Minutes of the meeting of the Confidentiality Advisory Group

08 December 2022 via Zoom

Present:

Name	**Role**
Dr Patrick Coyle (VC)	CAG Vice Chair
Dr Murat Soncul (AVC)	CAG Alternate Vice Chair
Dr Malcolm Booth	CAG Member
Dr Sandra Duggan	CAG Member
Dr Rachel Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Ms Rose Payne	CAG Member
Mr Umar Sabat	CAG Member

Also, in attendance:

Name	Position (or reason for attending)
Mr Will Lyse	HRA Approvals Administrator
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Kathleen Cassidy	HRA Confidentiality Advisor
Dayheem Sedighi	HRA Approvals Administrator (Internal Observer)
Dr Sam Oddie	Applicant - NNAP Clinical Lead, Consultant Neonatologist (attended for discussion of item 3a only)
Rachel Winch	Applicant - NNAP Project Manager (attended for discussion of item 3a only)
Calvin Down	Applicant - Head of Audits (attended for discussion of item 3a only)

1. Introduction, apologies, and declarations of interest

No conflicts of interest were declared.

2. Support decisions

Secretary of State for Health & Social Care Decisions

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

Health Research Authority (HRA) Decisions

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

Minutes:

27th October 2022 full CAG meeting minutes published
21st October 2022 and 18th November 2022 PS minutes published

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

a. 21/CAG/0007 - National Neonatal Audit Programme (NNAP) data flow

Scope of NDO deferral request

The National Neonatal Audit Programme (NNAP) was established in 2006. IT was originally commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and operated under CAG reference ECC 8-05(f)/2010. In 2021, NNAP was given support under 21/CAG/0007.

The Audit Programme assesses whether babies admitted to neonatal units in England and Wales receive consistent high-quality care and to identify areas for service and quality improvement in relation to the delivery and outcomes of neonatal care. Participating neonatal units input confidential patient information for all babies admitted to NHS neonatal units in England and Wales associated with a delivery unit into the BadgerNet system. Data extracted for the audit is held in the dedicated NNAP SQL Server Dataset within the Clevermed Microsoft Azure environment. A pseudonymised version of the NNAP is held within the Royal College of Paediatrics and Child Health (RCPCH) Azure environment and it is this pseudonymised version of the data that the NNAP project team use.

Confidentiality Advisory Group advice

1. Deferral rationale: patient safety

The applicants had advised that the data loss from even a small number of patients would negatively impact on the ability of the audit to monitor the quality of care and patient safety. The reporting of uncommon, serious complications or prematurity or important interventions given to a small number of babies at each unit would also be negatively affected.

Women of child-bearing age are more likely to register with the National Data Opt-Out. Take up of the National Data Opt-Out also varied widely across ethic groups and geographical areas. The variations in application of the National Data Opt-Out

would impact on the usefulness of the NNAP in identifying poorly performing units and in assessing the quality of the care provided. The CAG recognised the potential impact on patient safety.

2. Deferral rationale: Introduction of bias

The applicants noted that applying the National Data Opt-Out may introduce bias. Application of the National Data Opt-Out is not random, shown by the variation in opt-out rates within the NNAP dataset by neonatal unit, neonatal network and by mother's ethnicity. Introduction of bias may adversely impact the ability of assess care equity and undermine the integrity of the risk adjustment procedures relating to issues such as ethnicity and deprivation.

3. Local Opt-Out, Notification Strategy and Materials

Should the deferral be granted, patients would still be able to opt-out via the existing NNAP opt-out mechanism. A project-specific opt-out mechanism exists within BadgerNet. Parents can approach neonatal unit staff and request that their child's data is opted-out of NNAP data collection.

The applicants provided the draft Privacy Notice, which will be used should the National Data Opt-Out be deferred. A Dissemination and Engagement Plan was also provided. As well as the updated Privacy Notice, a short description of the National Data Opt-Out deferral will be highlighted on the landing page of the NNAP website. More detailed information would be available on the further webpage. A patient and parent guide to the audit is also available on the RCPCH website.

The applicants will also work with relevant clinical teams to ensure that they understand by the deferral has been given and discuss how best to communicate this with parents and carers. The BadgerNet provider, Clevermed ltd, will also be included in discussions about how to disseminate information about the National Data Opt-Out deferral. The NNAP project team will also work with colleagues within the RCPCH Media and Public Affairs team to brief charity partners and other stakeholders.

