Health Research Authority

Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on *05 October 2023* via video conference.

Present:

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Clare Sanderson	Alternate Vice Chair
Dr Murat Soncul	Alternate Vice Chair
Dr Martin Andrew	CAG Expert Member
Dr Malcolm Booth	CAG Expert Member
Mr David Evans	CAG Expert Member
Dr Harvey Marcovitch	CAG Expert Member
Dr Stephen Mullin	CAG Expert Member
Ms Rose Payne	CAG Lay Member
Mr Dan Roulstone	CAG Lay Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr William Lyse	HRA Approvals Administrator
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor (item 4a only)

Ms Hayleigh Keating	HRA approvals specialist (Observer)
Professor Andrew Pollard	Chief Investigator for 23/CAG/0155 (item 4a only)
Nelly Owino	Senior Clinical Trials Project Manager, 23/CAG/0155 (item 4a only)
Dr Parv Aley	Director of Global Operations, 23/CAG/0155 (item 4a only)
Helen Duckworth	Applicant for 23/CAG/0147 (item 5b only)
Chloe Whittle	Senior Information Governance Consultant, 23/CAG/0147 (item 5b only)
Jim Hughes	Data and Digital Strategy Director, 23/CAG/0147
Professor Elizabeth Draper	Chief Investigator for 23/CAG/0143 (item 5a only)
Georgie Page	Study Administrator for 23/CAG/0143 (item 5a only)

1. APOLOGIES FOR ABSENCE

Professor James Teo and Professor Lorna Fraser (CAG members) gave their apologies. The CAG Chair Tony Calland only attended regarding item 4a.

2. DECLARATIONS OF INTEREST

2.1	23/CAG/0147	Cheshire and Merseyside: System Supplier processing of Confidential Patient Information to create a de-identified data mart for secondary uses
	Conflict:	CAG Member Mr David Evans declared an interest in this item 5b – as he is conflicted with all non-research applications due to working in the same team as the Department of Health & Social Care senior civil servant who is the decision maker for CAG non-research applications on behalf of the Secretary of State for Health & Social Care. The Committee agreed that Mr David Evans did not need to leave the meeting but should not participate in the discussion.

2.2	23/CAG/0155	CAG Overarching Application for Oxford Vaccine Group (OVG) Studies
	Conflict:	CAG Member Dr Stephen Mullin declared an interest in this item- as he is involved in the preparation of an application similar trial to this application. The Committee agreed this did not constitute a conflict of interest and they could participate in the full study discussion.

3. 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 **07 September 2023** meeting, however there was a request to remove one of the CAG requests for further information regarding application 23/CAG0131.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **07 September 2023** meeting applications.

Minutes:

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

- **24 August and 7 September full meetings**
- **01 September precedent set meeting**

4. CONSIDERATION ITEMS

4.1 Resubmission

4.a	**23/CAG/0155**	**CAG Overarching Application for Oxford Vaccine Group (OVG) Studies**
	Chief Investigator:	Professor Sir Andrew Pollard
	Sponsor:	University of Oxford
	Application type:	Research
	Submission type:	Resubmission

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present.

Summary of application

This application from the University of Oxford set out the purpose of recruitment of patients to vaccine clinical trials.

The Oxford Vaccine Group (OVG), based in the Department of Paediatrics at the University of Oxford, conducts studies of new and improved vaccines for children and adults. It conducts a range of clinical trials on the basis of consent each with relevant approvals from the MHRA and REC. Previously, a range of recruitment methods have been used but because the number of studies has increased the applicants wish to undertake a range of identification and recruitment procedures.

This application, specifically for the studies below, requests support to allow NHS England to search for eligible patients within specific postcodes surrounding the Oxford area (where the trial centre is based). This extract of name, address and postcode will be transferred to PSL Print Management Ltd to send invitations. Oxford Vaccines Group will not receive any confidential patient information until the patient proactively contacts them if interested in a particular study, at which point all activities operate under consent. Patients will be sent no more than 3 mailouts in any given year, with at least a three-month period between mailouts.

