Minutes of the meeting of the Confidentiality Advisory Group

23 March 2023 via Zoom

Present:

Name	**Role**
Dr Murat Soncul	CAG Alternate Vice Chair
Ms. Clare Sanderson	CAG Alternate Vice Chair
Dr Malcolm Booth	CAG Member
Professor Lorna Fraser	CAG Member (absent from discussion of 4c onwards)
Dr Katie Harron	CAG Member
Mr. Anthony Kane	CAG Member
Dr Rachel Knowles	CAG Member Absent for 22/CAG/0032
Dr Harvey Marcovitch	CAG Member
Mr Marc Taylor	CAG Member
Dr Joanne Bailey	CAG Member
Dr Stephan Mullin	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 Michael Pate	HRA Confidentiality Advisor
Mr Dayheem Sedighi	HRA Approvals Administrator
Mr Mark de Belder	Applicant - Chairman, National Cardiac Audit Programme Operational & Methodology Group, NICOR. Attended for discussion of item 3a only.
Mr Nadeem Fazal	Applicant - National Clinical Audit Services Manager, National Institute for Cardiovascular Research (NICOR) . Attended for discussion of item 3a only.
Mr Richard Arnold	Applicant - Clinical Programme Lead, NHS England. Attended for discussion of item 3a only.
Mr Adam Levine	Applicant for 23/CAG/0032. Attended for discussion of item 4b only.

1. Introduction, apologies and declarations of interest

There were no conflicts of interest declared.

2. Support decisions

Secretary of State for Health & Social Care Decisions

No Non-Research applications were discussed at the 16 February 2023 meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **16 February 2023** meeting applications.

Minutes:

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

- February subcommittee minutes
- 16th February 2023 Full CAG meeting

3. Consideration Items

a. 22/CAG/0117 – Request to defer application of the National Data Opt-Out for NICOR Commissioning through Evaluation Registries/Audits:

• Percutaneous Mitral Valve Repair,
• Left Atrial Appendage Occlusion and
• Patent Foramen Ovale Closure in Adults

Scope of NDO deferral request

The applicants have existing support to undertake three registries, Percutaneous Mitral Valve Repair, Left Atrial Appendage Occlusion and Patent Foramen Ovale Closure in Adults. Confidential patient information is submitted from NHS and private hospitals in England and Wales to NICOR (hosted at NHS Arden and Greater East Midlands Commissioning Support Unit (Arden and GEM)).

Confidentiality Advisory Group advice

1. Deferral rationale: patient safety

The applicants aim for 100% inclusivity, including the highest-risk and most urgent cases. The number of patients registering a National Data Opt-Out varies significantly between regions, as well as the number of Opt-Outs having increased overall. The non-random nature of Opt-Outs increases the difficulty of monitoring public health and healthcare delivery.

The inability to monitor outcomes for all patients who undergo these treatments jeopardises the ability to ensure that the benefits of treatment outweigh the risks and the ability of NHS England to support the Medical Devices Safety Programme. This would put NHS England in the position of being unable to fulfil its obligations under the Health and Social Care Information Centre (Establishment of Information Systems for NHS Services: Data Services for Commissioners) Directions 2015.

The applicants noted that the audits potentially have implications for changes in clinical care pathways at local, regional and national level.

2. Deferral rationale: Introduction of bias

The applicants had advised that failure to track all patients, whatever their demographic profile, risk status, frailty or vulnerability, would result in an inability to weigh the benefits against risks for all patient groups.

The CAG asked that further details were given on the impact application of the National Data Opt-Out would have on the audit. The applicants noted the difficulty in providing exact figures. The new registries had not yet been set up and it would take time to build up sufficient data for modelling the potential impact of application of the National Data Opt-Out.

The CAG noted that analysis would need to be undertaken and reported back on at annual reviews.

Informing the patient population

The applicant provided a “Patient and Public Information sheet modifications.” This showed the draft information that would be provided should deferral of application of the National Data Opt-Out be granted. Patients are still able to dissent to use of their data in NICOR specifically. Telephone, postal and email contacts were provided.

The CAG noted some inconsistencies between the different patient notification materials and a lack of clarity over how patients could opt-out to use of their data in these audits. Members also noted that patients who dissent should be asked whether they are happy for their anonymised data to be retained or want their full data to be deleted.

Patient and public involvement and engagement

The CAG requested further detail on the patient and public involvement carried out and membership of the Patient Advisory Group. The applicants explained that a minimum of two patient representatives were included on every working party in the NICOR structure. A separate Patient Advisory Group would be created for each registry. Recruitment had not yet taken place to the Groups for these specific audits and the main Patient Representative Group had been consulted.

The CAG agreed that patient and public involvement needed to be continued. Reports on the activity carried out needed to be provided in annual reviews.

