Minutes of the meeting of the Confidentiality Advisory Group

14 July 2022 via Zoom

Present:

Name	Role
Dr Tony Calland (Chair) MBE	CAG Chair
Dr Patrick Coyle	CAG Vice Chair
Dr Martin Andrew	CAG Member
Mr David Evans	CAG Member
Dr Lorna Fraser	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Umar Sabat	CAG Member
Mrs Diana Robbins	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator
Mr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Theodora Chortara	HRA Approvals Administrator (Observer)
Claudia Bywater	HRA Approvals Manager (Observer)
Sharon Northey	HRA Approvals Manager (Observer)
Zoher Kapacee	HRA Head of Data and AI Programmes (Observer)
Mr Craig Russell	Clinical Project Lead. Consultant Cleft, Plastic and Reconstructive Surgeon, NHS Greater Glasgow and Clyde (attended to answer questions on item 3a only)
Dr Jan van der Meulen	Methodologist, Clinical Effectiveness Unit, RCS. Professor of Clinical Epidemiologist, LSHTM (attended to answer questions on item 3a only)
Ms Jibby Medina	Methodologist, Clinical Effectiveness Unit, RCS. Professor of Clinical Epidemiologist, LSHTM (attended to answer questions on item 3a only)

1. Introduction, apologies and declarations of interest

CAG members Professor Will Bernal, Ms Clare Sanderson and Dr Rachel Knowles gave apologies.

No conflicts of interest were declared.

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 has not yet provided a response to the advice provided by the CAG in relation to the **16 June 2022** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **16 June 2022** meeting applications.

Minutes:

No minutes had been ratified since the previous meeting.

3. Consideration Items – request for National Data Opt-Out Exemption

a. ECC 7-05(h)/2011 - The Cleft Registry and Audit NEtwork (CRANE) Database

Scope of NDO deferral request

This is a request to defer the national data opt out for ECC 7-05(h)_2011, non-research application. Royal College of Surgeons of England undertake this national audit of individuals born with cleft lip and cleft palate. CRANE is commissioned and funded by the National Health Service of England /Improvement (NHSE/NHSI).

CRANE has been supported since 2007 (originally supported by PIAG), and these original applications were superseded by this ECC application. Prior to PIAG, it appears this database was set up in 1998 by the Department of Health, although the paper notes it has been running since 2000. The applicant has consistently submitted annual reviews since supported.

Support is in place for clinical teams to provide the audit team with confidential patient information. The applicants also link data with NHS Digital and the National Pupil Database, although the full scope of support regarding these linkages needs to be clarified.

Refreshed application

Due to the age of the application, and the lack of clarity surrounding both the 's251' support required for the initial data collection, and the following linkages, a new refreshed application to CAG is required, which would supersede ECC 7-05(h)_2011. The applicant is welcome to apply for an NDO exemption as part of that refreshed application, with any further evidence to show any negative outcomes of having had to apply the NDO to the dataset. It was noted by CAG that it might be possible to use National Congenital Anomaly and Rare Disease Registration Service (NCARDS) as a denominator to evidence any missing data, as this data collection operates under Regulation 3, and therefore the NDO does not apply. It was also noted that the registry contains data form Wales and Northern Ireland, where the NDO does not apply, so this data could also be used to model any effect.

Consent

Many of the patients are consented into CRANE, via their parent/care. 90% have either consented or declined, and of those 90%, 98% of the decisions were consent. Therefore for these individuals, consent would override the NDO, and the NDO should not be applied by the direct care team when submitting registry data, or by NHS Digital regarding linked outcomes. The applicants reasoned that there was an issue at NHS Digital where 2 differing legal bases can't be used in the same application for data, and therefore the NDO has to be applied to the whole of the CRANE cohort, regardless of whether the legal basis for a patient is consent or 's251'. However, the Confidentiality Advice Team (CAT) have clarified with NHS Digital that it is now possible to apply 2 separate legal bases to the same application for data, and therefore those who have consented should not have the NDO applied.

The exemption of the NDO should therefore only apply to the remaining 10% of CRANE participants.