Confidential information requested

Cohort	Patients meeting the broad inclusion criteria for the below research studies: 1. Development of a Live Attenuated Vaccine against Salmonella Paratyphi A (VASP) IRAS Project 2. A single-blind, randomised, phase II multi-centre study to determine reactogenicity and immunogenicity of heterologous prime/boost COVID-19 vaccine schedules in adolescents (COMCOV-3) 3. A phase I study to determine the safety and immunogenicity of a new vaccine against Middle East Respiratory Syndrome Coronavirus in Adults aged 50 to 70 (MERS) 4. A phase 1 safety and immunogenicity study of a Crimean-Congo haemorrhagic fever virus vaccine, ChAdOx2 CCHF, in healthy adult volunteers in the UK (CCHF) 5. An open label Phase I/IIa clinical trial to assess the safety, immunogenicity and efficacy of the malaria vaccine candidate RH5.2-virus-like particle (VLP) in Matrix-MTM, and to compare the safety and immunogenicity of the malaria vaccine candidates RH5.2-VLP in Matrix-MTM and RH5.1 soluble protein in Matrix-MTM used in various regimens (BIO-001) 6. Phase I clinical trial to assess the safety and immunogenicity of the malaria vaccine

	candidate RH5.1 soluble protein in Matrix-MTM using two dosing regimens (BIO-002) 7. Heterologous Boosting for Hexavalent Paediatric Vaccines in the UK Schedule (6in1 Part 2) 8. Safety and Immunogenicity of a Shigella tetravalent bioconjugate vaccine in adults (SIS4V)
Data sources	1. The Personal Demographics Service (PDS) held by NHS England
Identifiers required to determine eligibility	1. Date of birth 2. Postcode
Identifiers required for sending of invitation letters	1. Name 2. Address 3. Postcode
Additional information	Date of birth is used to ensure eligibility and are not transferred to PSL Print Management Ltd. No identifiers are sent to Oxford Vaccines Group. They will not have any contact until a patient proactively approaches them interested in a trial.

Main issues considered, discussed and outcomes

Members noted that this was a reconsideration of 23/CAG/0091 which was considered at the 24 August 2023 CAG meeting and rejected. The reconsideration was made based on concerns raised by the applicants following receipt of the outcome from the 24 August 2023 meeting.

The CAG felt that the previous application lacked detail in several key areas that the Group have a remit to consider under Section 251 of the NHS Act 2006 and the NHS (Control of Patient Information) Regulations 2022 and agreed this was a contributory factor in the previous outcome. Members thanked the applicants in providing further information for this meeting which aided the review.

Members agreed that the science and aims of the research studies under this application were not in question and agreed that there was a high public interest in the research studies. Members were reassured that this activity fell within the definition of medical research and were therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members asked what proportion of vaccine trials would be Phase I, to which the applicants estimated approximately 50%. No further questions were asked related to this point.

The CAG queried whether clinical information in addition to age, postcode and vaccine status would be used in order to identify potential participants. The applicant clarified this would not happen. Potential participants would self-report their eligibility and this would be checked with their GP, following consent. No further questions were asked by CAG on this aspect.

Previous applications using the same methodology and approach as stated in this application have been supported, and members agreed that the methodology used was not in question. The CAG were also assured that the applicants have measures in place to handle concerns from invitees, and of the commercial aspect of these trials.

However, members agreed they have a responsibility to ensure public trust is maintained when confidential patient information is used and balance the benefits of this use without consent against possible risks. In this application it means considering the benefits of large-scale use of confidential patient information to aid vaccine trial recruitment against the risk to public trust of their information with such use. To do this, there are a number of specific areas that members consider.

As part of the Regulations, CAG cannot support any application if there is a practical alternative to using confidential patient information without consent. Members agreed that the justifications on why other approaches are no longer viable on their own, and why these need to be supplemented with this approach, were sufficient. However, the CAG felt that Oxford Vaccines Group should still consider whether recruitment can be undertaken through alternative, less disclosive methods. As such, before any future amendment for new vaccine trials, the applicants should consider the necessity of using this recruitment approach and why other less disclosive approaches alone are not viable **(Condition 1)**.

To support CAG considerations as to whether any activity is in the public interest, views from patients and the public are key for all applications. For this application it means specifically testing the acceptability of using this recruitment approach, which involves review of patient information at NHS England to determine eligibility and the large scale sharing of name and address to a mailing company without consent, with a representative group of patients. Members noted that the research may use sites across the UK and queried whether the patient group is representative of the UK. The applicants stated that whilst their work is based in Oxford, the patient and public group has members from across the UK.

The CAG reviewed broad details about patient and public events undertaken in the past, as provided by the applicants, and that no concerns had been raised by attendees. Members felt that the information provided did not provide enough assurance that full informed discussion on this particular recruitment

method has been had with the public and queried the applicants further. The applicants stated that a further session with their public group, specifically on this recruitment method, was held three days prior to the CAG meeting and broad support was provided.

