion of patients remain unwell with T4 and therefore some practitioners treat such patients with an alternative form of treatment called T3. Although many patients who receive T3 report significant improvement in well-being, the long-term safety of the drug has not been established and current UK and international guidelines do not recommend its routine use in practice.

The applicants seek support to use data collected for patients treated with T3 in an independent medical clinic between 1996 to 2013 in order to evaluate the long-term risk of death, heart disease and strokes. This data is held by the Vaccine Research Trust. The clinic dataset contains data for over 4000 patients. This data will be compared with data for patients treated conventionally for hypothyroidism with T4 and a control group of patients without hypothyroidism. The clinic data will be linked to NHS hospital admission and mortality records via NHS Digital and the Wales Secure Anonymised Information Linkage (SAIL) Databank. Administrators of the Vaccine Research Trust will identify eligible patients through a review of electronic clinic records held by the Trust. Patients treated with T3 will be identified and their

demographic clinical and treatment details will be forwarded to NHS Digital and SAIL using a split-file approach in which patient identifiable data (NHS number, gender, date of birth) is sent to NHS Digital and clinical and treatment data is sent to SAIL. A final file comprising pseudonymised linked data with a new encrypted ID for the data groups (T3, T4 and controls) will be made available to Cardiff University researchers via the SAIL portal.

A recommendation for class 1, 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 aged 18 years and over who were treated with T3 for at least 3 months at an independent medical clinic between 01 January 1996 to 31 December 2013 3100 - patients treated with T3. 3100 - patients treated with T4. 24800 – control subjects, with no thyroid disease Patients in the control group will also have received treatment between 01 January 1996 to 31 December 2013, and will be age and sex matched to the T3 and T4 cohorts.
Data sources	1. Electronic patient records held by the Vaccine Research Trust 2. HES and ONS data, held by NHS Digital 3. Patient Episode Database for Wales (PEDW), ONS, and the Primary Care GP dataset, held by SAIL
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth

Identifiers required for analysis purposes	1. Gender
Additional information	The applicants advised that they would request the week of birth and week of death from SAIL. These will then be truncated to age of death once the survival calculation was completed.

Confidentiality Advisory Group advice

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

Public interest

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

Legal basis for continued holding of the dataset

This application is a resubmission of a previously deferred application. During the CAG's previous review, the CAG had raised queries over the existing legal basis for the continued holding of the dataset by the Vaccine Research Trust.

The applicants advised that, after Dr Skinners death, the patient records had not been transferred to another practitioner, as patients were already under the care of their GP. Dr Skinner was a private practitioner and his only affiliation was with the Vaccine Research Trust. Following Dr Skinners death, the Vaccine Research Trust had attempted to find another organisation that could take over responsibility for the patient data, but no organisation approached wanted to take that responsibility.

The Vaccine Research Trust agreed that no legal basis for the current holding of the dataset was in place and sought support under Regulation 5 to continue to hold the dataset and use the data in the proposed research project.

The CAG agreed that the data already collected should be used to answer the research question, so that patients can be advised of the safety or otherwise of T3 compared to T4. Support was recommended for the retention of confidential patient information until the data linkage required for this specific research project was complete.

Members agreed that the ongoing retention of the dataset, after the current research had concluded, could not be supported as it was unclear why it was necessary to continue to hold the dataset after answering the research question. Once the current research was concluded, the dataset either needed to be anonymised, so that no confidential patient information was held by the Vaccine Research Trust. The confidential patient information was retained, then another, more suitable, data custodian needed to be identified and ownership of the dataset transferred.

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 explained that it was not feasible to seek consent as the study involved a historic patient cohort, treated between 1996 and 2013. A number of patients may be deceased or lost to contact and the applicants noted that seeking consent from only those living and contactable may mean that only those in good health were included, potentially biasing the results. The CAG agreed that seeking consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to undertake linkage of patient data from the Vaccine Research Trust to datasets held by NHS Digital and SAIL. This cannot be undertaken in any other way.

'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 advised that the study will be publicised on the British Thyroid Foundation website. The text of the website notification was provided with the application. The notification letter included specific details about the location of Dr Skinner’s clinic, as requested in the previous deferral letter.