There was some confusion in the meeting regarding the difference between consent, a decline of consent, opting out, and patient notification materials (which are different to patient consent materials). As the applicants ask the clinical team to consent early on in the patients treatment, there is a small gap between the timepoint they could be included in the register, and the timepoint they are offered to consent into it, at which point they can decline, or consent. The time period before this, when they are included in the register under 's251' support, does not appear to have any patient notification available to the general cohort, which offers an opt out option of this processing of their confidential patient information, prior to being offered the chance to consent into it. This is something that can be clarified during the resubmission process, and the applicant is advised to liaise with the CAT for advice on this point.

It was therefore noted by the CAG that these 10% of individuals are not actually approached at all for consent, and therefore it appears they do not have an opt out mechanism at all. Therefore the Members felt it was very important that the NDO still apply to this subset, as this would be the only opportunity for opt out.

Confidentiality Advisory Group advice

This request was considered by Members with the provided rationale predominantly relying on patient safety, bias, and technical issues. However CAG agreed that the rationale provided was not sufficient to override patients' objections for their data to be shared for secondary purposes under Regulation 5 support.

1. Deferral rationale: patient safety

Members considered the paper provided by the applicants, where the patient safety reasoning provided was that to ensure and improve patient safety, applicants must have a robust evidence-base evaluating the care received, and the loss of a handful of records also affects CRANEs ability to detect whether or not a NHS cleft service is an outlier. This would be adversely impacted by missing data that would result from applying the NDO.

If the applicant had 100% case ascertainment, these arguments surrounding outlier detection would hold more weight. However, the applicant reported that case ascertainment is estimated at **95%**. With this in mind, that the applicant is already missing approximately **40-50** patients annually. Given that the NDO already does not apply to the 90% consented cohort, in relation to applying the NDO to the remaining **10%** of cases, this would number **2 or 3** individuals a year. Therefore the CAG could not understand how applying the NDO would have any effect, as an additional **2 or 3** cases missing when the applicant is already missing **40 or 50** cases would not appear to cause any exceptional harm to patient safety.

Given the lack of evidence and justification on direct impact on patient safety, members agreed that they could not override patient rights to disapply the NDO.

The applicant did describe in the meeting a potential geographical distribution issue regarding NDO application, as most services have high consent rates as a whole, However one service in London did not consent any individual for 3 years. These services will still be able to include people to CRANE using 's251', however if the NDO was applied to these services, but not to those services where the consent rates were high, the data could become highly skewed, and this could have commissioning repercussions, as it may be these very same services that are functioning poorly. This argument does suggest how harm could be caused, but the Members agreed that on its own this did not meet the threshold required to defer the NDO.

2. Deferral rationale: Introduction of bias

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDO will introduce a biased sampling frame due to non-random opt-out patterns.

The applicant confirmed that the NDO would be applied only to live born children rather than their mothers, or to any unborn children.

In the paper, the applicant reasons that applying the NDO could reduce CRANE by about **3%**, based on estimates for children ages 0-19. These estimates appear to more surrounding the loss of linked outcome data rather than inclusion into CRANE initially, as it was unclear what evidence there is surrounding NDO rates for newborns. CRANE follows up children until they are 16, so the NDO application will affect linkage more than initial data collection. As per the above reasoning, the CAG were agreed that the bias arguments provided do not hold any weight, because the applicant is already missing **40-50** of their cases, and the CAG did not feel that an additional **3% (of 10%** of the cohort) of missing cases was justification enough to override patient rights in order to disapply the NDO. The applicant is welcome to provide further evidence of rates of newborn opt out rates when this evidence is forthcoming, at the time of resubmission of their full application to CAG.

Additionally it was noted that it might be possible as time goes on, to consent these individuals and therefore the NDO would not apply.

3. Deferral rationale: technical impacts

The applicants indicated that applying the NDO would generate additional workload for hospital teams, which could lead to disengagement across the audits, either through delayed entry, reduced entry or complete disengagement from data entry due to the increased burden. The applicants also reason that the systems that healthcare services have available to check whether patients have opted out are built on a file upload system, which is incompatible with the direct data entry that is adopted by all cleft services contributing to the CRANE Database. This is likely to cause disruption to data entry and may result in significant additional bureaucracy for cleft services causing records not being entered into the CRANE Database.