The CAG discussed the patient and public involvement evidence provided to date. Members accept and understand that the Oxford Vaccines Group have undertaken patient and public involvement on the trials themselves to date, as agreed with funders and the Research Ethics Committee and this is not in question. However, CAG are focussed on specific and ongoing patient and public involvement that tests the acceptability of using confidential patient information without consent to digitally search centrally held medical records in order to identify and invite people into these vaccine trials. Members agreed that, whilst broad statements have been provided to date, this was insufficient evidence.

As such, members requested that a report is provided on the patient and public involvement undertaken to date specifically on the recruitment via NHS England route, and the acceptability of the use of confidential patient information without consent. This should include the specific involvement undertaken on each study listed on the initial application, plus the broader work undertaken on 2 October 2023. For each piece of patient and public involvement details should be provided on the number of participants, summary of the demographics of the participants, what format the involvement took (e.g. focus group, survey), and a summary of the discussions and comments made by the participants. For the 2 October 2023 event, members also wished to see any content that was presented to the applicants to describe the use of confidential patient information without consent and what was asked to the participants. Where concerns were raised, the report should detail any actions taken to mitigate those concerns. **(Action 1)**

The CAG agreed that a key element of any research should be to undertake ongoing patient and public involvement, aligned with HRA principles. This should include testing the acceptability of using Confidential Patient Information without consent, as per CAG principles. Given this is a long term operation with multiple studies both currently and the future CAG were unclear what plans were in place to ensure ongoing patient and public involvement on this recruitment method both generally and specifically for each vaccine trial. Members therefore requested a broad plan for ongoing patient and public involvement on the recruitment method and the acceptability of using confidential patient information without consent. This should include details on how the recruitment method will be tested in general with the patient and public involvement group, as well as for each future study and trial site. (**Action 2)**

Members discussed with the applicants that some of the trials may be multi-site (sometimes involving up to 10 sites across the UK). The applicants clarified that their patent and public involvement group currently contains approximately 26 members, and that the membership is spread across the country. The CAG agreed that it is good to have a core group to use, but that this should be supplemented with wider patient and public involvement in the area local to

each site to ensure local acceptance. This may be through surveys, focus groups or other methods felt appropriate by the applicants, but should provide a short detail on the study and how patient information will be used to identify and invite people into the vaccine trial, and test views on using this approach. Members therefore requested:

1. For the current eight vaccine trials listed within the initial application, undertake patient and public involvement within areas local to the currently known trial sites. A report on these trial sites should be provided at first annual review. **(Condition 2)**
2. For future vaccines trials which use new trial sites to Condition 2, undertake patient and public involvement within these local areas and provide a report with the amendment to add the trial **(Condition 3)**.

The CAG noted to the applicants that maintaining public trust in any activity that uses confidential patient information without consent is key, not just for the application in particular but for the benefit of all research. Members have seen in the past where this is lost the public will enact their National Data Opt Out which, if it rises significantly, will have a detrimental impact to all activities (research and non-research) that operate under Section 251 support.

Members reviewed the template invitation letter, specifically the section on "*Accessing data for research mailouts*" and "[*For NHS database extracts include:]*". The CAG agreed that, whilst the wording of the section provide some detail on how patient data is used, some patients may have questions on what data is used. On review of previous wording approved using the same methodology, CAG requested the following additional line be added to ensure complete clarity to participants:

"*NHS England holds information from the records that health and social care providers in England keep about the care and treatment they give. The data they hold can be used to plan and improve health services, including medical research*." **(Action 3)**

Subject to the Actions being satisfactorily responded to, members agreed they would be content to support this overarching application for the current eight studies listed. However, the CAG were clear that this support did not allow future vaccines trials to use the same methodology without CAG oversight and safeguards in place. Therefore, members agreed a proportionate approach to adding future new vaccine trials to the application via an amendment. Each amendment to add a new vaccine trials submitted to CAG should include the following (**Condition 4)**:

1. Completed CAG amendment form
2. Supporting document that provides:
    a. A summary of the vaccine trial (as per the lay summary of the study provided to REC and MHRA as part of the combined review form)
    b. A description of the cohort to be included in the trial
    c. The target number of participants to be recruited
    d. An estimated number of letters to be mailed through NHS England/ PSL Print Management Ltd

e. Information as to whether this is a single site (in Oxford) or multi-site vaccine trial
f. A summary of why this recruitment method is necessary for this application.
g. A summary of the study specific patient and public involvement within the area local to sites (including numbers, format of event, what was presented and asked of attendees and summary of comments).