The study opt-out information will be published on the websites of the British Thyroid Foundation, the Vaccine Research Trust (VRT) and Thyroid UK (TUK). As per the previous deferral letter, the opt-out information will be placed in a more visible position on the website. The website of the British Thyroid Foundation is currently being redesigned to make the opt-out information more visible amongst other changes.

The patient notification is clear that confidential patient information will be disclosed from the Vaccine Research Trust to NHS Digital and SAIL. The notification included information on the National Data Opt-Out and an email address for the data protection officer at the Vaccine Research Trust.

The CAG noted that they had requested in the previous deferral letter that any communications sent to patients at Dr Skinners clinic following his death were provided. The applicants advised that they could not find any record of letters sent from the clinic. There were also no records of any queries or complaints following Dr Skinner’s death.

The CAG reviewed the notification materials and asked that the project-specific opt-out mechanism was displayed more prominently that the National Data Opt-Out. Members also asked that the Patient opt out information version 2.5 31st January 2022 was renamed to make it clear that the document relates to the Thyroid T3 study.

The CAG asked that further ways of publicising the study were explored.

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 explained that the study protocol had been reviewed by executives from the British Thyroid Foundation who had expressed support, including for the proposed method of data linkage.

During the early protocol development stage, the study was discussed with individual patients. The study was discussed with T3 and T4 users, both within and outside of the NHS in informal group discussions held during annual meetings of the British Thyroid Foundation. More formal discussions were held with executives of the BTF, who reviewed the study protocol in detail. The response from the BTF and patients was positive regarding undertaking the study and the use of confidential patient information without consent. A letter of support from the BTF executives was provided.

In the applicant's response to the deferred outcome, the applicant advised that the original discussions with patient groups were done informally and written feedback was not obtained at the time. The Vaccine Research trust have since approached a mix of former patients of Dr Skinner's clinic and sent them information on the proposed study along with a questionnaire survey which was e-mailed out in September 2020. The survey included questions on participants' opinions of the study relevance, the study data approach, the transfer of confidential patient information from the Vaccine Research Trust, and whether they would be happy for their data to be used as part of the research study. Out of 10 patients surveyed, 6 responded, with an overwhelmingly positive response. These responses were provided in "Thyroid Patients Questionnaire Response." Four individuals did not respond. Of these, two did not reply to the e-mail sent to them and were therefore uncontactable, while 2 individuals chose not to respond for personal reasons.

In addition, an announcement has been placed on the website of the Vaccine Research Trust to say that the data will be used for research and that confidential patient information will be transferred from the trust to NHS Digital for linkage, anonymisation, and forwarding to SAIL. This will clarify that confidential information will be transferred to NHS Digital (date of birth, gender, NHS number) and SAIL (date of death) but that none of this confidential information will be made available to researchers since the data will be anonymised before being made available to patients.

The CAG agreed that the patient and public involvement carried out provided an appropriate response to the previous queries.

Exit strategy

The final dataset provided to the applicants from NHS Digital and SAIL will be anonymised.

The CAG noted that the retention of confidential patient information in the original dataset needed to be treated separately to the dataset created by the linkage to NHS Digital and SAIL. As noted above, the original dataset needed to be anonymised or ownership transferred to a more suitable organisation.

The CAG requested clarification on whether patients dates of death would be retained in the linked dataset, or if this data item would be converted to age at death or other alternative.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Confirm that, once the current research project has concluded, the dataset will either be anonymised (i.e. all items of confidential patient information deleted) or another, more suitable, data custodian needed to be identified and ownership of the dataset transferred.
2. The *Patient opt out information version 2.5 31st January 2022* document needs to be revised as follows:
    a. The project-specific dissent mechanism needs to be displayed more prominently that the National Data Opt-Out.
    b. The document needs to be renamed to make it clear that the document relates to the Thyroid T3 study.
3. Further ways of publicising the study are to be explored.

4. Clarify whether patients dates of death will be retained in the linked dataset, or if this data item could be converted to age at death or other alternative.