Whilst the CAG noted the potential technical challenges articulated in the paper, it was also noted there had been a long lead-in period for implementation of the NDO. CAG understood that the NHS had 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 provided sufficient reasonable justification to disapply the NDO.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the NDO, is not taken lightly, and that the Group is only minded to do so in exceptional circumstances. The CAG recommendation is based on the documentation provided, and discussion with the applicant during the meeting. Given members felt a sufficient rationale as to why patient safety would be impacted by the NDO was not provided, CAG recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request to be rejected.

4. New Applications – SDDR Pilot

a. 22/CAG/0104 - Peripheral arterial disease, High blood pressure and Aneurysm Screening Trial (PHAST)

Context

Purpose of application

This application from the University of Leicester set out the purpose of medical research that seeks to investigate whether screening men for peripheral arterial disease and high blood pressure when screening for abdominal aortic aneurysm is effective.

People with peripheral arterial disease (PAD) (furred up blood vessels in the legs) and high blood pressure (BP) are at high risk of heart attacks, strokes and other cardiovascular problems. 30% to 40% of people over the age of 65 have PAD and/or high BP, and at least two-thirds don't know that they have these conditions. Men aged 65 are invited for an ultrasound scan to check of abdominal aortic aneurysm (AAA). Attendance for AAA screening is good, with 8 out of 10 men attending. The AAA screening also presents an opportunity to screen for PAD and/or high BP with little extra effort. The trial will be undertaken to provide evidence for the UK National Screening Committee to make a recommendation for or against screening men for PAD and high BP when screening for AAA.

Support is sought for Work Package 3 (WP3), a cluster crossover trial of combined PAD, high BP and AAA screening vs AAA screening. Over 2 screening years, AAA screening units will deliver 1 year of AAA+PAD+BP screening and 1 year of AAA screening in a randomised order. Confidential patient information will be disclosed from the NHS Screening Programmes to NHS Digital for linkage to HES and mortality data. The data will then be disclosed to the research team at the University of Leicester in a pseudonymised format.

Confidential patient information would be disclosed at two time points. The first, from 31 March 2027 will be to establish the linkage process and obtain preliminary data. This first dissemination will allow the research team to set up data processing algorithms and an analysis pipeline in preparation for the second dissemination after 31 March 28. This approach is because there is a short timescale from the end of the trial follow-up period (31 March 28) to the point where outcome reporting needs to be complete (the end of the funding period). Confidential patient information will

therefore be disclosed from 31 March 2027 due to the initial linkage but will not be kept for research outputs and will be deleted when the analysis processes/pipeline has been established. After 31 March 2028 the second dissemination will be retained and used for research 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	Men invited to participate in the AAA screening programme between 01 April 2023 – 31 March 2024, and 01 April 2024 and 31 March 2025.
Data sources	1. Patient information from the NHS Screening Programme 2. HES and mortality data from NHS Digital
Identifiers required for linkage purposes	1. Date of birth 2. NHS Number
Identifiers required for analysis purposes	1. Ethnicity 2. AAA screening programme unit

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.

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 had conducted a feasibility study, PHAST-F, where consent had been sought from patients. This had slowed AAA screening clinics while consent was sought. The impact of this was significant at sites participating in the feasibility study, with appointments delayed, and sometimes a bottleneck effect of men having to wait longer for their appointment as the time required for the consent process was unpredictable. The applicants advised that one of the reasons that the NHS AAA screening programme was successful was the high-throughput nature. The effect of men having to wait longer for their appointments would also impact on the number of patients who could be approached. Staff may also need to suspend research recruitment in order to recover the clinic schedule, meaning fewer patients would be approached.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for NHS Digital to conduct linkages to HES and mortality data.

'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 layered approach to patient notification would be adopted. Posters had been produced for display in NHS premises. Information would also be disseminated by relevant charities and support groups. Information would be made available on the University of Leicester's website. A research leaflet will be sent alongside the invitation for screening, which will provide information about the website, who to contact for a paper patient information sheet, if this is requested, and information on how to opt-out. Verbal reminders would also be given when patients attend for screening.

