# Minutes of the meeting of the Confidentiality Advisory Group

**27 April 2023 via Zoom**

## Present:

| Name | Role |
|---|---|
| Dr Patrick Coyle | Vice Chair |
| Dr Murat Soncul | Alternative Vice Chair |
| Mr David Evans | CAG Member |
| Dr Malcolm Booth | CAG Member |
| Mr Anthony Kane | CAG Member |
| Professor Sara Randall | CAG Member |
| Mr Dan Roulstone | CAG Member |
| Mrs Sarah Palmer-Edwards | CAG Member |
| Dr Joanne Bailey | CAG Member |
| Dr Pauline Lyseight-Jones | CAG Member |

## Also in attendance:

| Name | Position (or reason for attending) |
|---|---|
| Ms Katy Cassidy | HRA Confidentiality Advisor |
| Mr Will Lyse | HRA Approvals Administrator |
| Ms Emma Marshall | HRA Confidentiality Specialist |
| Mr Paul Mills | HRA Confidentiality Advice Service Manager |
| Mr Dayheem Sedighi | HRA Approvals Administrator |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |
| Mr Andy Bush | REC Member (Internal Observer) |
| Mr Jim Elliott | HRA Public Involvement Lead (External Observer) |
| Ms Megan Leach | Public governor of Essex Partnership foundation trust (External Observer) |
| Professor Keith Hawton | Chief Investigator - (attended for discussion of item 3a only) |
| Galit Geulayov | Applicant - (attended for discussion of item 3a only) |
| David Walliker | Applicant - (attended for discussion of item 4a only) |
| Kerrie Woods | Applicant - (attended for discussion of item 4a only) |
| Jim Davies | Applicant - (attended for discussion of item 4a only) |

## 1. Introduction, apologies and declarations of interest

The following conflicts of interest were declared;

- COI – CAG Member Mr David Evans has two conflicts of interest with items 4a and 4b, and did not participate in the development of the recommendation provided by the CAG.

## 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 **23 March 2023** meeting applications.

### Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **23 March 2023** meeting applications.

### Minutes:

The minutes of the following meetings have been ratified and published on the website:

- Full CAG Minutes – 23 March 2023
- PS CAG Minutes – 17 March 2023
- PS CAG Minutes – 31 March 2023

## 3. Consideration Items - Requests for National Data Opt-Out exemption.

### a. PIAG 2-07 (b) 2004 – The Oxford Monitoring System for Attempted Suicide (OSMAS)

#### Scope of NDOO exemption request

This is a request to defer the national data opt out for PIAG 2-07(b)/2004. The Department of Health and Social Care fund the University of Oxford, to undertake The Oxford Monitoring System for Attempted Suicide.

OMSAS has been collecting data since 1976, and was supported under section 60 in 2004, with submission of annual reviews since that time. The 2022 Annual review was pending at the time of CAG review, however has been submitted since.

OSMAS has existing support to collect confidential patient information on patients who deliberately self-harmed and presented to the John Radcliffe hospital in Oxford, from 1976 onwards. It appears support is also in place to link to NHS England (previously NHS Digital) data to receive mortality outcomes.

## Research

It was noted that this is a research application, however it appears there are potentially both research and non-research purposes. This is an historic application, receiving section 60 support prior to any distinction made between research and non-research applications to PIAG. The CAG were in agreement there are clear non-research elements to this application, which had an impact on clinical services, noting that the main objective stated in the application to REC is detailed as '*to investigate different aspects of Deliberate Self Harm (DSH) that will inform and contribute to the evaluation of national strategies on DSH and suicide prevention'.* This purpose aligns with the non-research purpose of clinical audit. The purpose as described in this NDOO exemption application is to improve patient care and outcomes and also public health, through providing information to policy makers and agencies (e.g. DHSC, NICE, MHRA) by collecting comprehensive data via the monitoring system for attempted suicide. This described purpose appears to also reflect non-research aims.

The Members were clear that they did not wish to request the applicant make a new non-research application prior to the NDOO exemption being supported, as this could have an impact on patient safety. However the applicant is provided conditional support for a time limited period of 6 months, to allow for the applicant to make a clear distinction between research purposes and non-research purposes, make a new non-research application to CAG, and a new refreshed research application to CAG, if one is required. The applicants are advised to talk to the Confidentiality Advice Team (CAT) for advice if needed. The HRA has a tool to help define if your application is research or non-research; Is my study research? (hra-decisiontools.org.uk). 's251' support can be provided for research purposes (usually medical research), or non-research purposes, relating to the management of Health and Social Care, however the latter does not require review by a Research Ethics Committee. The CAG were clear they did not support

the non-application of the NDOO for research purposes, but this will be clearly demarked at the point of refreshed applications.

## Refreshed application

The exact scope of support is difficult to gather, due to the age of the application. The applicant is therefore requested to make a new refreshed non-research application to CAG, in lieu of the next annual review, to clarify the scope, as well as clarifying the purposes (which are described in the section above). This will be considered at a full CAG meeting at that time. The annual review is due 17 November annually, therefore the new non-research application should be submitted by 17th November 2023. As per research section of this letter, the applicant is to determine if a research application to CAG is also required, if data collected under 's251' support is used for research purposes also. The CAG were however clear, that the application presented to the Group regarding this NDOO deferral request, seemed to describe clear non-research purposes.

## Confidentiality Advisory Group advice

As part of the request, the applicant provided three core reasons why application of the NDOO would impact the running of OSMAS.

1. Patient safety – loss of data will reduce the ability to detect signals of concern to patient safety, and damage care for all individuals who present to hospital emergency departments for self-harm.
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, and will further exacerbate health inequalities, as the cohort is often a marginalised group.
3. Technical impacts – application of the NDOO would generate additional workload for hospital teams, which may potentially harm good relationships with organisations.

1. <u>Deferral rationale: patient safety</u>

The paper set out a strong argument detailing the potential impacts of a substantial overall loss of information on patient safety. OSMAS provides evidence and recommendations that help shape policy and inform national guidelines for the treatment and care of people who self-harm. Study outputs, are a key evidence base for work in self-harm and suicide prevention. Applicants rely on complete case ascertainment in order to provide this evidence and make recommendations.

Applicants are concerned that applying the NDOO to the OSMAS data collection will introduce bias that could potentially damage the future care and safety of people who self-harm, with a disproportionate bias in relation to particularly vulnerable groups.

