Minutes of the meeting of the Confidentiality Advisory Group

13 July 2023 via Zoom

Present:

Name	**Role**
Dr Patrick Coyle	CAG Vice Chair
Dr Murat Soncul	CAG Alternative Vice Chair
Mr David Evans	CAG Member
Dr Lorna Fraser	CAG Member (left during discussion of 3b)
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Dr Rose Payne	CAG Member
Professor Sara Randall	CAG Member
Mrs Sarah Palmer-Edwards	CAG Member

Also in attendance:

Name	**Position (or reason for attending)**

Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Paul Mills	HRA Confidentiality Advice Service Manager
Mr Dayheem Sedighi	HRA Approvals Administrator
Mr Steve Tebbutt	HRA Company Secretary and current HRA Decision Maker (Observer)
Dr Emma Cheshire	Chief Investigator, Senior Research Fellow, University of Leicester (item 3a only)

1. Introduction, apologies and declarations of interest

CAG members, Professor Will Bernal, Dr Rachel Knowles and Dr James Teo gave apologies.

There were no conflicts of interest declared.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care has not yet provided a response to the advice provided by the CAG in relation to the **15 June 2023** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **15 June 2023** meeting applications.

Minutes:

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

3. New Applications

a. 23/CAG/0085- A study of rib fractures in early childhood using micro computed tomography and histology

Context

Purpose of application

This application from the University of Leicester set out the purpose of medical research that seeks to investigate the micro-anatomy of rib cages to determine whether or not fractures/microfractures occur outside of abuse and/or CPR.

When investigating child abuse, medicolegal professionals work together to understand the cause of death. A current widely discussed topic amongst paediatric/forensic pathologists is how/when rib fractures occur. Rib fractures are often seen in cases where a baby has been forcefully squeezed but may also occur when cardiopulmonary resuscitation (CPR) is performed. The applicants seek to investigate the micro-anatomy of rib cages to determine whether fractures and microfractures occur outside of abuse or CPR. The applicants will also look at the exact locations of rib fractures from abuse, CPR and non-abuse cases. The aim is to create a more robust evidence base for medicolegal professionals involved in child death investigations.

The applicants will conduct pilot study of 10 paediatric rib cages using micro-CT and histology to assess the occurrence of fractures in infants that have been resuscitated but not likely to have been subjected to abuse. Findings from these control cases will be compared to suspected abuse cases by retrospective review of autopsy reports. The cohort involved in the study will be children up to the age of 3 years who have undergone a post-mortem at University Hospitals of Leicester NHS Trust. HM Coroner will send a death report and confidential patient information to the consultant paediatric pathologist who will undertake the post-mortem examination. This information will be shared to the research team to check patient eligibility. If a patient is eligible, the research team will inform the Coroner, who will then contact the parents to seek consent to be contacted about the research. Should parents agree, their participation will proceed on a consented basis.

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

Confidential patient information requested

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

Cohort	Live birth babies to children up to the age of 3 years that are deceased and have been request by HM Coroner to have a post-mortem at the University Hospitals of Leicester NHS Trust. Less than 50 children will be included in this pilot study.
Data sources	1. Death report & hospital notes for children who underwent a post-mortem at the University Hospitals of Leicester NHS Trust.
Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Telephone number
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Date of death 4. Gender 5. Age 6. Telephone number

Confidentiality Advisory Group advice

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

Public interest

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

The CAG noted that the medical purpose of the research was to enable the improved differential diagnosis of fractures in babies and infants. The applicants anticipated that a larger scale study would be undertaken in the future.

Following consideration of the risks to patient confidentiality versus the benefits of the study, the CAG agreed that the application was in the public interest.

Scope

The Confidentiality Advice Team has asked the applicant to confirm the legal basis for the disclosure of information for the control cohort from the Coroner to the research team. The Coroner had advised that the post-mortem reports are under the control of the Coroner, under s14 of the Coroners and Justice Act 2009. Dr Emma Cheshire, the Chief Investigator for the study, attended the meeting and advised that, further to the above, the data included in the post-mortem reports was not generated within the NHS and would not necessarily include patients' NHS numbers.

