Confidentiality Advisory Group

Minutes of the meeting of the Confidentiality Advisory Group held on *15 February 2024* via video conference.

Present:

Name	Capacity
Professor William Bernal	Alternate Vice Chair
Ms Clare Sanderson	Alternate Vice Chair
Dr Malcolm Booth	CAG Member (Expert)
Dr Ben Gibbison	CAG Member (Expert)
Mr Anthony Kane	CAG Member (Lay)
Dr Pauline Lyseight-jones	CAG Member (Lay)
Mrs Sarah Palmer-Edwards	CAG Member (Expert)
Ms Rose Payne	CAG Member (Lay)
Professor Sara Randall	CAG Member (Lay)
Mr Dan Roulstone	CAG Member (Lay)

Also in attendance:

Name	Position (or reason for attending)
Mr Paul Mills	Confidentiality Advice Service Manager
Ms Caroline Watchurst	Confidentiality Advisor
Ms Katy Cassidy	Confidentiality Advisor
Mr William Lyse	HRA approvals Administrator
Mr Dayheem Sedighi	HRA approvals Administrator
Mr Mark Sidaway	(Internal Observer) - HRA Approvals Specialist - items 4a and 4c only

Claire Edgeworth	(External Observer) - Head of Strategic Information Governance, NECS/NHS England - items 4a and 4c only
Helen Duckworth	Applicant - CI (4a only)
Jim Hughes	Applicant - director of data strategy cheshire and Mersey ICB (4a only)
Chloe Whittle	Applicant - Information Governance Officer (4a only)
Matt Hennessey	Applicant - CI (4c only)
Graham Hayler	Applicant – Data Custodian (4c only)
George Tilston	Applicant – data engineer, and co-ordinator of the IRAS application (4c only)
Dr Mohammad Mahdi Saeidinejad	Applicant - Hepatology Research Fellow, UCL/Royal Free, and PhD student (4d only)
Arron Bernard	Applicant - OCC Programme Business Assurance Lead (4e only)
Lindsay Wells	Applicant - OCC Programme Information Governance Lead (4e only)
Jon Elsom	Applicant - OCC Programme Data Architect (4e only)

1. APOLOGIES FOR ABSENCE

Apologies for absence were received from: Mr Umar Sabat, Dr Sandra Duggan.

2. DECLARATIONS OF INTEREST

2.1	**24/CAG/0019**	**Biomarkers in severe acute hepatitis**
	Conflict:	Alternate Vice-Chair Professor William Bernal declared an interest in this item (4d) – this is because he is an active co-investigator with the CI, in other studies. The Group agreed that Professor William Bernal should leave the meeting for the review of this application.

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 has agreed with the advice provided by the CAG in relation to the **18 January 2024** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **18 January 2024** meeting applications.

Minutes:

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

- December & January Sub-Committee
- 12 January PS
- 18 January full

4. NEW APPLICATIONS FOR CAG CONSIDERATION

4.a	**24/CAG/0033**	**North West Sub-National Secure Data Environment: Cheshire and Merseyside ICB**
	Chief Investigator:	Helen Duckworth
	Sponsor:	Cheshire and Merseyside ICB
	Application type:	Research Database
	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 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 Cheshire and Merseyside Integrated Care Board (C&M ICB) sets out the medical purpose to create a create a research database

Cheshire and Merseyside ICB are developing the Northwest sub-national Secure Data Environment (SNSDE). This is part of a national initiative to move

towards access of NHS data by default, rather than data sharing and is part of the Data Saves Lives strategy. SNSDEs across the country will also become interoperable to enable access. Further details on this national initiative and progress to date is here. Note that the Northwest SDE is using a federated approach and each ICB in the North West is submitting separate applications (Greater Manchester ICB in this meeting, and Lancashire and Cumbria at a later date).

C&M ICB are linking data from multiple sources to create a deidentified dataset for research use. Support is requested for Graphnet to pseudonymise the local shared care record and share with Arden and GEM CSU (processing on behalf of C&M ICB), for Arden and GEM CSU to pseudonymise national datasets processed by Data Service for Commissioners Regional Office (DSCRO) for use in the SDE, and for local organisations to share identifiable information to Arden and GEM CSU, where they are unable to pseudonymise at source. Other national sources are shared under Directions, or pseudonymised at source and are outside the scope of CAG. Support is also requested for the retention of confidential patient information within the SNSDE environment.

