Minutes of the meeting of the Confidentiality Advisory Group

03 December 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr Martin Andrew	Yes	CAG Member
Ms Sophie Brannan	Yes	CAG Member
Dr Patrick Coyle	Yes	CAG Vice-Chair
Mr. Myer Glickman	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Dr Harvey Marcovitch	Yes	CAG Member
Ms Diana Robbins	Yes	CAG Member
Mr Marc Taylor	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)

Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Introduction, apologies and declarations of interest

Any declarations of interest are detailed for each application below.

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 agreed with the advice provided by the CAG in relation to the **05 November 2020** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **05 November 2020** meeting applications.

3. Response to Deferred Outcomes – Research

a. 21/CAG/0003 - Transforming research with routinely collected linked clinical data using an umbrella ethics and governance approach at Newcastle Hospitals (Resubmission of 20/CAG/0092)

Context

Purpose of application

This application from Newcastle upon Tyne Hospitals NHS Foundation Trust set out the purpose of medical research which aims to link data from datasets held within Newcastle upon

Tyne Hospitals NHS Foundation Trust for use in research projects under this 'umbrella' application.

The Newcastle-upon-Tyne Hospitals NHS Foundation Trust is moving to the use of electronic patient records and allows for these to be used for a wide range of research that has the potential to improve patient care. For example; a better understanding of disease patterns and risk factors for disease, as well as new information on how effective treatments are in the real world, how to make diagnoses more efficiently, and a better understanding of how healthcare services are used by patients.

Researchers wishing to access the data will apply through the Newcastle-upon-Tyne Hospitals NHS Foundation Trust. The application will be considered by the Data Access Committee, which includes lay representation. On approval through this committee the required data will be linked from the datasets, held by Newcastle-upon-Tyne Hospitals NHS Foundation Trust. This involves access to identifiable data by a member of staff who does not have a legal basis under common law to do so. A deidentified dataset will then be created and shared with the researcher, who will need to access the data through Trust systems.

The applicants are seeking 'umbrella' support to use this methodology for any applicants that apply for data from Newcastle upon Tyne Hospitals NHS Foundation Trust. A separate, permanent database is not being created. Instead, bespoke datasets will be created from Newcastle upon Tyne Hospitals NHS Foundation Trust medical records upon request.

A recommendation for class 1, 4, 5, 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	All patients accessing Newcastle upon Tyne Hospitals NHS Foundation Trust service since 2009 and have a Trust record.

Data sources	1. Newcastle upon Tyne Hospitals NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Date of Birth 5. Postcode (unit level)
Identifiers required for analysis purposes	1. Postcode (District level)
Additional information	Note that whilst the Trust electronic record went live in 2009 some patients with an electronic record may have scanned information from contacts prior to 2009, and these will be included in the research.

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.

Scope

It was noted that this application had been submitted as a research database application. However, the submission did not relate to the creation of a permanent database, separated from clinical records. Rather it is for bespoke linkages of clinical data, undertaken upon request. In the review of the previous, deferred, application, the CAG had requested further details on why the application had been submitted as a research database.

In discussion with the Confidentiality Advice Team, the applicants had determined that "research database" was the application type that best fit the activity proposed. This is because the applicants will set up a committee for considering requests to access data for specific projects, with this being an application to set up the infrastructure. A specific project IRAS application is not appropriate given the data is not being used for a specific project. The CAG noted this information and was satisfied that the query had been addressed.

The Group noted that the applicants had selected Category 3 in categories of the support required. Members asked if either the applicants or those who applied to use data in the database intended to use the data collected to contact patients to seek consent for their participation in future research.

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 applicants advised that researchers would not have access to identifiable information. It was noted that the data may include scanned information from pre-2009. Members noted that the scanned information will be reliably anonymised.

The Group noted a query that had been raised in the CAG review of the initial submission around the potential risk of re-identification, particularly where small numbers of patients were involved, and asked that further details were provided on how this risk would be minimised. This needed to include whether researchers applying to use the database would be asked about other datasets they hold and whether the combination of those datasets with this database would potentially increase risk of re-identification.

- **Feasibility of consent**

When reviewing the original submission, the CAG had been unable to make a determination on whether consent was feasible, due to the uncertainty around whether the application should have been submitted as a research database. Following review of this re-submission, the CAG accepted that consent was not feasible.

- **Use of anonymised/pseudonymised data**

Members agreed that the proposed activities required could not be undertaken with anonymised/pseudonymised data only.

It was noted a pseudonymisation key would be held in case of the need for reidentification of a patient. The Group queried how the access arrangements would ensure that only those with a justified purpose are able to access the key. The applicants confirmed that the pseudonymisation key will only be accessed by those undertaking linkages of data under support. The CAG raised no further queries in this area.

Governance Procedures

During the previous review, the CAG was unclear on the governance arrangements to manage and approve research requests. The protocol provided by the applicants did not offer sufficient detail to guide the panel in assessing and managing the risks that might lead to re-identification. Members also sought clarity on the representation of the panel that will approve such requests. The Group also noted that the quoracy arrangements for approving such requests was three people, which was considered too low. Members requested that the applicant revisits the quoracy arrangements to ensure proper oversight requests.

The applicants identified instances where reidentification was a risk and provided further details on how this risk can be manged. This included adding detail about how the data access panel can order aggregation of rare variables prior to data being released to research teams, providing further detail on how separate password-controlled IT virtual workspaces will be set up for each researcher dataset so that researchers have access to only one dataset at a time, precluding further linkage between datasets by researchers. The study protocol had also been revised to include these details.

The applicants propose to include a minimum of nine people on the committee (minimum 3 lay members), with two-thirds (minimum 2 lay members) require for a quorate decision. The applicants explained that the Newcastle Joint Research Office will be responsible for selecting and appointing panel members. Further details could not be provided until the applicants had the relevant support and approvals in place to move forward with the application activity.