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 depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 03 April 2020.**

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 **2020/21** DSPT reviews for **Cardiff University, the Vaccine Research Trust, SAIL (Swansea University) and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2022).

5. New applications – Research

a. 22/CAG/0034 – Artificial Intelligence Stress Echo (FINESSE)

Context

Purpose of application

This application from the Milton Keynes University Hospital NHS Foundation Trust set out the purpose of creating a research database to be used to conduct a 15 year follow up of patients who underwent stress echocardiography using a pharmacological agent.

Stress echocardiography using a pharmacological agent, dobutamine, is a bedside test with good tolerability and accuracy, and which relies on the recognition of regional wall motion abnormalities at rest and during progressive stages of dobutamine administration. The FINESSE Stress Echocardiography (SE) database currently contains data from over 3000 patients who underwent SE for chest pain assessment at Milton Keynes University Hospital (MKUH) by a single Cardiologist over a 15-year period. The database was initially set up for audit purposes. In 2019, the applicants submitted a Research Ethics application to convert the database to a research database and to collect follow-up data for patients. The applicants are now applying for support under s251 in order to undertake linkages to NHS Digital in order to follow-up patients.

The applicants seek support for the disclosure of confidential patient information from the FINESSE Audit Database at Milton Keynes University Hospital NHS Foundation Trust to NHS Digital for linkages to NHS Digital held datasets. NHS Digital will apply a Unique Research ID to patient records before returning the now pseudonymised, linked dataset to Milton Keynes University Hospital NHS Foundation Trust. The dataset will then be anonymised prior to use in analysis.

A recommendation for class 1, 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 aged 18 years and over who underwent SE for chest pain assessment at Milton Keynes University Hospital between 01/10/2002 - 01/12/2017.
Data sources	1. The FINESSE Audit Database, held by Milton Keynes University Hospital NHS Foundation Trust 2. NHS Digital held datasets: a. Hospital Episode Statistics (HES) database b. Office for National Statistics (ONS) database c. Hospital Admitted Patient Care (APC) database d. A&E Attendances and Emergency Admissions (AE) database
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. Date of birth 5. Year of birth 6. Date of death 7. Gender
Identifiers required for analysis purposes	1. Full Name 2. NHS Number 3. Hospital ID number 4. Date of birth 5. Year of birth 6. Date of death 7. Gender

Confidentiality Advisory Group advice

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

Public interest

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

Data flows

The CAG asked that an updated and clear data flow diagram was provided. This needed to outline the specific data items needed for linkage and the information returned.

The application referenced that Natural Language Processing may be undertaken. The CAG requested clarification on whether this would be taken internally at Milton Keynes University Hospital NHS Foundation Trust, or if a third-party would be involved.

Practicable alternatives

- **Feasibility of consent**

The applicants advised that the database was created for a clinical audit and contained details for over 3000 patients who received treatment over 15 years ago. It was not feasible to trace and contact patients to seek consent after such a long period had elapsed. Many patients will also now be deceased.

The applicants advised that consent was not sought from patients for the use of their data in research when they underwent the SE for chest pain assessment. Originally the database was created to be used by the direct care team only. The applicants are now applying for support to undertake data linkages to NHS Digital held datasets.

The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required so that NHS Digital can undertake the proposed data linkages. This could not be undertaken in any other way.

Justification of identifiers

The CAG queried whether patients dates of death needed to be retained, or if this could be converted to be less identifiable, such as age at death, or survival rate used instead.

‘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 applicants provided details on how the results of the study would be publicised. This related to activity that would be carried out after the study concluded. NHS Digital will apply the National Data Opt-Out.

The CAG agreed that patient notification needed to be undertaken prior to the data linkage taking place, so that patients could dissent to use of their data in the study. Details of this, including postal, email and telephone contacts, needed to be included in the patient notification documents.

Patient and Public Involvement and Engagement

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

The applicants advised that they had consulted with the NIHR Thames Valley and South Midlands Clinical Research Network Patient Ambassadors. Feedback was that it was a worthwhile project. No concerns were raised regarding the use of patients’ historical data without their consent due to the exceptional circumstances.