Requests for data access are governed by the Data Access and Asset Group. The group contains a range of members, including two lay members. Whilst this is currently specific for C&M ICB, there are plans to consolidate to have one data access route in the Northwest.

Confidential information requested

Cohort	The registered and resident population of Cheshire and Merseyside and the individuals who have received care at the providers within Cheshire and Merseyside.
Data sources	1. Local Shared Care record (GP data via Graphnet) 2. Data sources processed by Data Service for Commissioners Regional Office (DSCRO) at Arden and GEM CSU a. Alcohol Dependence b. Ambulance Data c. Assuring Transformation (learning disabilities) d. Community Services Dataset e. Clinical Audits and Registries f. Continuing Health Care g. CVD Prevent h. Diagnostics Imaging Dataset i. e-referral system dataset j. Faster Data Flows k. Maternity Services Dataset l. Medicines dispensed in primary care m. National cancer waiting times n. NHS Pathways Dataset (111/999) o. Patient reported outcomes dataset (PROMS)

	p. Patient Level Contract Monitoring (Pathology tests done) q. Virtual Wards r. Telehealth Service s. Civil Registrations Births t. Civil Registrations Deaths 3. National Data Sources covered under the national NHS Direction from health and social care for use for research a. Secondary Users Service (SUS) b. COVID 19 Data Assets c. Improving Access to Psychological Therapies d. Mental Health Minimum Dataset e. National Diabetes Audit f. Summary Hospital Mortality Indicator set (SHMI) g. Adult Social Care 4. Local organisation data a. Pseudonymised at source b. Unable to be pseudonymised at source
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death 4. Postcode
Identifiers required for analysis purposes	1. Year of birth 2. Gender 3. Ethnicity 4. Lower Super Output Area

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 discussed the possibility of patients being treated at the hospitals and GP's, who were not residents in the local area. The CAG asked the applicant to explain how they intended to notify this population. The applicant clarified that the data of both residents, and non-residents who have been treated within the area, will be included. The applicant explained that as part of their communication campaign they had created electronic and paper patient leaflets to be made available and posted within clinics and treatment rooms. These notification materials would signpost further information as well as contact

information.

The CAG was content with the applicant's response.

The CAG queried whether the research team could provide a Welsh language version of the notification materials, for Welsh nationals travelling to Cheshire and Merseyside ICB for treatment. The applicant confirmed that this possibility was currently under review with their communications team. The CAG requested for the applicant to confirm whether a Welsh version of the patient notification materials was possible. **(Condition 1a)**

The CAG informed the applicant that Section 251 Support would only support requests for research that have a medical purpose, given the Regulatory remit that CAG operates. CAG commented that this consideration should be part of the data access process. **(Condition 2)**

The applicant was satisfied with the CAG's comment.

The CAG queried the applicant on whether the database would be provided access for commercial use. The applicant clarified that they were happy with sharing for educational purposes, however, currently not for commercial. The applicant stated that the future intention would be to expand to commercial use, however further engagement and development was needed. The applicant wished to also explore the benefit and value of commercial use further to the NHS.

The CAG was satisfied with the applicant's response.

The CAG queried whether there was a plan to work with organisations, who currently cannot pseudonymise at source, to move to doing so. The applicant confirmed that this was correct, however was a slow process. The applicant clarified that they received funding for Chesire and Merseyside to further roll-out pseudonymisation at source, however the issue was also around capacity, which was currently under review.

The CAG was satisfied with the applicant's response.

The CAG requested for the applicant to explain the extent of where the National Data Opt-out would be applied to the data flows. The applicant confirmed that the National Data Opt-out will be applied at source as early as possible.

The CAG was satisfied with the applicant's response.