Patients have until the 31st March 2028 to opt-out. The patient information sheet contained email and postal contacts to request opt-out. Patients can withdraw their data after 01 April 2028. Withdrawal will no longer be possible once data has been transferred to the University of Leicester and is therefore effectively anonymous at the institutional level with there being no possible mechanism for the researchers to identify people.

The applicants advised that postal, email and telephone contacts can be included in the patient notification materials, however the applicants expressed concerns over using a postal address for opt-out in case the request did not arrive.

The CAG agreed that the patient information sheet provided a good explanation of the study. However, the poster required revision to ensure the language used is suitable for a lay audience. Members asked that the poster was reviewed by a PPI group, or other appropriate group of patients. The revised poster was to be provided to CAG within 2 months of the issuing of this outcome letter.

The CAG agreed that the National Data Opt-Out needed to be applied.

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 PPI group, comprised of 10-12 patients aged 60-69 years, and a wider group of 30 patients have been consulted. Male members of the groups have lived experience of AAA screening.

The applicants also consulted with closed-member, national and international AAA, PAD, and more general cardiovascular theme Facebook groups.

Views on the study documentation and research design, including the recruitment process, were sought.

The main focus of the PPI group discussions were to develop the survey to generate wider public opinion rather than relying on the local PPI group to determine the acceptability of the approach. The use of confidential patient data without consent were discussed with the PPI group at length. Discussions surrounding consent models were undertaken early in PPI group discussions and later enabled the development of the survey.

The applicants advised that notes from the PPI meetings can be provided if requested.

Exit strategy

The dataset used for analysis will be anonymised. The screening programmes will hold the pseudonymised codes which the researchers will not have access to. NHS Digital will delete the identifiers following receipt and confirmation from the University of Leicester that transfer and data linkage is complete.

The screening programme will delete the pseudonymisation key following completion of the research and following notification from the University of Leicester that this research has been completed.

University researchers will not be able to reidentify patients from the dataset held at the University, making the dataset disclosed to the University effectively anonymised.

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. The poster needs to be reviewed by a PPI group, or other appropriate group of patients and the revised poster provided to CAG within 2 months of the issuing of this outcome letter.

2. Confirmation is to be provided that the National Data Opt-Out will be applied.

5. New Applications

a. 22/CAG/0099 - ABATED - Automated Brain Image Analysis for Timely and Equitable Dementia Diagnosis

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research that seeks to investigate whether a new artificial intelligence technology can be used to support more timely, accurate and equitable diagnosis of dementia within memory clinics.

Patients are referred to memory clinics if dementia is suspected. However, other conditions may cause memory difficulty and it is often difficult to know whether a patient has dementia when first assessed. This uncertain situation is referred to as “mild cognitive disorder” (MCD). Currently, the only way to establish a diagnosis of dementia is to follow-up patients over time to see if their condition worsens. This follow-up is often not available, and patients are discharged without a clear diagnosis. Brain scans are routinely used in memory clinic assessments as dementia causes shrinking of the brain. However, when humans interpret the scans, this only provides a clear diagnosis when the dementia is quite advanced. The applicants seek to test computerised interpretation of brain scans.

Two cohorts of patients with MCD, a retrospective cohort and a prospective cohort, will be identified from East London Memory Clinics. Patients in the prospective cohort will be identified from attendance at formulation meetings and MCD groups at East London NHS Foundation Trust (ELFT) Memory Clinics. Retrospective patients will be identified via electronic patient records at ELFT. Support is required to allow members of the research team, working alongside members of the direct care team, to identify patients suitable for inclusion in the retrospective cohort and link records held in ELFT. The core clinical dataset is recorded in a pseudonymised CRF. Patients NHS number will be

deleted after linkage to scans to make CRF anonymous before transfer to the Queen Mary University of London for 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	1200 patients: Prospective cohort of 200 patients who received an MCD diagnosis (outside the scope of support). Retrospective cohort of 1000 patients who had an initial diagnosis of MCD. The prospective cohort will include patients attending memory clinic between 01/06/2022 and 21/07/2023, and the retrospective cohort will include patients attending memory clinics from 01/01/2003.
Data sources	1. Electronic patient records at East London NHS Foundation Trust 2. Electronic patient records at Barts Health NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	1. Gender 2. Ethnicity 3. Age

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The applicants stated that support under the Regulations was required for patients in the retrospective cohort.