The CAG noted the patient and public involvement that had been undertaken. Members agreed that further patient and public involvement needed to be undertaken around the change from a database for internal use only to a research database. Discussion of the proposed data linkages also needed to be included.

Applications for access to the Research Database

The CAG agreed that the process to be followed for applications to use the database needed to be provided. This needed to include details on who would review applications to ensure that the request was justified.

Exit strategy

The Data-linkage with NHS-Digital is estimated to take at least 16 weeks. Once the local Electronic Patient Record system (EDM and e-Care) data had been extracted as well as the NHS Digital outcome data received the generated FINESSE research database will be fully anonymised/pseudo-anonymised.

The applicants confirmed that the linkages with the local Electronic Patient Record system and NHS Digital are planned to be a one-off activity and repeat data linkages are not planned.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. An updated and clear data flow diagram needs to be provided. This needs to explain the specific data items needed for linkage and the information returned.

2. Clarify whether the Natural Language Programming will be undertaken internally at Milton Keynes University Hospital NHS Foundation Trust, or if a third-party would be involved.

3. Clarify whether dates of death needed to be retained, or if this could be converted to be less identifiable, such as age at death, or survival rate used instead.

4. Patient notification needed to be undertaken prior to the data linkage taking place, so that patients could dissent to use of their data in the study. Details of the opt-out mechanism, including postal, email and telephone contacts, need to be included in the patient notification documents.

5. Further patient and public involvement needs to be undertaken around the change from a database for internal use only to a research database. Discussion of the proposed data linkages also needs to be included.

6. The process to be followed for applications to use the database needed to be provided. This needs to include details on who would review applications to ensure that the request was justified.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 08 February 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 **2020/21** DSPT reviews for Milton Keynes University Hospital NHS Foundation Trust and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2022).

b. 22/CAG/0032 - A Foucauldian discourse analysis of clinicians' language regarding standards of care in the current socio-political NHS context.

Context

Purpose of application

This application from Surrey and Borders Partnership NHS Foundation Trust set out the purpose of medical research that seeks to investigate the discourses that clinicians draw upon in relation to standards of care when speaking in routine NHS meetings and the implications of the different discourses used.

Research suggests that clinicians working in the NHS experience high pressures to meet service targets and provide 'cost-effective' treatment. Paradoxically, meeting these targets can sometimes feel in conflict with clinicians' person-centred values. Broader issues such as political climate and the government's management of the NHS may play a role in shaping these pressures. However, research exploring these broader issues appears to be absent. The applicants seek to explore how clinicians talk in routine meetings, and specifically, how they may refer to standards of care within the current NHS context. This will require collecting and analysing conversations from various organisational meetings to highlight different ways of talking clinicians may use.

The study findings will be used to develop understanding of the different influences and pressures that NHS clinicians experience.

The applicants will undertake review of video recordings of NHS staff meetings held in the South London and Maudsley NHS Foundation Trust. Confidential patient information is not required to meet the aims of the study, however the researchers may be exposed to confidential patient information when reviewing the recordings.

A recommendation for class 1 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 aged between 18 and 75 years whose care is discussed at Psychology & Psychotherapy Leads Meeting, Covid Meeting, Reflective Practice Meeting, Monthly Service User Involvement Group Meeting,

	Carers Group Meeting, Inpatient Managers Meeting, Performance and Quality Meeting, Referral Meeting. All meetings will take place within South London and Maudsley NHS Foundation Trust between 01/03/2022 – 01/04/2022. Up to 7 meetings would be recorded, but the applicants could not estimate how many patients may be discussed at these meetings.
Data sources	1. Recordings of NHS staff meetings held at South London and Maudsley NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be used for linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information will be used for analysis purposes.

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 application activity was undertaken as part of the applicants PhD qualification. The CAG agreed that the medical purpose and public interest in the application, outside of contributing to the PhD qualification, were unclear. Members asked that

further details were provided on how the results of the study would be used to improve or inform patient care.

Applying organisation

The CAG noted that the application was from the Surrey and Borders Partnership NHS Foundation Trust, however the researcher appeared to be based at Kent and Medway NHS Foundation Trust, where the transcription of the recordings would take place. The CAG requested confirmation that Surrey and Borders Partnership NHS Foundation Trust was the applying organisation.