Confidentiality Advisory Group advice conclusion

The CAG agreed that, although the justification given in the written request was not as strongly argued as in other, similar applications, the applicants had made a strong case for deferral when attending the meeting.

The CAG agreed that they were supportive, in this specific instance, of the request for the application of the National Data Opt-Out to be disapplied in relation to the non-research activities contained within 22/CAG/0117. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

1. The patient notification materials need to be revised for consistency across the documents and to make it clearer how patients can opt-out.
2. The below are to be provided in the first annual review:
    a. Modelling work, to demonstrate the potential impact of the National Data Opt-Out on the audit, if it were applied, needs to be undertaken and reported back on.
    b. Ongoing patient and public involvement needs to be undertaken and reported back on.
3. The National Data Opt-Out is not to be applied to patients included in the activities specified in 22/CAG/0117.
4. A local patient objection mechanism must continue to be used in relation to 22/CAG/0117.

4. New Applications

a. 23/CAG/0038- National Audit of Inpatient Falls (NAIF)

Purpose of application

This application, from the Royal College of Physicians, set out the purpose of a national audit of the standard of care delivered to patients who have experienced a fall while an inpatient in hospital, specifically those that result in hip fracture.

The Falls and Fragility Fracture Audit Programme (FFFAP) was conceived by The Department of Health (now Department of Health and Social Care), clinical experts, national clinical audit suppliers and the Health Care Quality Improvement Partnership (HQIP), to audit the standard of care received by patients who have suffered fragility fractures and the methods used to prevent future fractures. FFFAP includes three audits, the Fracture Liaison Service Database (FLS-DB), the National Hip Fracture Database (NHFD) and the National Audit of Inpatient Falls (NAIF). In December 2018, the applicants were given support, via submission of an amendment, to include the National Audit of Inpatient Falls (NAIF) under the existing 's251 support' for the Hip Fracture Audit (CAG 8-03(PR11)2013). In October 2022, the applicants submitted an amendment to the Hip Fracture Audit. Given the age of the existing application and the scope of the amendments, particularly the amendment to National Audit of Inpatient Falls (NAIF), new applications were requested, both to bring the applications up-to-date and to separate NAIF from the National Hip Fracture Audit.

Falls are among the most frequently reported patient safety incidents in hospitals. Around 250,000 inpatient falls occur every year in English hospitals. Hip fracture is one of the most serious consequences of a fall and of the more than 50,000 hip fractures recorded each year in England and Wales, around 2,000 are sustained in an inpatient setting. Many older people will not recover fully from a hip fracture, with around one third never regaining previous levels of mobility function. Hip fracture is also associated with increased mortality. Data are collected through retrospective audit notes and Key Performance (KPI) Indicators reflect fall prevention actions undertaken before the fall that caused the fracture as well as the immediate post-fall management. The standards measured against are taken from NICE Clinical Guidelines and NICE Quality Standards.

All patients in England and Wales with a femoral fracture sustained in any NHS commissioned inpatient setting (acute, community or mental health) are eligible for inclusion in NAIF. Confidential patient information will be entered by the NAIF team at participating trusts directly into the NAIF webtool. Patients will be cross-referenced with the NHFD for duplicate case reports. Confidential patient information is then stored by Crown Informatics, who link the data and share anonymised and aggregated data to the NAIF team at the Royal College of Physicians. Additionally, Crown Informatics will transfer identifiable, patient level audit data to NHS England and/or Digital Health and Care Wales when a request has been approved by the RCP and HQIP by way of the FFFAP Scientific and Publication committee. NHS England transfer HES and ONS to the third-party applicant NWIS transfer PEDW

data to third party applicant, following application to Digital Health and Care Wales Information Services.

Data is also provided from the NHFD. Data initially arrives to the NAIF webtool from cases identified as a hip fracture occurring in an inpatient setting, entered via the NHFD. This identifiable information is then transferred from the NHFD team to the same trusts' NAIF team to confirm the fracture was a result of a fall that occurred in their trust or to allocate to the appropriate trust if the fracture occurred in another NHS organisation. Once the case has been received at the appropriate trust, Crown informatics (IT contractors), will then link validated identifiers and use the data in the webtool to inform the live KPI performance data. Upon finalising the analysis of the data, the analyst contractors will then share anonymised and aggregated data to the RCP NAIF team for commentary and to publish the annual report. Additionally, IT contractors will transfer identifiable, patient level audit data to NHS England and/or Digital Health and Care Wales when a request has been approved by the RCP and HQIP by way of the FFFAP Scientific and Publication committee. NHS England transfer HES and ONS to third party applicants (following application to NHSD DARS, facilitated by Crown and the RCP). Digital Health and Care Wales transfer PEDW data to third party applicant, following application to NWIS Information Services (facilitated by Crown and the RCP).