The CAG noted the plans for notifying the public that the National Data Opt-Out would not be applied. Members agreed that the patient notification materials required revision as the information given was very detailed and complex. The CAG suggested that a layered approach was implemented, where simplified, easy-read

versions of the material were available, with more detailed information to be provided on request.

Patients wishing to opt-out were advised to speak to the nursing staff at the unit. Dr Sam Oddie, the NNAP Clinical Lead, advised that this had been decided on as the local opt-out needed to be applied at trust level and it was thought that nursing staff would be less intimidating to approach than the doctors.

The CAG noted this explanation. Members asked that telephone and email contact details were provided, should parents wish to register an opt-out after their child had left the unit.

4. Patient and public involvement and engagement

The NNAP Methodology and Dataset Group and Project Boards, which include parent representatives and the parent representative charity, Bliss, have requested that the NNAP project team submit an application to the CAG seeking an exemption from the National Data Opt-Out.

The NNAP and Bliss held a joint online focus group in early November to discuss the National Data Opt-Out deferral. 14 people took part, including current and immediate past NNAP parent representatives, members of the Bliss Insight and Involvement Group, members of parent advisory groups (PAGs) within neonatal networks in England and representatives of the Sands and Best Beginnings charities. The majority of attendees were parents of babies who had required neonatal care, but also adults who themselves had received neonatal care as babies. The applicants provided examples of the feedback received in their paper.

Confidentiality Advisory Group advice conclusion

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 21/CAG/0007. 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 as follows:

    a. A layered approach is to be adopted, making simple, easy-read versions available, with more detailed information to be provided on request.

    b. Telephone and email contacts need to be provided.

2. The National Data Opt-Out is not to be applied to patients included in the activities specified in 21/CAG/0007.
3. A local patient objection mechanism must continue to be used in relation to 21/CAG/0007.

4. New Applications

a. 22/CAG/0168 – Opioid use after surgery in opioid-naive patients: a qualitative study

Purpose of application

This application from University College London set out the purpose of medical research that seeks to explore the themes and experiences of previously opioid-naïve patients who were discharged with opioids for pain control after surgery, the barriers to opioid taper and cessation, and drivers for continued use.

Long-term opioid use for pain carries various risks and can affect patients' quality of life. The likelihood and intensity of these risks tends to increase as dosage and duration of therapy increases. Many patients who use opioids develop a tolerance to their analgesic effects and some become dependent on them. Population surveys have found that long-term opioid use is associated with increased side effects, worse health outcomes and no improvement in pain relief. Prescription of opioids increased by 34% and the total oral morphine equivalent dose increased by 127% between 1998 and 2016. In 2017 – 2018, 12.8% of England's population had an opioid prescription dispensed, with approximately 50% taking opioids for at least one year. There is no consensus about the most acceptable and effective way of tapering opioid use. The applicants seek to follow-up previously opioid-naïve patients' surgical patients three months after surgery and discharge with a prescription for opioids.

A list of patients aged 18 years and over who underwent any elective surgical procedure within University College London Hospitals NHS Foundation Trust (UCLH) will be created from the electronic patient record system via an automated process. A list of eligible patients and their contact details will be disclosed to the researchers. Patients will be contacted by email with information about the study and an invitation to participate. The email will be followed by telephone call after 2-7 days. Those who

accept the invitation will have their eligibility status assessed and consent taken. Their participation will then proceed on a consented basis.

A recommendation for class 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients aged 18 years and over who underwent an elective surgical procedure at UCLH in the three-month period before the report is run, were not taking opioids prior to surgery and were prescribed opioids at discharge. 60 patients will be included.
Data sources	1. Electronic patient records at University College London Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Email address 4. Telephone number
Identifiers required for analysis purposes	1. Gender 2. 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. The CAG agreed that the application was strongly 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**

Patients will be recruited three months after they are prescribed opioids. The main reasons for not seeking is that only a very small proportion of postoperative patients will require opioids to take home and it is impossible to predict which patients this will be. While in hospital the patients will only be seen by NHS staff who could not be expected to make this prediction or obtain consent for patients who will be recruited into the study much later.

Utilising student researchers who are not part of the care team and unfamiliar with the many tasks that must be completed pre-operatively and at discharge, would represent an additional responsibility for the care team to manage and would risk affecting routine patient care negatively.

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

- **Use of anonymised/pseudonymised data**

Confidential patient information is required so that the applicants can identify and contact eligible patients.