The CAG noted the information given and was assured that there will be appropriate lay oversight of the research requests.

'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 objection 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 applicant provided no patient notification materials with the original application and had explained that the Trust were developing of a Patient Engagement Platform application to provide a mechanism to inform patients about this umbrella governance process and about the research that is taking place, for patients to opt out of their data being used for research.

Members were not content to recommend support without seeing patient information materials. The Group also queried the additional notification routes that would be used for the proportion of patients who may not have access to electronic applications and requested further detail on the notification aspects.

The applicants advised that, since the initial application, it had become clear that the Patient Engagement Platform will not be sufficiently advanced in development to be part of the processes described in this application. The applicants no longer plan to use this Platform as part of this application. Notification of patients and opt-out using this application will not therefore take place. In future when this platform is fully developed and live, the applicants will propose a refreshed set of processes for approval.

Instead of using the Patient Engagement Platform, the applicants will instead include text on the Newcastle Hospitals NHS Foundation Trust website and in-patient leaflets. The draft text for the website notification and leaflets was provided. The National Data Opt-Out would also be applied.

The CAG noted that the National Data Opt-Out will be applied but no local mechanism for dissent would be used. Members asked that either a local opt-out process was put into place or that a strong justification was given on why a local opt-out process was not needed.

The CAG asked that the National Data Opt-Out and how it will be applied in this application was explained in the patient notification material.

The Group noted that the population served by Newcastle Hospitals NHS Foundation Trust was diverse and queried whether there were any plans to provide patient notification materials in languages other than English.

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.

Members noted the Patient and Public Involvement and Engagement undertaken to date as detailed in the initial queries raised by the Confidentiality Advice Team. However, members felt that the evidence provided did not show sufficient feedback on the use of confidential patient information without consent for the purposes described and requested further work and evidence to be provided.

The applicants had undertaken further consultation with a diverse panel of lay people, many of whom live with multiple long-term conditions and as such are frequent and regular users of healthcare facilities and thus contribute a large amount of data to electronic health care records. Feedback from the panel was supportive; panel members agreed that using routinely collected data in the way proposed was important for conducting healthcare research, and that requiring everyone to consent to the proposed use of data would not allow the type of research proposed to take place.

Panel members were supportive of using pseudonymised data for these analyses but did emphasise the need to ensure that reidentification, for example due to having a rare disease, was protected against. They were reassured that the applicants were aware of this issue and that had plans in place to aggregate variables or combinations of variables that were rare or could enable re-identification.

The patient and public involvement undertaken appears appropriate for the activities undertaken.

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, the applicant was required to respond back to all of the requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Either a local opt-out process needs to be created and details provided to the CAG, or a strong justification provided as to why a local opt-out process is not needed.

2. The patient notification materials need to be revised to contain an explanation of the National Data Opt-Out and how it will be applied in this application.

3. Clarify why Class 3 support is sought and if this is because either the applicants or those who applied to use data in the database intend to use the data collected to contact patients to seek consent for their participation in future research.

4. Further detail needs to be provided on how the potential risk of re-identification will be minimised. This needed to include whether researchers applying to use the database will be asked about other datasets they hold and whether the combination of those datasets with this database would potentially increase risk of re-identification.

5. Clarify if the patient notification materials will be provided in languages other than English.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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 10 August 2020.**

2. Confirmation provided from the IG Delivery Team at NHS Digital 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. **DSPT for 2019/20 pending for Newcastle Upon Tyne Hospitals NHS Foundation Trust.**

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0144 - Follow-up of the QUEST Cohort - Wave 3 Additions

Context

Purpose of application

This application from King's College London set out the purpose of medical research that aims to identify the early childhood personal, family, genetic and wider environmental factors for significant mental health and/or behavioural problems in adolescents with Autism Spectrum Disorder (ASD).

ASD is a severe and lifelong developmental disability, affecting about 1% of children and characterized by pervasive impairments in social communication, and also stereotyped and restricted interests. The application related to the follow-up of participants who were involved in the original QUEST study, which was operated on a fully consented basis. QUEST began in 2008 and 277 families with children aged 4-8 years and diagnosed with ASD were recruited. In 2015-16, the applicants followed up the original cohort, who were then aged 11-15 (QUEST Wave 2), to examine the personal, family and wider environmental risk/protective factors that may predict severe mental health/behavioural problems in adolescence. The same sample

was allowed followed up at age 13-17 (wave 3) in 2017-18, to determine which young people had persistent mental health/behavioural problems and which factors were predictive. 214 of the original QUEST families were followed-up in Wave 3.

In the third "wave" of the QUEST study (time 3), the applicants wish to follow up the children again, now that they are aged 12-16, years old, to determine which young people have persistent severe maladaptive behaviour or mental health problems, and to determine which factors were predictive.

The QUEST study team are seeking to add DNA samples and family history information, which would provide them with valuable information on additional potential additional risk factors. During the course of the study, 14 families were lost to follow up. Following the previous s251 application, which was deferred, the applicants are now applying again to use the confidential patient information they have to use the NHS Personal Demographics Service (run by NHS Digital and accessed through South London and Maudsley NHS Foundation Trust) to obtain up to date contact details for patients, including their GP details. Patients' GPs will then be contacted and asked to forward the cover letter to the participants. The team plan to then consent those that make contact. For those who do not make contact the team would delete the details gained from the Personal Demographics Service.