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 over the age of 60 who fall and sustain a fracture of the hip or thigh bone in acute, mental health, community and specialist NHS trusts/health boards in England and Wales.
Data sources	1. Patient data provided by participating trusts 2. HES and ONS data at NHS England 3. Digital Health and Care Wales
Identifiers required for linkage purposes	1. NHS Number 2. Date of Birth 3. Postcode – unit level 4. Sex 5. Surname 6. First name

Identifiers required for analysis purposes	1. NHS Number 2. First name 3. Surname 4. Date of birth 5. Sex 6. Postcode – unit level

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

Public interest
The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006 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 CAG was not clear why the research needed to retain identifiable data for five years after patients have passed away. The CAG requested that justification for retaining data for five years was provided, or that the applicants delete the confidential patient information after a shorter period.

The CAG noted that the research will be collecting full names for linkages. The CAG asked that the applicants reconsider whether full names are needed for linkage and report back at annual review whether the number of identifiers collected can be reduced.

- **Feasibility of consent**

The applicants advised that consent was not feasible as patients may have moved to a different organisation for care of the hip fracture and it would be difficult to seek consent. It may also create inequities in the way data was collected, with patients receiving hip fracture care in the same organisation more likely to provide consent, leading to potentially poorer care in organisations that can't collect data such as community and mental health settings (where there is no hip fracture ward).

NAIF data also indicates a high mortality rate (12% 30-day mortality) and high rates of delirium after hip fracture (54% of total sample). This means that less than half of the eligible participants would have the capacity to provide consent. The degree of

missing data this would create would severely compromise the value and effectiveness of the audit. Moreover, missing data would not be random but the patients at highest risk of poor outcomes would be least likely to be included, therefore introducing bias.

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

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to link the data provided from trusts to HES and ONS data at NHS England and Digital Health and Care Wales.

The confidential patient information is needed to undertake data linkages with NHS England and Digital Health and Care Wales.

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.

NAIF has a fair processing statement which includes information for patients including the following: what the national audit of inpatient falls is, what a clinical audit is, how patients can say 'no thank you'/ opt out, how patient information is processed, and how to raise concerns. The applicants noted that no patients had contacted NAIF to request opt-out since the start of the audit.

Information on the audit is made available through the RCP website and audit webtool, as well as patient resources (posters and booklets when available) sent by post when requested by the public or audit participants when physical copies are available. Videos are also shared with participating sites via email to share in their waiting rooms and wherever they are able to display to their patients.

Pending the outcome of the new contract, the applicants will look into dissemination of patient notification and dissent information, from potentially creating digital posters and video resources, and making sure they are more accessible in lay language.

If a patient does not want their information to be included in the audit, they are advised to speak to a member of their clinical team. The clinical team will ensure that the patient's information is not included in the audit. By not participating in the NAIF, a patient's care and treatment will not be affected.

If they are happy for their data to be used for the audit, but not to be shared with researchers, when appropriate legal approvals have been met, they can specifically opt out of their data being used by researchers by contacting the NAIF team.

Currently NAIF has exemption from the National Data Opt-Out because it falls under NHFD, but this will no longer be the case with this new, stand-alone application. The applicants intend to apply for exemption once support is given.

The CAG stated that the leaflet was too long and complex, making it challenging for patients to understand. The CAG suggested that a layered approach was implemented, where simplified, easy-read versions of the material are made available which then provided a link or QR code to a longer more detailed document, if people wanted further information.

The CAG requested that the patient notification explain how a patient can request the removal of their data, both via local opt-out and the National Data Opt-Out.

The CAG has noted that a clear explanation of the project-specific opt-outneed to be included on the poster.

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.

FFFAP has a patient and carer panel which serves as the patient and public involvement workstream of the overall programme. Three members are part of the NAIF advisory group. All three have direct experiences of the needs of patients who are at risk of having an inpatient fall that could lead to hip fracture.

In preparation for this application, members of the panel were asked to share their personal experiences and views on the challenges of getting consent from patients. Generally, members agreed that seeking consent from patients who have recently had delirium would be difficult. More detailed comments were provided in the supporting documents.

The applicants also undertook a focus group to review the public facing resources. This resource was aimed at those who wished to positively influence improvement of care by sharing realistic actions in an animated video and downloadable infographics to help find out whether their hospital was meeting recommended targets as well as directing patients or carers to ask the hospital Patient Advice and Liaison Services (PALS) to speak more on topics covered. For those with lay governance roles, this resource was also designed to help raise the profile of areas in need of improvement with the board of governors, commissioners, or other groups.

The CAG was satisfied with the patient and public involvement carried out.

Exit strategy

Crown Informatics will hold all confidential patient information for the FFFAP, including NAIF data, for the duration of the audits. Should the audit come to an end, the confidential patient information will be held for a further 5 years before deletion.

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 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 following sets out the specific conditions of support.