The CAG noted that the patient leaflet displayed hyperlinks to further URLs, however highlighted that this would be ineffective on paper versions. Furthermore, the CAG stated that the leaflet's wording was too complex for a lay population and therefore requested the applicant to amend it. The applicant stated that they had been continually working on their notification materials since the start of CAG submission. The applicant was aware of the complexity of wording on the materials and would provide CAG with simplified versions. As

well, the applicant clarified that the leaflets will be available in both hard-copy and electronic forms. **(Condition 1b)**

The CAG highlighted the applicants use of public involvement and engagement to date. Members recognised that whilst the current number of people involved was quite limited the work was high quality and the applicants had plans to continue this work in the coming months. As such, CAG requested a summary of the outputs of further public involvement work at first annual review, as well as a summary of whether there were any changing attitudes that had resulted in a change of approach. **(Condition 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
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	

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.	The CAG requests the following regarding patient notification materials: a. Confirm whether a Welsh version of the patient notification materials was possible. b. Provide CAG with the most up to date lay-friendly patient notification materials.	
2	Ensure that the data access process includes consideration of the medical	

	purpose.	
3.	Provide a summary of the outputs of further public involvement work at first annual review, as well as a summary whether any changing attitudes that had resulted in a change of approach	

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

4.b	**24/CAG/0026**	**Assembling the data jigsaw: MSK research using linked social care data**
	Chief Investigator:	Professor Will Dixon
	Sponsor:	University of Manchester
	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 Manchester set out the purpose of medical research that seeks to understand the number of patients with musculoskeletal conditions accessing social care and the types of social care accessed.

People with musculoskeletal (MSK) conditions often experience pain and reduced physical function as symptoms of their condition. Reduced function and its effects on activities of daily living and wellbeing can be a driver of demand for social care services, particularly for services involving personal care, such as home care. It can also be a driver for support from family and friends ('informal' social care). However, the proportion of adults with chronic MSK pain accessing social care services is not known. The applicants will undertake analysis of linked data on retrospective cohorts of individuals receiving hospital outpatient NHS and Adult Social Care contact over one year, between 1 January to 30 December 2022.

Secondary care data provided by the Northern Care Alliance NHS Foundation Trust (NCA) will be disclosed to Salford Council for linkage to Adult Social Care (ASC) data. NCA will extract NHS numbers and dates of birth for patients with Rheumatoid Arthritis (RA) who have attended a hospital outpatient clinic at the Trust during 2022. NCA will create a unique identifier for all patients in the dataset and add this to the NHS numbers and dates of birth. This list will be transferred to Salford Council via MESH. Salford City Council will extract ASC data for patients found in their system. The ASC extract will include NHS number, DOB and Unique identifier. Salford City Council will remove and delete

the NHS number from the list retaining only DOB and unique identifier. Salford City Council will upload this ASC dataset (with DOB and unique identifier) to MESH. NCA will pull down the ASC dataset and link it to the extract of hospital outpatient data. The linked dataset will be de-identified and made available to the research team.

Confidential information requested

Cohort	Patients aged 18 years and over with a long-term condition, including musculoskeletal diagnosis, who attended a hospital outpatient clinic at the Trust during 2022.
Data sources	1. Secondary care data, Northern Care Alliance NHS Foundation Trust 2. Social Care data, Salford City Council
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	1. Postcode – unit level 2. Gender 3. 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 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 that further clarification on the cohort was needed, as there was some ambiguity in applicant's response to the validation queries asked by the Confidentiality Advice Team prior to the meeting. In their response to validation queries, the applicants had advised that the cohort was "Adults with a long-term condition, including musculoskeletal diagnosis" and had attended an outpatient clinical in 2022. The CAG was unclear whether they sought to include anyone attending any outpatient clinic or only intend to include patients attending outpatient clinics related to musculoskeletal conditions and asked that the applicants clarify. **(Action 3)**

The CAG noted that the information in the notification provided dates for a patient's data to be included as being between January 2019 and December 2019. The CAG was unclear whether that was accurate because a broader time

frame for inclusion was given elsewhere in the application. The CAG was unclear whether 20,000 was an over-estimate. Members asked that the applicant confirm the dates for inclusion, the estimated number in the pool from which participants will be selected and the specific support which applicants were asking for. **(Action 4)**

The CAG noted that the application did not specify the flows of adult social care data that required support, only that it was linked to the unique identifier and the date of birth. It was unclear if the data was structured for free text. Therefore, the CAG requested a clear explanation of the adult social care data to be processed under Section 251 support and whether it included free text or structured data. **(Action 5)**