The CAG noted that the definition of "confidential patient information" given in s251 of the NHS Act 2006 is not limited to information generated within the NHS. The definition includes information provided under circumstances where the individual is owed an obligation of confidence and/or where information about an individual's physical or mental health, a diagnosis of their condition, or information about their care or treatment is included. The CAG agreed that the post-mortem reports may fall under this definition and asked that the applicant discuss the issue with their local information governance and data protection experts. If support under s251 is not required for the control cohort, then an explanation of why this information is not "confidential patient information" and the alternative legal basis relied on will need to be provided.

The CAG requested an amended data flow diagram, which clearly shows the flows of confidential patient information both within and between organisations. The data flow also needs to explain where support under s251 is required and where processing of confidential patient information will be undertaken under another legal basis (such as consent or processing by the direct care team only), and where anonymised or pseudonymised data will be processed.

The CAG asked the applicant to explain how the information in this pilot study will help in further research. Dr Cheshire advised that currently, different practitioners use different interpretations of micro-CT and histology to assess the occurrence of fractures in infants. Should the pilot study lead to a scaled-up study, involving a larger number of centres would help to develop standardisation of the use of micro-CT and histology within the specific patient group. The CAG was satisfied with the response.

The CAG asked the applicant to explain what sort of data they were going to obtain from the micro-CT. The applicant responded that in the pilot study they will initially look at the locations and number of fractures found in micro-CT compared to the histology. The applicant also intend to look how the dates fractures occurred could be established. The CAG was satisfied with the response.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Minimising flows of identifiable information**

The CAG asked the applicant to explain whether it was possible for the pathologist to decide on the eligibility of potential participants in the screening of patients. Dr Cheshire responded that the pathologist did not have capacity to look at the cases until the day of the post-mortem, which would be too late for the researcher to contact the coroners to arrange consent.

The CAG was noted this response and asked that an explanation was provided written form. The CAG also asked whether the pathologist could make an initial assessment of the eligibility, to reduce the amount of confidential patient information disclosed to the research team, for example, at the very least, only records for patients in the eligible age group (0-3 year-olds) should be sent to the researcher.

Feasibility of consent

The applicants explained that it was not feasible to seek consent before the eligibility screening due to the short time frame between the request for the post-mortem and the post-mortem being performed.

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

- **Use of anonymised/pseudonymised data**

The applicants require access to confidential patient information in order to screen for eligibility.

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

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants have advised that, due to time constraints, it will not be possible for records to be screened for any expressions that parents would not want their child's information used in research before the records are disclosed from HM Coroner to the research team. However, should the researcher note that any objections in the records, the parents will not be contacted about the research.

The applicants have advised that the National Data Opt-Out will not be applied. The CAG informed the applicant that the National Data Opt-Out needed to be applied and asked the applicant to advise how they would comply with the National Data Opt-Out policy.
The CAG asked the applicant to confirm that the process of the Coroner approaching parents for consent was considered to be the local opt-out.

Patient and Public Involvement and Engagement

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

The applicants have not undertaken any patient and public involvement specifically for this project.

The CAG noted that it was necessary for the research to incorporate patient and public involvement to strengthen the public interest in the study.

The CAG asked that patient and public involvement was undertaken. The discussions needed to include the use of confidential patient information without consent as proposed in the application and details of what is going to happen in the research, such as the removal and retention of the infants' rib cages.

The CAG also requested that the patient and public involvement group include group of parents who have lost children or local organisations e.g., the Stillbirth and Neonatal Death Charity (SANDS).

Exit strategy

The data retained for analysis will be pseudonymised.

The CAG was content with the exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health

Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

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

Request for further information

1. Clarify whether the disclosure of information for the control cohort from the Coroner to the research team would fall under the definition of "confidential patient information" given in section 251 of the NHS Act 2006.