1. The patient information materials need to be revised with the help of patient's advisory representatives as follow:

    a) The patient information leaflets need to adopt a layered approach making simple, easy-read versions available, with more detailed information to be provided on request.

    b) Please provide updated patient notification documents, with clarity on how a patient can request that their data is removed, either via a local opt-out or the National Data Opt-out. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data.

    c) The poster needs to contain a clear explanation of the project-specific opt-out.

2. Please reconsider the time given for the deletion of data for patients who are deceased and did not want to be included in the audit.

3. Future annual reviews need to explain why it is necessary to use full name for linkages and whether it's possible to remove that identifier in future.

4. 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. **Confirmed:**

    Due to the number of participating organisations involved it is the responsibility of researcher as controller, to ensure that participating

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.

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

b. 23/CAG/0032 – Natural language processing of histopathology reports (Pilot Application)

Purpose of application

This application from University College London set out the purpose of medical research that seeks to investigate use of natural language processing (NLP) in the analysis of histopathology reports.

Histopathology is a medical specialty in which cellular and tissue specimens from patients are examined to identify and characterise disease. Histopathological findings are described in histopathology reports. These contain a wealth of information of clinical and scientific value; however, analysing them in a systematic way at scale in an automated manner is generally not possible because of their unstructured nature. The applicants seek to establish a dataset of histopathology reports from multiple NHS Trusts. Natural language processing (NLP), a computational methodology used to process, analyse and extract information from natural language text, will be implemented to enable high quality, reliable and accurate data extraction at scale. In doing so, this study aims to provide novel pathological, epidemiological and clinical insights.

Patients at participating NHS trusts will be identified by the pathology or informatics department by staff with an existing legal basis to process the data. The data will be anonymised as much as possible prior to transfer to University College London. However, the applicants stated that items of confidential patient information could be included in the free text health data, as it was not possible to guarantee that data was completely de-identified. To enable data from the same individual both within and across different NHS Trusts to be linked, the NHS number will be converted into a pseudonymised identifier via a unidirectional hash algorithm with a shared key that is held by each NHS Trust and not accessible to researchers.

A recommendation for class 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 patients at participating hospital NHS Trusts who had a histopathology specimen processed from the time of commencement of computerised pathology records (approximately 01/01/1990)
Data sources	1. Electronic patient records at participating NHS trusts
Identifiers required for linkage purposes	None
Identifiers required for analysis purposes	None

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

To enable support under the Regulations to be provided, the activity must have a medical purpose as defined in s251 (12) of the NHS Act 2006. Following review, it was unclear whether the application provided a medical purpose. The CAG requested that the applicant provide examples on the types of research that can be undertaken with the proposed database.

The applicant explained that the histopathology reports contain sensitive information on the prevalence and mutation of disease. Currently, markers are used to treat diseases, such as, tumours and lymphomas, however, there is no evidence to suggest which markers work best. The creation of this database would help tackle this issue and help improve on patient treatment plans as well as survival rates.

The CAG requested clarity on the type of database that would be created.

The applicant explained that, unlike typical research databases, this database would be only used internally and therefore not shared outside of the research team.

The CAG was satisfied with the applicant's response.

Scope

The CAG requested clarity on the coding for Free-Text.

The applicant stated that identifiers would be manually deleted by the research team and then processed through a computer algorithm. These reports would then be sent to the Safehaven and reviewed by a specialist. Once the extractions were complete, the research team would collect the anonymised information for review.

The CAG was satisfied with the applicant's response.

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 Committee queried how data would be managed inside and out of the Safehaven.

The applicant stated that only aggregate or summary data would be processed outside the Safehaven. All other analysis would take place within the Safehaven.

- **Feasibility of consent**

The applicants noted that a number of patients will be deceased. The applicants explained that consent was not feasible due to the large number of patients that would be involved.

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

- **Use of anonymised/pseudonymised data**

The applicants do not require confidential patient information; however support is sought as it cannot be guaranteed that the data is completely de-identified prior to transfer from participating NHS trusts to University College London.

The applicants advised that the full text of the histopathology reports is needed as specific pathological features of specific diseases, such as the positive and negative status of different markers, are only included in the free text. This information is not available in the structured text. This study proposes to utilise NLP to extract these IHC profiles and populate a database of this information for use by diagnostic

pathologists to indicate the most appropriate IHC markers to utilise for specific indications and how to interpret the findings. It is hoped that this could lead to more accurate and efficiently made diagnoses across a wide range of pathologies.

The applicants do not require confidential patient information; however, support is sought as it cannot be guaranteed that the data is completely de-identified prior to transfer from participating NHS trusts to University College London.

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 study will be listed on research databases, such as UCLH Find a Study and on the Department of Cellular Pathology website at each participating NHS Trust.

The applicants provided a copy of the Patient Notification information which would be included on websites.