The CAG noted that the application did not specify whether date of birth would be removed after receipt and there was reference to it possibly being needed for secondary linkage. The CAG agreed that, if date of birth was going to be retained for secondary linkages, justification needs to be provided as further Section 251 support would be required. **(Action 6)**

The CAG agreed that the public involvement was adequate and proportionate for the cohort of the study. However, the applicant did not clarify whether the participants were asked the specific question about the use of confidential patient information without consent. Therefore, the CAG requested that the applicant confirm whether they had explored the use of confidential patient information without consent. If not, specific public involvement needs to be undertaken with a sub-group, to discuss the use of confidential patient information, without consent, for the purpose of this application. **(Action 7)**

The CAG noted that the terms of reference for the programme suggested that it would conclude in February 2024. The Jigsaw protocol (19th December 2023) stated the study duration as between 17/03/2023 and 1/03/2025. The CAG requested that the publicly available information was amended to reflect the slippage or extension of the work. **(Action 8a)**

The CAG noted that the application provided an option for study specific opt-out but the process of how patients could request removal of their data was not explained. Therefore, the CAG requested that the patient notification include an explanation on how patients could request the removal of their data via local opt-out. **(Action 8b)**

The CAG requested that the notifications were made available at least 6 weeks prior to any data being extracted so the patients could be advised to opt-out if they wished. **(Action 8c)**

The CAG felt that the notification on websites alone were not enough, and that the applicant should develop a layered approach by creating a poster for relevant clinical areas. **(Action 8d)**

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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	
2.	Security assurances for 2022/23 are outstanding for the following organisations. • *Salford City Council* 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.	
3.	Provide a clear explanation as to whether the cohort includes patients attending any outpatient clinic or only patients attending outpatient clinics related to musculoskeletal conditions.	
4.	Confirm the dates for inclusion and the specific support requested.	
5.	Provide a clear explanation on the adult social care data to be processed under Section 251 support and whether it included free text or structured data.	
6.	Provide explanation on what will happen to patients' date of birth after receipt. If the date of birth is going to be retained for secondary linkages, justification needs to be provided.	
7.	Clarify whether the research team have explored the use of confidential patient information without consent with the Patient and Public Involvement group. If so, please	

	provide the queries asked and feedback given. If not, further specific patient and public involvement needs to be undertaken with a sub-group, 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.	
8.	Update the patient notification materials as follows and provide to CAG for review: a. Amend all the publicly available information to reflect the slippage or extension of the work. b. Update the patient notifications to explain how a patient can request the removal of their data via local opt-out. c. The notifications need to be made available at least 6 weeks prior to when any data is extracted so the patients can be advised to opt-out if they wish. d. Further methods of patient notification also need to be developed, adopting a layered approach, making information available in brief accessible posters for relevant clinical areas as well as online.	

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

4.c	**24/CAG/0034**	**Northwest Sub-National Secure Data Environment: Greater Manchester ICB**
	Chief Investigator:	Mr Matt Hennessey
	Sponsor:	NHS Greater Manchester Integrated Care Board (ICB)
	Application type:	Research Database

	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 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 Greater Manchester Integrated Care Board (GM ICB) sets out the medical purpose to create a create a research database.

Greater Manchester ICB are developing the Northwest sub-national Secure Data Environment (SNSDE). This is part of a national initiative to move towards access of NHS data by default, rather than data sharing and is part of the Data Saves Lives strategy. SNSDEs across the country will also become interoperable to enable access. Further details on this national initiative and progress to date is here. Note that the Northwest SDE is using a federated approach and each ICB in the North West is submitting separate applications (Cheshire and Merseyside ICB in this meeting, and Lancashire and Cumbria at a later date).

GM ICB are linking data from multiple sources to create a deidentified dataset for research use. Support is requested for Graphnet to pseudonymise the local shared care record and share with Arden and GEM CSU (processing on behalf of GM ICB), for Arden and GEM CSU to pseudonymise civil registrations and deaths for use in the SDE, and for local organisations to share identifiable information to GM ICB, where they are unable to pseudonymise at source. Other national sources are shared under Directions, or pseudonymised at source and are outside the scope of CAG. Support is also requested for the retention of confidential patient information within the SNSDE environment.