2. Patient and public involvement needs to be carried out, and feedback provided to CAG:

    a) Discussions need to include the use of confidential patient information without consent as proposed in the application.

    b) The removal and retention of the infant's rib cage needs to be explained.

    c) Parents, including parents of living children and parents who have lost children, need to be included. Groups such as the Stillbirth and Neonatal Death Charity (SAND**S**) should be approached.

3. A basic screening for eligibility needs to be undertaken before records are disclosed to the researcher to undertake a more detailed eligibility check. At the very least, **only records for patients in the eligible age group (0-3 year-olds) should be sent to the researcher.** If a basic screening is not possible, a detailed explanation on why not needs to be provided.

4. Explain how the research will comply with the National Data Opt-Out policy.

5. Confirm whether the process of the Coroner approaching the parents for consent is considered to be the local study Opt-Out.

6. Provide an amended data flow diagram, which clearly shows the flows of confidential patient information both within and between organisations. The data flow also needs to explain where support under s251 is required and where processing of confidential patient information will be undertaken under another legal basis (such as consent or processing by the direct care team only), and where anonymised or pseudonymised data will be processed.

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Pending**

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

   The NHS England **21/22** DSPT review for **University of Leicester, University Hospitals of Leicester** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (18 July 2023)

b. 23/CAG/0075- A Multi-Center Registry of Cardiovascular Magnetic Resonance Data for Research, Education, and Quality Control Purposes

Context

Purpose of application

This application from King's College London and Guy's and St Thomas NHS Foundation Trust set out the purpose of creating a research database to evaluate the impact and benefit of cardiac magnetic resonance imaging for the diagnosis and prognosis of cardiac pathology.

Over 100,000 patients each year in the UK receive cardiac MRI imaging for the purpose of diagnosis or the evaluation of heart disease. Most exams are reviewed for immediate clinical needs only and are not used to evaluate the cost/benefit or for quality assessment. The applicants seek to use data already collected as part of clinical care to evaluate which types of imaging protocols are run, and the relationship between imaging markers and outcomes. The applicants also seek to develop and validate machine learning methods of deriving imaging biomarkers.

An anonymised database of patients who have undergone MRI imaging for the diagnosis or evaluation of heart disease will be created. Patients meeting the inclusion criteria will be identified by either the clinical care team or by a member of the research team at the participating sites. A dataset containing items of confidential patient information will be disclosed to NHS England for linkage to HES and ONS datasets. Once the linked data is returned to the participating Trust, an anonymised dataset will be disclosed to King's College London to create the SCMR Registry.

A recommendation for class 1, 4 and 6support was requested to cover access to the relevant unconsented activities as described in the application, which can be got from the CAT assessment form, class support requested section.

Confidential patient information requested

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

Cohort	All patients who underwent MRI imaging for the diagnosis or evaluation of heart disease at Guy's and St Thomas' NHS Foundation Trust or Leeds Teaching Hospitals NHS Trust between 1 Jan 2010 and present (1 Jan 2024 at the latest).
Data sources	1. Electronic and paper patient records at Guy's and St Thomas' NHS Foundation Trust and Leeds Teaching Hospitals NHS Trust 2. HES and ONS data, held by NHS England
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Postcode 4. Date of birth 5. Gender
Identifiers required for analysis purposes	1. Gender 2. Ethnicity
Identifiers retained in the research database	1. Year of birth 2. Gender 3. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Following consideration of the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

Scope

The CAG noted that support was recommended to allow the disclosure of confidential patient information from Guy's and St Thomas' NHS Foundation Trust and Leeds Teaching Hospitals NHS Trust to NHS England for linkage to HES and ONS datasets, and the return of linked data to the Trusts.

The CAG was unclear about the relation between the study and the registry held within the USA and asked for clarification regarding how the UK based research related to the USA held registry.

The CAG asked the applicant to provide further details on plans for expansion and future partnerships.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Minimising flows of identifiable information**

The CAG noted that a number of items of confidential patient information were required for data linkage. The CAG generally expects to see NHS number, full name and date of birth for reliable linkage. Members asked for justification on why gender and postcodes were also needed to undertake linkage.