The applicants had advised that, given the wide variety of physical clinical locations that histopathology specimens are sent to histopathology laboratories from placing posters or leaflets at participating sites was not felt to be an efficient or effective means of notification.

The CAG encouraged the applicant to explore alternative options for promoting the study notification. Members suggested conducting a social media campaign or notifying patients of the research within the main page of the hospital websites.

The applicant was happy to discuss these ideas with the research team.

The CAG agreed that the patient notification needed to be clearer, simpler and more succinct; and asked that the materials were reviewed by lay individuals. Members also asked that an email address was provided for each participating trust was included on the patient notification, should patients wish to opt-out or have questions about the study.

The CAG queried the use of one email as a contact point for all those wishing to opt out of the study, as opposed to one email per trust.

The applicant stated that they had a central contact point within University College London Hospital for those Opting Out of the study. However, were happy to review this further.

The CAG recommended having one point of contact per trust. However, stated it was the researcher's responsibility to whether they wished to make this change.

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 circulated an anonymous survey via public engagement and patient networks, including Cancer Research UK, NIHR People in Research, the UCL/UCLH BRC PPI Network and social media. 57 responses were received. Of these, over half (63%) reported having had a biopsy or undergone surgery to remove tissue that was reviewed by histopathology. 100% of respondents felt the research was important. The majority of respondents felt that it was acceptable to analyse de-identified histopathology reports in the described way for the described task (recognising a small risk of the reports containing identifiable data) with 95% giving 4/5 or 5/5. An equivocal response regarding acceptability (3/5) was given by only 5% of respondents.

A focus group was also undertaken. Eleven lay individuals and a lay facilitator, alongside two study investigators, were involved. This lasted two hours and a wide variety of questions were raised relating to all aspects of the project.

Two lay research advisors are also involved. The advisors have provided advice regarding the lay summary and the study design and feasibility. They will provide ongoing advice on the study from the patient perspective throughout the study duration.

The full PPI survey with the questions asked was provided in Appendix 1 of the Study Protocol and in the applicant's response to CAT validation queries. Given the relatively small scale of the breach in the common law duty of confidentiality, the activity undertaken seems proportionate.

The CAG requested for patient and public involvement contribution within the amended notification materials.

Exit strategy

The data will be de-identified as far as possible prior to transfer from the participating trusts to University College London. However, the applicants note that it will not be possible to completely anonymised all free text data.

Prior to transfer of the data from the source to the recipient organisation, all identifiable data will be removed as best as is practically possible and achievable. In addition, the NHS number will be converted into a pseudonymised identifier through

the use of a unidirectional hash algorithm with a shared key. This is required so that histopathology reports from the same individual both within and across different NHS Trusts can be linked. The key will be held securely by each NHS Trust and will not be accessible to researchers. Should the researchers reading the free text reports come across any identifiable data, this will be flagged such that the reason it was not removed by the de-identification tool can be investigated/rectified and it will be immediately deleted from the dataset. 2. Attempts are being made to implement a process in the future whereby all patients in the participating NHS Trusts will be consented for the use of their data for ethically approved research prospectively to circumvent the need for further Section 251 support.

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

1. The patient notification needs to be revised as follows:
    - **a.** A clear opt-out process needs to be described.
    - **b.** The patient notification materials need to be reviewed by lay people.

2. Consider whether an email address should be provided for each participating trust, should patients wish to opt-out or have questions about the study. This needs to be reported back on at the first annual review.

3. Please report at annual review whether any items of confidential patient information have been found in the free text data.

4. If a research database, for use by organisations other than University College London, will be created then a research database application will need to be submitted.

5. An amendment is to be submitted if additional data processors are included.

Favourable opinion from a Research Ethics Committee. **Confirmed 16 March 2023.**

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

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: As there are more than 5 organisations processing confidential patient information, these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

c. 23/CAG/0034 - Precision Treatment Strategies in Multiple Sclerosis Using Next-generation Machine Learning

Purpose of application

This application from University College London set out the purpose of medical research that seeks to explore how multiple sclerosis types that will predict treatment effects and the risk of worsening disability can be redefined.

Multiple sclerosis (MS) is an incurable disease, but more than 15 treatments are in existence that can help to modify its course. These treatments vary in strength and the risk of side effects. It is known that the stronger treatments delay disability, but many have greater risks, alongside more demanding administration and monitoring schedules. As balancing the harms and benefits of the treatments is challenging, many patients switch therapies within two years of initiating therapies. The applicants seek to define MS types based on the underpinning pathobiological changes to address these ambiguities and benefit patients by recommending the right treatment to the right patients according to biological sub-types.

Care teams at participating trusts will review patient records to identify eligible patients and compile a list of patients. The care team and the research team within the trusts will extract the required data from electronic health records and linked to MRI data. All confidential patient information will be stored and analysed within individual trusts and will not be disclosed outside the trust.