Requests for data access are governed by the Data Access Committee (DAC), who are advised and informed by the Application Review Group (ARG). The ARG contained 2 public members. The DAC make the final decision, based on advice received by the ARG. Whilst this is currently specific for GM ICB, there are plans to consolidate to have one data access route in the Northwest.

Confidential information requested

Cohort	The registered and resident population of Greater Manchester and the individuals who have received care at the providers within Greater Manchester.
Data sources	1. Local Shared Care record (GP data via Graphnet)

	2. Data sources processed by Data Service for Commissioners Regional Office (DSCRO) at Arden and GEM CSU a. Alcohol Dependence b. Ambulance Data c. Assuring Transformation (learning disabilities) d. Community Services Dataset e. Clinical Audits and Registries f. Continuing Health Care g. CVD Prevent h. Diagnostics Imaging Dataset i. e-referral system dataset j. Faster Data Flows k. Maternity Services Dataset l. Medicines dispensed in primary care m. National cancer waiting times n. NHS Pathways Dataset (111/999) o. Patient reported outcomes dataset (PROMS) 3. National Data Sources processed by Data Service for Commissioners Regional Office at Arden and GEM (CSU) a. civil registrations - births b. civil registrations - deaths 4. National Data Sources covered under the national NHS Direction from health and social care for use for research (described in section 2.2.2 of the protocol) 5. Local organisation data a. Pseudonymised at source b. Unable to be pseudonymised at source
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death 4. Postcode
Identifiers required for analysis purposes	1. Year and quarter of birth 2. Year and month of death 3. Gender 4. Ethnicity 5. Lower Super Output Area

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 was unclear whether those organisations that are unable to pseudonymise at source will flow information to Greater Manchester ICB or Arden and GEM Commissioning Support Unit (CSU). The applicants however referred to national data flows rather than the specific flow CAG asked about.

As such, the CAG requested further clarification on whether organisations that are unable to pseudonymise at source will flow information to Greater Manchester ICB or Arden and GEM Commissioning Support Unit (CSU) **(Condition 1)**

The CAG queried whether the applicant wished to include any additional national data sets from organisations involved. The applicant confirmed that this may happen in the future, as well as any other new sources.

The CAG was content with the applicant's response though noted addition of a new national dataset or new data source (outside of healthcare organisations within Greater Manchester ICB) will need an amendment to CAG.

The CAG queried the applicant on whether the database would provide access for commercial use. The applicant clarified that Greater Manchester ICB will be instilling tight controls around the type of research they wish to conduct, with the public data access group having a prominent voice in whether the commercial use can be approved.

The CAG was satisfied with the applicant's response.

The CAG noted and commended the public involvement to date, but reminded the application that this should be a continuous, including with underrepresented groups.

The CAG also requested a summary on whether there were any changing attitudes that had resulted in a change of approach at first annual review.. **(Condition 2)**

The CAG discussed the possibility of patients being treated at the hospitals and GP's, who were not residents in the local area or registered with the local practices. The CAG asked the applicant to explain how they intended to notify this population. The applicant stated they conducted two large scale engagement exercises specifically around notifying these populations. The outcome was the creation of an engagement tool kit, so that notification is clearly displayed within Greater Manchester hospitals.

The CAG was satisfied with the applicant's response.

The CAG queried whether notification or links to the SNSDE could be added

into the NHS app. The applicant stated that this would be investigated. **(Condition 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
1.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place.	

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.	Clarify whether organisations that are unable to pseudonymise at source will flow information to Greater Manchester ICB or Arden and GEM Commissioning Support Unit (CSU).	
2.	Provide a summary on whether there were any changing attitudes that had resulted in a change of approach at first annual review.	
3.	Investigate whether notification or signposting to the study can added onto the NHS app and provide an update at first annual review.	

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

4.d	24/CAG/0019	Biomarkers in severe acute hepatitis
	Chief Investigator:	Dr Mohammad Mahdi Saeidinejad (Student Researcher)
	Sponsor:	University College London
	Application type:	Research
	Submission type:	New application

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

Prior to the meeting the applicants were informed that there were observers in attendance at the meeting. The applicants confirmed that they had an objection to the observers being present. The observers left the meeting for the applicant discussion.

