Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on 26th October 2023 via video conference.

Present:

Name	Capacity
Dr Tony Calland, MBE	Chair
Professor William Bernal	Alternate Vice Chair
Dr Martin Andrew	Expert CAG Member
Dr Sandra Duggan	Lay CAG Member
Mr David Evans	Expert CAG Member
Mr Tony Kane	Lay CAG Member
Professor Sara Randall	Lay CAG Member
Mr Umar Sabat	Expert CAG Member
Dr Joanne Bailey	Expert CAG Member
Mr Thomas Boby	Expert CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
William Lyse	HRA Approvals Administrator
Miss Sadi Cisse	Observer (Internal - HRA)

1. APOLOGIES FOR ABSENCE

There were no apologies for absence.

2. DECLARATIONS OF INTEREST

2.1	**23/CAG/0160**	**Where is all the heart failure? A community study**
	Conflict:	CAG Member Mr Umar Sabat declared an interest in this item – Umar was the Data Protection Officer for an organisation involved in the application, however he was not involved in the application. The Committee agreed this did not constitute a conflict of interest and he could participate in the 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 **21 September 2023** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **21 September 2023** meeting applications.

Minutes:

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

- 15 September – Precedent Set
- 29 September – Precedent Set
- 21 September - Full minutes

4. CONSIDERATION ITEMS

There were no items for consideration.

5. NEW APPLICATIONS FOR CAG CONSIDERATION

5.1.	**23/CAG/0153**	**Coventry and Warwickshire population health management programme**
	Contact:	Ben Wilczynski
	Data controller:	Coventry and Warwickshire Integrated Care Board

	Application type:	Non-research
	Submission type:	New application

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

Summary of application

This application from Coventry and Warwickshire Integrated Care Board set out the purpose of collecting patient data for use in population health management.

Embedding Population Health Management (PHM) in patient care and decision making throughout Coventry and Warwickshire Integrated Care System (ICS) is a key goal of the ICS as it works to improve patient care and to improve preventative care. Having access to high quality data through a PHM approach is also a key system capability outlined in NHS England's national ICS planning guidance. The PHM Programme seeks to improve understanding of the population's health to provide insights into the health and social care needs and wider determinants of health of the population now, as well as their needs for the future, the impact of services that we put in place and bringing data together to provide a holistic view of individual people in the population.

The data collected will include Primary Care from GP Practices, Acute Hospital Care, and Community and Mental Health care, from GP practices within the ICB area, George Elliot Hospital, South Warwickshire Foundation Trust, University Hospital Coventry & Warwickshire and Coventry and Warwickshire Partnership Trust. The data will be disclosed to HealtheIntent, within Oracle Cerner, for linkage. Linked confidential patient information will be made available to members of the direct care team from the organisations that supplied the data. Anonymised data will be made available to supporting team members.

Confidential information requested

Cohort	Patients and service users of partner organisations who are resident in Coventry and Warwickshire. Inclusion Criteria: • Patient has an active registration with a GP practice. • OR a patient has a post code in Coventry and Warwickshire. • OR patient has been treated at one of the data controllers and has a homeless/no fixed abode code. Exclusion Criteria:

	• Patient has objected (either through a type 1 opt-out with their GP practice or through the centralised objection process) • National Data Opt-Out
Data sources	1. Primary Care data supplied by GP Practices in Coventry & Warwickshire ICB 2. Acute Hospital Care, supplied by George Elliot Hospital NHS Trust, South Warwickshire University NHS Foundation Trust, University Hospitals Coventry and Warwickshire NHS Trust and Coventry and Warwickshire Partnership Trust
Identifiers required for linkage purposes	1. Given Name/First Name/Nickname 2. Middle Name/Initial 3. Last Name/Surname/Family Name 4. NHS Number 5. Date of Birth 6. Medical Record Number (MRN) 7. Addresses 8. Telephone Numbers 9. Email Addresses 10. Gender 11. Race 12. Ethnicity
Identifiers required for analysis purposes	1. Patient name 2. NHS number
Additional information	As part of Population Health Management system, use of Patient Identifiers such as Post Code, Date of Birth, Gender, Ethnicity and Language may be used for risk stratification or cohort identification. Identifiers such a Name and NHS Numbers are not used for analysis but displayed back to users (who have a legitimate relationship with the patient) to ensure that to the correct patient is identified for direct care purposes.