In order to maintain an accurate record of current applications using this method of recruitment, members requested that CAG is notified when a vaccine trial completes recruitment and therefore is no longer reliant on Section 251 support. **(Condition 5)**

The CAG discussed that whilst the methodology has been supported in the past, the type of arrangement detailed in this application has not been. Members accepted that this was a practical and proportionate way forward for this application in the area of vaccine research, which target infectious and highly virulent organisms with the potential to give rise to outbreaks causing serious morbidity and mortality. However, the CAG agreed that annual reviews should be considered at a full meeting of the CAG. **(Condition 6)**

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Provide a report on the patient and public involvement undertaken to date specifically on the recruitment via NHS England route, and the acceptability of the use of confidential patient information without consent. This should include the patient and public involvement undertaken on each study listed on the initial application, plus the broader work undertaken on 2 October 2023. For each piece of patient and public involvement detail should be provided on: • the number of participants • demographics of the participants • what format the involvement took (e.g. focus group, survey) • summary of the discussions and comments made by the participants. For the 2 October 2023 event, please also	

	provide any content (e.g. slides, information sheets) that was presented to the applicants to describe the use of confidential patient information without consent and what was asked to the participants. Where concerns were raised, the report should detail any actions taken to mitigate those concerns.	
2.	Provide a broad plan for ongoing patient and public involvement on the recruitment method and the acceptability of using confidential patient information without consent. The plan should include details on • how the recruitment method will be tested in general with the patient and public involvement group, and frequency of such testing • how involvement will be undertaken for future specific studies with the Oxford Vaccines Group Patient and public involvement group • how involvement will be undertaken with the wider public in geographical areas close to each trial site. Plans should align with HRA principles and should include testing the acceptability of using Confidential Patient Information without consent, as per CAG principles.	
3.	As per previous precedents with similar applications, the following line should be added to the patient invitation letter, specifically in the section on "*Accessing data for research mailouts*", "[*For NHS database extracts include:]*". "*NHS England holds information from the records that health and social care providers in England keep about the care and treatment they give. The data they hold can be used to plan and improve health services, including medical research*."	

The CAG also set out the following provisional specific conditions of support in addition to the standard conditions of support.

Number	Condition

1.	Before any future amendment for new vaccine trials, the applicants should consider the necessity of using this recruitment approach and why other less disclosive approaches alone are not viable
2.	For the current eight vaccine trials listed within the initial application, undertake patient and public involvement within areas local to the currently known trial sites. A report on these trial sites should be provided at first annual review.
3.	For future vaccines trials which use new trial sites to Condition 2, undertake patient and public involvement within these local areas and provide a report with the amendment to add the trial.
4.	Future vaccine trials from Oxford Vaccines Group should be submitted as an amendment before Section 251 support is confirmed. Each amendment to add a new vaccine trials submitted to CAG should include the following: 1. Completed CAG amendment form 2. Supporting document that provides: a. A summary of the vaccine trial (as per the lay summary of the study provided to REC and MHRA as part of the combined review form) b. A description of the cohort to be included in the trial c. The target number of participants to be recruited d. An estimated number of letters to be mailed through NHS England/ PSL Print Management Ltd e. Information as to whether this is a single site (in Oxford) or multi-site vaccine trial f. A summary of why this recruitment method is necessary for this application. g. A summary of the study specific patient and public involvement within the area local to sites (including numbers, format of event, what was presented and asked of attendees and summary of comments).
5.	Notify CAG when a vaccine trial completes recruitment and therefore is no longer reliant on Section 251 support.
6.	Annual reviews will be considered at a full meeting of the CAG.

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5. NEW APPLICATIONS FOR CAG CONSIDERATION

5.a	**23/CAG/0143**	**Development of the International Stillbirth Alliance Perinatal Death Classification System for Ending Preventable Stillbirths and Neonatal Deaths in Data-Rich Settings**

	Chief Investigator:	Professor Elizabeth Draper
	Sponsor:	University of Leicester
	Application type:	Research
	Submission type:	PILOT

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had no objection to the observers being present.

Summary of application.

This application from the University of Leicester sets out the purpose of medical research to establish a classification system to accurately classify perinatal deaths. The research will also compare and evaluate the recently developed International Stillbirth Alliance (ISA) Classification System, in comparison to existing classification systems. The aim is to establish a cause of death (COD) coding system (either the ISA system, an existing system, or an adapted version of either) that allows the collection of the highest quality data in respect to causes of perinatal death, thus allowing for data comparison between international settings and prioritisation for prevention strategies to minimise unexplained stillbirths and neonatal deaths.