Summary of application

This application from University College London sets out the purpose of medical research to assess the correlation between hepatic markers of inflammation, senescence, regeneration, and the risk of mortality in patients with severe acute hepatitis (sAH).

Acute liver failure (ALF) is a rare condition where patients, without any prior liver disease, sustain major liver injury (i.e. acute hepatitis) leading to liver and brain failure. This is a life-threatening condition with mortality rates of around 25% in the first month of admission to hospital. No definitive treatment is available beyond liver transplantation and supportive therapy remains the mainstay of management. The process of decision making to list a patient for liver transplantation is challenging and requires careful day to day assessment, however there is no clear way to predict if recovery can be achieved without transplantation. Additionally, late transplantation is associated with a greater risk of mortality and therefore the decision regarding this needs to be made in a timely manner. Use of a test which can give a clear indication of the prognosis prior to any further deterioration would be of great value to earlier and better preparation of patients for surgery and aid in decision-making in situations where chances of recovery without transplant are unclear. Studies in animal and human samples have shown that p21 is a protein which is involved in processes that can hinder recovery post-liver injury. The applicants seek to undertake a retrospective study, making use of samples that have been collected in the past from patients presenting with acute liver injury. The samples are mainly in form of liver tissue, but the applicants also seek to access blood samples stored from the same admission episode.

Seven transplant centres in the UK will be approached through the British Association for the Study of the Liver specialist interest group in acute liver failure. Members of the local research or healthcare team will search local databases to identify eligible patients. Living patients will be contacted to seek consent, if this had not previously been given. Support is sought to allow members of the research team to access confidential patient information to contact patients and seek their consent. The applicants anticipate that many patients will have died or moved away, therefore support is sought to include

samples from patients who are deceased or who are otherwise uncontactable. Biological samples and clinical data, pseudonymised by use of a study ID number, will be transferred to University College London.

Confidential information requested

Cohort	300 patients aged 18 years and over with severe non-paracetamol acute hepatitis.
Data sources	1. Paper and electronic patient records held at participating sites
Identifiers required for linkage purposes	1. Date of Death
Identifiers required for analysis purposes	1. Date of Death 2. Gender 3. 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. The CAG was unclear on whether Section 251 support was specifically sought for accessing patient details to send study invitations, or for the use of confidential patient information and tissue samples for non-responders, or both.

The CAG noted that the remit under Section 251 relates to Confidential Patient Information only, and CAG has no legal authority to waive consent for the use of tissue for non-responders. It was unclear to CAG how the use of tissue would be permitted under the Human Tissue Act 2004 if consent was sought and not received.

As well, CAG was also unclear whether the use of Confidential Patent Information associated with the tissue was still justified, if the tissue sample was unable to be used.

The Confidentiality Advice Team agreed to work with the Applicant and the HRA Approvals staff to come to a resolution that meets the requirements of the Human Tissue Act 2004 and whether an application for Section 251 Support is necessary. **(Issue 1)**

Where patients had previously given consent to participate, the CAG asked that patients were recontacted to inform them of the new research but not to seek

further consent. The applicant was content with the CAG's request.

The CAG highlighted that one of the sites was located in Scotland. The Group informed the applicant that the CAG remit was limited to confidential patient information generated within England and Wales. Advice would need to be sought from the NHS Scotland Public Benefit and Privacy Panel for Health and Social Care.

The applicant accepted the CAG's comment.

The CAG requested clarification over whether the research team was part of the clinical care team. If not, Section 251 support would be required to allow processing of confidential patient information. The applicant informed the CAG that each site was different, however, specified that Section 251 support would be sought for sites where this applies. **(Issue 2)**

Confidentiality Advisory Group advice: Deferred

The CAG was unable to recommend support to the Health Research Authority 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.	Consider the consent requirements and clarify how tissue will be used within the confines of the Human Tissue Act 2004 if consent is not provided. As well, consider whether Confidential Patient Information is still required if consent is not provided.
2.	Consider, with NHS organisations, whether individuals providing information from each NHS organisation are part of the direct care team, and whether Section 251 support is necessary for their involvement.

