Confidentiality Advisory Group

Minutes of the meeting of the Precedent Set Review Sub Committee of the Confidentiality Advisory Group held on 01 December 2023 via correspondence.

Present:

Name	Capacity	Items
Dr Tony Calland, MBE	CAG Chair	2a, 2b, 2c, 2d
Dr Malcolm Booth	CAG Expert Member	2a, 2b
Mr. Anthony Kane	CAG Lay Member	2b, 2c
Dr Harvey Marcovitch	CAG Expert Member	2a, 2d
Professor Sara Randall	CAG Lay Member	2d
Mr Umar Sabat	CAG Expert Member	2c

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	HRA Confidentiality Advisor
Mr William Lyse	HRA Approvals Administrator

1. DECLARATIONS OF INTEREST

There were no declarations of interest.

2. NEW PRECEDENT SET REVIEW APPLICATIONS FOR CAG CONSIDERATION

2.a	**23/CAG/0178**	**Genetics of neurodevelopmental traits and disorders in ALSPAC**
	Chief Investigator:	Professor Matthew Hurles
	Sponsor:	University of Bristol (ALSPAC)
	Application type:	Research

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

Summary of application

This application from the University of Bristol (ALSPAC) set out the purpose of medical research to study the contribution of rare and common variants to the genetic architecture of neurodevelopment in the general population and related neurodevelopmental conditions such as global developmental delay, ADHD, and autism. A secondary goal is to generate exome sequence data on ~11,000 ALSPAC participants to create an important resource that will enable many other genetic studies within the cohort.

The applicants seek support to process confidential patient information regarding mental health from GP records, NHS England and Avon and Wiltshire Mental Health Partnership, in line with ALSPAC's existing approval.

ALSPAC wish to:

- Repurpose sensitive data already collected though a previous project specific s251 support within ALSPAC, for this specific project, in order to reduce flow of confidential information.

- And for data not already collected though a previous project specific s251 support, request data from GP providers, NHS England and Avon and Wiltshire Mental Health Partnership using existing processes.

The data will then be combined/anonymised by the ALSPAC team within UKSeRP (managed by the University of Swansea but managed by ALSPAC staff). ALSPAC staff will then make the anonymised combined data available to the researchers within UKSeRP.

Confidential information requested

Cohort	individuals enrolled in ALSPAC (excluding those who have explicitly withdrawn from ALSPAC, declined consent to linkage to their health record, have not received ALSPAC fair processing information or have consented to data linkage)

	13,500 ALSPAC participants have been contacted, of whom over 5,500 have responded. This support is therefore regarding approximately 8000 individuals.
Data sources	1. ALSPAC administrative database (University of Bristol) 2. NHS England a. Hospital Episode Statistics (HES), b. Mental Health Minimum Dataset (MHMD) c. Mental Health and Learning Disabilities Data Set (MHLDDS) d. Mental Health Services Data Set (MHSDS) 3. GP data software providers 4. Avon and Wiltshire Mental Health Partnership NHS Trust
Identifiers required for linkage purposes	1. Study IDs 2. NHS number 3. Date of birth 4. sex 5. postcode For those in the ALSPAC database where linkage has already been undertaken: 1. NHS ID to ALSPAC ID pseudonymised linkage ID number.
Identifiers required for analysis purposes	1. Gender 2. Age at event Effectively anonymous for analysis.
Additional information	Of the 15,000 ALSPAC participants around 5500 consented (or dissented) to data linkage and are not part of this request for support.

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.

Regarding patient notification, ALSPAC has provided the cohort with ongoing materials informing them about the study's intention to link to health and social

data (including primary and secondary care) routine records for the enrolled cohort, and only the records of those who have been provided with the materials will be used. Their website provides full information about the study and how to opt out. https://www.bristol.ac.uk/alspac/participants/using-your-records/. In addition, materials specific to this proposal will be made available via the study website and promoted via the study social media channels. The CAG have not yet been provided with this study specific patient notification, and therefore the study specific notification materials should be provided to CAG within 3 months. (Condition 1)

Confidentiality Advisory Group advice: Conditionally supported

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority. subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

The following sets out the specific conditions of support.