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

Confidential patient information requested

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

Cohort	Patients aged 18 years and over and diagnosed with multiple sclerosis at participating NHS Trusts within the last 20 years. 13,000 patients will be included.
Data sources	1. Patient records at participating NHS trusts: a. University College London Hospitals NHS Foundation Trust b. Imperial College NHS Healthcare Trust c. Sheffield Teaching Hospitals d. King's College Hospital NHS Foundation Trust e. Public Health Wales NHS Trust f. Cambridge University Hospitals NHS Foundation Trust g. Leeds Teaching Hospitals NHS Trust h. Barts Health NHS Trust i. University Hospital Coventry and Warwickshire NHS Trust NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board
Identifiers required for linkage purposes	1. NHS number 2. Hospital ID number
Identifiers required for analysis purposes	1. Ethnicity 2. Patient reported sex

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006 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 advised that the data to be processed will be up to 20 years old. More than half of the patients will not be contactable. Only including patients who are contactable would mean that those who are more disabled or who have died will be excluded.

The applicants also cited the logistical difficulty in contacting patients to seek consent, particularly due to the additional needs of patients, e.g. patients who are unable to use keyboards and/or computers, or who have a visual impairment, that would need to be taken into account.

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

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to identify eligible patients and to extract the required information.

The CAG noted that the data extraction was being done by the researcher rather than the medical team. Therefore, the CAG was content that the support that using anonymous information was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

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

A patient notification document was provided. This would be displayed on the study website and at MS clinics at participating trusts. The study will also be promoted via social media and online patient forums. The patient notification will also be sent via email to a large network of MS patients registered at the UK MS Society (called "UK MS Society Patient Network"). The patient notification will be displayed at least 6 weeks before data processing begins.

The National Data Opt-Out will be applied.

A project-specific opt-out will also be offered. Patients will be asked to email or telephone the Chief Investigator at UCL or complete an online opt-out form. Contact email addresses and telephone numbers of a member of the direct care team at the participating trusts will also be included in the posters and online, so patients can opt-out by contacting the trust directly.

The CAG stated that the notification was too long and complex, making it challenging for patients to understand. Depending on their disability, some patients may need the help of carers or family members to access the material. The CAG therefore suggested that a layered approach was implemented, where simplified, easy-read versions of the material were available which then provided a link or QR code to a longer more detailed document, if people wished to read on.

The CAG noted that the study specific opt out needs to be suggested as the initial option for dissenting, rather than directing to the National Data Opt-out.

Patient and Public Involvement and Engagement

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

The applicant has recruited a steering committee, comprised of 5 members, which will meet twice a year to provide feedback on the results of the research and on the dissemination of findings. The steering committee is diverse, covering patients from a range of ethnicities, a balance of genders (50% female) and a large age range (30 to 70 years). One of the applicant's mentors and an MS nurse will also join the steering committee meetings.

To ensure a representation of patients from across the UK and other centres involved in the MS-PINPOINT study, the MS-PINPOINT project was presented to ten MS patients, two MS nurses and two people caring for MS at the Sheffield Biomedical Research Centre. The meeting took place on 21 Feb 2023. The procedures for anonymising patient data and the reasons for accessing patient-identifiable data and linking electronic health records with medical images were discussed. Patients and carers were highly supportive of using patient data without consent to maximise the use of their data.

The patient notification is relatively small in scale, however appears proportionate to the small scale of the breach.

Exit strategy

All confidential patient information will be held within the relevant trust. No confidential patient information will be transferred outside the trust. The exit strategy is anonymisation.

The CAG requested clarification on when all confidential patient information would be deleted and the dataset anonymised. Members also asked the applicant to

confirm that no items of confidential patient information would be included in the dataset disclosed outside of the participating trusts.

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. Clarify when all patient identifiers will be deleted from the dataset.
2. Confirm that no items of confidential patient information will be included in the dataset disclosed from participating trusts.

3. Patient notifications need to adopt a layered approach making simple, easy-read versions available, with more detailed information to be provided on request. Please provide posters in clinical areas including QR codes or links leading to further information.

4. The study specific opt out option needs to be displayed more prominently than the National Data Opt-out.

5. Favourable opinion from a Research Ethics Committee. **Confirmed 24 January 2023.**

6. 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. **Confirmed:**

Due to the number of participating organisations involved it is the responsibility of researcher as controller, to ensure that participating 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.

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

d. 23/CAG/0035 – Linked Cancer Registration dataset from the Royal Surrey NHS Foundation Trust with the primary care database of the University of Oxford – RCGP Clinical Informatics Digital Hub (ORCHID)

Purpose of application

This application from the University of Surrey set out the purpose of setting up a research database to collect data on cancer diagnosis and treatment.