The CAG noted that the answer to Q26 of the IRAS form described that prospective participants will be identified through attendance at formulation meetings and MCD groups at ELFT Memory Clinics.

Members requested clarification on whether members of the research team would attend the formulation meetings and MCD groups. If so, support under the Regulations will be needed to provide a legal basis for any incidental disclosures of confidential patient information that may be made during these meetings. If another legal basis is in place for these disclosures, this needed to be explained.

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**

Consent will be sought for the prospective cohort. However, it will not be possible to seek consent from patients in the retrospective cohort who are no longer attending the memory clinics. Many patients will have died or be unable to consent due to dementia.

- **Use of anonymised/pseudonymised data**

Researchers require access to confidential patient information in order to carry out data linkage for eligible patients to records within ELFT. The CAG agreed that the retrospective data collection could not be conducted 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 study will be publicised via the applicants PPI work with community groups in East London, and they will provide specific study information on the East London NHS Foundation Trust website.

When publicising the study, the applicants will provide contact details for the research office at East London NHS Foundation Trust to allow patients to opt out of this study locally without needing to contact the study team directly.

The applicants advised that, as the memory clinics involved in the study only see people at initial diagnosis, so patients eligible for the retrospective cohort will no longer be attending the clinic by definition, the patient notification strategy cannot include providing information through the clinic. The CAG noted this, but also noted that many patients would still be accessing services, even if they were not attending the MCD clinics. Members asked that further efforts were made to promote the study, such as placing posters in relevant services and online.

The National Data Opt-Out will be applied.

Patient and Public Involvement and Engagement

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

The applicants have partnered with patient-facing organisations, including the Alzheimer’s Society, the National Dementia Action Alliance and Alzheimer’s Research UK. Views were sought around dementia research priorities and the type of research they would be prepared to participate in. Patient and public involvement was also undertaken around recruitment strategies.

Two lay members will be appointed to the study steering committee. The lay members will review the study documentation and assist with the planning of focus groups.

The applicants plan to hold three PPI focus groups, one in each year of the project. The first focus group will plan the project, including seeking views of the design and recruitment strategy. The second focus group will address understanding of dementia diagnosis. The third focus group will seek input on the dissemination and communication of the project results.

The applicants have also conducted PPI work in a related study and consultation with the Hackney Caribbean Elderly Organisation and Alzheimer's Research UK PPI network regarding this study specifically. Those consulted were in favour of the project.

The CAG agreed that it was not clear whether the patient and public involvement conducted had included seeking views around the specific issue of use of confidential patient information without consent. Members asked that feedback from any discussions around this specific issue were provided. If this issue had not been discussed, further patient and public involvement needed to be undertaken.

Exit strategy

The applicants advised that confidential patient information would be retained for only as long as it takes to link the clinical and imaging data. NHS number will be recorded by researchers to link the two data sources, and this will be deleted prior to transfer of data to Queen Mary University of London. Support is required up until the projected end of the project, 31 May 2025.

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. Clarify whether members of the research team will attend the formulation meetings and MCD groups.

    a. If so, support under the Regulations will be needed to provide a legal basis for any incidental disclosures of confidential patient information that may be made during these meetings.

    b. If another legal basis is in place for these disclosures, this needs to be explained.

2. Feedback from any patient and public involvement discussions around the specific issue of use of confidential patient information without consent need to be provided. If this issue has not been discussed, further patient and public involvement needs to be undertaken and feedback provided to the CAG.

3. Confirm that further efforts will be made to promote the study, such as placing posters in relevant services and online.

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:** 08 June 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:**

3. The NHS Digital **202021** DSPT reviews for **East London NHS Foundation Trust and Bart's Health NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 July 2022).

b. XX/CAG/XXXX – Cancer Patient Experience Survey 2022

Context

Purpose of application

This application from NHS England and Picker Institute Europe set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2022-2024.