For the purpose of this project, the applicant requires access to 100 mother and baby hospital notes for perinatal deaths occurring in July to December 2019 that have already been supplied to and processed by MBRRACE-UK under the terms of the Confidential Enquiry (CE) programme commissioned by HQIP. The processing of these records without consent for the purpose of the MBRRACE-UK Confidential Enquiry Programme has been undertaken using Section 251 approval (15/CAG/0119).

Support is requested for this specific project as the purpose of the data processing is research and is in addition to the Section 251 support for a non-research purpose for MBRRACE-UK for the CE programme.

Confidential information requested

Cohort	100 cases of perinatal death in England and Wales in 2019*
Data sources	1. MBRRACE-UK Confidential Enquiry case notes 2. MBRRACE-UK Perinatal Surveillance data
Identifiers required for linkage purposes	1. Date of birth – infant 2. Date of death – infant 3. Gender – infant and mother 4. Ethnicity – infant

Identifiers required for analysis purposes	1. Date of birth – infant 2. Date of death – infant 3. Gender – infant and mother 4. Ethnicity – infant
Additional information	*cases already processed by MBRRACE-UK for the Confidential Enquiry Programme under 15/CAG/0119

Main issues considered, discussed and outcomes

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.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG requested clarification as to why consent could not be sought for the 100 participants.

The Applicant clarified that they were not including any new participants from the original cohort collected within their previous application (15/CAG/0119 - MBRRACE-UK) and that for MBRRACE-UK they did not have direct contact with participants. Therefore, it would not be possible to contact participants to obtain consent for this project.

The CAG was satisfied with the applicant's response.

The CAG asked the applicant to clarify if the research team working on the data for this project were different to those working on MBRRACE-UK.

The Applicant clarified that this project would be undertaken by the same panel of reviewers that worked on MBRRACE-UK.

The CAG was content with the Applicants response.

The CAG requested the Applicant to provide an overview on what Patient and Public Involvement had been undertaken.

The Applicant specified that the research team were in regular contact with the International Stillbirth Alliance, a multidisciplinary group, which has been running since 2017. The Applicant also stated that they held separate discussions with their stakeholder group which occur one to two times a year.

The CAG requested a further detail of the makeup surrounding the International Stillbirth Alliance

The Applicant clarified that the alliance was made up 1200 members with one fifth being parents.

The CAG was satisfied with the applicant's response.

The CAG requested clarification on how the research team would apply the National Data Opt-out as well as a Local Opt-out.

The Applicant clarified that MBRRACE-UK employ their own standardised opt-out system, which the research team will utilise for this study.

The CAG requested for the applicant to provide a clear explanation of the project specific opt-out in their patient notification materials **[Action 1]**

The CAG requested clarification on how the research team were going to apply the National Data Opt-out, noting that this would only apply to parents. The CAG also requested that the patient notification materials should state that the National Data Opt-out will be respected **[Action 2]**

The CAG also requested for the applicant to reconsider where the patient notification materials would be published. Although the application stated that notification materials would be uploaded to MBRRACE-UK's website, the CAG requested for the Applicant to explore additional websites, such as the International Stillbirth Alliance's website or any still birth charity/organisation websites. **[Action 3]**

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
	Security assurances for 2023/24 are outstanding for the following organisations. • University of Leicester Please contact NHS England at exeter.helpdesk@nhs.net and provide the CAG reference number, the organisational names and references that require review, and ask NHS England to review the DSPT submissions due to a CAG application.	

1.	Provide a clear explanation of the project specific opt-out in the patient notification materials	
2.	Clarify how the National Data Opt-out will be applied, noting that this would only apply to parents. The CAG also requested that the patient notification materials should state that the National Data Opt-out will be respected	
3.	Explore additional websites, such as the International Stillbirth Alliance's website or any still birth charity/organisation to highlight the patient notifications materials.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5.b	**23/CAG/0147**	**Cheshire and Merseyside: System Supplier processing of Confidential Patient Information to create a de-identified data mart for secondary uses**
	Contact:	Ms Chloe Whittle
	Data controller:	Cheshire and Merseyside Integrated Care Board (ICB)
	Application type:	Non-research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Applicants attended to discuss the application.

Prior to the meeting the applicants were informed that there was an observer in attendance at the meeting. The applicants confirmed that they had no objection to the observer being present.

Summary of application

This application from Cheshire and Merseyside Integrated Care Board (C&M ICB) sets out the medical purpose to create a resource for secondary non-research use of the patient information in the C&M ICB footprint. This will be closely linked to the North West Secure Data Environment (SDE) following a future research application, but this is separate from the wider NHS England sub-national SDE programme, and is specific to Cheshire and Merseyside.