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 meetings would be recorded, and the recordings transferred to Kent and Medway NHS Foundation Trust for transcription.

The application was focused on the language used by clinicians and the applicant wanted to capture conversations as naturally as possible, which was one reason why the meetings would be recorded, rather than the researcher attending the meeting. Members noted that those taking part in the MDT meetings would be asked to avoid using patient names or other disclosures of confidential patient information. This would impact on the flow of natural conversation.

The CAG requested further justification on why the meetings needed to be recorded, rather than the researcher attending and transcribing during the meeting, so that no recordings needed to be transferred.

- **Feasibility of consent**

The applicants advised that it was not practicable to seek consent as the study is not directly related to service users experience and any patient information mentioned is

likely to be contextual information used by clinicians for service-related decision making. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants do not require access to confidential patient information, however the researchers may be exposed to confidential patient information when undertaking the review of the meeting recordings.

‘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 poster has been devised and will be distributed in buildings where service users may be present, such as hospital wards, the services' waiting rooms and/or reception areas where selected meetings would have normally taken place. The poster described the purpose of the study, benefits of the study, how the data will be processed, and their right to object to their information being used in this study.

The poster describes actions to follow if they wish to discuss the study and/or express their right to object.

Patient Notification Poster will inform service users that they can dissent to the researcher being exposed to their information by contacting the researcher and informing her of this. In this case, the research team would not include that meeting in the study.

The CAG requested that the poster was revised to include an explanation of the SLAM acronym. The opt-out process also needed to be explained and a postal address for queries or requests to opt-out needed to be provided. The poster also needed to explain that video recordings will be made of virtual meetings.

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 Service User Consultant was recruited by the external supervisor's trust. The Consultant has provided feedback on the ethical aspects of the study and will continue to be involved throughout the project.

Representatives from each group of individuals that the study analysis may pertain to, i.e. NHS staff and service users, have been included. The Service User Consultant represents a service user's/carer's perspective. The issue of acceptability of using patient identifiable data in this study without consent was discussed with the Service User Consultant. The Consultant did not identify any other concerns or issues to be addressed regarding using such meetings for the purposes of the study, as patient information will not be traceable back to individual patients.

The applicant advised that the Service User Consultant was paid for their time and was considered to be an equal member of the research team. The scale of the breach in the common law duty of confidentiality was small and the CAG agreed that the activity was proportionate to the scale.

Exit strategy

The meetings will be recorded in Microsoft Teams. The video recordings will be transferred from SLaM to Kent and Medway NHS Foundation Trust. The applicants advised that written transcripts of the meetings would be produced as soon as possible, but no later than within 14 days. The written transcripts will contain no items of confidential patient information. Once the transcription has taken place, the recordings will be deleted.

Time frame for inclusion

The CAG noted that the application stated that meetings taking place within South London and Maudsley NHS Foundation Trust between 01/03/2022 – 01/04/2022 would be recorded. Members asked if the dates had been revised, as the start date had now passed.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Provide further details on how the results of the study will be used to improve or inform patient care, in order to justify the public interest and medical purpose.
2. Provide further justification on why the meetings need to be recorded and transferred to the Kent and Medway Trust for transcription, rather than the researcher travelling to South London and Maudsley NHS Foundation Trust to transcribe the recordings, so that no recordings need to be transferred.
3. The poster needs to be revised as follows;
    a. An explanation of the SLAM acronym needs to be included.
    b. The opt-out process needs to be explained.
    c. A postal address needs to be provided for queries or requests to opt-out.
    d. The poster needs to explain that video recordings will be made of virtual meetings.
4. Clarify if the dates that the recordings will take place have been revised, as the start date given in the application has now passed.
5. Confirm that Surrey and Borders Partnership NHS Foundation Trust is the applying organisation.

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. **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 2020/21 DSPT review for South London and Maudsley NHS Foundation Trust was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 March 2022).

6. Minutes of the meeting held on 10 February 2022

The minutes of the meeting held on 10 February 2022 were not reviewed as an outcome is pending.

7. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date