The applicants seek to work with NHS trusts to collect and use data for approximately 125,000 cancer patients to carry out the Cancer Patient Experience Surveys for 2022, 2023 and 2024. The applicants also seek to collect email and mobile telephone numbers for the first time, in order to explore the digital potential for the survey. Survey fieldwork will be conducted annually. The survey methodology, data transfer arrangements and consent issues are the same as previous iterations of the study. The questionnaire, developed with engagement from a variety of stakeholders including patients in 2021, will be used unchanged for 2022.

The results of the survey will be used to enable comparisons between Trusts, for commissioners, providers and patients (all of whom could access the published results), would allow for monitoring of improvements in services, drive further improvements, and provide NHS England with an up-to-date overview of cancer patient experience across England.

Each participating NHS trusts will extract confidential patient information required for the survey and disclose this to Picker Institute Europe. Picker Institute Europe then check that patients are still living and that the sampling guidance has been followed. Picker Institute Europe and Greens Ltd then mail the initial questionnaires and reminders, if required, to participants. Patient participation then proceeds on a consented basis.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All adult patients (aged 16 and over), with a primary diagnosis of cancer, who have been admitted to hospital as inpatients for cancer related treatment, or who were seen as day case patients for cancer related treatment, and have been discharged between 1st April and 30th June of the survey year will be included in the survey (for example the 2022 survey will include those discharged between 1st April 2022 and 30th June 2022)
Data sources	1. Electronic patient records at participating Trusts in England
Identifiers required for linkage purposes	1. Date of birth 2. NHS number 3. Name 4. Sex 5. Address 6. Postcode – unit level 7. Email address 8. Mobile telephone number 9. Site treated at 10. Treating NHS trust
Identifiers required for analysis purposes	1. Postcode 2. ICD 10/11 code 3. Main speciality code

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.

Scope

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

Practicable alternatives

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

- **Minimising flows of identifiable information**

The applicants sought support to collect patients mobile telephone numbers and email addresses, however there were no plans to use these details yet to send or follow-up the surveys. Members asked whether these data items needed to be collected at this point or if the trusts could instead record whether the items of information were available.

- **Feasibility of consent**

The applicants presented a number of arguments as to why consent was not feasible. These arguments included; the potential duplication of contact with patients, the burden on clinicians and patients and the possible introduction of bias in the patient sample. The CAG agreed that consent was not feasible.

Use of anonymised/pseudonymised data

Patient names and addresses are required to enable the surveys to be sent out. Checks that patients are still alive also need to be carried out before sending the surveys. The CAG agreed that the application activity could not be conducted 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.

Patients consent to taking part in the survey by returning questionnaires and decline by not returning them, or by returning blank questionnaires. Confidentiality information is presented to patients in both the covering letter and questionnaire front cover. The information states that by completing the questionnaire respondents are consenting to take part in the survey and to the use of their information.

For the 2022 survey, NHS England have provided all participating trusts with fair processing information. Trusts have been made aware that the poster and leaflet can be displayed on digital screens where available. The design of the poster and leaflet was made suitable for display on digital screens, and trusts have been able to request them in alternative languages to English. The purpose of this material is to publicise the survey to patients ahead of fieldwork and provide people who are eligible for the survey with a mechanism to opt-out of the survey in advance, should they wish to do so.

The survey covering letter, first and second reminder letter, and questionnaire front cover will emphasise that participation in the survey is entirely voluntary. They will provide details about the basis upon which the information will be held and processed and provide details of how to opt out of the survey.

Information relating to individuals who have informed their trust that they would like to opt-out of the survey ahead of the sample being drawn and sent to Picker will be excluded from the sample.

The CAG noted that the survey was exempt from application of the National Data Opt-Out and asked that this exemption was explained in the patient notification materials. This needed to include an explanation that the exemption had not been granted by CAG, but via policy consideration. A link to the information around the exemption on the NHS Digital website should be included on the patient notification materials.

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.