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	QUEST participants for whom the study team have lost contact with (n=14)
Data sources	1. NHS Personal Demographics Service (accessed via South London and Maudsley NHS Foundation Trust)

Identifiers required for linkage purposes	1. Name 2. NHS Number
Identifiers required for analysis purposes	1. Name 2. NHS Number 3. Date of Birth 4. Gender 5. Unit level postcode 6. Last known address 7. Date of Death
Additional information	Note that the identified for analysis are those obtained from the PDS for trying to re-establish contact in order to consent. Date of death to ensure no inappropriate contact.

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 was satisfied that the activity was in the public interest and had a medical purpose.

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.

- **Feasibility of consent**

The study team are looking to re-establish contact with participants in this longitudinal study and will look to consent once contact is established again. Following feedback during patient and public involvement, the applicants had revised the consent process so that participants

would be contacted by their GPs rather than the study team. The CAG agreed that this revised approach was appropriate.

- **Use of anonymised/pseudonymised data**

The study team requires patient identifiable information in order to identify up to date contact details. The CAG agreed that the research could not be undertaken in any other way.

'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 objection 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.

No patient notification materials had been provided. The CAG noted that the 14 participants would be contacted directly with information about the further activity undertaken.

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 issue of processing confidential patient information without consent was discussed at the IAMHealth PPI meetings on 03/07/2020. IAMHealth PPI are patient and public involvement groups that have been meeting for over six years to provide their thoughts and feedback on research. A copy of the minutes with the relevant sections highlighted in yellow, and other parts redacted, was provided. The first patient and public involvement group consisted of parents of autistic young people, and the second patient and public involvement group consisted of autistic adults. While the views were diverse, the applicants felt that an appropriate way forward was to contact families via their GPs, rather than writing to them directly.

The applicants therefore proposed using the PDS to look up GP details for the 14 participants who are the subject of this application, and asking GPs to forward the cover letters to participants. This is a change from the previous proposal, which was that the applicants would write to participants directly.

The CAG noted this revision and was content with the amended contact process.

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 actions were 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, the applicant was required to respond back to the actions required to meet the specific conditions of support where indicated, within one month.

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 01 June 2020**

2. Confirmation provided from the IG Delivery Team at NHS Digital 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:** NHS Digital and South London and Maudsley NHS Foundation Trust (by check of the NHS Digital DSPT tracker on 04 December 2020) have confirmed 'Standards Met' grade on DSPT 2018/19).

- King's College London (The Institute of Psychiatry) – **DSPT pending**

Declarations of Interest

There were no declarations of interest.

4. New applications - Research

a. 20/CAG/0153 - Twins' Early Development Study (TEDS) Medical Record Linkage

Context

Purpose of application

This application from King's College London set out the purpose of medical research that seeks to investigate how genetic and environmental factors influence development, with a particular focus on psychological development and mental health.

The Twins Early Developmental Study (TEDS) is a longitudinal study which recruited over 16,000 twin pairs who were born in England and Wales between 1994 and 1996. Approximately 10,000 families are still actively engaged. The twin pairs have been assessed across cognitive, emotional and behavioural domains from early infancy into adulthood. Genotyping data is available for 10,346 individuals. The applicants now intend to link the already collected data with data from patients' medical records, obtained from NHS Digital, in order to build predictive longitudinal, genetic and clinical models of mental health outcomes, such as disorder risk and response to treatment. The applicants noted that it was important to gather information at this stage in patients' lives, as new mental health conditions often peak in the mid-twenties.

Support under Regulation 5 of the Control of Patient Information (COPI) Regulations (s251 support) has been requested for the disclosure of confidential patient information from the TEDS dataset to NHS Digital, who will link to the Patient Demographic Service and return patients' current address and GP details to the applicants. The applicants will then send out fair processing (opt-out) notices to participants in TEDS, which will describe the linkage of their TEDS data to HES, Mental Health Services Dataset (MHSDS) and Improving Access to Psychological Therapies (IAPT) data, held by NHS Digital. Once the information has been sent, participants will have four weeks to respond. The applicants will then disclose

confidential patient information for TEDS participants who have not chosen to opt-out to NHS Digital for linkage to the HES, MHSDS and IAPT databases and the linked dataset will be returned to the South London and Maudsley NHS Foundation Trust (SLAM) Clinical Data Linkage Service (CDLS) Safe Haven. The GPs of patients in the TEDS cohort will also be contacted by the applicants to seek assent to access the health records of those in the cohort. Patients' confidential patient information will be disclosed to the GP practice software providers. A linked dataset will then be returned to the SLAM CDLS Safe Haven.

A recommendation for class 1, 2, 3, 4, 5 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	Sets of twins born between 1994 and 1996 who were enrolled into TEDS. 26000 patients will be included.
Data sources	1. TEDS database at King's College London/SLaM CLDS Safe Haven 2. HES and MHSDS datasets held by NHS Digital 3. IAPT service data 4. Locally held information contained in the lifetime primary care electronic patient record, provided by participants' GP surgery
Identifiers required for linkage purposes	1. Name 2. NHS number 3. GP Registration 4. Date of birth 5. Postcode – unit level
Identifiers required for analysis purposes	1. Gender 2. Occupation 3. Ethnicity

Confidentiality Advisory Group informal advice

The following sets out the informal 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 was unsure whether the potential public interest and value of the database justified the breaches of confidentiality involved. The final database would potentially contain very rich and sensitive data. Members asked that the applicants provided examples of the research questions that the database would be used to answer.

Scope of support

Consent had previously been sought from participants in the 1990's. The applicants had attempted to maintain contact with participants via sending of annual reviews and birthday cards, as well as with website updates. The applicant cited the expectation of fair processing as a legal basis for holding confidential patient information until now and were seeking support under s251 within this application for the ongoing holding of confidential patient information. The CAG was uncertain about the legal basis for the continued holding of confidential patient information up until the CAG application was made, and asked that further details were given on the legal basis previously relied on.

