Health Research Authority

Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on 21 September 2023 via video conference.

Present:

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Ms Clare Sanderson	CAG Alternate Vice Chair
Dr Rachel Knowles	Expert CAG Member
Dr Pauline Lyseight-Jones	Lay CAG Member
Mr Andrew Melville	Lay CAG Member
Mrs Sarah Palmer-Edwards	Expert CAG Member
Mr Dan Roulstone	Lay CAG Member
Mr Umar Sabat	Expert CAG Member
C. Marc Taylor	Expert CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Kathleen Cassidy	HRA Confidentiality Advisor (Present for item 5a)
Mr William Lyse	HRA Approvals Administrator
Mrs 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
Dr Linda McDonald	Chair of Harrow REC (Internal Observer)

Graham Hayler	Applicant for item 5a (Deputy Director of Data and Analytics, NHS GM Integrated Care Board)
Matt Hennessey	Applicant for item 5a (Chief Intelligence and Analytics Officer, NHS GM Integrated Care)
Peter Richards	Applicant for item 5a (Head of Communications, Health Innovation Manchester)

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from: Dr Joanne Bailey (CAG member) and Professor William Bernal (CAG Alternate Vice-Chair).

2. DECLARATIONS OF INTEREST

There were no declarations of interest from members attending the meeting.

All members have a potential conflict with item 4e, as the applicant is a CAG Alternate-Vice Chair, and therefore members sit on the same committee as the applicant. However, he did not attend this meeting, and therefore did not form part of the consideration recommended by CAG. All Members reviewed the application as usual.

3. SUPPORT DECISIONS

Secretary of State for Health & Social Care Decisions

There were no applications requiring a decision by the Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care in relation to the **24 August 2023** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **24 August 2023** meeting applications.

Minutes:

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

- **11 August precedent set meeting**
- **August sub-Committee**

4. CONSIDERATION ITEMS

There were no items for consideration.

5. NEW APPLICATIONS FOR CAG CONSIDERATION

5.a	**23/CAG/0145**	**Greater Manchester ICS Secure Data Environment (GM SDE) – Analytics and Data Science Platform (ADSP) Non-Research uses**
	Contact:	Graham Hayler
	Data controller:	NHS Greater Manchester Integrated Care Board
	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 Greater Manchester Integrated Care Board (GM ICB) sets out the medical purpose to create a resource for secondary non-research use of patient information within the GM ICB area.

The data will be used for a wide range of secondary non-research uses, including population health management, risk stratification and health and care commissioning intelligence. Those wishing to use the data will access the data within a secure environment, rather than patient information being externally shared with the user. Use cases will be considered by the Greater Manchester Secondary Uses and Research Group, which has two public members and will ensure that any uses have a medical purpose and is in the public interest.

Information from national datasets, GP data from the GM Care Record, and local datasets (for example local authority data) will be linked using a pseudonymised NHS number. Support is requested to allow the deidentification of confidential patient information of GP practice data within the GM care record received by GM ICB for secondary purposes. Support is also requested for the flow of confidential patient information from local authorities and subsequent deidentification for secondary purposes.

This activity will be closely linked to the North West Secure Data Environment (SDE) following a future research application.

Confidential information requested

Cohort	All patients who have a health record at an organisation within the Greater Manchester ICB area. For social care data this is restricted to adult records only
Data sources	1. GP data from the Greater Manchester Care Record (via Graphnet) 2. Data from the following Local Authorities in the Greater Manchester area: • Tameside • Bolton • Bury • Manchester • Oldham • Rochdale • Salford • Stockport • Trafford • Wigan 3. Pseudonymised national datasets from Arden and GEM CSU (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 highly commended the applicants on their approach to engaging and informing their population, and felt it was exemplary.

The CAG asked the applicant to clarify who was the data controller of this data set and at what point the GPs lose the responsibility of controlling the data. The applicant responded that they had a joint data controller agreement with the GP

practices. If they were going to approve anything that was outside the scope of joint data controller agreement, then they would reach out to all the GP data controllers to discuss what data was being used and for what purpose. The applicant reassured the CAG that the GP practices were ultimately the data controllers for their own data. The CAG was satisfied with the response.

The CAG noted that the application mentioned local identifiable data sets, particularly in description of social care arrangements. The CAG asked the applicant to clarify the study's description of social care arrangements. The applicant responded that all local authorities were mandated to submit and add a social care data set to NHS England through a Data Provision Notice. However, the local authorities would prefer to use Greater Manchester ICB as a processor to do this on their behalf, whilst also allowing the ICB to pseudonymise the dataset and link with the GP and national datasets for use in this application. This minimises the flow of data out of local authorities. The CAG was satisfied with the response.