NHS England commissioned Picker to carry out a review of the CPES in 2018. As part of this review two focus groups were carried out with patients in London and Manchester. The focus groups provided patients with the opportunity to comment on

a range of aspects relating to the CPES. The findings of the review were published in August 2018 and discussed at the Cancer Patient Experience Advisory Group (CPEAG) meeting of July 2018. In light of the review's findings and reflecting a consensus among CPEAG members, the 2018 CPES survey went ahead with only minor changes / developments to maintain the comparability of the 2018 survey with those of previous years.

In 2020/21, the CPEAG supported the development of a new questionnaire for use in 2021. This questionnaire remains unchanged for 2022. During 2021/22 NHS England established a new Representation Sub-group of the advisory group which is made up of patients from a wide range of demographic groups, with the aim of helping us to understand the characteristics of those less likely to respond to the survey and to work with the survey provider to develop targeted initiatives to try to encourage participation in the survey from those under-represented groups. The Representation Sub-Group has already provided advice on how the information for patients could be improved.

The CAG agreed that it was unclear whether any patient any public involvement had been carried out since 2018. Members asked that further patient and public involvement was carried out, including discussion of the collection of patient mobile telephone numbers and email addresses.

Exit strategy

The confidential patient information used to identify patients to take part in the survey and to analyse the results will be kept where patients consent to this.

Those patients' details will be held securely and in accordance with the UK GDPR and the need for retention will be reviewed after 20 years. This includes the right for those patients to have their personal data erased. The CAG raised no queries under this heading.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The first three conditions below need to be reported back on within 3 months of the issuing of this outcome letter:

1. Confirm whether patients mobile telephone numbers and email addresses need to be collected, or if the trusts could instead record whether or not the items of information were available.

2. The National Data Opt-Out exemption needs to be explained in the patient notification materials. This needs to include an explanation that the exemption had not been granted by CAG, but via policy consideration. A link to the information around the exemption on the NHS Digital website also needs to be included on the patient notification materials.

3. Further patient and public involvement needs to be carried out, including discussion of the collection of patient mobile telephone numbers and email addresses.

4. 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 NHS England & NHS Improvement, Picker Institute Europe and Greens Ltd were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 July 2022).

c. 22/CAG/0103 - Supporting the NHS Long Term Plan: An evaluation of the implementation and impact of NHS-funded tobacco dependence services

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research that seeks to explore how the new NHS-funded tobacco dependence services are delivered in acute hospital, mental health inpatient and maternity settings, and the service's impact on health and care.

NHS-funded tobacco dependence services are delivered in England as part of the NHS Long Term Plan. The applicants seek to evaluate how these services are delivered in five geographical regions, the North-East and North Cumbria, Greater Manchester, Yorkshire and Humber, West and West Midlands.

The applicants will survey NHS staff and service users. Hospital records will be accessed to determine the number of smokers who have been offered and used the service and to calculate the cost of providing the service. Support is required for Work Packages B and C, where confidential patient information will be extracted from patient records by members of the direct care team and by members of the research team. The dataset will be transferred to Newcastle University and the pseudonymisation key held

by the participating trusts, making the dataset at Newcastle University effectively anonymised.

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 aged 18 years and over who: • Identified as smokers aged 18 years or over where length of stay in acute settings is greater than one day • Identified as smokers accessing maternity services • Identified as smokers accessing mental health (inpatient) services The applicants estimate that around 180,000 patients will be included under support.
Data sources	1. Electronic patient records at: • Manchester University NHS Foundation Trust • Gateshead Health NHS Foundation Trust • Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust • Northumbria Healthcare NHS Foundation Trust • South Tyneside and Sunderland NHS Foundation Trust • Tees, Esk and Wear Valleys NHS Foundation Trust • Sandwell and West Birmingham Hospitals NHS Trust • Gloucestershire Hospitals NHS Foundation Trust

	• The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. Ethnicity 4. Age

Confidentiality Advisory Group advice

Public interest

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

Scope

The CAG agreed that the scope of the support required was not clear. The applicants had stated that only aggregate data would be obtained from HES and no linkage to HES patient level data would be conducted. It was unclear how the aggregate data would provide useful information for the health economics aspect and the CAG asked that further details were provided on how this aggregate data would be used.

The applicants had advised that support was required as, while staff in the participating NHS trusts will undertake the data extraction, they may require assistance from research staff. The study protocol states that research staff will undertake the data extraction. The CAG members requested clarification on who would undertake the data extraction.