The data will be used for a wider range of secondary non-research uses, including population health management and commissioning intelligence. Use of data will be through a model of data access, rather than data sharing. Use cases will be considered by the Data Asset and Data Access Group (DAAG), which has two public members and will ensure that any uses have a medical purpose and public interest.

Information from national datasets, data from the C&M Care Record, and local datasets (for example local authority data) will be linked using a pseudonymised NHS number. Support is requested for the deidentification and secondary use of data from the C&M Care Record by Graphnet before subsequent linkage.

Confidential information requested

Cohort	All patients who have a health record at an organisation within the Cheshire and Merseyside ICB area.
Data sources	1. GP data from the Greater Manchester Care Record (via Graphnet) 2. Pseudonymised national datasets from Arden and GEM CSU (outside scope of support) 3. Local dataflows deidentified at source (outside scope of support)
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	None – all data is pseudonymised and then has a further code applied to it to prevent reidentification by the analyst

Main issues considered, discussed and outcomes

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.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that the application mentioned including genomic data as one of the data sets and was concerned that this data set would make pseudonymised database identifiable. The CAG asked the applicant to justify why they were going to include genomic data specially for a non-research

application. The applicant responded that they were not sure why this data set was included and needed to discuss with their team regarding inclusion of genomic data set. The applicant agreed to provide a response to CAG later in their correspondence. The CAG requested a clear justification on why genomic data set was being used in this application. **(Action 1)**

The CAG discussed the possibility of patients being treated at the hospitals who were not residents in the local area or registered with the local GPs. The CAG asked the applicant to explain how they intended to reach out to this population. The applicant responded that this application was intending to include people who were registered or residents in Cheshire and Merseyside but also suppliers of healthcare that might supply healthcare to people who were outside the area. The applicant explained that as part of their communication campaign they were exploring options on how to target and reach populations outside the local areas. The CAG requested a strategy plan on how the applicant was going to target their communication campaign in the future around the people who were not locally residents of Cheshire and Merseyside area. **(Action 2)**

In terms of PPI, The CAG noted that as well as patients, the applicants were also engaging with staff and GPs/providers. The CAG commended the applicants regarding their work around the GP engagement. The CAG requested that GP engagement to be an ongoing campaign. **(Action 3d)**

The CAG requested further patient and public involvement was undertaken, particularly around the specific issue of use of confidential patient information without consent. The CAG also requested that discussion should include questions around commercial use if the applicant was likely to use the information for the commercial purposes. **(Action 3 a-b)**

The CAG noted that the patient notification was inadequate for the purposes of dissemination. The notification should clearly explain and demonstrate the benefits of the outcome of this application so the patients can understand why their data was going to be used. The notification should also clearly explain the mechanism of specific local opt-out. The CAG requested that the notifications to promote use of the local opt-out whilst still respecting the National Data Opt-Out. Finally, all notifications should be reviewed by the patients and the public group for accessibility. **(Action 4)**

The CAG was concerned whether the application was clear regarding the terminology around ‘pseudonymisation’ and ‘anonymisation’. The CAG asked the applicant to clarify whether this application was aiming to use anonymised data set as well as pseudonymised data set. The applicant confirmed that they were planning to only use pseudonymised data set as anonymised data set involved a level of aggregations. The CAG was satisfied with the response.

Confidentiality Advisory Group advice: Provisionally supported

The CAG was unable to recommend support to the Secretary of State for Health and Social Care for the application based on the information and

documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Provide clear justification on why genomic data set is going to be used for the purpose of this application.	
2.	Provide a strategy plan to explain how the applicant is going to target the communication campaign in the future around the people who are not locally residents of Cheshire and Merseyside area.	
3.	Further patient and public involvement need to be carried out. The discussion should include: a) The specific issue of use of confidential patient information without consent is to be undertaken and feedback provided to the CAG for review. b) Questions around commercial use if the application is planning to use the information for the commercial purposes. c) Provide an ongoing patient and public involvement plan and continuous GP engagement.	
4.	Please update the patient notification materials as follows, in line with advice in this letter: a) Clearly explain and demonstrate the benefits of the outcome of this application so the patients can understand why their data is going to be used.	

	b) An explanation on how patients can request removal of their data using a local opt-out or the National Data Opt-Out needs to be provided. 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) Promote use of the local opt-out whilst still respecting the National Data Opt-Out. d) Patient notification materials should be reviewed by a patient and public involvement group.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5.c	**23/CAG/0150**	**Intimate partner violence and mental health of parents & children – an ALSPAC Substudy**
	Chief Investigator:	Dr Rebecca Lacey
	Sponsor:	ALSPAC (University of Bristol)
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from ALSPAC (University of Bristol) set out the purpose of medical research to investigate the relationships between exposure to intimate partner violence (IPV), parental mental health and children's mental health.