NHS England and NHS Improvement has an aim to reduce health inequalities, with a focus on: people with severe mental illness, people in deprived areas, ethnic minority communities, people with multi-morbidities, protected characteristic groups, people experiencing homelessness, drug and alcohol dependence, vulnerable migrants, and other socially excluded groups. Whilst there is little information about opt-out rates in specific vulnerable communities, the applicants reason that it is feasible that many of these groups would have high opt-out rates. For example, the National Data Opt-Out Equality Impact Assessment identified that rates were likely to be high among ethnic minorities and people with lower incomes – both groups where suicide prevention is a particular concern. The National Data Opt-Out Equality Impact Assessment also cites the transgender community as historically having a distrust of health services (e.g. due to perceived barriers being placed in the way of accessing health care), and suggest that this may lead to higher opt-out rates. Data being skewed in this way has the potential to harm public health rather than improve it, by worsening existing inequalities.

Higher NDOO rates will reduce the potential for identifying and learning from self-harm presentations from members of these groups. Being part of one of these vulnerable groups, may indicate an increased risk of self-harm. If those individuals with an increased risk of self-harm are also more likely to apply an NDOO, variation in the impact of the NDOO means that OSMAS are not collecting data about those individuals who will be most affected, and this would undermine the safety of current patient care, for those who have or have not opted out.

Signal changes are not large, and if any information was missed, this could prevent the ability of OSMAS to provide effective outputs. For example, any changes over time in self-harm in smaller sub-groups (e.g., ethnic minority groups, LGBTQ+) may be hidden, and inhibit the ability of OSMAS to identify new factors and emerging trends (e.g., new methods of self-harm), which applicants would otherwise seek to make clinicians, health services, and policy makers aware of. In the paper provided, applicants provided evidence from a 2021 paper looking at self-harm in children and young people from ethnic minority backgrounds. A more rapid increase in self-harm was detected over time in people from ethnic minority

groups than in age-equivalent white people. The numbers included in these analyses were small for the ethnic minority groups. These increases could have been masked by applying the NDOO. Even minimal amounts of lost data due to NDOO may impact the outcome of such analyses, leading to incorrect conclusions and recommendations, and worsening existing health inequalities.

The applicants explained in their paper that self-harm is very strongly associated with suicide risk - people who present to hospital following self-harm are more than 50 times more likely to go on to die by suicide compared to people in the general population. Therefore it is very important that individuals are provided with the recommended care and interventions to prevent suicide. If inclusion into OSMAS was reduced by applying the NDOO by 5-10%, this would potentially overestimate the effectiveness of some service changes, and possibly even suggest that some service changes were effective when they were not, and could impair the ability of OSMAS to identify if interventions are working, leading to possible preventable suicides in individuals treated in the future, both those who have opted out or those who have not opted out.

Members were supportive of exempting the NDOO, due to the strong patient safety impact, and the impact on health inequalities.

2. <u>Deferral rationale: Introduction of bias</u>

The paper focused on concern around the non-random nature of existing objections. The paper indicated that excluding patients that have registered against the NDOO will introduce a biased sampling frame due to non-random opt-out patterns. As is explained in detail above, there may be a differential loss of information about vulnerable groups of people whose safety OSMAS are most concerned about. Additionally, application of the NDOO would undermine any detection of trends – applicants may miss a rise in a small group that OSMAS would otherwise have taken action on. Applying the National Data Opt-Outs to OSMAS data collection would therefore mean inaccurate reports of any trends in self-harm numbers and rates over time. Missing data from vulnerable groups therefore has the potential to skew analysis and recommendations for clinical improvements, and to worsen existing health inequalities.

The applicant has indicated that case ascertainment is as close to 100% as possible. The applicant has also confirmed that there are no comparable sources of data on self-harm available. OSMAS is held up as the 'gold standard' for data surrounding self-harm presentations to hospital, as routinely collected hospital data such as from Hospital Episode Statistics (HES) or the Emergency Care Dataset (ECDS) only capture approximately 34% of all self-harm cases that present to the emergency department in the Oxford area. These central datasets are therefore missing approximately 60% of individuals. It would therefore not be possible for applicants to compare to anything to see which demographics were missing from their dataset, should the NDOO be applied.

Another project within the Multicentre Study of Self-harm in England, the Derby Monitoring Study of Self-Harm (CAG reference 19/CAG/0135), sits within Derbyshire Healthcare NHS Foundation Trust, and was an early adopter of NDOO. Derby researchers were able to run a one-year cohort of self-harm data to check for NDOO rates. Comparing the numbers before and after the check was completed, there was an overall loss of 10% of self-harm cases due to NDOO. This evidence shows that the self-harm cohort may be opting out at disproportionate rates, and therefore OSMAS which currently has 100% case ascertainment would be disproportionately affected by such a high NDOO rate. Members were convinced that the NDOO would cause an additional significant amount of bias.

The Manchester Self-Harm Project (PIAG 2-07 (c) /2004), which is part of the Multicentre Study of Self-harm in England, have been granted an exemption from the NDOO. The applicant reasons that applying the NDOO in some but not all of the Multicentre Study sites will introduce a differential loss of data. The populations of the three sites differ substantially, and also differ in terms of rates of self-harm. Therefore any differential loss may introduce a further bias, and as such may compromise the conclusions and recommendations made on the basis of data from the multi-centre analysis, and therefore could be detrimental to patients care.

Members were supportive of exempting the NDOO, due to the impact of bias, as there is high case ascertainment currently, and a disproportionately high NDOO rate suggested, and this would worsen health inequalities and impact patient safety.

3. <u>Deferral rationale: technical impacts</u>

The applicants indicated that due to the nature of OSMAS methodology, which combines data from different sources, multiple screenings for NDOO may be required. The applicant therefore stated that applying the NDOO would generate additional workload for clinicians, which could potentially harm good relationships with submitting clinical organisations.

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 NDOO. CAG understood that the NHS had been under considerable pressure during recent years due to COVID-19 and there has been necessary focus on other matters. However, Members were clear that practical difficulties around the NDOO implementation would have to be very clear with evidence and not just statements of potential negative impact. Requests for deferral from the NDOO 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 NDOO.

### Informing the patient population

In order to ensure that the relevant patient population are informed that the NDOO would not be applied, the CAG agreed that it would be critical, as a general principle, for clear communication methods around the deferral to be established. The applicant confirmed 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.