The applicants estimated that 10,000 GP practices would be contacted. It appeared that patients' NHS number and date of birth would be disclosed to their GPs annually for an unspecified length of time. The CAG queried whether the datasets obtained from NHS Digital and the GPs would be contained in separate datasets at SLaM or in one dataset.

The CAG noted that a rich dataset could potentially be created, particularly if all of the data acquired was held in one database, and asked that further clarification was provided over the

data that would be returned from GPs and confirmation provided that patients' GP records would not be replicated within the TEDS database.

The applicants were reliant on participants' GP practices participation. Members asked if the applicants had made contact with GP surgeries in advance to ascertain whether they were willing to contribute to the study.

Wales was referred to but it was not clear whether support for processing of confidential patient information originating from Wales was sought in this application. The CAG asked if any data from Patient Episode Database for Wales (PEDW) would be processed.

Data flows

The CAG agreed that the data flow diagram provided was not helpful in understanding the flows of confidential patient information. Members asked that a clearer data flow diagram was included with any resubmission made, which lists the identifiers being shared at each of linkage and the data included in the final TEDS dataset held within SLaM.

The application explained that the TEDS team would send the list of patients who had registered an opt-out to NHS Digital and queried if that was correct, or if only the details of patients who had not opted-out would be shared.

The CAG noted that the application contained a reference to genetic data but did not explain this further. Members queried whether genetic data would be obtained and, if so, the reason for obtaining this data and the format it would be held in.

IAPT data would be collected. Participants, or their parents, had initially consented to their confidential patient information being processed for research into their health and wellbeing, and it was unclear whether patients would expect that information about any psychological therapies they had received would also be processed. Justification on the inclusion of IAPT data needed to be provided. The data items the applicants expected to receive from the IAPT datasets and the GP data also need to be specified, including whether this included free text.

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.

- **Feasibility of consent**

The applicants explained that attempts to re-contact patients for participants in Generation 1 of ALSPAC had resulted in a low response rate (43% of the patients contacted responded to contact attempts), across seven years of contact attempts. The usual response rate for TEDS was 70% of participants, which applicants noted was good but meant that information was not collected for 30% of participants. The proportion of non-responders in longitudinal studies was also noted to grow over time. Non-response was often linked to social and health status and the applicants did not want to risk excluding participants from families with lower education and employment levels, as this would potentially introduce bias as well as reducing the power. The applicants were therefore seeking to utilise an opt-out process, rather than consent.

The CAG noted that the participants had been recruited as children and it was not clear whether they had ever been approached for consent to participate in the study since reaching adulthood. The applicants were now seeking to link to IAPT data and GP data, which may contain sensitive information, and it also was not clear whether these potential linkages had been explained to participants. Further justification needed to be provided on why an opt-out approach was preferable to seeking consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required firstly to contact patients with information about the further data collection and provide an opportunity to opt-out. Confidential patient information for those who did not opt-out would then be used to link the TEDS cohort to HES, MHSDS, IAPT datasets at NHS Digital and to GP held data. The CAG accepted that this could not be done in any other way.

‘Patient Notification’ and mechanism for managing dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection 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 the Data Protection Act 2018.

Although often confused with a requirement to seek consent, patient notification is not the same as seeking consent from individual patients. Patient data is still accessed without consent, however information is provided to patients so they have the option to find out about this use of their data and to express an objection if they so wish. The method for respecting any such objections should be described in the application and a copy of the information must be provided as well.

The notification should provide a description of the activity, listing the purpose of the study and who is carrying out the study. It should explain how service users can opt out or dissent, where appropriate, to the use of their information for this purpose.

The materials used to contact patients were provided. Patients had been recruited as children and members queried whether they would be aware that they had previously been recruited into TEDS. The CAG noted that the first paragraph of the information sheet described the definitions of pseudonymised and anonymised data, which was potentially off-putting, and suggested that information about the study was provided at the beginning of the sheet instead.

Patients were given one month to register dissent, with a reminder sent after the first two weeks. Members asked that a telephone number, as well as email and postal contacts, was included as a contact option. The CAG asked that a copy of the reminder letter was provided for review.

Patient and Public Involvement and Engagement

The applicant advised that they had undertaken a similar project within the USA, also involving LBGTQ+ patients. Feedback from that project had influenced the topic and design. The applicant also intends to seek feedback from peers in LGBTQ+ parenting support groups on the survey measures, however these reviewers have not yet been confirmed. The applicant noted that it was likely that these reviewers would not be UK residents or NHS patients. The applicant had sought advice from clinical staff in the relevant settings, who had advised that that the asking of these questions is not mandatory, so are also sometimes avoided by clinical staff because they feel uncomfortable asking about a patient's gender identity and/or sexual orientation.

The CAG reviewed the patient and public involvement material provided. The questionnaire was a good attempt at ascertaining views from the patient population. However the questions asked could be seen as leading questions and were not explicit enough in exploring the

acceptability of utilising an opt-out process rather than seeking consent. Members asked that further patient and public involvement was carried out, in which more open questions were asked, including around the consent process, the data collected and its potential sensitivity, and to gain views on whether the public interest value of the dataset balanced the breach of confidentiality.

Database Management Policies

The CAG asked that the management policies for access to the database were provided. These needed to explain how requests from researchers seeking to access the data would be processed and how the risk of re-identification would be handled. A membership list for the oversight committee needed to be provided, which detailed whether any lay members were involved.

Exit strategy

The linked data in the TEDS database appeared to be retained indefinitely and it was unclear how long support was required for. The CAG asked that a clear exit strategy and clarification on how long support would be required for was provided.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Following advice from the CAG, the Health Research Authority recommended to the Secretary of State for Health that the application was deferred.