The CAG asked the applicant to clarify which local authorities required Section 251 support for the transfer of the data. The applicant responded that based on the discussions they had with the local authorities, subjected to receiving section 251 support they were all happy to submit their data to the ICB. The CAG requested that the applicant to confirm that the scope of support was for all the local authorities within the Greater Manchester, listed below, to share their data with the ICB to act as a processor: (Condition 1)

- Tameside
- Bolton
- Bury
- Manchester
- Oldham
- Rochdale
- Salford
- Stockport
- Trafford
- Wigan

The CAG noted that previously the lack of NHS number for linkage between social care data set was an issue. The CAG asked the applicant to clarify whether the linkage of NHS numbers to social care data set have now improved. The applicant responded that it was generally improved however it was still variable across local authorities. The CAG was satisfied with the response.

The CAG asked the applicant to confirm whether this data included free text information. The applicant responded that all the data was coded. The CAG confirmed that support was therefore only for the use of coded data.

The CAG asked the applicant to confirm that the aim of this application was to gain section 251 support only for non-research purposes. The applicant

confirmed that the purpose of the application was to gain support for non-research purposes, and they would later apply for a new application for research purposes. The CAG was satisfied with the response.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Number	Condition	Response from the applicant
1.	Confirm that the scope of support is for all the local authorities within Greater Manchester, listed below, to share their data with the ICB to act as a processor: • Tameside • Bolton • Bury • Manchester • Oldham • Rochdale • Salford • Stockport • Trafford • Wigan	
The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.		

5.b	23/CAG/0139	Retrospective cohort study of professional footballers in England
	Chief Investigator:	Prof Damien McElvenny
	Sponsor:	Institute of Occupational Medicine
	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 Institute of Occupational Medicine (IOM) sets out the purpose of creating a research database of former professional footballers aged over 40 who have died to understand whether mortality rates from neurological disorders are higher in former professional footballers than the general population of England and Wales. It also aims to look at aspects of participants playing career such as the estimated lifetime numbers of headers, playing position and level played at, which may be important in relation to risk of neurological disorders.

The study cohort (as detailed below) will be identified and collected by the IOM from the publicly available database Barry Hugman's Footballers (barryhugmansfootballers.com). The study cohort identifiers will be sent from IOM to NHS England for linkage and to request mortality data. Support is requested to allow the disclosure of confidential patient information for the study cohort from NHS England's mortality data to the IOM and for IOM to create a pseudonymised research database.

Confidential information requested

Cohort	Professional footballers aged over 40
Data sources	1. Barry Hugman's Footballers database
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Geographic location based on the club played for e.g. Nottingham Forest = Nottingham
Identifiers required for analysis purposes.	1. Month and year of birth 2. Month and year of death 3. Region of England at time of death 4. Ethnicity
Additional information	Estimated number of participants 15-20,000

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 recognised the benefit of creating the dataset for the purpose described in the application however, they were not satisfied that there was a strong justification presented to operate this as a research database. Therefore,

the CAG agreed that support should only be provided for the purpose described in the application. Should the applicant wish to operate a research database for additional areas of research an amendment would need to be submitted to CAG including detail on the following:

- A breakdown of the number and types of membership of the data access committee **(Action 1a)**
- The terms of reference for the data access committee including the criteria used to determine applications to access the data (applications should always have a medical purpose) **(Action 1b)**
- Further detail on how the data will be protected. This should include consideration around the risk of re-identification of the pseudonymised data given that some data is already in the public domain **(Action 1c)**

The CAG requested several revisions to the patient notification leaflet. Firstly, was to amend the current description surrounding CAG having 'approved' the study, as the role of CAG is advisory, and research is approved by the HRA on advice from CAG. **(Action 2a)**

The CAG requested for the applicant to more clearly outline in the patient notification leaflet the purpose of the study and clarify why the study was being undertaken. **(Action 2b)**

The CAG requested for the leaflet to clarify how those affected within the study would be notified of the results. **(Action 2c)**

The CAG requested that the leaflet should clarify that those who opt-out will only be opting out of their data being linked for the purposes of this study. **(Action 2d)**

The CAG requested for the applicant to explore possibilities to expand the patient and public involvement work to include representation of those over 40 who are alive and may be affected by the study. The CAG agreed that this work should include seeking views on the breach of patient confidentiality when linking data **(Action 3)**