4.e	**24/CAG/0014**	**Our Care Connected Falls Risk Tool**
	Contact:	Mr Dan Hughes
	Data controller:	East Sussex Healthcare NHS Trust (ESHT) as the host organisation for Our Care Connected
	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.

Summary of application

This application from the East Sussex Healthcare NHS Trust (ESHT) as the host organisation for Our Care Connected, sets out the non-research purpose of using risk stratification techniques to implement a Falls Risk Tool that will help identify patients with 'the greatest risk' of falls, to identify patients who may require additional healthcare interventions. Risk stratification is a tool to identify patients that are at high risk of health deterioration and may require use of multiple services. This identification allows GPs to prioritise the management of their care to reduce and prevent poor outcomes.

Sussex is an outlier for injurious falls in vulnerable patients compared to national figures, therefore this activity will directly benefit patients of Sussex, by enabling clinicians to target patients with interventions to directly support their individual care needs. This application will also enable a better understanding of the implications patients at risk of falls have on hospital admissions, health service and cost.

Risk stratification for falls risk necessitates the use of large scale, whole Sussex area population, use of secondary care data combined with GP data. Support is not requested for the flow of confidential patient information from GP suppliers or ESHT to NHS South, Central and West Commissioning Support Unit (NHS SCW CSU), as alternative common law legal bases are already in place for these flows. 's251' support is requested to link this information together using NHS number. This data is pseudonymised at the point of linkage and during the falls risk tool processing, however the CSU have the ability to re-identify, (and are processing confidential patient information in order to create a pseudonymous dataset and retain the key) and therefore 's251' support is required. The Falls Risk Model produces a score measuring the probability of an injurious fall for each patient in the cohort. Support is not being requested for reidentification, as that is undertaken for direct care purposes. The applicant envisaged this as an ongoing process, with linkages undertaken monthly.

Confidential information requested

Cohort	86,000 Sussex patients over the age of 65 registered with a Sussex GP.
Data sources	1. NHS South, Central and West Commissioning Support Unit (NHS SCW CSU) – • GP data • East Sussex Healthcare NHS Trust (ESHT) data
Identifiers required for	1. Pseudonymised NHS number

linkage purposes	
Additional information	Key between pseudonymised NHS number and NHS number retained by CSU during the risk stratification process. This process is envisaged to be ongoing, and linkage will be undertaken monthly

Main issues considered, discussed and outcomes

The CAG noted that this application sets out the non-research purpose of using risk stratification techniques to implement a Falls Risk Tool that will help identify patients with 'the greatest risk' of falls, to identify patients who may require additional healthcare interventions. with regards to scope, the CAG was unclear as to whether this application was for a research purpose or a non-research purpose. The CAG stated to accept the application as non-research, evidence is required as to whether the tool is already validated.

The CAG asked the applicant to explain whether they had validated the tool, and if so, what is the performance of the tool. The applicant responded that they trained the tool on 2022 data and had tested the tool on 2023 data. In terms of performance of the tool, the applicant stated the tool appeared to have an AUROC of 0.81. The CAG queried the applicant on how it could be evidenced if the tool was of benefit, once applied to the cohort. The applicant responded to state that they would run a re-evaluation of the risk score monthly and recalibrate the tool on 6 monthly datasets. The CAG concluded that if support was provided for non-research purposes, CAG would require clear confirmation that the tool is validated and the risk tool was ready for routine use in a clinical setting. If the applicant is unable to provide assurance that the tool is validated, a research application to CAG will be required. **(Issue 1)**

The CAG asked the applicant to explain what intervention would follow if they identified a patient at high risk of falling. The applicant responded that one of the falls risk markers is polypharmacy, and therefore a review of the drug regime could be one of the interventions. Other interventions could include an Occupational Therapy (OT) referral to identify if any home improvements could be made, or looking at the modes of transport the patient uses. However the applicant stated this would be more relevant to the clinicians. The CAG felt that the application required more clinician input to identify how it will work in practice. Without this the CAG was not assured that the proposed activity was in the public interest. The CAG would require confirmation of both the interventions that would follow identification of patients using this tool, and the benefit to patients as a consequence of this identification. **(Issue 2)**