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 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 agreed with the premise of the application but determined that support could not yet be recommended. Members noted that the medical records for over a million patients would potentially be accessed and agreed that further work was needed to clarify the data flows and the access arrangements to the data.

The applicants proposed using software currently used in the USA, which used a complex algorithm to link patient records. Linking patient records across different systems is difficult in the USA as patients are not assigned a centralised record number, such as an NHS number. The CAG queried whether the number of identifiers listed in the application were needed in the UK, where records can be reliably linked using NHS number and a small number of identifiers **[Action 1]**.

Further clarification was needed on which data flows required Section 251 support and where another legal basis would be relied on. A clear data flow diagram and a written explanation of the processing of confidential patient information and the support required **[Action 2]**.

The applicants proposed to use the data collected to undertake a number of activities. Data would be made available to clinicians and support staff, and for audit and public health work. Further details were needed to explain the difference between use of data for population health management and direct care, and the different proposed uses of the data **[Action 3]**.

Further details were also needed on who would have access to the data, the level of access, and the Information Governance controls in place. For example, GPs would have a legitimate need to see patient level data for their practice, but it was unclear whether they would be able to see data for patients from other practices. Also, support staff would be able to access the data and it wasn't clear if this included access to confidential patient information. The support staff to which we refer are in secondary care which is much wider than only the GP support staff, many of whom have access to the records (receptionists, secretary etc). Social care data would be included, and it was unclear who would have the right to access this. **[Action 4]**.

The CAG queried whether free text data would be included. If so, further details needed to be provided on how this would be processed and who will have access **[Action 5]**.

The applicants would retain data for deceased patients. Members queried whether any items of confidential patient information would be retained for deceased patients **[Action 6]**.

In the notification materials (poster and leaflet), the CAG agreed that postal and email address details needed to be provided, for patients who are unable to access data via QR code, due to lack of access to the internet and/or a smartphone. Members agreed that a telephone contact needed to be provided on the patient notification materials, not only for patients to register dissent but also to contact with queries **[Action 7]**.

Members noted that patients' postcodes and dates of birth were included in the dataset used for analysis, which would mean that this data was identifiable and not anonymised. The CAG requested clarification on the items of confidential patient information included in the dataset used for analysis **[Action 8]**.

The CAG queried whether any data, including confidential patient information, would be shared with the USA **[Action 9]**.

The CAG noted that it was unclear how many people had been consulted during patient and public involvement. The information given in the Comms and Engagement Plan suggested that around 20 people had been consulted, which was small given the number of patients whose records could be processed. Members also noted that 60% of those consulted had answered that the PHM approach was a good idea, which seemed low. The CAG asked that further patient and public involvement was undertaken with a larger group and that information is provided about how they are recruited and their demographic characteristics. **[Action 10]**.

Confidentiality Advisory Group advice: Deferred

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. The CAG noted that the following points should be taken into consideration and addressed prior to resubmitting this application in future.

Number	Issue:
1.	Clarify whether the number of identifiers listed in the application were needed in the UK, where records can be reliably linked using NHS number and a small number of identifiers.
2.	Clarify which data flows required Section 251 support and where another legal basis would be relied on. A clear data flow diagram and a written explanation of the processing of confidential patient information and the support required.