The applicant provided a draft patient information sheet and privacy notice, alongside an FAQ document, regarding informing the population that the NDOO would not be applied. A communications plan has not been provided, and the applicant notes that communications are particularly sensitive for this cohort.

Members were broadly content with the notification wording, although the CAG commented that the phrasing ‘NHS Spine Opt Out’, should be altered to ‘National Data Opt Out’, as the former may not be understood by the public.

The Members also commented that the process described for opting out, which advised a phone call to discuss initially, rather than being clear that somebody could opt out if they wished, appeared to slightly pressurise individuals into not opting out.

The Members agreed that these points can be responded to by refreshing the notifications in line with this advice, and submitting as part of the new non-research application.

## Patient and Public Involvement

The applicant noted that with regards to patient and public involvement, service users and carers have been involved. An advisory group is also mentioned. The applicant states the groups have reviewed the PIL, privacy notice and FAQ and commented on the wording.

The CAG were unclear on who is part of the service users and carers forum or the advisory group, and whether these individuals represent the cohort. As part of the meeting discussion, the applicant confirmed there was no diversity in the group with regards to ethnicity, and noted that a couple of service users and the parents of service users are represented. The CAG felt that further patient and public involvement should be undertaken with more individuals, and with a more diverse group of individuals that represent the wider cohort, including the vulnerable communities mentioned in the application.

There was also no indication of what information was presented to the individuals mentioned, how many people were involved, and any comments on the NDOO exemption specifically. Therefore as part of the refreshed application to CAG, the applicant is requested to provide evidence of discussions regarding the non application of the NDOO with a representative group, as CAG would like to review the outcomes of patient and public involvement and engagement, that supported the non-application of the National Data Opt-Out. The CAG asked that feedback from further patient and public involvement was provided as part of the refreshed applications requested.

## 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 NDOO, 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. Following thorough review of the request rationales, members agreed that the patient safety rationale and health inequalities explanations were strong and provided appropriate rationale for advising why the NDOO should not be applied to this data flow.

CAG therefore recommended, in this specific instance, to the Health Research Authority that the National Data Opt-Out deferral request be conditionally approved, for a time limited period of 6 months, to enable the applicant to develop a distinction between the research and non-research purposes of OSMAS, as the Members accepted that application of the NDOO to this application would result in patient safety consequences and disadvantage vulnerable groups.

## Specific conditions of support

1. This outcome confirms a change to the original conditions of support. The National Data Opt-Out is not to be applied to patients included in the activities specified in PIAG 2-07(b)/2004.

2. This support is in place for a time limited period of 6 months, within which time, the applicant is requested to submit a new refreshed non-research application to CAG, (and consider if an additional refreshed research application is also required), which will supersede PIAG 2-07(b)/2004, before the next annual review date of 17 November 2023.

3. Please provide evidence of discussions with patients and the public, surrounding the non-application of the National Data Opt-Out, as part of the resubmitted application.

4. Please provide updated patient notification documents, as part of the resubmitted application.

## 4. New Applications

### a. 23/CAG/0046 - Thames Valley and Surrey (TVS) sub national secure data environment (SNSDE) programme

**Context**

**Purpose of application**

This application, from Oxford University Hospitals NHS Foundation Trust, proposes to collect patient data from all primary and secondary care of all patient's seeking care in the Thames Valley and Surrey (TVS) area (approximately 4.3 million people). The data will be collated into a Sub-National Secure Data Environment (SNSDE) for the purposes of conducting medical research.

Support is requested for the flows of confidential patient information from participating organisations to Oxford University Hospitals NHS Foundation Trust to create the SNSDE. Confidential Patient Information will flow from GP practices (via system suppliers such as EMIS/TPP) and NHS Trusts (including mental health and ambulance Trusts). Specialist data (e.g. radiology data) may flow direct from a processor (e.g. Insignia) rather than the Trust extracting the data themselves. A core set of data will flow at time intervals agreed with each processor, with additional specialist extracts required for specific research projects. Data will retrospectively be collected from the time that a full electronic patient record is available and prospectively, and shared care records will not be used to collate data.

Patient data will be transformed in the data processing environment, to produce a research database that can be used to produce extracts for research purposes. This area can be accessed only by the data management team for the TVS SNSDE, all of whom are employed by or contracted to the coordinating organisation, Oxford University Hospitals NHS Foundation Trust. Extracts from the database – produced for specific, approved research programmes – will be prepared within the data processing environment and subjected to additional checks before being securely copied across the area that researchers will access. A data access committee will review and approve applications to access extracts from the database, with a particular interest in research proposals from within the Thames Valley and Surrey region. Upon approval, researchers will be provided with secure access to the data to undertake analysis, without the data leaving the NHS. The SNSDE will be used to conduct translational research to improve delivery or patient care across a broad spectrum of disease and clinical areas.

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** | All patients receiving NHS treatment within the Thames Valley and Surrey (TVS) area. |
| **Data sources** | Electronic patient records held at:<br><br>1. Buckinghamshire, Oxfordshire and Berkshire West Integrated Care System (BOB ICS)*<br>2. Oxford University Hospitals NHS Foundation Trust<br>3. Oxford Health NHS Foundation Trust<br>4. Berkshire Healthcare NHS Foundation Trust<br>5. Royal Berkshire NHS Foundation Trust<br>6. Buckinghamshire Healthcare NHS Trust<br>7. South Central Ambulance Service NHS Foundation Trust<br>8. Frimley Health and Care Integrated Care System (ICS)*<br>9. Frimley Health NHS Foundation Trust<br>10. South East Coast Ambulance Service NHS Foundation Trust<br>11. Surrey and Borders NHS Foundation Trust |

| | |
|---|---|
| | 12. Sussex Partnership NHS Foundation Trust<br>13. Surrey Heartlands Health and Care Partnership Integrated Care System (ICS)*<br>14. Ashford and St. Peter's NHS Foundation Trust<br>15. Epsom and St Helier University Hospitals NHS Trust<br>16. Royal Surrey County Hospital NHS Foundation Trust<br>17. Surrey and Sussex Healthcare NHS Trust<br>18. Great Western Hospitals NHS Foundation Trust<br>19. Milton Keynes University Hospital NHS Foundation Trust<br>*this includes a total of 343 GP practices within the TVS |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Hospital ID number<br>4. GP registration<br>5. Date of birth<br>6. Date of death<br>7. Postcode – unit level |
| **Identifiers held in the data processing environment** | 1. Initials<br>2. Full name<br>3. Address<br>4. NHS number<br>5. Hospital ID number<br>6. GP registration<br>7. Date of birth<br>8. Year of birth<br>9. Date of death<br>10. Postcode – unit level |
| **Identifiers available to researchers** | 1. Postcode – sector level<br>2. Gender<br>3. Ethnicity |

**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.

Members were aware that this was the first of a series of Sub-National Secure Data Environment (SNSDE) applications that the CAG may see and noted the broader policy direction around Secure Data Environments. CAG carefully considered this application and the anticipated benefits this may bring, balancing the scale of the use of confidential patient information of all patients seeking care in the Thames Valley and Surrey area against the intended uses and outcomes of the SNSDE. Members also noted that the design of the SNSDE would also mean that confidential patient information does not leave the control of the NHS and is not accessible by researchers. Given these considerations CAG considered that the application was in the public interest.