The applicants will link data from the University of Oxford – Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) and Cancer Registration dataset from the Royal Surrey NHS Foundation Trust (RSFT), to create a linked Cancer Registration dataset. NHS numbers for patients treated at the Royal Surrey NHS Foundation Trust will be "hashed" and transferred to ORCHID for linkage to data held within that database. ORCHID will then transfer the linked dataset, with the hashed NHS number, to the Royal Surrey NHS Foundation Trust. The Royal Surrey NHS Foundation Trust will then send their Cancer Registration dataset for the linked patients only to ORCHID.

The applicants seek support for the disclosure of NHS numbers from patient records at the Royal Surrey NHS Foundation Trust to staff working in the Department of Scientific Computing within the Trust to hash the NHS numbers, as these staff do not have a legal basis to process this confidential patient information. The hashed numbers only will be transferred to ORCHID for linkage.

A recommendation for class 1, 2, 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 diagnosed and/or treated with/for cancers at the Royal Surrey NHS Foundation Trust within the last ten years.
Data sources	1. Cancer information on diagnosis and treatment from the Cancer Registration database at the Royal Surrey NHS Foundation Trust

	2. University of Oxford – Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID)
Identifiers required for linkage purposes	1. NHS number
Identifiers required for analysis purposes.	1. Lower Super Output Area 2. Gender 3. Occupation 4. Ethnicity
Identifiers held in database	1. GP registration 2. Year of birth 3. Lower Super Output Area

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 requested further details on the types of cancer that would be investigated.

Scope

The CAG requested clarification on which specific cancers were being investigated within this study. The CAG noted that it was unclear whether ORCHID had a legal basis, under the common law, to undertake processing of confidential patient information without consent. Members asked that the applicants seek confirmation of the legal basis from ORCHID.

The applicants had advised that support isn't needed for the transfer of "hashed" NHS numbers from the Trust to ORCHID and back. However, both the Trust and ORCHID will be able to re-identify patients via the hashed numbers. Members asked that the applicants discuss this with ORCHID and their local information governance leads to confirm whether support is needed for the transfer of the hashed NHS numbers.

Members asked requested clarification on whether ORCHID or the Royal College of Physicians held the SALT key.

Practicable alternatives

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

- **Feasibility of consent**

The applicant advised that consent was not feasible due to the number of patients involved. The applicants also had no way of identifying and contacting patients.

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

- **Use of anonymised/pseudonymised data**

Staff at the Department of Scientific Computing at the Royal Surrey NHS Foundation Trust require access to confidential patient information from the Cancer Registration dataset at the Trust to carry out the process of de-identifying the NHS numbers.

The hashed NHS number will be used to link data from the Trust Cancer Registration dataset and the ORCHID dataset. The staff at the Department of Scientific Computing require access to the NHS numbers in order to carry out the “hashing” process.

The CAG requested clarification on who would holds the SALT key as well as information on who is responsible for un-hashing the 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.

The information about the use of the usages of Cancer Registration data in research by the Royal Surrey NHS Foundation Trust is available on the Royal Surrey NHS Foundation Trust website.

ORCHID lists all the research projects on their website (https://orchid.phc.ox.ac.uk/) and this project will be listed there too. ORCHID makes every effort to inform people registered with the practices who contribute data to ORCHID on how their data are used. This is via waiting room posters which list the research studies and materials to use in practices patient participation groups.

All applications to the University of Oxford Joint Research and Surveillance Committee (JRSCC), an independent committee that reviews application to use their data, are also published on the ORCHID website.

The National Data Opt-Out will be applied.

The CAG requested for a layered approach towards the notification materials. Whether this was through displaying posters on the walls of the waiting room, leaflets, or on the Royal Surrey NHS Foundation Trust website.

The CAG requested for the notification materials to clearly display how patients can opt out of this research project, as an alternative to directing them to the National Data Opt-Out.

The CAG asked that information about the study was included on the ORCHID website.

Patient and Public Involvement and Engagement

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

The applicants explained that Orchid and Royal Surrey engage with patients, service users, or members of the public by publishing the way they use data and their research on their websites.

The applicants have close working relationships with Prostate Cancer UK (PCUK), Pancreatic Cancer Action (PCA) and Pelvic Radiation Disease Association (PRDA), who are supporting this study. The applicants will continue working with PCUK, PCA and PRDA in terms of the specific research projects undertaken, the priorities for research and how the results will be disseminated.

Two patient representatives are included on the team. One is a prostate cancer survivor and PCUK PPI representative. The other person is a pancreatic cancer survivor and establisher (CEO) of the Pancreatic Cancer Action Charity. Both were consulted about the project and expressed full support of the study design. The applicants will continue regular meetings with the patient representatives.

The patient and public involvement activity undertaken appears proportionate to the scale of the breach.

Patient and public involvement, specifically around the use of confidential patient information without consent, needed to be undertaken on an ongoing basis and reported back on at annual reviews.