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Examples of the research questions that the database will be used to answer need to be given to confirm that the potential public interest and value of the database justifies the breaches of confidentiality involved.

2. Further clarification on the scope of the support required was needed:

    a. Further details need to be given on the legal basis previously relied on for the continued holding of confidential patient information.
    b. Clarify whether the datasets obtained from NHS Digital and participants' GPs would be contained in separate datasets at SLaM or in one dataset.

    c. Clarify whether patients' NHS numbers and dates of birth will be disclosed to GPs on an annual basis for an indefinite time.

    d. Clarify the data items that will be returned from participants' GPs.

    e. Confirm that patients' GP records would not be replicated within the TEDS database.

    f. Clarify whether support for the processing of confidential patient information originating from Wales was sought in this application and if any data from Patient Episode Database for Wales (PEDW) would be processed.

    g. Clarify whether any genetic data will be obtained and, if so, the reason for obtaining this data and the format it would be held in.

3. A clear exit strategy and clarification on how long support will be required for needs to be provided.

4. Clarify if the list of patients who registered an opt-out would be sent to NHS Digital or if only the details of patients who had not opted-out would be shared.

5. Justification for the inclusion of IAPT data needs to be given and the data items that would be disclosed provided, including whether this includes free text.

6. Justification for the inclusion of GP data needs to be given and the data items that would be disclosed provided, including whether this includes free text.

7. Further justification needed to be provided on why an opt-out approach is preferable to seeking consent.

8. Clarify if GP surgeries had been contacted in advance to ascertain whether they were willing to contribute to the study.

9. The management policies for access to the database need to be provided. These need to explain how requests from researchers seeking to access the data will processed and how the risk of re-identification would be handled. A membership list for the oversight committee also needs to be provided, which details whether any lay members will be involved.

10. Further patient and public involvement is to be carried out, exploring the consent process, the data collected and its potential sensitivity, and to gain views on whether the public interest value of the dataset is balanced against the breach of confidentiality.

11. The patient notification and dissent material need to be revised as follows:

    a. The first paragraph of the information sheet needs to be revised to give details about the study.

    b. It needs to be explained that participants were recruited into the TEDS study as children and may not have been approached for consent as adults.

    c. A telephone number needs to be given for patients to register dissent.

    d. A copy of the reminder letter, sent two weeks after the initial letter, needs to be provided for review.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0149 - Yorkshire & Humberside Haematology Network Register

Context

Purpose of application

This application from the University of York set out a refreshed application for the Yorkshire & Humberside Haematology Network Register (YHHN Register). This Register was created to provide a comprehensive population-based patient cohort ("registry") of patients newly diagnosed with haematological malignancies in the regions covered by the West Yorkshire & Harrogate and Humber, Coast & Vale Cancer Alliances.

Haematological malignancies are comprised of a heterogenous group of cancers, with differing treatments and prognoses. Haematological cancers comprise a comparatively neglected cancer group, largely because of the complexities associated with their diagnoses and treatment. The YHHN Register was set up to monitor patient care by collating clinical and demographic real-world data, combined with accurate and complete follow-up information. The Register covers a population of around 4 million. In addition to the provision of real-world descriptive data for commissioning purposes and national guidelines, the YHHN Register also provides the infrastructure to facilitate studies in other research areas, which includes; examining the potential causes of haematological cancers and investigating factors associated with a delay in diagnosis, gaining a greater understanding of the biology of these tumours to potentially improve disease management and outcome, and investigating health inequalities, summarizing health resource utilization and costing the treatment pathways, and examining end-of-life of care and place of death.

The patient population is comprised of adults and children who were newly diagnosed with a haematological malignancy on or after 1 September 2004, who are resident in West Yorkshire & Harrogate and the Humber, and Coast & Vale Cancer Alliances. Informed consent is sought from patients whenever possible, however, due to the nature of haematological cancers, it may not always be possible to obtain consent. This may be due to aggressive disease and/or co-morbidities, meaning patients are too unwell to be consented, or have died before consent could be sought. Patients may also have died before a formal diagnosis of haematological malignancy was diagnosed. In 2007, the applicants sought exemption under Section 60 of the Health and Social Care Act 2001 (PIAG 1-05(h)/2007). A refreshed application has now been submitted to update the application and to add Hull University Teaching Hospitals NHS Trust as a joint data controller, alongside the University of York.

As part of the routine diagnostic process, samples from patients across the Network are sent to the Haematological Malignancy Diagnostic Service (HMDS) based at Leeds Teaching Hospitals NHS Trust. Patients' name, date birth and NHS number are sent with the sample and entered onto MHDS's web-based sample tracking and reporting system, HMDS Information Laboratory Integrated System (HILIS). The applicants have support under s251 to allow research nurses, employed by the University of York, to access confidential patient information within HILIS to identify suitable patients and seek their consent for inclusion in the study. Support is also requested to allow patients who were too unwell to be approached for consent or died before they could be approached. The research nurses will liaise with the patient's clinical team to determine whether they are too unwell to be approached for consent. Where patients are too unwell, the research team will check with the clinical care team at a

later date to ascertain whether patients are well enough to be consented. Approximately 6 months after the diagnosis, the applicants will begin the data collection process. A cancer-specific data collection form is generated from the patient's HILIS record at LTHT. This form is sent to the patient's treating hospital for prognostic, treatment and outcome data to be abstracted from the medical records. Data abstraction is then undertaken for consented and non-consented patients by University of York research nurses. For all patients, a pseudonymised dataset is download from HILIS containing demographic, diagnostic, prognostics, treatment and outcome data. No identifiable data will be included, and this file is securely exported to the University of York where data are analysed. Confidential patient information will be disclosed from the University of York to NHS Digital to HES, Death notification and cancer registration datasets held by NHS Digital. Data received from NHS Digital does not contain any personal identifiers, just the study identifier; and these data are stored in their own separate database.