3.	Provide an explanation of the difference between use of data for population health management and direct care, and the different proposed uses of the data.
4.	Provide details on: Who will have access to the data. The level of access available, for example, to GPs and support staff, including wider support staff and those at GP practices. The Information Governance controls in place. If social care data would be included and details on who would have the right to access this data and how access will be managed needs to be provided.
5.	Clarify whether any free text data will be included. If so, further details needed to be provided on how this would be processed and who will have access.
6.	Clarify whether any items of confidential patient information will be retained for deceased patients.
7.	Postal and email address details needed to be provided on patient notification materials, for patients who are unable to access data via QR code, due to lack of access to the internet and/or a smartphone. A telephone contact needs to be provided on the patient notification materials.
8.	Clarify whether any items of confidential patient information will be included in the dataset used for analysis. If so, please list the items of confidential patient information included.
9.	Clarify whether any data, including confidential patient information, will be shared with the USA.
10.	Further patient and public involvement, with a larger group, needs to be conducted.

5.2	**23/CAG/0157**	**Young people's barriers to Mental Health Services (ALSPAC Sub-study)**
	Chief Investigator:	Dr Corine Driessens
	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 explore inequalities in mental health service utilisation of young people experiencing emotional mental health problems and to identify characteristics of young people experiencing long-term emotional mental health problems yet not receiving mental health services.

Research has discovered that every day in England, 28.5% of young people experience mental health problems, and that as little as one in four receive formal support for these problems. Mental health problems have been shown to limit economic, vocational, and social functioning. The applicants seek to use data to determine which young people are less likely to receive professional support for their mental health problems and the characteristics are of those young people not receiving mental health services for their problems. It will also be determined how many young people who do not receive mental health services for their problems continue to experience mental health problems in young adulthood and how resilient these young people were during the COVID pandemic.

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 MHSDS datasets, NHS England 2. GP Records 3. ALSPAC Databank

Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death 4. Postcode – sector level
Identifiers required for analysis purposes	1. Gender
Additional information	Date of Birth will be used (by ALSPAC) to derive 'Age at Event' (expressed in days, minutes, seconds) and time intervals. This allows ALSPAC to provide information to researchers in event sequence order without disclosing Date of Birth or event date

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 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 a lack of clarity on where Section 251 support was specifically required. The CAG queried whether new data was being collected from NHS England for the purpose of this study, or whether the research team were analysing pre-existing data stored within an ALSPAC secure location. The CAG requested clarification on the processing of confidential patient information which will be undertaken under Section 251 support. **[Action 1]**

The CAG queried whether any new data would be collected and clarification on how this data would be managed. **[Action 2]**

The CAG noted potential difficulty with locating the study information posted on the website. The CAG requested that a link to this information was included on the front page of the ALSPAC communication document. **[Action 3]**

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.	Clarify where processing of confidential patient information will be undertaken under 'Section 251' support.	
2.	Clarify whether any new data will be collected, and how this data would be managed.	
3.	A link to the study information is to be included on the front page of the ALSPAC communication document.	

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

5.3	**23/CAG/0161**	**The link between questionnaire-reported disordered eating and eating disorder medical diagnosis.**
	Chief Investigator:	Dr Helen Bould
	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 explore the association between disordered eating, self-reported on questionnaires, and eating disorder diagnoses.

Eating disorders (including Anorexia Nervosa (AN) Bulimia Nervosa (BN), Binge Eating Disorder (BED) and Other Specified Feeding and Eating Disorders (OSFED)) are severely impairing and have the highest mortality of any psychiatric condition. Prevalence of eating disorders in the general population is around 5% but up to a third of young women and one fifth of young men report disordered eating behaviours, such as fasting, purging, binge-eating, excessive exercise, that are impacting their lives. However, very little research has been conducted into the association between disordered eating behaviours (often reported on questionnaires) and eating disorder diagnoses (confirmed by medical records), or on factors that lead to a lack of eating disorder diagnosis in individuals who report disordered eating behaviours consistent with diagnostic criteria. The applicants will look broadly at the association between disordered eating captured by questionnaire reports and eating disorder diagnoses from linked medical records. Firstly, to assess whether individuals with disordered eating reported on questionnaires also have an eating disorder medical

diagnosis. Secondly, to explore what factors are associated with obtaining an eating disorder diagnosis in the whole sample and in those reporting diagnostic level disordered eating behaviours via questionnaire.