Patients NHS numbers and postcodes were required for data linkage, but the planned data linkages had not been clearly described. The CAG requested clarification on whether the data linkages referred to were linkages to data held within the participating

trusts or if any linkages to other datasets, such as HES patient-level data, were planned.

If patient identifiers were only needed to collect follow-up data, the CAG queried whether other ways of conducting the data linkages could be explored, such as application of a study ID number. Members agreed that further justification needed to be given on why the research team required access to confidential patient information and why anonymised data only could not be used.

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 data items required for analysis were unclear. The applicants described that anonymised data only was used, however full postcode would be collected and used for analysis. The CAG queried whether the postcodes could be converted to Lower Super Output Area (LSOA), and then the full postcodes could be deleted.

- **Feasibility of consent**

The applicants advised that consent was not feasible due to the potential size of the cohort. The CAG agreed that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The researchers require access to confidential patient information in order to identify eligible patients and extract a pseudonymised dataset. The dataset will be transferred to Newcastle University and the pseudonymisation key held by the participating trusts, making the dataset at Newcastle University effectively anonymised. As noted above, the CAG was not satisfied that the application activity required that the researchers processed confidential patient information and queried why anonymised data could not be used.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster was provided. Patients wishing to opt-out are advised to contact their local trust. Space was included on the poster for postal, telephone and email contacts. The programme manager email address was provided, should patients have complaints.

Further methods of patient notification also needed to be considered, such as adopting a layered approach, making information available online as well as leaflets and posters.

The CAG advised that the National Data Opt-Out needed to be applied. The National Data Opt-Out needed to be explained on the study posters.

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 study proposed was reviewed by an independent public advisory panel. A dedicated Public Advisory Panel (PAG) have been put together. This is comprised of 4 members who have provided regular feedback on the study design and protocols. This included feedback on recruitment and consent, and the data collection materials.

The PAG also discussed the submission of an application to CAG and determined that a CAG application was the most appropriate option.

The CAG noted that the patient and public involvement undertaken was small in scale. The participants in the patient and public involvement had provided useful comments, but it was not clear whether these comments had been applied to the application. The CAG asked that further patient and public involvement was conducted with a larger group. This further activity needed to include a review of the patient notification materials and the asking of an open question on the use of confidential patient information without consent.

Exit strategy

The linkage process is anticipated to last 12 months. Trusts will send data to the research team on a monthly basis over a 10-month period, plus a 2-month buffer period.

The pseudonymisation key will be retained by the participating trusts and researchers at Newcastle University will not be able to access it.

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. Provide further details on how the aggregate data would be used to provide information for the health economics aspect of the study.

2. Provide clarification on who will undertake the data extraction, members of the research team or members of the direct care team.

3. Provide clarification on whether the data linkages referred to in the application are linkages to data held within the participating trusts or if any linkages to other datasets, such as HES patient-level data, are planned.

4. If patient identifiers are only needed to collect follow-up data, please advise whether other ways of conducting the data linkages could be implemented, such as application of a study ID number.

5. Further justification needs to be given on why the research team require access to confidential patient information and why anonymised data only cannot be used.

6. Advise whether the postcodes can be converted to Lower Super Output Area (LSOA), and then the full postcodes deleted.

7. Confirm that the National Data Opt-Out will be applied.

8. Further methods of patient notification also need to be considered, such as adopting a layered approach, making information available online as well as leaflets and posters. A communications plan and any additional documents are to be provided to the CAG for review. The National Data Opt-Out also needs to be explained on the patient notification materials.

9. Further patient and public involvement needs to be conducted with a larger group. This further activity needs to include a review of the patient notification materials and the asking of an open question on the use of confidential patient information without consent.

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.

Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

6. Any other business

No other business was raised.

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

Signed – Chair		Date
Dr Tony Calland MBE, CAG Chair, and Dr Patrick Coyle, CAG Vice-Chair		*22 September 2022*
Signed – Confidentiality Advice Team		Date
Ms Kathleen Cassidy, HRA Confidentiality Advisor		*02 August 2022*