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

Justification of Identifiers

Patients dates of birth would be included in the data provided to the research team. Eligible patients would be identified via an automated search, run on the electronic medical records. The CAG noted that patient age could be set as a search parameter or the data filtered to remove patients outside of the required age range before sharing of the dataset with the researchers, therefore it was unclear why patients dates of birth needed to be shared with the research team. The CAG asked the applicant to advise whether date of birth was needed in the data disclosed to the research team in order to facilitate contact and, if so, provide justification on why it was needed.

'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.

Information about the study will be placed on the UCLH website. A contact telephone number and email will be included, so that patients can register dissent prior to the data extraction.

The text of the website information was provided.

The CAG noted concern regarding the wording of the patient information materials. The CAG stated that the notification was too long and complex in parts, making it challenging for patients to understand. The CAG therefore requested the applicant to produce a simplified lay summary of the notification, with signposting to a more detailed version; should patients wish to read it.

Secondly, the CAG was not satisfied regarding the number of attempts to contact the participant. An attempt of 5 separate calls was perceived as too excessive by the committee, and therefore requested a maximum of 3 telephone calls.

Lastly, the CAG requested clarification as to whether the research team were applying the National Data Opt-out. If so, the CAG requested for it to be stated so within the patient notification.

Patient and Public Involvement and Engagement

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

The applicants have consulted with a patient-partner in Versus Arthritis and a patient with experience of taking opioids for pain. Further consultation has taken place through a focus group convened via the UCL PPI Helpdesk Patient Network. The focus group gave favourable views on the proposed design, in particular the fact that initial patient contact and identification of the patient cohort will take place prior to enrolment to the trial. This was not viewed to present a significant breach of confidentiality, and the members of the focus group were reassured by the fact that the process of generating the patient contact list was automated, that no other patient identifiable data were visible to investigators apart from name and contact details prior to enrolment. They were also satisfied that there were no other practicable alternatives of identifying eligible patients.

Members of the focus group were also given the opportunity to comment on the invitation email, participant information sheet and semi-structured interview schedule.

The CAG was satisfied with the use of Patient and Public involvement within the application.

Exit strategy

The applicant clarified that the exit strategy would be directed through obtaining consent.

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. Clarify whether date of birth needs to be included in the data disclosed to the research team in order to facilitate contact and, if so, provide justification on why it is needed.
2. Please produce a simplified lay summary of information sheet, with signposting to access the full version, should the participant wish.

3. Confirm that a maximum of 3 phone calls to the applicant will be attempted, instead of the proposed 5.

4. Please confirm that the notification material will be updated to reflect the position around the National Data Opt-out

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 **University College London** & **University College London Hospitals NHS Foundation Trust** were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 12 November 2022)

b. 22/CAG/0173 – Preservation of the Boyd Orr Cohort Database Version 1

Purpose of application

This application from the University of Bristol set out the purpose of continued storing of confidential patient information retained for patients who participated in the “The Carnegie Survey of Family Diet and Health in Pre-war Britain”.

The Survey was originally conducted in England and Scotland between 1937 – 1939. In the early 1990s, the applicants used the information originally collected for around 85% of the cohort on the NHS Central Register and, until 2013, the applicants received death and cancer notifications for the cohort. The applicants have agreed a data retention period for ONS cancer and mortality data to 2039 but there has been no research activity on the database since 2013, and no processing of data from NHS Digital since 2008. The applicants advised that the dataset was unique, as the detailed records of childhood diet and health for patients held is older than those collected in any other dataset. The dataset has been used to investigate childhood body size and diet in relation to adult chronic disease, and to demonstrate protective associations between childhood fruit and vegetable intake and adult cancer risk. This application was originally supported by CAG in 2014 under reference CR19/2014. After the applicant submitted the first annual review in 2022, they were requested to re-submit a refreshed application due to the length of time that had passed without CAG oversight. This refreshed application 22/CAG/0173 will therefore supersede CR19/2014. The applicants are now seeking support to allow one final download and linkage of cancer registration and death certificate data from NHS Digital and to allow secondary analysis of the data. Once the applicants have obtained mortality outcomes on all participants, which is likely to be achieved within the next 3-5 years, they will explore the use of a pseudonymised approach. The applicants note that this process will be relatively easy with the electronic data they hold, however they also hold an archive of paper records covering a thirty-year period which will be more challenging to anonymise. The applicants therefore seek to hold the confidential patient information until this process can be completed.

A recommendation for class 1, 2 and 6 support were requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application

form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients who participated in the Carnegie Survey of Family Diet and Health in Pre-war Britain 1937-1939.
Data sources	1.Data held in the Boyd-Orr dataset at the University of Bristol. 2.Datasets held by NHS Digital, which have not been specified.
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Gender 4. 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. The CAG agreed that the application was strongly in the public interest.