A recommendation for class 1, 2, 3, 4, 5 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	Adults and children (from age 0 upwards) newly diagnosed with a haematological malignancy whilst resident in the regions covered by the West Yorkshire & Harrogate and Humber, Coast & Vale Cancer Alliances. Since the inception of the study in 2004 to date, approximately 36,000 patients have been ascertained. 2,500 are added each year. The applicants estimate that 45,000 patients will have been recruited by the current planned end date of September 2024 and that approximately 27,500 of this number will not have given consent.
Data sources	1. Electronic diagnostic and pathology records held on the Haematological Malignancy Diagnostic Service's (HMDS) Integrated Laboratory Information System (HILIS) 2. HES, Death notification and cancer registration data held by NHS Digital

	3. Hospital medical records at participating trusts: a. Airedale NHS Foundation Trust b. Bradford Teaching Hospitals NHS Foundation Trust c. Calderdale and Huddersfield NHS Foundation Trust d. Harrogate and District NHS Foundation Trust e. Hull University Teaching Hospitals NHS Trust f. Leeds Teaching Hospitals NHS Trust g. Mid Yorkshire Hospitals NHS Trust h. Northern Lincolnshire and Goole NHS Foundation Trust i. York Teaching Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. GP Registration 5. Date of birth 6. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – unit level 4. Gender 5. Occupation 6. 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.

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.

- **Feasibility of consent**

The applicants will consent patients where possible but are seeking support to include patients who could not be consented, either because they were too unwell to be consented or died before consent could be sought.

The CAG noted that most participants would not have given consent. This included deceased patients and those too unwell to be approached, but also a large number of patients who would have been approached for consent but would not have responded. Members noted that guidance from the Information Commissioner's Office was that non-response was to be considered as dissent and not assent. Therefore, if patients were approached for consent but did not respond to the approach, then their confidential patient information could not be processed under s251 support. The CAG asked that further details were given on the consent process and how non-responders had been dealt with so far.

Some patients may be too unwell to be approached or lack capacity to consent. The CAG noted that s251 support could only be used as a last resort, if no other legal basis for processing confidential patient information was available. The applicants needed to determine whether a legal basis under the Mental Capacity Act could be used for adults lacking capacity.

The CAG asked the applicants to explain how patients who did not respond to requests for consent via post had been dealt with until now.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link patients across various datasets. This cannot be undertaken in any other way.

'Patient Notification' and mechanism for managing dissent

The patient notification and dissent process described is focused on patients who will be consented.

The applicants had provided an “Appendix” document, which included information materials to be used by hospitals when informing patients about the Register. These materials would be used in haematology outpatient clinics and at events held by individual hospitals to publicise ongoing research. These materials included contact details for YHHN.

The Yorkshire and Humberside Haematology Network project website also contains the Privacy Notice for the project, which explains how personal information will be collected and processed, and contact details for patients to request that use of their data is restricted.

The information given in the application relates to patients approached for consent. The applicants have provided contact details for the YHHN team on the patient information materials, but the ability to opt-out and how to do so is not clearly described. The CAG noted that the patient notification was dated. Members asked that the applicants work with their patient and public involvement groups to bring the notification materials up to date. The role the University of York plays in the study needs to be fully explained.

Patient and Public Involvement and Engagement

The applicants advised that, since 2009, YHHN has had an established Patient Partnership, which works in collaboration with researchers and members of the Clinical Network. The Patient Partnership, which spans the two former Cancer Networks of Yorkshire & Humber and Yorkshire Coast, is a formally recognized entity, and its activities are overseen by a Steering Group which meets at regular intervals to discuss patient, carer and public involvement across the project as a whole. The partnership currently has over 900 members (patients and carers); all of whom have agreed to participate in research either by sharing their experiences and/or by commenting on YHHN research activities. Members of the Partnership routinely input into YHHN funding applications, acting as co-applicants and feeding into work streams at study management meetings. Members also continue to take part in focus groups, complete questionnaires, and help to review YHHN literature and update the website. This committee is aware that information may be used without consent and take this into consideration when discussing YHHN and its nested studies.

Use of identifiable data without patient consent has also been discussed at length with members of the Network Audit Committee, which includes patient and relative representation. Issues such as linkage to data from routine sources from NHS Digital have also been raised at these meetings.

The applicants advised that a steering committee had been set up to oversee the projects that are embedded in the YHHN Register. At least one service user was included in this committee.

The setting up of studies, the findings of the research and how they will be disseminated are discussed at meetings of the steering committee.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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

1. Further clarification on the consent process and the scope of the s251 sought is required:

    a. Provide further clarification on the consent process and how non-responders have been dealt with so far.

    b. Clarify if a legal basis under the Mental Capacity Act could be used for adults lacking capacity.

2. The patient notification material needs to be revised and updated, in collaboration with the patient and public involvement group, and the role of the University of York fully explained.

3. Favourable opinion from a Research Ethics Committee. **Confirmed 03 September 2004.**

4. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold.

- University of York – Department of Health Sciences – DSPT pending for 2019/20
- Hull University Teaching Hospitals NHS Trust – DSPT pending for 2019/20
- Leeds Teaching Hospitals NHS Trust - DSPT pending for 2019/20

- **Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.**

Declarations of Interest

There were no declarations of interest.

c. 20/CAG/0146 - Congenital Hypothyroidism with Gland in Situ: establishing risk factors and outcomes using population-based data linkage methods

Context

Purpose of application

This application from UCL Great Ormond Street Institute of Child Health sets out the purpose of medical research that aims to link clinical and education data from a cohort of all children born and screened at the GOSH newborn screening laboratory between 2000 and 2020, to examine why the birth prevalence of congenital hypothyroidism with gland in situ (CH-GIS) has increased among children, and to examine health, education and treatment outcomes for children affected by congenital hypothyroidism (CH), compared to unaffected children.