The CAG noted that one of the documents that was submitted with this application (the Data Dictionary), contained variables that would constitute identifiable data. This data would be disclosed to the third party processor

‘consultant’ in order to run the tool. However, the applicant had stated throughout their application that no identifiers would be disclosed in order to run the tool. The CAG asked the applicant to explain whether the data was going to flow in pseudonymised form to the ‘consultant’. The applicant responded that the identifiable elements of that document would not flow to the ‘consultant’. The applicant assured the Members that the ‘consultant’ would not be able to see any identifiable data at any point in order to run the tool. The CAG accepted the response, however for any resubmission, the CAG requested an updated Data Dictionary document, which shows the specific data items that would be flowing to the ‘consultant’ for assurance that this was truly pseudonymised data. **(Issue 3)**

The CAG noted that the application mentioned planning an application specific opt-out for patients who would like to remove their data for these purposes. However as there are currently no patient notification documents it was not clear how the application specific opt-out would operate. The CAG asked the applicant to explain the application specific opt-out mechanism. The applicant responded that the opt-out would work based upon patients applying for the opt-out directly from the GP clinics. The applicant explained that they were going to discuss with their Patient Involvement panel on how to best approach opting out from the data set in an efficient manner. The applicant confirmed that the opt out mechanisms were not yet defined. The CAG noted that the generic GP privacy notices provided were inadequate for the purposes of a patient notification mechanism for this application, and some contained out of date information.

The CAG asked the applicant to confirm whether they were planning to develop new patient notifications specific to this project. The applicant confirmed that they would eventually develop new patient notifications specific to this project.

The CAG requested newly developed patient notification documents which were specific to this project, such as posters and leaflets for display in GP practices and acute Trusts, and website notifications. The notifications need to include details of how to opt out via the project specific opt out, and state that the National Data Opt-Out would be respected. The CAG would also need to clearly understand the communication plan as to how those notifications were going to be disseminated where the relevant cohort might see them. **(Issue 4)**

The CAG noted a significant amount of Patient Involvement has already been undertaken across Sussex. However, this engagement appeared generic, rather than specific to this project, and it was not clear whether the use of confidential patient information without consent has been discussed with regards to this specific project. Therefore, the CAG requested further patient involvement which is specific to this project, particularly around the use of confidential patient information without consent. **(Issue 5)**

The CAG asked the applicant to confirm in terms of exit strategy whether this was a process that they would expect be running in perpetuity or if this was a time limited project. The applicant explained that this would be something that would run in perpetuity, and therefore ‘s251’ support would be requested in an

ongoing fashion. The CAG noted that any resubmission would likely be time limited to a 5 year support, and that a duration amendment could be applied at the 5 year mark to extend support. **(Issue 6)**

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.	To accept this application as a non-research submission, CAG require evidence that the tool is validated. Otherwise please re-submit as a research application.
2.	In a resubmission, please provide confirmation of interventions that will follow identification of patients using this tool, and the benefit to the public that will arise as a consequence.
3.	For any resubmission, please ensure an updated Data Dictionary is provided, for assurance that the data flowing to the 'consultant' is truly pseudonymised.
4.	The CAG requested newly developed patient notification documents which are specific to this project, for example posters and leaflets for display in GPs and acute Trusts, and website notifications. The notifications need to include details of how to opt out of this project specifically, and state that the National Data Opt-Out is respected. A communication plan should be submitted with any resubmission, to indicate how these notifications are going to be disseminated.
5.	As part of any resubmission, further patient involvement specific to this project should be undertaken, particularly around the use of confidential patient information without consent.
6.	With regards to exit strategy, the CAG would likely apply a 5 year time limited support on any resubmission, with the ability to extend via amendment

5. CONSIDERATION ITEMS

There were no items for consideration.

6. ANY OTHER BUSINESS

There was no other business for discussion.

Ms Clare Sanderson	25/02/2024
Professor William Bernal	23/02/2024
……	……..
Signed – Chair	*Date*
William Lyse	28/02/2024
……	……..
Signed – Approvals Administrator	*Date*