In any two-year period, almost one quarter of children are exposed to maternal mental illness. Mother's mental health problems are associated with

problems in children's cognitive development, physical and mental health. Exposure to intimate partner violence (IPV) and parental substance misuse during childhood increases the risk of negative mental health outcomes. There is some evidence that parental mental health problems may reduce children's resilience to the impact of IPV. However, the relationships between IPV, parental mental health and children's mental health and factors that promote resilience in children exposed to IPV.

The applicants seek to undertake a specific project to investigate these relationships, using data collected by ALSPAC. The research proposes to include all the young people whose families have enrolled into the study, who have been sent fair processing information and who have not explicitly withdrawn from the study or denied consent for record linkage to their health records. ALSPAC will undertake the data extraction and linkage in line with their standard methodology. When the data is received by ALSPAC it will be pseudonymised as soon as it has been linked to the ALSPAC dataset and processed. The processing occurs in the ALSPAC Data Safe Haven. The research team will only have access to anonymised data within the UKSERP system. The identifiable NHS data will remain within the ALSPAC Data Safe Haven and will be stored on encrypted hardware.

Confidential information requested

Cohort	All ALSPAC participants who have been contacted for consent to extraction of their medical records but have not responded. 15,000 patients will be included in total, around 7,500 of which will be under s251 support.
Data sources	1. HES and data, NHS England 2. GP Records 3. Local health records 4. ALSPAC Databank
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – sector level
Identifiers required for analysis purposes	1. Gender

Additional information	

Main issues considered, discussed and outcomes

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.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

Section 251 support was sought for the continued collection of data from those who did not respond to consent. The CAG noted that, in line with guidance from the Information Commissioners Office, non-response is generally considered to be dissent and queried whether support should be recommended. Following the meeting, the CAG was informed that the original support for ALSPAC (ECC 1-05(b)/2012) covered the inclusion of non-responders, as the Fair Processing information explained that patients would be included unless they specifically dissented.

The CAG asked the applicant to provide the specific wording used within the Fair Processing Information Leaflet, as it was unclear whether the up-to-date wording was on file. **[Action 1]**

Confidentiality Advisory Group advice: Conditionally supported

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.

Number	Condition	Response from the applicant
1.	The specific wording used within the Fair Processing Information Leaflet, explain the consequences of non-response, needs to be provided for review.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

5.d	23/CAG/0151	**CORECT-R: the UK COloRECTal Cancer data Repository**
	Chief Investigator:	Professor Eva JA Morris
	Sponsor:	Nuffield Department of Population Health, University of Oxford
	Application type:	Research
	Submission type:	New application

The Group reviewed the above application in line with the CAG considerations.

Summary of application

This application from the University of Oxford set out the purpose of setting up a research database containing data for all individuals who are at risk of, or are diagnosed with, colorectal cancer in the UK.

Colorectal cancer is a major public health problem. In the year UK, around 41,000 each year are diagnosed with the disease and 16,000 die from it. High-quality data could be used to improve the outcomes of patients diagnosed with colorectal cancer. Linked colorectal cancer data are already available from some data providers in England, Scotland, Wales and Northern Ireland. However, a UK wide cancer data resource does not exist resulting in researchers and analysts being forced to go through lengthy, resource intensive and costly processes to access numerous cuts of data. The applicants anticipate that CORECT-R will reduce this duplication of effort and increase the security of the data. The first iteration of CORECT-R sought to undertake linkage of datasets within the National Disease Registration Service (NDRS). However, the remit of the NDRS is data generated within England only and the applicants seek to include data from all 4 UK nations.

Support is sought to link data from consented cohort & trial datasets and from datasets held by National Cancer Registration and Analysis Service, NHS England, NHS Bowel Cancer Screening Programme, Health Quality Improvement Partnership, Welsh Cancer Intelligence and Surveillance Unit and Public Health Wales. The datasets will be disclosed to the University of Oxford for linkage. A dataset containing confidential patient information will be held within the CORECT-R Trusted Research Environment.