All children in the UK are offered screening for a number of rare conditions at five days of age. One of these conditions is CH, which without early detection and treatment can result in severe learning disability. Since the introduction of newborn screening 40 years ago, there has been an increase in the proportion of babies born with congenital hypothyroidism (CH), particularly a type called congenital hypothyroidism with gland in situ (CH-GIS). It is not clear why CH-GIS is becoming more common, or how it affects health, development and learning as children grow up. Some studies have shown reduced school performance even in children with very mildly suppressed thyroid hormone levels in the neonatal period, however there is a risk of suboptimal educational outcomes that have been associated with overtreatment. The proposed study aims to provide evidence based on demographic, clinical and genetic risk factors to help inform parents and endocrinologists regarding the dosage and length of treatment expected once a child is diagnosed with CH-GIS, and the health and education outcomes of children with CH-GIS. In addition, findings regarding the mechanisms driving the increase in CH-GIS may inform the evaluation and forward planning for the National Newborn Screening Programme, and help target prevention strategies.

The study will link together two clinical databases held at GOSH to create the GOSH NBS database (**dataset A)**. Identifiers alongside the NBS Cohort identifier will be sent to NHS digital to link with Hospital Episode Statistics (HES) data, Office of National Statistics Birth and Deaths registration data (ONS), and National Child Measurement Programme (NCMP) data.

Mothers' identifiers will be linked to longitudinal HES records, prior to the birth of their children. This is to be able to derive variables to indicate maternal long-term conditions which may predispose to childhood thyroid dysfunction or other childhood conditions.

PHE will send identifiers, alongside a PHE pseudonymised identifier to NHS Digital for babies born in North Thames from Newborn hearing screening data (NBHSD), and identifiers for people with congenital abnormalities and rare diseases recorded in National Congenital Anomaly and Rare Disease Registration System (NCARDRS). NHS Digital as a trusted third party will then link the GOSH NBS dataset, together with linked HES, ONS, and NCMP data, to NCARDRS and NBHSD PHE identifiers, to create **Dataset B.** Dataset B is sent back to GOSH from NHS Digital, which includes the date of death. GOSH link dataset B with dataset A, modify the postcode to Lower Super Output Area, and send the dataset to UCL Data Safe Haven for analysis. NHS Digital will send the linkage key back to PHE, to enable PHE to link back to clinical data from NCARDS and NBHSD and send this pseudonymised clinical data to UCL Data Safe Haven.

NHS Digital will also link the GOSH NBS database to the Personal Demographics Service (PDS), to obtain postcode histories. Department for Education (DfE) will send identifying variables from the National Pupil Database (NPD), alongside an NPD pseudo ID, which contains information on school performance and special educational needs. DfE will only send details for children going to school in the South East of England (e.g., London and surrounding counties) and only for children born in and before August 2015 to ensure children are old enough for at least one year of data from school. NHS Digital will then link the GOSH NBS database identifiers to the DfE identifiers, to create **Dataset C**. NHS Digital will securely send the linkage key to DfE, to enable DfE to send pseudonymous attribute data to the ONS SRS about children in the NBS cohort.

All the datasets will be pseudonymised for analysis so that all mother and baby identifiers will be kept separate from clinical and demographic data. The linked health data will be held in UCL's Data Safe Haven, and the linked NPD data, with some derived health variables, will be held in the ONS Secure Research Service. However a smaller number of derived health variables from the linked NBS cohort and the datasets linked by NHS Digital will be securely transferred to the ONS SRS from UCL DSH, In order to analyse data to examine long-term education outcomes.

A recommendation for class 2, 4, 5 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	All babies born in the North Thames region (including North London, Bedfordshire, Hertfordshire and Essex), whose newborn screening blood spot sample was tested at the Great Ormond Street Hospital (GOSH) newborn screening laboratory between 1 January 2000 and 31 December 2020 (approximately 2.2 million children) This will include approximately 1800 children with congenital hypothyroidism in the GOSH CH database. Age limit: 0 - 20 Years The childrens mothers will also be included, however this will be less than 2.2 million mothers as some children will have the same mother.
Data sources	1. **Great Ormond Street Hospital for Children NHS Foundation Trust**: a. North Thames Newborn blood spot screening database– held at GOSH (GOSH NBS database). (**legal basis =Clinical database**) b. GOSH Congenital Hypothyroidism (CH) Database – held at GOSH (GOSH CH database). (**legal basis = Clinical database)** 2. **NHS Digital**: a. Hospital Episode Statistics (HES), Admitted Patient Care (HES-APC), Accident & Emergency/Emergency Care Dataset (HES A&E), Outpatient Data (HES-OPD): Note, HES records for both mother and baby will be linked and analysed for this study. These datasets are held at NHS Digital. b. Office of National Statistics Birth and Deaths registration data (ONS) (held by NHS Digital) c. National Child Measurement Programme (NCMP, held by NHS Digital; height and weight