## Scope

This application was previously deferred, following advice from CAG at the 08 September 2022 meeting. One of the primary reasons was the uncertainty whether the SNSDE would used for solely research purposes, or whether there were non-research uses as well. The applicants confirmed in this application that the SNSDE would solely be used for research uses, which the CAG accepted.

The CAG noted the intention to ingress free text data into the SNSDE, and requested clarity on the flow of this into the SNSDE and the processing of such data.

The applicants confirmed that they will not be requesting free text data from GP notes. Free text may be included in source data from records such as discharge summaries and pathology reports. The imported free text will not be presented to researchers in the final extract. Instead, a code will be written to extract key information from the free text and a derived version which will be checked automatically to guarantee it is free of identifiers before being provided to researchers. The applicants also confirmed that the effectiveness of the code will be checked periodically by the technical team at Oxford University Hospitals NHS Foundation Trust to ensure it remains effective.

The CAG was satisfied with the applicant's response.

The CAG also understood the original application intended to use data from shared care records where available, and requested clarity on whether the applicants still intended to use the shared care records as part of the source data. The applicants stated that they had considered using the shared care records but concluded that any association with this service could complicate communications and raise concerns regarding re-use. Therefore, they confirmed that they would not be using

the shared care records, instead sourcing data direct from each provider organisation.

The CAG was satisfied with this response.

The CAG queried whether the applicants planned to link to mortality data from ONS (Office for National Statistics). The applicants indicated that they had no current plans to collect mortality data from the ONS or any other source. However the applicant considered whether in future they could retrieve mortality data from the NHS Spine as they will be using this to check whether data received should be subjected to the National Data Opt Out.

The CAG indicated that the current support will not extend to retrieving mortality data through any source and an amendment should be submitted if this is requested in the future. Members however raised concern that the applicants indicated that the National Data Opt will only be applied once the data is received into the SNSDE. The CAG considered that this would be outside the principle of the National Data Opt Out, and that the opt out should be applied prior to data leaving the provide organisation. Members therefore asked for further clarity and confirmation that the National Data Opt Out will be applied by the provider organisation, prior to transfer to Oxford University Hospitals NHS Foundation Trust.

The CAG noted the inclusion of two acute Trusts which were outside of the Thames Valley and Surrey SNSDE area, but part of the Thames Valley cancer alliance. Members queried whether it was proposed that cancer data only would be shared from these Trusts. The applicant confirmed that all data from these Trusts will be used as there may be co-morbidities.

The CAG were content with this response but noted that specific patient and public involvement and patient notification should be undertaken specifically with these Trusts.

### Findings of clinical significance

The CAG requested clarity on the applicant's proposal in the application to notify patients if anything clinically significant is found. The applicants stated that this is not something that the SNSDE are expecting to happen and are not actively requesting this of researchers, but a researcher may identify something in the extracts e.g., indication that a patient may have a condition that was previously unknown. In this instance the researchers would be expected to flag it to Oxford University Hospitals NHS Foundation Trust for it to be managed from there by contacting clinicians and/or the Caldicott Guardian at the relevant participating organisation. The applicants stated that this is a process that is already in place across NHS trusts to flag if something unusual is identified.

The CAG were content with this response but noted that further confirmation from the applicants should be provided to clarify that patients will not be re-identified as part of this process

### 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 stated in their application that it is neither practical nor appropriate to seek informed consent. Writing to patients to seek consent would likely result in a very low response rate. Obtaining consent in a clinical setting would be burdensome on organisations and staff and many patients will not be visiting a clinical setting soon. A consent-based approach is also unlikely to achieve fair and adequate coverage and the value of the research would be substantially diminished.

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

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to support and validate linkage. However, the design of the SNSDE means that confidential patient information will not be accessible to the researchers, and the data will never leave the control of the SNSDE.

The CAG were content that using anonymous information was not a practicable alternative.

On approval from the Data Access Committee, researchers will have access to extracts from the database, which will be minimised to meet the needs of each specific project. These extracts will be made available only to the researchers working on the specific project and will not contain any confidential patient information.

The CAG queried the membership of the Data Access Committee, specifically the proportion of lay members. The applicant confirmed that they plan to include a total of 14-15 members, 4 of which will be lay members. Lay members will be recruited using NIHR recruitment processes and will be compensated for their time. Lay members will also be supported by a PPIE manager and administrative assistant. Members were broadly content with this but requested more information on the progress of recruitment, including lay members, and details on when the committee will be fully established.

### ‘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 provided an information leaflet and poster intended to be displayed in all care settings participating in the SNSDE. It is also proposed that for research projects utilising the SNSDE that are targeting particular therapeutic areas or clinical themes the poster and leaflet will be displayed in relevant areas e.g., a project using chest X-rays would display posters and leaflets in the radiology departments of participating hospitals.

The CAG noted that the poster and patient information leaflets had been provided as draft versions and that final versions would need to be submitted for the group to review. The group noted that the language used in the leaflets and poster was not lay friendly and did not adequately explain what the SNSDE is, its purpose, what types of data will be used and how it will operate. Further, the group also noted that Sussex was mentioned in the materials and that care homes had been included as a data source. The applicant confirmed that this was likely to be a typo and that this would be checked before final versions were released for review.

The CAG noted that a QR code was included on the patient notification materials that did not appear to link to any specific information on the SNSDE and requested that this be updated in final versions.