GP records for consenting cases have been extracted, anonymised and transferred securely into the UKSeRP system at Swansea University via the NHS Wales Informatics Service. ALSPAC will use existing information within ALSPAC. The data will be extracted into ALSPACs Data Safe Haven before being migrated to UKSeRP. Within UKSeRP, ALSPAC will combine (using effectively anonymous identifiers which cannot be linked back to the ALSPAC databases) the consenters and non-consenters' GP/HES/MHSDS/LOCAL NHS, ALSPAC self-reported data/other relevant information, and clean and process these within the UKSeRP system. ALSPAC Data Safe Haven staff will make a subset of the combined data available to this project as a study specific dataset within a study specific (access controlled to allow only individuals working on this project) partition of UKSeRP. 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. Civil Registrations – Deaths, HES and MHSDS datasets, NHS England 2. GP Records 3. ALSPAC Databank
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death 4. Postcode – sector level
Identifiers required for analysis purposes	1. Gender
Additional information	Date of Birth will be used (by ALSPAC) to derive 'Age at Event' (expressed in days, minutes, seconds) and time intervals. This allows ALSPAC to provide information to researchers in event sequence order without disclosing Date of Birth or event date

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 on the detail of support, specifically around whether these were new data flows or whether the data collected was already stored within an ALSPAC secure location. **[Action 1]**

The CAG noted the complex data flow diagrams and requested confirmation as to what level of de-identified data is to be used for analysis in Workflow 2 and retained for results storage as Section 251 support is apparently requested for this by the applicant, but the members were unclear on why this would be required. **[Action 2]**

The CAG requested that the notification materials be published on the public facing website. Clarification needs to be included on how the data collected would be used. **[Action 3]**

The CAG noted potential difficulty with locating the study information posted on the website. The CAG requested that a link to this information was included on the front page of the ALSPAC communication document. **[Action 4]**

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.	Clarify whether new data will be collected, or whether they are already stored within an ALSPAC secure location.	
2.	Clarify what level of de-identified data is to be used for analysis in Workflow 2 and retained for results storage, as it is currently unclear why section '251 support' would be required for this.	
3.	The notification materials need to be published on the public facing website. The notification materials need to explain how the data collected would be used	

4.	A link to the study information is to be included on the front page of the ALSPAC communication document.	

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

5.4	**23/CAG/0160**	**Where is all the heart failure? A community study**
	Chief Investigator:	Professor Andrew L Clark
	Sponsor:	Hull University Teaching Hospitals NHS Trust
	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 Hull University Teaching Hospitals NHS Trust set out the purpose of medical research to determine the true prevalence of heart failure in primary care by assessing all patients with a marker of heart failure.

The applicants advised that they suspect that a significant proportion of patients diagnosed as having heart failure with normal ejection fraction may have a cardiomyopathy due to deposition of an abnormal protein called transthyretin cardiomyopathy (ATTR). Epidemiological data on ATTR cardiomyopathy is scarce and estimates of prevalence come from populations of patients with known heart disease. The applicants aim to define the prevalence of ATTR cardiomyopathy in a primary care population, many of whom will not have a diagnosis of heart failure but have an indicator of heart failure on electronic care records.

Identifiable data will be collected from different GP surgeries within the Beverley Primary Care Network and disclosed to Hull University Teaching Hospitals NHS Trust for linkage to datasets held by the Trust. The electronic records of all patients on a practice's heart failure register will be scanned by the research team to find whether each patient is appropriately on the list, whether the appropriate investigations (echocardiogram, NTproBNP) and whether the appropriate treatment and up-titration of treatment has been performed. Where tests are missing and where appropriate medication has not been started, patients will be invited for review in a face-to-face consultation. At this stage, the clinical research team, who are cardiologists in secondary care, will be acting as the direct care team. They will then be offered the appropriate tests and/or treatment. SystmOne, a software used for electronic health records in the primary care, will then be used to identify all patients not on the heart failure register but who may have the disease by performing a series of hierarchical

searches on the practice electronic record. Two datasets will be created. The first dataset will contain confidential patient information. This will be used in different GP practices and secondary care to obtain and link primary and secondary care data. The second dataset will contain fully anonymised information.