Researchers seeking to access data will apply via the Hub team. Individuals submit a request and are contacted to discuss their request and availability of data. If the project is feasible, they are then supported to complete a study protocol and to discuss their planned work with the Patient-Public Group. Once complete, the study protocol is considered by the Hub Access Committee. If accepted, and after necessary checks, access is provided to a project specific folder in the CORECT-R Trusted Research Environment. Researchers are only given access to tailored, project specific, pseudonymised datasets in line with their approved protocol.

Confidential information requested

Cohort	All patients in England and Wales with a diagnosis of, or suspect diagnosis of, colorectal and/or anal cancer since 01 January 1997.
Data sources	1. National Cancer Registration and Analysis Service a. Cancer Registry Data b. National Radiotherapy Dataset (RTDS) c. Systematic Cancer Therapy Dataset (SACT) d. Patient Reported Outcomes (PROMS) e. Patient Reported Experience Survey 2. NHS England a. Hospital Episode Statistics (HES) b. Diagnostic Imaging Dataset (DID) c. Cancer Waiting times (CWT) d. NHS Bowel Cancer Screening Programme 3. Health Quality Improvement Partnership (controller) a. National Bowel Cancer Audit (processors - NHS England and Royal College of Surgeons of England) b. National Emergency Laparotomy Audit (processors - Royal College of Anaesthetists and Royal College of Surgeons of England) 4. Welsh Cancer Intelligence and Surveillance Unit a. Cancer Registry Data b. National Radiotherapy Dataset (RTDS) c. Systematic Cancer Therapy Dataset (SACT) d. Patient Reported Outcomes (PROMS) e. Patient Reported Experience Survey 5. Public Health Wales a. Patient Episode Database Wales (PEDW) b. Bowel Screening Wales
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. GP Registration 5. Date of birth 6. Date of death 7. Postcode – unit level
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. Occupation 4. Ethnicity
Identifiers held in database	1. Initials 2. Full name 3. Address 4. NHS number

	5. Hospital ID number 6. GP registration 7. Date of birth 8. Year of birth 9. Date of death 10. Postcode – unit level 11. Gender 12. Occupation 13. Ethnicity

Main issues considered, discussed and outcomes

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.

Having reviewed the application and considered the risks and benefits involved, the CAG was also assured that the proposed activity was in the public interest.

The CAG noted that the application referred to both research and non-research purposes. Members agreed that this application had been considered for research purposes and that the applicant was required to submit a separate application for non-research purposes. **(Action 1)**

The CAG noted that the scope of support for this data set was up to 31 May 2023. The CAG noted that application was planning to get consent for the data set post 31 May 2023 even though it was not clear how they were going to do that. The CAG requested confirmation that the scope of support for this data set was up to 31 May 2023. **(Action 2)**

In terms of Patient and Public Involvement, the CAG was satisfied with the discussions undertaken with the Patient and Public Involvement group. However, it was noted that there were not enough representative groups within the Patient and Public Involvement group. Therefore, the CAG requested that wider specific patient and public involvement was undertaken with representative groups, to discuss the acceptability of this use of confidential patient information without consent for the purpose of this application. **(Action 3)**

In terms of patient notification, the CAG requested that the patient notifications should clearly explain how patients can request removal of their data using a local opt-out or the National Data Opt-Out. **(Action 4)**

The CAG requested further details on the criteria the data access group will use to assess the application, including how the medical purpose is assessed. **(Action 5)**

<u>Confidentiality Advisory Group advice:</u> Provisionally supported

The CAG was unable to recommend support to the Health Research Authority for the application based on the information and documentation received so far. The CAG requested the following information before confirming its final recommendation:

Number	Action required	Response from the applicant
1.	Provide confirmation that support is only requested for research purposes and a new application for non-research purposes will be submitted separately.	
2.	Provide confirmation that the scope of support for this data set is up to 31 May 2023 and application is planning to get consent for the data set post 31 May 2023.	
3.	Further patient and public involvement need to be undertaken with representative groups, to discuss the use of confidential patient information, without consent, for the purpose of this application. Feedback from the discussion is to be provided to the CAG.	
4.	Update the patient notification materials to include an explanation on how patients can request removal of their data using a local opt-out or the National Data Opt-Out needs to be provided.	
5.	Provide further details on criteria the data access group will use to assess the application, including how the medical purpose will be assessed.	

The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.

6. ANY OTHER BUSINESS

There was no other business for discussion.

Dr Tony Calland, MBE, CAG Chair, Ms Clare Sanderson & Dr Murat Soncul, CAG Alternate Vice-Chairs	*20 October 2023*
…….	……..
Signed – Chair	*Date*
Dayheem Sedighi & Will Lyse	*10 October 2023*
…….	……..
Signed – HRA Approvals Administrator	*Date*