Although information is included in the poster and leaflet regarding the national data opt out and a SNSDE specific opt out, the CAG felt that too much emphasis was given to the national data opt out and that this was an easier route for patients to opt out of the SNSDE if this was their choice. The CAG requested that the SNSDE specific opt out should be much clearer on the poster and leaflet and that the process for the regional opt out is simple for patients to enact.

Members agreed that the patient notification materials needs to be revised, taking into account the points above, and suggested asking for review and comment by a patient group.

The CAG queried if there were any other routes planned for notification. The applicant confirmed that it is planned that each data controller participating in the SNSDE update will update their privacy policy on their website to include information on the SNSDE. The applicant went on to explain that a separate website had been proposed for the SNSDE. However, feedback from the patient and public involvement and engagement workshops indicated that a separate website would not be beneficial to the public as it would not fully contextualise the information. Preference was for the

current website in use for the Thames Valley and Surrey area which includes information on patient data use across the area to be updated with a link to a new section on the SNSDE.

### 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 provided a communications and engagements plan and a copy of slides used in workshops carried out with patients and public health and care staff. The workshops brought together patients, members of the public, clinicians and health care managers. Over 30 participants attended, including people from minority ethnic groups, the trans community, people with lived experience of mental ill health and people with disabilities. The workshops were the first of an ongoing set of discussions which will include specific work with larger groups of people from seldom heard communities.

The CAG commended the applicants on their patient and public involvement and engagement efforts to date, however they noted that the number of participants was relatively low considering the proposed size of the SNSDE. Members also commented that they would like to see further involvement and engagement with groups such as mental health, cancer, private patients and harder to reach groups of people. The group noted that plans were in place to engage with Healthwatch but commented that further engagement with privacy advocacy groups and research charities would be welcomed. The applicants confirmed that these suggestions will be included in further stakeholder engagement plans. The applicants also stated that going forwards they were planning to offer 1 to 1 conversations with participants who may not feel comfortable speaking in large groups.

The group queried whether the question of acceptability of using confidential patient information without consent was included during the workshops. The applicant confirmed that this question was included in discussions and that participants had a good understanding of the need to have high quality data in order for the SNSDE to be effective.

The group were content with this response but noted that more detail on the outputs of both the workshops and engagement with privacy advocacy groups to date should be provided including any negative feedback or concerns raised.

### Exit strategy

The linked version of the data will be constantly refreshed and retained for the lifetime of the database. It will be deleted as soon as no longer required to produce de-identified data extracts.

Support is requested for a database that operates for five years. If, at the end of this period, feedback from patients, the public, staff and researchers agree that the database is a valuable asset within the regional research ecosystem, and if there is funding to continue, the applicants may apply for an extension of existing approvals.

CAG were content with the exit strategy and period of support requested.

**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 information on plans for continued public involvement and engagement to include:

    a. Focus on specific groups such as mental health, cancer, private patients and harder to reach groups of people

    b. Further engagement with privacy advocacy groups and research charities

    c. Inclusion of specific patient and public involvement with the two acute trusts out of catchment area (Great Western Hospitals NHS Foundation Trust and Milton Keynes University Hospital NHS Foundation Trust)

2. Provide more information on the outputs from patient and public involvement and engagement activities to date, particularly around any negative feedback or concerns raised, and feedback from privacy advocacy groups

3. Provide final versions of patient notification materials which should:

    a. Provide clear information on what is a SNSDE, its purpose and what types of data will be used

    b. Be written in lay language

    c. Be clear on how patients can opt out specifically from the SNSDE

d. Ensure that the QR code links directly to information on the SNSDE

e. Correct inclusion of Sussex where appropriate

f. Remove mention of care homes

g. Correct the statement regarding CAG to read 'The HRA has given Section 251 support for the activity following advice from the Confidentiality Advisory Group.'

4. Provide confirmation that the shared care record will not be used.

5. Provide confirmation the national data opt out, and any SNSDE specific opt out will be applied by the provider organisation, prior to transfer to Oxford University Hospitals NHS Foundation Trust.

6. Provide update on progress of recruitment to the Data Access Committee including lay membership, and when it is expected to be fully formed.

7. Provide confirmation that patients will not be re-identified if anything of clinical significance is identified

## Specific conditions of support (provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. Confirmed:
The NHS Digital 21/22 DSPT reviews for **Oxford University Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 April 2023)

3. Support is provided for research purposes only.

4. Support is provided for 5 years from the date of the final outcome letter.

## b. 23/CAG/0045– National Respiratory Audit Programme (NRAP) Adult asthma and COPD clinical audits.

**Context**

### Purpose of application

This non-research application from the Royal College of Physicians set out the purpose of continuing the National Asthma and COPD Audit Programme.

National Respiratory Audit Programme (NRAP) will launch on 01 June 2023 and is a continuation of the National Asthma and COPD Audit Programme. This three-year programme will include workstreams on adult asthma (AA), COPD, pulmonary rehabilitation (PR) in England and Wales and primary care (in Wales only).

Participating NHS trusts and health boards will enter data into the webtool. Annually Crown Informatics will extract data from the webtool. The NHS number will be replaced with a study ID, the postcodes reduced to Lower Super Output Area (LSOA) and date of birth converted to month and year of birth. This anonymised data will be disclosed to Imperial College London for data cleaning and analysis. Following cleaning and analysis of the data, aggregated data will be transferred from Imperial College London to the Royal College of Physicians who will publish audit programme outputs.

Once a year, Crown Informatics will transfer confidential patient information, including NHS numbers, dates of birth and postcodes, plus a unique audit identifier to NHS England for linkage to HES, ONS, Admitted Patient Care (APC) data, and to Digital Health and Care Wales for linkage to Patient Episode Database for Wales (PEDW). The pseudonymised linked dataset will then be disclosed to Imperial College London for analysis.

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** | Patients aged 35 years and over who: |

| | |
|---|---|
| | Have been admitted to hospital with a primary diagnosis of COPD exacerbation, or where an initial, or unclear, diagnosis is revised to an acute exacerbation of chronic obstructive pulmonary disease (AECOPD).<br><br>Patients aged 16 years and over who:<br>Have been admitted to hospital with a primary diagnosis of asthma attack, or where an initial, or unclear, diagnosis is revised to asthma attack |
| **Data sources** | 1. Data provided by participating NHS trusts and health boards<br>2. ONS and HES data, from NHS England<br>3. PEDW data, from Digital Health and Care Wales |
| **Identifiers required for linkage purposes** | 1. NHS Number<br>2. Date of birth<br>3. Home postcode<br>4. Date and time of death |
| **Identifiers required for analysis purposes** | 1. NHS Number<br>2. Date of birth<br>3. Home postcode<br>4. Date and time of death |

**Confidentiality Advisory Group advice**

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

## Public interest

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

## Scope

The CAG requested clarification on the size of the cohort to be included in the application.