Exit strategy

This will be a one-off linkage and data transfer to ORCHID from the Royal Surrey NHS Foundation Trust.

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. Seek confirmation of the legal basis under the common law for ORCHID to process confidential patient information without consent.
2. Provide details on the cancers that will be investigated in the study.
3. Discuss with ORCHID and local information governance leads to confirm whether support is needed for the transfer of the hashed NHS numbers between the Trust and ORCHID.
4. Provide clarification on whether ORCHID or the Royal College of Physicians hold the SALT key, and which organisation is responsible for un-hashing the NHS numbers.

5. Alternative means of promoting the study need to be explored.

6. The patient notification materials need to contain a clear explanation of how patients can dissent from the inclusion of their data in the study.

7. Information about the study needs to be included on the ORCHID website.

8. Patient and public involvement, specifically around the use of confidential patient information without consent, needs to be ongoing and reported back on at annual reviews.

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. The NHS Digital **21/22** DSPT reviews for **Royal Surrey NHS Foundation Trust** & University **of Oxford – Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID)** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 27 March 2023)

5. Amendment request

a. 22/CAG/0137 - West Yorkshire ICB s251 non research purposes

Amendment request

As of 01 February 2023, NHS Digital merged with NHS England. All references to NHS Digital have therefore been revised to NHS England.

The applicants have existing support to allow the disclosure of confidential patient information from participating GP practices to North of England Commissioning Support Unit (NECS) and disclosure of confidential patient information from NHS England to NECS, and the continued holding of confidential patient information by NECs and the holding of the linked dataset by West Yorkshire Integrated Care Board. As part of this process, support is in place to allow re-identification of patients by their GPs, for direct care purposes. In this amendment, the applicants seek support to re-identification of patients by clinicians, other than patients GPs, for direct care purposes.

Confidentiality Advisory Group advice

The amendment request was considered by the Confidentiality Advisory Group.

The CAG agreed that the applicants had not provided adequate justification on why the amendment should be supported. An explanation of why the re-identification of data for use of non-GP clinicians was necessary and what would be achieved had not been given. Members noted that, should the amendment activity go ahead, large quantities of patient information would be made available without the justification for this being made clear. The CAG agreed that further information needed to be provided to evidence that the amendment activity will improve the current system and to explain how the system will be improved. Members queried whether the eventual purpose was to create a patient level dashboard, with re-identified patient data, for use in direct care.

The applicants have stated that the health and social care professionals would have an existing legitimate relationship to the patients. However, it was unclear what this relationship was. It was also unclear what new information the staff would be able to access as a result of this amendment, which they didn't already have access to. It also wasn't clear what urgent healthcare needs would be identified which couldn't be dealt with by the patients GP.

The triggers for re-identification had not been explained, including whether the re-identification would be undertaken at a request from the ICB or from the non-GP clinicians. The process followed to re-identify patients was unclear, including whether this would be carried out by community or hospital trust staff, or GP practice staff.

The CAG queried whether the non-GP clinical staff would be community or hospital-based staff only, or whether administrative and management staff would also be able to request that reidentified data was provided.

Information had also not been provided on where the re-identified patient records would be stored and who would have access.

Little patient and public involvement had been undertaken. Members noted that this would be important to demonstrate the need for the amendment and the public interest in the amendment activity.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Secretary of State for Health and Social Care recommended that the application was deferred.

Further information required

To support a future amendment request or revised application, the below points should be taken into consideration. A detailed covering letter should be provided to support the revised submission, which addresses the below points and sets out where revisions have been made to the revised request. The CAG noted that such a fundamental change may mean that a new, separate application, for this activity is required.

1. Members agreed that, should the applicants wish to submit a new amendment request, the below would need to be addressed;

    a. Justification on why the amendment is needed is to be provided. This needs to include examples of the specific uses of the re-identified data and evidence that the amendment activity will improve the current system.

    b. The process of re-identification needs to be explained, including the governance procedures for identifying the need for analysis and re-identification, and who can request re-identification.

    c. It also needs to be explained whether the non-GP clinical staff would be community or hospital-based staff only, or whether administrative and management staff would also be able to request that reidentified data was provided.

    d. Patient and public involvement needs to be undertaken, to demonstrate the need for the amendment and the public interest in the amendment activity.

    e. Clarification needs to be provided on where the re-identified patient information will be stored and who will have access to it.

6. Any other business

No other business was raised.

The CAG noted the meeting would be Dr Katie Harron last meeting with the CAG. The CAG thanked Dr Katie Harron for her valuable contributions to the CAG over their memberships and advised they were sorry to see her leave the CAG.

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

Signed – Chair		Date
Dr Murat Soncul, CAG Alternative-Vice Chair		*03 April 2023*
Signed – Confidentiality Advice Team		Date
Dayheem Sedighi, HRA Approvals Administrator		*31 March 2023*