- **Feasibility of consent**

The applicants advised that consent was not feasible due to the number of patients involved.

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

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link data supplied by participating Trusts to HES and ONS data, held by NHS England.

The CAG asked for clarification on how access to the anonymised research dataset will be managed needed to be provided.

The CAG noted that there is a Committee that will review applications to use this research database. The CAG was unclear whether the Committee was based in the USA or UK and asked for clarification. The CAG noted that any decision involving UK data needs to includeUK representation. If a the Committee was not UK-based, then a UK representative needed to be included.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants explained that information on the use of data in research was included on the local NHS trust websites and provided links to the information provided by Guy's and St Thomas NHS Foundation Trust. The applicants will also work with Guy's and St Thomas NHS Foundation Trust and King's College London to publicise the study. A screen shot of information on the Trust website was provided, however this was general information about how the Trust used data and not specific to this project.Information will also be included on the website for Leeds Teaching Hospitals NHS Trust.

The National Data Opt-Out will be applied.

The applicants have advised that a mechanism will be provided for giving feedback and dissent on the website, including information about the NHS opt-out mechanism. However, no details have been given on this process.

The CAG asked that a layered approach to patient notification was developed, where simplified, easy-read information was provided in the first instance, with more detailed information available on request.

The CAG asked that the patient notification explain how a patient can request the removal of their data, both via a local opt-out and the National Data Opt-Out.

The CAG also asked for all the notification to be reviewed by a patient and public involvement group.

Patient and Public Involvement and Engagement

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

The database project was presented to members of the Next Generation Medical Imaging Public and Patient Involvement Advisory Group (PPIAG) on the 29th of November 2022. The applicant provided an overview of the demographics of those involved.

The CAG asked further patient and public involvement was undertaken, particularly around the specific issue of use of confidential patient information without consent. Members suggested that the applicant engage with the representatives of the **Next Generation Medical Imaging Public and Patient Involvement Advisory Group (PPIAG)**

The CAG noted that they needed an estimation of the cohort size to consider whether the patient and public involvement undertaken in the research was proportionate. The CAG asked the applicant to provide an estimation of the cohort size and how it might increase as the research progresses.

Exit strategy

The dataset retained at King's College London will be anonymised. Dates of birth and all other dates will be offset by random number of days. Actual dates of birth will not be able to be recovered from the database.

The CAG was content with the exit strategy.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Clarify how this research relates to the registry held in the USA.

2. Clarify how access to the anonymised research dataset will be managed.

3. Clarify whether the Committee reviewing applications for research using this research data base is based in the USA or the UK. The CAG noted that any decision involving UK data needs to include UK representation. If the Committee was not UK-based, then a UK representative needed to be included.

4. Provide details on plans for expansion and future partnerships.

5. Justify why gender and patients' postcodes are also required to facilitate the data linkage.

6. Patient notification materials need to be created. The materials must include the following:

    a) A layered approach is to be adopted.

    b) The materials need to be proof-read to ensure lay language is used.

    c) The purpose of the research and lay language explain the research and justify the use of data.

    d) An explanation on how patients can request removal of their data using a local opt-out or the National Data Opt-Out needs to be provided. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data.

    e) All notification material to be reviewed by a patient and public involvement group.

7. Further patient and public involvement, particularly around the specific issue of use of confidential patient information without consent is to be undertaken and feedback provided to the CAG for review.

8. Provide an estimation of the cohort size and how it might increase as the research progresses.

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 22 June 2023**

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

   The NHS England **21/22** DSPT review for **Guy's and St Thomas' NHS Foundation Trust, King's College London and Leeds Teaching Hospitals NHS Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (18 July 2023)

4. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Dr Patrick Coyle, CAG Vice Chair	*24 July 2023*

Signed – Confidentiality Advice Team	Date
Dayheem Sedighi, HRA Approvals Administrator	*19 July 2023*