Furthermore, the CAG requested for the applicant to clarify how the research team intended to disseminate the results of the study. **(Action 4)**

Lastly, the CAG wished to notify the applicant that Section 251 support will be provided for the duration needed to link the data. **(Condition 1)**

<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.	If the applicant wishes to operate a research database, an amendment would need to be submitted to CAG including detail on the following: a) A breakdown of the number and types of membership of the data access committee b) The terms of reference for the data access committee including the criteria used to determine applications to access the data (applications should always have a medical purpose) c) Further detail on how the data will be protected. This should include consideration around the risk of re-identification of the pseudonymised data given that some data is already in the public domain	
2.	Please revise the patient notification leaflet as follows: a) Amend the current description surrounding CAG having 'approved' the study. The following wording should be used: 'The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported, and the Decision Maker within the Health Research Authority approved this' b) Clearly outline the purpose of the study and why the study is being undertaken.	

	c) Clarify how those affected within the study would be notified of the results. d) Clarify that those who opt-out will only be opting out of their data being linked for the purposes of this study.	
3.	Provide plans for further patient and public involvement work to include representation from those over 40 who are alive and may be affected by the study. This should include seeking views on the breach of patient confidentiality when linking data.	
4.	Clarify how the research team intend to disseminate the results of the study	

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

Number	**Condition**	**Response from the applicant**
1.	Please note that Section 251 support will be provided for the duration required to link the data	

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

5.c	**23/CAG/0140**	**Suicide Prevention in Probation**
	Chief Investigator:	Laura Pope
	Controller:	HM Prison & Probation Service (HMPPS) & The University of Manchester, National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)
	Application type:	Research/Research Database
	Submission type:	New application/Amendment/Annual review/NDO exemption request

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

Summary of application

This application from the University of Manchester sets out the purpose of

examining death by suicide occurring under probation supervision in England and Wales to better identify prevention and intervention opportunities.

In order to build a comprehensive profile of suicide by people on probation, one of the central aims of the study is to establish (and test feasibility) of the national case series of suicide deaths by people on probation. The study will link information held by HM Prison & Probation Service on all individuals who were under probation supervision who have died by suicide in England & Wales since April 2019 up to March 2025 with information held by NCISH at the University of Manchester on all registered deaths by suicide in the general population and suicide deaths of people who had been in contact with health services prior to death (up to 12 months prior to death).

Support is requested to link identifiable NCISH data on registered suicides and open verdicts with identifiable HMPPS data on deaths under probation supervision to identify people who have died by suicide while under probation supervision since April 2019. The data linkage will also be used to identify deaths of people under probation supervision who were in contact with health services prior to death (up to previous 12 months). The linked dataset will be pseudonymised by HMPPS and sent from HMPPS back to NCISH. After the initial dataset is provided, NCISH will undertake an annual update to identify new suicide cases that have occurred in the last 12 months and identify reclassified cases for inclusion/ exclusion.

Confidential information requested

Cohort	All individuals who were under probation supervision who have died by suicide in England & Wales since April 2019 up to March 2025 Approximately 300 individuals
Data sources	1. National Confidential Inquiry into Suicide & Safety in Mental Health (University of Manchester) – registered morality data, clinical and health service contact prior to death, diagnosis, treatment 2. HM Prison & Probation Service: a) nDelius - Offence & sentence details, supervision and contact prior to death b) OASys - Offence details/ risk and criminogenic needs, prior self harm history c) PNOMIS/DPS - Time spent in custody prior to release/ self-harming behaviours, ACCT, adjudications/ family contact 3. Other relevant reports (e.g. serious incident reports, Prison and Probation Ombudsman reports (where applicable and available) - Circumstances leading up to death, contact with services
Identifiers required for	1. Name 2. Date of birth

linkage purposes	3. Date of death 4. Postcode – sector level 5. Gender 6. Probation case reference number/prison number
Identifiers required for analysis purposes	1. Date of birth 2. Postcode - sector level 3. Gender

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 clarity on who the data controller was for this application. **(Action 2)**

The CAG discussed that it would be useful if new notification material was created for the family or friends of those people whose data was being used. Therefore, the applicant was requested to develop a new patient notification for the purposes of dissemination for family and friends using a layered approach. The CAG requested the notification to describe the use of confidential patient information for the purposes described in this application as well as the types of confidential patient information to be used. The notification should also state that 'section 251 support' was recommended by the Health Research Authority, on advice from the Confidentiality Advisory Group (CAG). The patient notification needs to state that National Data Opt-out would be respected. **(Action 3a-d)**