Confidential information requested

Cohort	Patients aged 16 and over who are registered with a GP in the Beverley Primary Care Network or the Hull Modality, and are diagnosed with either: • Heart failure • Amyloidosis However, it appears 's251' support would be required for The research team to screen the whole practice population.
Data sources	1. Electronic health records from GP practices Summary Care Records (SCR) from NHS Digital Electronic health records from Secondary Care
Identifiers required for linkage purposes	1. NHS number 2. Date of birth
Identifiers required for analysis purposes	3. Gender
Additional information	Patients age, rather than date of birth, will be retained for analysis. However, patients NHS number and date of birth will be retained in the linkage dataset (which is not used for analysis) for a maximum of 5 years post-study, and may be used for a follow-up outcome study in the future.

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 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, in the applicants' response to queries from the REC, the applicants had suggested that, should 'Section 251' support not be granted, the applicants would investigate whether the researcher could obtain an Honorary Research Contract to enable access to confidential patient information. 'S251 support' can only be recommended as a last resort, if no other common law legal basis is available. Members agreed that any alternative common law legal basis needed to explored. If the researchers are considered direct care team, then there would be no processing of confidential patient information, without consent, and outside the direct care team, and therefore no breach of confidentiality and no requirement for a CAG application. However an honorary contract does not equate to being considered part of the direct care team. If no other common law legal basis is available, then an application for 's251 support' can be made.

The CAG discussed whether the researcher could be considered a member of the direct care team. For this to be the case, the Caldicott Guardians at all participating Trusts and GP practices would need to agree that the researcher was part of the direct care team. Members agreed that this was unlikely to be practicable for the applicant, however it is the decision of the data controllers of the data accessed under 's251' support to define who is and who is not part of the direct care team.

The Members discussed whether it would be practicable for the practice staff who already have a legitimate common law legal basis to access confidential patient information to undertake any processing of confidential patient information without consent, to avoid a breach of confidentiality, and avoid the requirement for a CAG application. 's251' support cannot be provided where there appear to be practicable alternatives to the processing taking place.

The CAG considered that the Patient and Public Involvement (PPI) carried out was not sufficient given the potential number of patient records that would need to be accessed to identify the cohort. The PPI undertaken should be proportionate to the number of people whose identifiers would be screened, and therefore more individuals should be spoken to. The PPI should also cover the population whose records will be accessed without consent, ie, the whole practice population, not just those with heart failure who make up a small proportion.

In general the Committee noted that the application did not clearly demarcate between research and direct care, and although they were supportive of the application in principle, it was felt that it could not be supported in its current design, because the scope of support was not clear with regards to the research purposes versus any processing undertaken for the purposes of direct care, and there appear to be potential practicable alternatives to 's251' support.

Confidentiality Advisory Group advice: Rejected

In line with the considerations above, the CAG agreed that the application should be rejected.

5.5	**23/CAG/0162**	**Database of UK recipients of pituitary-derived human growth hormone**
	Chief Investigator:	Dr Gargi Banerjee
	Sponsor:	University College London
	Application type:	Research Database
	Submission type:	New application

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

Summary of application

This application from University College London set out the purpose of setting up two research databases which will be used to conduct research investigating whether people who received injections of pituitary-derived cadaveric human growth hormone (c-hGH) are at risk of developing a disease called iatrogenic cerebral amyloid angiopathy (iCAA).

Between 1959 and 1985, nearly 2000 individuals in the UK were treated with cadaveric human growth hormone (c-hGH). Some people who received this treatment went on develop a disease called iatrogenic cerebral amyloid angiopathy (iCAA). iCAA is a disease associated with strokes caused by bleeding in the brain, as well as seizures (or fits) and cognitive changes. This occurred because some batches of pituitary-derived human growth hormone were contaminated with an abnormal form of one particular protein, called the prion protein, which went on to cause their disease.