The CAG also requested clarification on the size of the governance group. Members asked queried whether the proportion of lay representatives included was

appropriate and asked the applications to clarify how many lay members were included.

Members also asked for clarification on  which data flows described within the dataflow diagram required section 251 support.

### 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 consent was not feasible as the NRAP team would have no direct patient contact. Clinical staff would need to undertake the consent process during patients' admission, which was not feasible due to time and resources. Patients may also be too unwell to give consent during their admission.

The applicants also advised that complete case ascertainment was needed to produce valid and comprehensive conclusions on the question of whether improved quality of care leads to better outcomes. Seeking consent could lead to the exclusion of the most unwell patients, resulting in bias.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to undertake data linkage between the information provided by trusts and ONS, HES, from NHS England, and PEDW data, from DHCW.

Confidential patient information is needed to undertake the required data linkages. The application activity could not be undertaken in any other way.

The applicants stated that all data sent to Imperial College London was pseudonymised.

The CAG requested clarification on a contradiction found between the CAT assessment and section (F) of the application form. Although, the application form stated that linked data would be sent to Crown Informatics and then to Imperial College London for analysis. In response to queries raised by the Confidentiality Advice Team in advance of the meeting, the applicant had stated that linked data

would be sent directly to Imperial College London and therefore not pass through Crown Informatics. The CAG requested clarity on the correct process.

The CAG requested clarification on when Crown Informatics will transfer the data to Imperial College London, including whether this transfer was performed annually or once every audit cycle (3 years).

The CAG requested clarification on whether Crown Informatics hold the pseudonymisation key as well as clarity on whether re-identification of patients needed support.

### '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.

Posters and leaflets will be made available for display in relevant hospitals.

The NRAP webpages will also include information on the audit programme for patients and their families/carers with the fair-processing information available online.

Patient flyers for the AA and COPD audits were provided. These advised patients to inform a member of their clinical team if they did not want their information to be included. The National Data Opt-Out is also referenced.

The fair processing information will also include information about patients' ability to object to their data being processed by specific audits under GDPR and the fact that NRAP will honour opt-outs of confidential patient information being used for secondary purposes under the National Data Opt-Out Programme for England.

Services are also required to screen for people who are on the Data Opt-out register before entering any patients into the NRAP audits. NHS England will screen requests for outcomes data in line with the National Data Opt-Out Programme.

Patient flyers for the AA and COPD audits were provided. These advised patients to inform a member of their clinical team if they did not want their information to be included. The National Data Opt-Out is also referenced.

The fair processing information will also include information about patients' ability to object to their data being processed by specific audits under GDPR and the fact that NRAP will honour opt-outs of confidential patient information being used for secondary purposes under the National Data Opt-Out Programme for England.

Services are also required to screen for people who are on the Data Opt-out register before entering any patients into the NRAP audits. NHS England will screen requests for outcomes data in line with the National Data Opt-Out Programme.

The CAG highlighted and commended the use of Twitter as a platform for notification. However, noted that the contact response was primarily from health professional, not patients. The CAG requested that the applicants explore other ways of promoting the application activity via social media, to help increase patient response. The materials produced also need to be reviewed during patient and public involvement to ensure the language used was lay appropriate.

## 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.

NRAP will co-produce a comprehensive patient and public involvement and engagement (PPIE) strategy. This will meet the Healthcare Quality Improvement Partnership's (HQIP) (2016) seven principles of involvement.

The audit team have subcontracted the Asthma + Lung UK (ALUK) and Royal College of Paediatric and Child Health (RCPCH) to coordinate the recruitment, retention and engagement of patients, including adults with asthma and COPD and their carers, in audit programme activities. NRAP have worked with and will continue to work with the panel to identify key patient priorities for improvement which have been used to inform the dataset.

The audit programme will ensure patient representation at governance meetings and incorporate this feedback into key decision making. NRAP will also co-produce resources that include lay friendly language for patients interested in learning more about the audit findings.

The CAG asked that updates on the Patient and Public Involvement undertaken were provided when annual reviews are submitted.

## Exit strategy

Data will be retained by Crown Informatics for the duration of the audits. NRAP is funded until 2026, although it is anticipated that this will be extended.

Once the audit is completed, the data will be held for 5 years and then destroyed in line with the Information Governance Alliance (IGA)'s Records Management Code of Practice for Health and Social Care 2016. The 5-year retention period will allow post-audit queries to be answered, the completion of outstanding longitudinal analyses and for the processing of third-party data requests.

The CAG was content with the exit strategy.

### 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

1. This application will supersede CAG 8-06 (b) 2013. The previous application will be expired on the CAG register of supported applications.
2. Clarify the number of patients to be included in the cohort.
3. Clarify the size of the governance group and whether the proportion of lay representatives included was appropriate.
4. Clarify which data flows described within the dataflow diagram require section 251 support.
5. Clarify whether linked data will be sent to Crown Informatics Ltd for analysis prior to Imperial College.
6. Clarify when Crown Informatics Ltd intend to transfer data and whether the transfer will be undertaken annually or once every audit cycle (3 years).
7. Clarify whether Crown Informatics Ltd hold the pseudonymisation key as well as clarify on whether re-identification of patients' needs support.
8. Ways of promoting the application activity via social media need to be explored. The materials produced also need to be reviewed during patient and public involvement to ensure the language used was lay appropriate.

9. Updates on the Patient and Public Involvement undertaken needs to be provided when annual reviews are submitted for the application.

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

Due to the number of 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.

## c.23/CAG/0044 - Optimisation of Protocol through Evaluation of mRi scan Analysis

### Context

#### Purpose of application

This application from North Bristol NHS Trust set out the purpose of medical research that seeks to define the parameters of scan acquisition that together produce a 'good' quality set of FAST-MRI images.