The CAG requested that all notifications needed to go on NCISH website as well as HMPPS website and any other relevant website/platform such as suicide support groups. **(Action 4)**

The CAG was impressed by the amount of engagement work that had been done with the probation services. The CAG requested feedback on the outcomes of the recommendations that were discussed at the October meeting. **(Action 5b)**

The CAG also requested an ongoing plan of relevant continuous patient and public involvement. Patient and public involvement should be undertaken with NCISH, to discuss the use of confidential patient information, without consent, for the purpose of this application. The CAG also recommended that PPI should include groups that support families who had experience with suicide. **(Action 5 a-c)**

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.	Security assurances for 2022/23 are outstanding for the following organisations. • *University of Manchester - National Confidential Inquiry into Suicide and Safety in Mental Health (NCISH)* 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.	
2.	Clarify who is the data controller for this application.	
3.	Please develop a new patient notification for the purposes of dissemination for family and friends, in line with advice in this letter, and provide to CAG for review. a. Clearly describe the purpose and content of this application. b. The notification should describe the use of confidential patient information for the purposes described in this application including the types of confidential patient information c. Add a statement to disclose that 'section 251 support' is recommended by the Secretary of State for Health and Social Care, on advice from the	

	Confidentiality Advisory Group (CAG). d. Add a statement to disclose that National Data Opt-out will be respected.	
4.	All notifications need to go on NCISH, HMPPS websites and other relevant website/platform such as suicide support groups.	
5.	Further patient and public involvement should be carried out in line with advice in this letter: a. Further patient and public involvement should be undertaken, with NCISH and suicide support group, which is specific to the linkages and purposes described in this application. b. Provide feedback on the outcomes of the recommendations that were discussed at the October meeting. c. An ongoing patient and public involvement plan is to be provided.	
The Group delegated authority to confirm its final opinion on the application to the Chair and reviewers.		

5.d	**23/CAG/0141**	**Kings College Hospital Liver Intensive Therapy Unit Research Database**
	Chief Investigator:	Professor William Bernal
	Sponsor:	King's College Hospital NHS Foundation Trust
	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 King's College Hospital NHS Foundation Trust set out the purpose of medical research which aims to create a research database from

existing information relating to people treated at the Liver Intensive Therapy Unit (LITU). The LITU is a unique specialist Intensive Care Unit that has been in existence since 1973, and since opening has cared for a very large number of critically ill people with a wide variety of liver diseases. The database will enable new studies in important aspects of the care of critically ill people with liver disease, which will include understanding the natural history of the conditions treated at the LITU, the changes seen over time and the effects of specific treatments, detailed statistical modelling to identify thresholds for the use of particular treatments including liver transplantation, and 'bench-marking' the outcome for specific conditions, to allow comparison to be made over time and between treating units.

The database will collate existing datasets relating to patients treated at the Liver Intensive Therapy Unit (LITU) at the Institute for Liver Studies (ILS) at Kings College Hospital, London. Identifiable data relating to the adult patients treated at the LITU is currently held securely in 3 legacy systems accessed only by the Direct Care Team. The research database will include data only for adult patients treated on the LITU, covering the period 1973-2023 with a core dataset of demographics, diagnosis and outcome common to all datasets. The only current plans for future data collection are for periodic updating of survival and opt-out status to be undertaken independently by the Business Intelligence Unit at Kings College Hospital using the hospital numbers held separately from the research database as part of the linkage file that contains both hospital and Study numbers. 's251' support is required because the Trust Caldicott guardian has confirmed that the Business Intelligence Unit are not considered to be part of the direct care team.

All access to and use of the database for research projects will be approved by the Data Access Committee (DAC) which will report regularly to the Care Group Research Governance Committee. The DAC will have lay representation, and terms of reference have been submitted. All research will be for a medical purpose, and assessed by the DAC as being in the public interest. All outputs provided to researchers will not include any identifying information.

Confidential information requested

Cohort	Approximately 15,000 adult patients treated on the LITU, covering the period 1973-2023
Data sources	1. Medical records from King's College Hospital NHS Foundation Trust from the following sources; a. LITU Acute Liver Failure Registry. b. The MEDTRACK Dataset. c. Intellispace Critical Care and Anaesthesia (ICCA) data management system. d. Physiology and labroratory data from KCHNHSFT data warehouse 2.NHS England a.NHS Spine

Identifiers required to be retained in the database	1. Date of birth (for updating survival) 2. Date of death (modified for analysis) 3. Gender 4. Ethnicity 5. Sector level postcode 6. Hospital number (for updating survival) 7. Database number
Identifiers required for analysis purposes	1. N/A analysis will be on pseudonymous data only
Additional information	Identifiers will not be held in the same database as the clinical data, but separately in a distinct database held elsewhere within the Trust network with access limited to senior staff managing the database and the from the Trust Business Intelligence Unit who will undertake any required update of case survival and opt-out status. This linking database will include both hospital number and a unique database number. NHS Spine checks will be annual.