Scope

As understood, this application involves the transfer of confidential patient information from the University of Bristol to NHS Digital to enable linkage. Given that previous linkages have been undertaken with NHS Digital, the CAG requested the applicant to check whether NHS Digital still hold details of the patient cohort and can provide refreshed data without trequiring additional disclosures of confidential patient information from the University of Bristol to NHS Digital

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**

Patients were initially recruited in 1937-1939 and are now in their mid-80s and older. A significant number will also have died.

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

- **Use of anonymised/pseudonymised data**

Confidential patient information is required so that the patient details can be verified when the applicants receive a death or cancer registration notification. This verification is needed as the dataset contains records from 80plus years ago and tracing is not always accurate.

The applicants seek to put in place appropriate research governance measures and a legal basis to undertake one final download of cancer registration and death certificate data from NHS Digital to allow secondary analysis of the data.

This verification is required as some patient records were incomplete, and tracing was not completely accurate.

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 a patient notification strategy had not been created. This was due to the age of the dataset and that patients were originally recruited over 80 years ago.

The applicant stated that no methods of dissent are available.

Whilst understanding the age of the cohort and the length of time passed since being recruited, the Group felt that the principle of transparency still needs to be upheld. As such the CAG requested for a notification strategy to be created and for the materials to clearly state that the research team hold access to confidential patient information. Furthermore, the CAG also requested that the notification martials clarify that section 251 and CAG support is in place for this study.

The Committee requested the applicant to develop a clear local opt-out process and to state this clearly within the patient notification, including different methods of contacting to opt out (e.g. phone, email, postal address).

Patient and Public Involvement and Engagement

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

The applicants have included a member of the public onto the Steering Group. The applicants also have established patient and public involvement groups within their research programmes, the Bristol Biomedical Research Centre and the Integrative Cancer Epidemiology Programme, and these groups will be consulted when developing the research questions. To reflect the Boyd Orr cohort members and the research, the member of the public on the Steering Group and about half the patient and public involvement groups are members of the general population with an interest in disease prevention, and not patients with specific health issues.

The CAG noted that minimal patient and public involvement had been conducted and requested that further engagement was undertaken. The Committee asked for this new involvement group to closely represent the original cohort from the hospital, and to discuss the newly developed notification as well as use of confidential patient information. The Committee requested the research team to provide all outcomes to CAG.

Exit strategy

Once the applicants have obtained mortality outcomes on all participants (likely within the next 3-5 years), they will explore the use of a pseudonymised approach. The applicants note that this process will be relatively easy with the electronic data they hold, however they also hold an archive of paper records covering a thirty-year period which will be more challenging to anonymise.

The CAG requested clarification on whether anonymisation would be used as the exit strategy.

Secondly, the CAG requested clarification on how the dataset would be managed once the study was concluded. The CAG recognised the historical value of the paper records and queried whether the research team would contact the National Archives to determine the best appropriate action.

Lastly, the CAG requested for a time scale regarding exiting support.

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. CR19/2014 will be expired from the date of this letter and superseded by 22/CAG/0173. Please note the new annual review date.

2. Please check whether NHS Digital still hold the identifiers from the original cohort within their database and are able to refresh the dataset without requiring the disclosure of confidential patient information form the University of Bristol to NHS Digital.

3. The CAG requested that patient notification materials were created and for the following to be included:

    a. Clearly state that the research team hold access to confidential patient information.

    b. Clarify that section 251 and CAG support is in place for this study.

    c. Develop a clear local opt-out process and explain this within the patient notification.

4. Please undertake further patient and public involvement with a representative group of the original cohort from the hospital. This should involve a discussion on the use of confidential patient information and provide the outcomes to CAG.