Despite effective treatments, 30 women die every day from breast cancer in the UK. Early detection of breast cancer saves lives and is the aim of the NHS Breast Screening Programme (NHSBSP), which screens 2.2 million women in England each year. However, mammograms are not good at showing some cancers. Delayed breast cancer diagnosis results in a worse prognosis, a much higher chance of the morbidity associated with metastatic breast cancer and its treatment, and ultimately of mortality. Recent studies have shown FAST-MRI (First post-contrAst SubtracTed Magnetic Resonance Imaging) has potential as a breast cancer screening test. It overcomes the shortcomings of mammography, including poor sensitivity for aggressive cancers. FAST-MRI is much quicker to acquire and interpret (cheaper for the NHS) than the gold standard breast screening modality, full protocol MRI (fpMRI), which is currently reserved to screen only women at high risk of breast cancer. FAST-MRI holds promise to save more lives through breast cancer screening because it can detect aggressive cancers earlier than mammography.

The applicants seek to define the parameters that provide optimal scan quality to produce guidelines for use of FAST-MRI. Clinical staff at participating NHS trusts will identify 10 breast MRI scans which show the types of cancers difficult to detect with mammograms, 5 scans showing grade 3 (aggressive) cancers and 5 showing

cancers with lobular histology at diagnosis. These scans will be identified from the local radiology information system and prepared for image transfer. Image transfer SciCom will set up dedicated Cloud storage and a dedicated node on the Image Exchange Portal (IEP) for image transfer. This node will enable automated de-identification of incoming images. To register that an image is being sent, sites will make use of the RSNFT SMART portal to register the case in advance. This portal will include a proforma to be completed by the clinical team that will detail the parameters used to acquire each scan and specific additional information from the scan's report and cancer histology. The proforma information associated with each study ID will be stored automatically along with the images (using a linked complex salted hash) by SciCom. The applicants do not anticipate that confidential patient information will be accessed by the researchers undertaking analysis, but noted that technical issues may occur in the automatic de-identification process. Should this happen, then Royal Surrey County Hospital staff, rather than staff at the patient's site, would have to intervene and may process confidential patient information.

A recommendation for class 1 and 6 supports 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 16 years and over who underwent breast MRI scans at participating hospital trusts from 01 January 2019 onwards. |
| **Data sources** | 20. Electronic patient records at:<br>a. Royal Surrey NHS Foundation Trust<br>b. University Hospitals Coventry & Warwickshire Gloucestershire Hospitals NHS Foundation Trust<br>c. North Bristol NHS Trust<br>d. Royal Cornwall Hospitals NHS Trust<br>e. University Hospitals Plymouth NHS Trust<br>f. St. George's University Hospitals NHS Foundation Trust<br>g. Great Western Hospital |
| **Identifiers required for linkage purposes** | 1. NHS Number<br>2. MRN Number<br>3. Name<br>4. Date of birth<br>5. Date of death |

| | |
|---|---|
| **Identifiers required for analysis purposes** | 1. Date of birth<br>2. Date of death |

**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 and the application was in the public interest.

### Practicable alternatives

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

- **Minimising flows of identifiable information**

The CAG noted that the applicants did not plan to use any confidential patient information and were seeking support in case the images were not fully anonymised when sent to the researchers. Members requested further explanation on why checks could not be carried out, to ensure that no items of confidential patient information were included, before any images or data were disclosed outside the relevant hospital trust.

The CAG requested clarity on where the pseudonymisation key would be held and who would be able to access it.

The CAG noted that the research will be collecting full names for linkages. The CAG requested that the applicant give justification on why full names are needed for linkage.

- **Feasibility of consent**

Whilst images will have been received with patient consent for medical care, the team did not think it was fair to approach women (who had had an MRI more than 3 years ago) for consent. The consent process was felt to put an unnecessary burden on women who had potentially been through (or still living through) a very difficult period of time. Unfortunately, there may also be women who are not still alive and therefore contacting family members was considered unnecessarily distressing.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The applicants don't require access to confidential patient information. However, patients' date of birth, NHS number and name will be sent by from participating sites via the Image Exchange Portal (IEP) to a dedicated research node, which would automatically de-identify the images on receipt and hold them in a dedicated HSCN research server at RSFT. Whilst this is a very secure process used for various studies, should a technical issue arise where this automatic deidentification has been unable to take place, then Royal Surrey County Hospital staff, rather than staff at the patient's site, would have to intervene and may process identifiable information.

The CAG was content that use of anonymous information was not a practicable alternative.

### 'Patient Notification' and mechanism for managing dissent

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

The applicants had advised that the patients included would no longer be attending for appointments and it was unlikely that patients would see any notifications.

Participating sites will be asked to apply the NHS National Data Opt-Out to the proposed lists of patients before they are sent for submission.

The CAG requested that the patient notifications materials are revised to clearly state that the research team may access confidential patient information when working on the study.

Furthermore, the CAG also requested that the notification materials clarify that section 251 support is in place for this 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.

Two PPI members are included on the RfPB Trial Steering Committee. Both are also members of cancer charities and have lived experience of breast cancer. The PPI members will attend the Programme meetings to discuss the dissemination of study findings.

Members of the network have links with patients and carers through BUST, ICPV, smaller local patient groups and also the National Cancer Research Institute Breast Group Consumer Members and will optimise dissemination of results to these groups, ensuring impact. PPI network membership will help us write outputs to optimise public understanding of our results and advise us on their immediate application for breast screening within the NHS.

The PPI members consulted had advised that, as the images will not be identifiable outside the care team and the rigorous measures in place to ensure confidentiality within the transfer system they felt the study was designed pragmatically, they had no issues with not seeking consent.

The CAG was content with the amount of engagement work that had been done with the PPI members. However, it was unclear whether it had been explained that confidential patient information may be disclosed outside the direct care team., The CAG requested that further patient and public involvement was undertaken with the representative group to discuss the acceptability of potential disclosures of confidential patient information. Feedback from these discussions is to be provided to the CAG.

### Exit strategy

Only anonymised data will be used for analysis. The date of birth and date of the MRI scan will be used to work the age the age of the woman when she had the scan. Patients age at death (if relevant) will also be calculated.

The CAG was content with the exit strategy proposed.

## 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 explanation as to why the images and data cannot be pseudonymised to ensure that no confidential patient information is included before leaving the trust.

2. Clarify who will hold the pseudonymisation key and how and when the key will be used.

3. Patient notification materials need to be created. The materials must include the following:

    a) It must be explained clearly that confidential patient information may be disclosed outside the direct care team.

    b) It must be explained that support under s251 is in place.