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 ‘s251’ support has been requested because the Trust Caldicott guardian has confirmed that the Business Intelligence (BI) Unit are not considered to be part of the direct care team by the Trust. The CAG commented that if not already confirmed by the Caldicott Guardian, CAG would have queried whether ‘s251’ support was required at all, as sometimes teams such as the BI Unit are considered direct care team by Trusts. The CAG accept the Caldicott guardians advice in this case, as it is the responsibility of the data controller to determine whether ‘s251’ support is required, and to make a decision about who is considered direct care team.

Firstly, the CAG wished to commend the applicant on their patient and public involvement work, as the members noted the questions had elicited interesting

and sensible answers. The CAG noted that the engagement reflected throughout the application, benefitting the study as a whole.

The CAG requested for several changes to be made to the patient notification materials.

The applicant should explore re-designing the poster, ensuring that it is more engaging towards its intended population. **[Action 1a]**

The CAG requested for the opening paragraph to state that the LITU is a research active unit. **[Action 1b]**

The CAG highlighted that both the poster and website text state that all identifiers are removed. The CAG requested for this to be amended, as this is incorrect, as some identifiers will be kept for linkage. **[Action 1c]**

The CAG requested for both the website and poster to clarify the cohort dates. It is understood that the cohort is patients treated on the LITU, covering the period 1973-2023, however the poster states 2024. **[Action 1d]**

The CAG also requested for the removal of the link to the National Data Opt-out within both notifications and to ensure that opt-out statements are consistent between the poster and website notification. **[Action 1e]**

Should there be sufficient room on the poster, the CAG recommended the research team to provide information to patients highlighting the potential benefits of the research. **[Recommendation 1]**

With regards to the exit strategy, the CAG noted that identifiers will no longer be required once an individual is deceased, as no more linkages will be required. However it is not clear when full date of death, date of birth, and hospital number will be deleted for individuals. From the responses to CAT queries these will likely be retained until an individual has died, however clarification is requested from the applicant. **[Action 2]**

It is noted that all access to the database for research projects will be approved by the Data Access Committee (DAC), which will report regularly to the Care Group Research Governance Committee. The DAC will have lay representation, and the applicants has submitted terms of reference (TOR) for the DAC. The applicant has stated that all research will be assessed by the DAC as an appropriate medical purpose, and in the public interest. The CAG noted that this was not explicitly stated in the (TOR), and requested that this be added to the section; '*1.2 The criteria for approval of research project applications will include the consideration of:'* **[Action 3]**

With regards to the length of time 's251' support is requested, the applicant has requested 10 year support to run the database. They will not be continuously

adding new patients, however linkage for outcomes will be continuous, and therefore support is required in an ongoing fashion. The CAG recommend 's251' support for 5 years, in line with other applications of this type (and in line with REC Research database approval). **[Condition 1]**

<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.	Please revise the following with regards to the patient notification materials: a) Update the poster, ensuring that it is engaging, and in lay language. b) State that the LITU is a research active unit. c) Clarify on both the poster and website that some identifiers would be kept for linkage purposes. d) Clarify the cohort dates on both the poster and the website. e) Remove the link to the National Data Opt-Out within both notifications and ensure that statements about the opt-out options are consistent between the poster and website notification.	
2.	Please confirm that identifiers will be deleted after patients have deceased.	
3.	Include into section 1.2 of the TOR that all research will be assessed by the DAC as an appropriate medical purpose, and in the public interest.	

4.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. This is currently **Pending**	

Recommendations

1.	Should there be sufficient room on the poster, the CAG recommended the research team to provide a passage highlighting the benefits of the research.	

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

1.	's251' support is in place for 5 years from the date of the final supportive letter. A duration amendment will be required at that time if 's251' support is still required.	

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

6. ANY OTHER BUSINESS

The Chair informed the members that a chairs report would be released in the following weeks.

The Chair thanked the members for their attendance and closed the meeting.

Dr Tony Calland MBE	02/10/2023
Ms Clare Sanderson	02/10/2023
……	……..
Signed – Chair	*Date*
William Lyse	09/10/2023
……	……..
Signed – Approvals Administrator	*Date*