1. The study specific notification materials should be provided to CAG within 3 months.

2. Favourable opinion from a Research Ethics Committee. This application activity is covered by main ALSPAC FO (3 February 2011), and addition of this study into main ALSPAC protocol has also been submitted an amendment to REC (AM21) - Date of FO for amendment 20 March 2023

3. 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. **Confirmed:**

   Due to the number of participating organisations involved it is the responsibility of the applicant, as controller, to ensure that all organisations processing confidential patient information meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about an organisation. These will not be individually checked by the CAT team due to the number of organisations involved.

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

2.b	**23/CAG/0180**	**An analysis of the malignancy risk following Gamma Knife Stereotactic Radiosurgery**
	Chief Investigator:	Mr Julian Cahill
	Sponsor:	Sheffield Teaching Hospitals NHS Foundation Trust
	Application type:	Research

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

Summary of application

This application from Sheffield Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which aims to evaluate the risk of Gamma Knife Stereotactic Radiosurgery (GKSRS) treatment in causing malignant transformation of benign tumours, for the purposes of improving patient care. The results are expected by the applicant to be generalisable to the worldwide population of patients treated by GKSRS.

This activity has previously been undertaken twice by the Trust, once under Section 60 support between 2002-2005 (MR777), and most recently in 2016 under 'S251 support' (CAG ref 16/CAG/0009). The outcome from this project will further support the outcomes from those previous pieces of work.

Gamma Knife Stereotactic Radiosurgery (GKSRS) is used worldwide to treat several different pathologies in the head. Most of these are non-cancerous (benign) tumours or vascular malformations. As with any radiation treatment, there is a theoretical risk of the tumour becoming malignant or the treated area developing a new cancer as a response to the treatment. This project aims to evaluate the risk of malignant transformation, or induced malignancies, that could reasonably be attributable to the treatment of patients with Gamma Knife. There are many thousands of patients treated by the Gamma Knife worldwide every year and this risk is incredibly small. Large centres such as Sheffield, with many years of patient treatment data, are in a unique position to be able to accurately evaluate the real risk of this malignant development to aid accurate patient counselling and consent. This would improve patient care both in the UK and internationally as patients worldwide will benefit from strengthened and updated information on the real risk of malignant induction or transformation after radiation treatment for mainly benign disease.

's251' support is requested to allow the applicant to flow identifiable information about all patients treated by the National Centre for Stereotactic Radiosurgery, Sheffield, prior to 01 January 2023, to NHS England. NHS England will link the confidential patient information provided to Civil Registrations of Death dataset and Cancer Registrations dataset, and return the following information to the applicant - date of cancer diagnosis, cancer type and location, and date and cause of death.

Confidential information requested

Cohort	All patients treated before 01 January 2023 by the National Centre for Stereotactic Radiosurgery,

	Sheffield excluding those who have opted out of data usage. Approximately 17,400 patients
Data sources	1. Sheffield Teaching Hospitals NHS Foundation Trust - Radiosurgery Patient Database (STH GKSRS database), clinical database retained by direct care team (out of scope for 's251' support). 2. NHS England • Civil registration of deaths dataset • Cancer registration dataset
Identifiers required for linkage purposes	1. NHS Number 2. Gender 3. Date of Birth
Identifiers required for analysis purposes	1. Date of death – modified to survival times 2. Date of birth – did not answer if this would be modified for analysis, but I think it is 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 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.

Although the CAG appreciated that both professional and patient engagement groups had been approached for this study, the CAG requested further clarity on the number of patients the application has been discussed with, and if the discussion was clear that this would be without consent. The CAG requested for these details to be provided to CAG within the next 6 months, or earlier if available. (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.	Support cannot be issued until a Favourable opinion from a Research Ethics Committee is in place. **(Pending)**	

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

Number	**Condition**
1.	Please clarify how many individuals participated within the patient and public involvement and engagement group discussions, and provide CAG with the questions asked to the engagement groups, particularly around the use of identifiable patient information without consent. The CAG request for these details to be provided to CAG within the next 6 months.
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. **Confirmed:** The NHS England **22/23** DSPT reviews for **NHS England & Sheffield Teaching Hospitals NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (checked 15 December 2023)

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

5.3	**23/CAG/0181**	**Does living by the coast negatively impact palliative and end-of-life care outcomes? An explanatory sequential mixed methods study exploring the inequality of provision and access to palliative care in a coastal region**
	Chief Investigator:	Dr Abigail Hensley
	Sponsor:	Norfolk And Norwich University Hospitals NHS Foundation Trust
	Application type:	Research

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

Summary of application

This application from Norfolk And Norwich University Hospitals NHS Foundation Trust set out the purpose of medical research which aims to identify if there are differences in palliative and end of life care (PEOLC), for patients who live in coastal regions compared to patients that live further in land.