4. Further patient and public involvement needs to be undertaken with the representative group to discuss the potential disclosure of confidential patient information. Feedback from the discussion is to be provided to the CAG.

5. Provide justification on why it is necessary to use patients full names for linkage.

### 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 DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

    Due to the number of participating organisations involved it is the responsibility of **North Bristol NHS Trust** as controller, to ensure that participating Trusts/Organisations meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

## d. 23/CAG/0047– A randomised controlled phase III trial of a novel behavioural intervention for primary care teams to promote the earlier diagnosis of cancer (ThinkCancer!)

## Context

### Purpose of application

This application from Bangor University set out the purpose of medical research that seeks to assess the effectiveness of use of the ThinkCancer! Intervention by general practice teams, compared with usual care.

Early diagnosis of cancer is key to improving patient outcomes. Over 70% of cancers present in primary care, meaning general practice is a good setting for behaviour change, quality improvement and education. The main aim of this randomised trial is to see how a behavioural and educational package can help the whole general practice team to pick up early symptoms and signs of cancer that mean the patient should receive an urgent referral. The ThinkCancer! intervention will be delivered remotely as an educational and quality improvement workshop via three distinct workshops. Each member of practice staff will take part in two workshops. Interviews will also be held with stakeholders and patients and carers. The applicants will collect primary care interval (PCI) data by search of patient records at participating GP practices. The PCI is time from first symptom suggestive of cancer, to time to referral to secondary care. This will be undertaken by research staff who are trained in these methods working alongside general practice staff. An anonymised dataset will be extracted.

To examine other factors which may be related to delayed Urgent Suspected Cancer (USC) referral or diagnosis, the applicants also intend to conduct a review of case notes for a sample of 60 patients. Consent will not be sought for this and the applicants are seeking support under s251. Records will be screened by a researcher to identify eligible patients and extract an anonymised dataset.

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 18 years and over with a primary care interval exceeding the 75th and 90th centile for a given cancer type. 60 patients will be included in the case note review. The applicants anticipate that 3078 will need to be reviewed in order to identify 60 patients. |
| **Data sources** | 1. Patient records at participating GP practice |

| | |
|---|---|
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. Date of birth |
| **Identifiers required for analysis purposes** | 1. Postcode – district level |

**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 reducing time from referral to treatment was strongly in the public's interest.

### Scope

The CAG highlighted GP surgeries as the data processors, however requested for clarity on which GP surgeries were involved. The CAG noted that full support could not be confirmed until the data processors had been identified.

### 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 anticipate that 3078 patient records will need to be accessed to identify and extract data for the required 60 patients and that it is not feasible to seek consent in advanced due to the large number of patients.

The applicants have advised that consent is not feasible due to the number of patients whose records will be accessed. However, this number is only around 3000 patients. Consent likely is not feasible, as patients would need to be identified in order to make contact and seek consent, which would require a larger breach in the Common Law Duty of Confidentiality than extracting an anonymised dataset. The CAG accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information to identify eligible patients and extract an anonymised dataset.

The CAG was content that using anonymous information was not a practicable alternative.

## 'Patient Notification' and mechanism for managing dissent

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

The applicants advised that practices would use their existing mechanism to inform patients that their practice is participating in 'ThinkCancer!'. These mechanisms will be tailored to the abilities of each practice.

The applicants noted that a variety of materials, such as project specific text messages, emails and posters, for display within the practices will be offered. The team is in the process of creating a project specific 'ThinkCancer!' short film which will explain the trial and what practice participation involves, to be run in the practices on their electronic waiting room displays.

All the methods outlined in the notification strategy will include information on how a person may inform their practice if they do not wish their data to be included in 'ThinkCancer!'.

Researchers will not access the data of any patient who has a read code attached to their medical records to say that they do not give permission for their data to be used for secondary purposes.

The CAG highlighted that the patient notification materials would be created in collaboration with the GP surgeries. The CAG requested that these notifications were submitted for review once the GP practices had been identified and the materials created.

## Patient and Public Involvement and Engagement

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

Two PPI representatives are included as co-applicants. A Patient Advisory Group (PAG) of four to six further PPI members will also be created. PPI members will also be included on the Trial Steering Committee (TSC).

The process of the case note review was discussed with the PPI co-applicants and another co-applicant who has experience in case note reviews. During this discussion, it was determined that accessing patient notes without consent was acceptable due to the difficulty in seeking consent.

The applicants also plan to involve existing patient forums at participating practices and will look to their members for feedback on the participation of their practice in the study. The applicants have links with other existing PPI groups including the SUPER Group at PRIME Centre Wales and the North Wales Cancer Patient Forum (NWCPF). The Chief Investigator has been asked by BBC Wales to contribute to an programme to be published about 'ThinkCancer!' and two members of the NWCPF have agreed to be interviewed for the article and provide patient perspectives.

The team are due to present 'ThinkCancer!' at the Cancer Research Wales Science Café in Wrexham, which is a public engagement event. The team will seek feedback from the public following the presentation and during the event. More public engagement events will take place during the progress of the trial.

The Chief Investigator has presented the 'ThinkCancer!' project to the Wales Senedd and received positive feedback on plans for the application.

The patient and public involvement carried out appears proportionate to the scale of the breach in the common law duty of confidentiality. However, little feedback has been provided.

The CAG commended the applicant on their patient and public involvement plan. However, as this plan was prospective, the CAG requested for their feedback to be submitted for CAG review.

The CAG requested for further patient and public involvement, particularly around the specific issue of use of confidential patient information without consent and suggested that the applicant engage with the Patient Advisory Group (PAG) on this point.

## Exit strategy

Data collection will take place at participating practices and anonymisation occurs at the point of data extraction. No confidential patient information will leave the practices.

The CAG was content with the proposed exit strategy.

### Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information 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. Once identified, please clarify the GP surgeries involved. Please note that CAG will not be able to issue support until these have been identified.
2. Once completed, please submit the patient notification materials for CAG review.
3. Please undertake patient and public involvement, particularly around the specific issue of use of confidential patient information without consent and provide the feedback to CAG for review.

### 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 REC review: **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:**

   Data processors to be confirmed.

## 5. Any other business

No other business was raised.

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

| Signed – Chair | Date |
| --- | --- |
| *Dr Patrick Coyle* | *08 May 2023* |

| Signed – Confidentiality Advice Team | Date |
| --- | --- |
| *Dayheem Sedighi, HRA Approvals Administrator* | *03/05/2023* |