The applicants seek to investigate whether patients who received pituitary-derived human growth hormone have been affected by diseases caused by iatrogenic protein transmission by using an existing historical database of recipients of pituitary-derived human growth hormone between 1959 and 1985, held by the UK Health Security Agency (HSA), to create two databases.

The first, the “Surveillance Snapshot” Research Database, will be created by linking data from the existing dataset to HES and ONS data, held by NHS England. This will provide a “snapshot” of data relating to admissions, A&E attendances, outpatients appoints and deaths, and to determine whether patients who received c-hGH are at an increased risk of neurological illness.

The second, the “Permission to Contact” Research Database, which will be used to invite patients who received pituitary-derived human growth hormone to participate in future research studies. The database will be created by linking data from the existing dataset to Personal Demographics Service (PDS) data, provided by NHS England to the UK HSA. This database will be retained at the UCL Data Safe Haven and used to contact patients in the database via their GP to ask for explicit consent to be included in the database. Patients will be contacted a maximum of three times and their data will be deleted if they dissent or do not respond.

Confidential information requested

Cohort	Patients included in a pre-existing database of recipients of cadaveric human growth hormone between 1959 and 1985, held at the UK Health Security Agency
Data sources	1. Both databases: a. Patient information in a pre-existing database of recipients of cadaveric human growth hormone between 1959 and 1985, held at the UK Health Security Agency • "Surveillance Snapshot" Research Database 1. The MESH (National Data Opt-Out) data set, and the HES and ONS datasets at NHS England • "Permission to contact" Research Database 1. The MESH (National Data Opt-Out) data set, and the HES and ONS datasets at NHS England 2. Personal Demographics Service (PDS) data set at UK Health Security Agency
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. GP Registration 4. Date of death 5. Date of birth
Identifiers required for analysis purposes	1. Gender
Additional information	The below data items will be retained in the Permission to contact" Research Database under consent. Patient name Date of birth NHS number Gender Address including postcode, email address and telephone number

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 for continued engagement from the patient and public involvement group for the duration of the study. **[Action 1]**

The CAG requested that the patient notification materials were revised to ensure they are appropriate for the intended cohort. , **[Action 2a]**

The CAG requested that the notification materials were revised to provide a clear overview of the research study. **[Action 2b]**

The CAG requested that the notification for primary care was revised explicitly state the role of CAG and Section 251 support. **[Action 2c]**

The CAG requested that the patient notification material was revised to specify that dissenting from the study would not affect the care they received. **[Action 2d]**

The CAG requested clarification on when the patient notification material would be used to promote the study, and how far in advance this would be before the confidential patient information is processed. **[Action 3]**

The CAG requested clarity as to how the National Data Opt-out was applied for both databases, and for the applicant to provide confirmation that the primary care team would review patient records to ensure patients had not previously been objected to use of their data in research. **[Action 4]**

The CAG requested clarity as to how both workflows one and two were handled. **[Action 5]**

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.	Continue engagement from the patient and public involvement group for the duration of the study.	
2.	Please amend the following within the patient notification materials:	

	a. Amend the readability to reflect the cohort of the study. b. Provide a clear overview of the study. c. State the role of CAG within the notification for primary care. d. Specify that dissenting from participating in the study would not affect standard of care.	
3.	Clarify when the patient notification material would be used to promote the study, and how far in advance this would be before the confidential patient information is processed.	
4.	Clarify how the National Data Opt-out was applied for both databases and provide confirmation that the primary care team will review patient records to ensure patients had not previously objected to use of their data in research.	
5.	Clarify how both workflows one and two are handled.	

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, & Professor William Bernal, CAG Alternate Vice Chair

08 November 2023

……. ……..

Signed – Chair *Date*

Mr William Lyse

03 November 2023

……. ……..

Signed – Insert job title *Date*