Over the last few years, it has become apparent that people who live in coastal communities are more disadvantaged. This is in terms of social deprivation, job opportunities, and access to healthcare. People that live in deprived areas are more likely to have health problems, including terminal illnesses. There is no current research looking at whether coastal communities are disadvantaged when it comes to palliative and end of life care, and this study hopes to fill that gap.

's251 support' is requested to allow the disclosure of confidential patient information (name, NHS number) from James Paget University Hospital (JPUH) and East Coast Community Healthcare (ECCH) to Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH), in order for the CI to use NHS number for de-duplication. Support is further requested for the researcher (who is not considered direct care team) to access electronic health records of the deceased patients at East Coast Community Healthcare (ECCH), in order to extract an anonymous dataset for analysis, however no '251' support is required for the researcher to extract a dataset for analysis from James Paget University Hospital, as she is direct care team at that Trust.

Confidential information requested

Cohort	Approximately 800 Patients deceased between April 2023-September 2023 from the Great Yarmouth and Waveney region of the Norfolk and Waveney Integrated Care Board, who meet the inclusion criteria: • Patient over 18 • Patient died at JPUH or died in community hospital or died in their usual residence receiving care from ECCH • Electronic records available Exclusion criteria: Traumatic or unexplained death (as these will not have received PEoLC)
Data sources	1. James Paget University Hospital (JPUH) and East Coast Community Healthcare (ECCH) electronic health records 2. Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) electronic health records

Identifiers required for deduplication and data extraction purposes	De-duplication: 1. Name 2. NHS number To extract anonymous dataset: 3. Postcode 4. Date of death 5. Medical records
Identifiers required for analysis purposes	1. N/A anonymous dataset for analysis
Additional information	The deceased patient records will be allocated a unique study number for pseudonymisation at time of identification, with no identifiable data recorded. A look-up table will be kept with the unique study number and the NHS number of the record, so the two data sets from the different trusts can be cross referenced to avoid duplication of records being included. The look-up table will be kept on the NNUH trust computer which is password protected, and will only be able to be accessed by the CI. Once data collection is completed this will be deleted.

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 Precedent Set Review Sub Committee agreed that this was a well-presented application with no issues. The Members noted that the applicant had undertaken very good patient and public involvement, as the applicant had already involved patients from a very early stage. The Members were satisfied with the level of detail provided. However, due to DSPT and REC Approval pending, the Precedent Set Sub-Committee were unable to issue Full Support for the study.

<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.	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. • East Coast Community Healthcare (ECCH) 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.	

The Group delegated authority to confirm its final opinion on the application to the Confidentiality Advice Team

2.d	23/CAG/0182	Suicide crisis and self-harm attendance at A&E in autistic children and young people
	Chief Investigator:	Dr Pooja Saini
	Sponsor:	Liverpool John Moores University
	Application type:	Research

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

Summary of application

This application from Liverpool John Moores University sets out the purpose of medical research that aims to look at rates of admission for children and young people (CYP) with autism who arrive in A&E for suicidal crisis, self-harm, or following a suicide attempt, to assess the prevalence of the issue and review the services accessed to determine whether the most effective pathways for CYP are accessed.

It is estimated that 1 in 100 CYP in the UK are diagnosed with autism. Suicide is the leading cause of death for young people aged between 20 and 34 years in the UK. CYP with autism are at a higher risk of suicide than non-autistic CYP,

and are more than four times as likely as their typical peers to be admitted to the hospital after harming themselves. It is currently unknown why self-harm rates are higher in CYP with autism, how mental health disorders present in CYP with autism, and how services and support should be best placed to accommodate the needs of CYP with autism.