5. Please clarify whether anonymisation would be used as the exit strategy.

6. Please provide clarification on how the dataset would be managed once the study was concluded.

7. Please provide a time scale regarding exiting support.

Specific conditions of support (provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed (23/08/2022)**

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

   The NHS Digital **21/22** DSPT reviews for **University of Bristol – Bristol Medical School** & **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 November 2022)

c. 22/CAG/0174– UNderstanding the Causes of hyperglycaemia in pRegNancy

Purpose of application

This application from King's College London set out the purpose of medical research to characterise the pathophysiological subtypes of gestational diabetes and to define mechanistic pathways. Gestational diabetes (GDM) is a condition causing high blood glucose (hyperglycaemia) and results from an imbalance between decreasing insulin sensitivity during pregnancy and beta-cell compensation. This description came from early studies in small numbers of high-risk women and used thresholds of diagnosis for GDM that are now outdated. As a result, current therapy in the UK is to counsel women for dietary change. If their glucose levels do not improve, metformin is prescribed, followed by insulin if the GDM is still not controlled. This process can take several weeks, and it is not known which therapy is most appropriate for individuals' patients. The method of undertaking the oral glucose tolerance test (OGTT), the main test for GDM diagnosis and which is undertaken at 24-28 weeks of pregnancy, is not standardised. This makes global interpretation of research difficult. Practical issues also make the OGTT an unreliable and outdated method of diagnosis.

Patient medical records will be screen by the research team to identify eligible patients. The research team will then make contact by telephone, text message or email in advance of their scheduled appointment. Patients will be sent a copy of the Patient Information Sheet and Consent Form as part of an invitation email. Contact may then continue via phone, email or in person. The applicants noted that patients may be approached by researchers in clinic, if the invitation was missed or the patients do not

use email or telephone. Should patients consent, their participation will proceed on a consented basis.

A recommendation for class 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	750 pregnant women of white or South Asian descent with a singleton pregnancy.
Data sources	1. Electronic medical records held at University Hospitals of Leicester NHS Trust 2. Electronic medical records held at Guy's and St Thomas' NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID 4. Date of Birth 5. Postcode 6. Ethnicity 7. Contact details (phone number, email and postal address)
Identifiers required for analysis purposes	1. N/A as any identifiers for analysis included with consent as the legal basis under common law

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG requested clarification on how the research team will access patient records. The members queried whether staff had been appropriately trained as well as requested clarity on how the access would be controlled throughout the duration of the study.

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**

Patients will be contacted by the researchers and consent sought. The applicants advised that seeking consent prior to screening was not feasible as they sought to avoid approaching women who were ineligible for the research and those who may have suffered pregnancy loss.

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

- **Use of anonymised/pseudonymised data**

The research team will access confidential patient information in patient medical records in order to identify eligible patients and make contact to seek consent.

The applicants required access to confidential patient information in order to screen

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.

No patient notification is planned, and patients will first become aware of the project when contact is made by the research team.

The National Data Opt-Out will be applied. Records of patients who have opted-out of use of their data in research, either locally or nationally, will be removed prior to screening by the research team.

The CAG requested for the creation of a patient notification, informing patients that their information may be accessed. Furthermore, this notification should be clearly displayed within the clinic waiting rooms. The creation of this notification will ensure that there are

no surprises when individuals are contacted, as well as provide clarity on how individuals are identified.

The CAG requested for the notification to explain section 251 and CAG, as well as a clear explanation of the local and National Data Opt-out mechanisms in place.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are 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.

UNiCoRN has its own patient and public involvement group that currently consists of 4 women of both ethnic groups and half with lived experience of Gestational diabetes. The PPI group were asked via email how they felt about the unconsented activity. No objections were raised. One of the groups supported the approach, although specified that she would want to know why she had been contacted and that only the relevant parts of her notes had been accessed.

The patient and public involvement group reviewed the study participant facing documentation. The study processes and visits deemed were acceptable.

The CAG recommended for the new patient notification materials to be shared with the patient and public involvement group.

Exit strategy

The applicant stated that consent is the exit strategy.

Should patients not wish to participate, minimal details will be retained to prevent re-contacting. The initial contact email will include a statement that explains this. Patients will be given the opportunity to object to retention of their data, with an explanation that they may be re-contacted if their details were not retained. In the case of no response to contact attempts, the data will not be retained.

The CAG is content with the exit strategy proposed by the applicant.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Please provide clarity on how the research team access patient records, as well as clarify, whether staff have been appropriately trained and how the access will be controlled throughout the duration of the study.

2. Please create a new notification, including the following:
    a. An explanation that patient data may be accessed

       Explain section 251 and the role of CAG.
    b. Clearly explain the local and National Data Opt-out mechanisms in place.

3. Confirm that the patient notifications will be displayed in relevant waiting areas and clinics.

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 **King's College London**, **University Hospitals of Leicester NHS Trust** & **Guy's and St Thomas' NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 12 November 2022)

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	15/12/2022
Dr Murat Soncul	16/12/2022

Signed – Confidentiality Advice Team	Date
Mr William Lyse	16/12/2022