This study requires 's251' support for data extraction at A&E sites only, all other elements of the study are out of scope for 's251' support. The initial identification of potential participants medical notes, using the electronic databases at each of six A&E sites, will be undertaken by the direct care team, who will inform the researcher. The named researcher, who is not a member of the direct care team, will have on-site access to patient medical records, which include confidential patient information. Retrieving information will be a time-consuming activity, and the direct care team have indicated that they do not have the time and resources to complete this work. Therefore 's251' support is required. Potential participants will be screened by the named researcher, and if eligible, pseudonymised data will be recorded. Although a key is retained between the NHS number and the unique anonymised study ID, this is retained by the direct care team only. Therefore support is not required for this retention, and the collected dataset can be considered anonymous to the named researcher. No confidential patient information will be recorded or retained by the researcher. Data will subsequently be analysed at Liverpool John Moores University.

Confidential information requested

Cohort	Children and young people (CYP) aged 5-30, with autism who arrive in A&E for suicidal crisis, self-harm, or following a suicide attempt Between the time period January 2015 – January 2025. Estimated 1200 per A&E site (a total of 7,200 for 6 A&E sites proposed)
Data sources	1. Electronic databases at 6 A&E departments, and associated Trust medical records: • Alder Hey NHS Foundation Trust – Alder Hey Children's Hospital • Greater Manchester Mental Health NHS Foundation Trust - Royal Manchester Children's Hospital & North Manchester General • Cheshire and Wirral Partnership NHS Foundation Trust - Arrowe Park & Countess of Chester Hospital • Mersey care NHS Foundation Trust – Royal Liverpool University Hospital
Identifiers required for	1. Researcher will view medical notes to extract a pseudonymised dataset

data extraction purposes	2. Hospital ID 3. NHS number 4. Date of Birth 5. Post code 6. Unique anonymised study number
Identifiers required for analysis purposes	1. Age 2. Sex 3. Ethnicity 4. Partial postcode (district level) 5. Unique anonymised study number It is not possible for the researcher to re-identify a patient from this data extract.
Additional information	A key that will be held within each Trust linking NHS number to a unique anonymised study number. If researcher needs to go back to a patient file this key will allow re-identification, however only the Trust would hold this information. No identifiable data will be held by the researcher.

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 PS Sub-Committee requested final confirmation from the applicant that the age range for this study was those aged between 5 – 30 years old. (**Action 3**)

The PS Sub-Committee asked the applicants to provide the patient notification poster for CAG, with updated wording. References to CAG approval should be changed to state that the study has been supported by the Health Research Authority on advice from the Confidentiality Advisory Group (CAG), as CAG is advisory. (**Action 4a**)

The study specific opt out was more focussed than the National Data Opt-Out, which if activated would opt-out the individual from all future research rather than just this study, to which they may have a particular objection. Therefore, the study specific opt out should be made more prominent, and mentioned first, and the National Data Opt Out should merely be stated as respected (**Action 4b**).

The Sub-Committee noted that if the applicant finds it difficult to get all the text onto a poster, if resources allow, the use of QR codes can be helpful to direct to

further information on a website. However this is merely a suggestion rather than a requirement.

The CAG requested for further clarity on the Patient and Public Involvement and Engagement already undertaken. The CAG requested for further clarification around how many individuals participated within these group discussions, who these people were and when discussions took place and in what format. Furthermore, the PS Sub-Committee requested clarification on whether use of confidential patient information without consent was discussed, and if so, to provide CAG without the outcomes from these discussions. **(Action 5**)

Confidentiality Advisory Group advice: Provisionally supported

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

Number	Action required	Response from the applicant
1.	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. • Mersey care NHS Foundation Trust – (Royal Liverpool University Hospital) 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	Please confirm whether the age range for this study was those aged between 5 – 30 years old.	
4	Provide the patient notification poster to CAG. The following updates should be made:	

	a) References to CAG approval should be changed to state that the study has been supported by the Health Research Authority on advice from the Confidentiality Advisory Group (CAG), as CAG is advisory. b) The study specific opt out should be more prominent, and the National Data Opt Out should merely be stated as respected.	
5	Please clarify the following regarding the Patient and Public Engagement undertaken: a) How many individuals made up the engagement group. b) Clarify the makeup of individuals within the engagement group to confirm they represent the cohort. c) Clarify the location of when and in what format these discussions took place. d) Clarify if the use of confidential patient information without consent was discussed and if so, provide CAG with feedback from these discussions.	

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

Dr Tony Calland, MBE, CAG Chair	*18 December 2023*
……..	*……...*
Signed – Chair	*Date*
Mr William Lyse, Approvals Administrator	*15 December 2023*
……	*……..*
Signed – Insert job title	*Date*