	of primary school children at 4-5yr and 10-11yr) (**legal basis = nationally mandated**) d. Personal Demographics Service (PDS) required to find all postcodes. **3. Department for Education (DfE):** a. National Pupil Database (NPD), information on school performance and special educational needs) (**has alternate legal basis – not defined as confidential patient information**) **4. Public Health England (PHE):** a. Newborn hearing screening data (NBHSD), records permanent, moderate, severe and profound deafness and hearing impairment in newborn babies) (**legal basis = UK national screening programme)** b. National Congenital Anomaly and Rare Disease Registration System (NCARDRS); records those people with congenital abnormalities and rare diseases across the whole of England) (**legal basis - CAG reference CAG 10-02(d)/2015**)
Identifiers required for linkage purposes	1. Name 2. NHS number (of child) 3. Mothers NHS number 4. Hospital ID 5. Date of Birth 6. Date of Death 7. Postcode (Unit level) 8. Postcode histories 9. NBS Cohort identifier PHE pseudonymised identifier also required for linkage for patients in NBHSD and NCARDRS NPD pseudonymised identifier also required for linkage for patients in NPD
Identifiers required for analysis purposes	No identifiers which have not been modified are required for analysis: identifiers will be deleted once they are modified. 1. Date of Birth - modified to analysis variable such as week of birth. This will be done by named researcher at UCL-DSH

	2. Date of Death - modified to month and year of death. Follow-up time from birth in days will also be calculated. This will be done by named researcher at UCL-DSH 3. Post code (unit level) - used to map to Lower Super Output Areas. This will be done by the GOSH DRE team. Researchers will not have access to full postcodes. 4. Gender 5. Ethnicity 6. Parent's country of birth 7. Parent's occupation 8. NBS Cohort identifier
Additional information	Linked health data is stored in the UCL Data safe haven. The linked NPD data will be kept in the ONS Secure Research Service. The linkage keys received back by PHE and DfE constitute lookup tables containing the NBS Cohort identifiers and the respective pseudo IDs supplied by PHE and DfE to NHS Digital for linkage. They will be kept at PHE and DfE until the attribute data for the children in the NBS cohort have been extracted and transferred to UCL DSH and ONS SRS, respectively. PHE and DfE will delete the linkage keys as soon as the attribute data have been received and the linkage checked – this is expected this to be maximum 3 months after data is received.

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 group wishes to place on record that they believe the public interest for this research is very high, and the outcomes will have the potential to bring real benefit to this patient group, and potentially to others. Whilst this application has been deferred because of the reasons set out below, members wish to encourage the applicants to take advice and resubmit this application; as it was agreed that this is important work that needs to be undertaken, and the CAG were supportive of this worthwhile project in principle.

Scope of Support

Members felt the scope of support being requested by the applicants was unclear. Despite the members understanding why support was requested for particular data flows, it was not clear to the CAG if this application was;

- Aiming to answer the research question proposed in the CAG application form (regarding examining why the birth prevalence of congenital hypothyroidism with gland in situ (CH-GIS) has increased among children, and to examine health, education and treatment outcomes for children affected by congenital hypothyroidism (CH), compared to unaffected children), or;
- If the aim of this application was primarily to support a research resource for future studies.

Although the applicant had mentioned that the GOSH team wish to retain the identifiers for possible future research, it was not an aim of the study. If it is likely to be used as a resource for further research, and possibly a research database, there may be further relevant questions which would be asked of the applicant as part of the application process to CAG. The CAG commented that there are many different proposed linkages about a large number of children undertaken as part of this proposed application, and as such the database would be of enormous value for much wider research than the proposed purposes of the current application alone. Where the applicants are considering to use this data as a research database, any future application to CAG should be submitted as a research database.

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.

- **Proportionality**

It was noted by the CAG that the number of controls seemed extremely disproportionate to the number of cases in order to answer the proposed research questions. The application is expected to include 1800 children with congenital hypothyroidism, which would leave remainder of the 2.2 million children as controls. It was commented that as per Principle 3 of the Caldicott Principles and Principle (c) of the Data Protection Act 2018; *information is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation'),* that applicants should use the minimum amount of controls necessary to answer the proposed research questions, or justify why nearly 2.2 million controls are required. It was noted by CAG members that if one of the purposes of this research was to build a useful database which could answer wider research questions about other disease areas, then this may provide justification, however this was not noted in the primary outcomes of this research application, see comments on scope of support, above.

- **Minimising flows of identifiable information**

It was noted that as part of the application the applicant had proposed potentially utilising confidential patient information already collected for other purposes to minimise the flow of identifiable data. However these data flows were not confirmed with the data controllers. It was agreed by the CAG that the review of the data flows would be limited to that described in the application, without considering the potential caveats. If the applicant agrees a way to undertake the study to reduce the flow of patient identifiers in the future, these should be clearly described in any future application, or submitted as a subsequent amendment. Regardless, any future application should only describe the current confirmed dataflows.

- **Feasibility of consent**

Members agreed that seeking consent for undertaking these linkages was impracticable, given the applicant's justification that this will involve a large number of children and would introduce a significant risk of bias due to substantial potential non-response.

- **Use of anonymised/pseudonymised data**

It was agreed by the Committee that the use of anonymised/pseudonymised data is impracticable for the activities requested, and the applicants are unable to complete these linkages without confidential patient information.

‘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 objection 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.

Patient notification materials have been provided, which will be placed on the Child Health Informatics Group (CHIG) website following support. Despite the improvements made to the patients notification as part of the application, it was commented that the text appears to be a mix of patient notification and a GDPR privacy notice.

The CAG advised that the applicant should consider a layered approach, and as part of the re-submission, should provide both a separate one page patient notification, which has an initial simple explanation of the purpose, and how to opt out, and then an option to link through to a separate full privacy notice for those that wish to read through further information.

It was noted also that the applicant could consider getting feedback from Patient and Public Involvement groups regarding the developed separate patient notification and privacy notice.

The Group also questioned if the patient notification could be displayed on other websites, for example the British Thyroid Foundation (BTF) website.

NHS digital will apply the national data opt out, and opt out options via PHE newborn screening leaflet for the use of data in research will also be respected. The patient notification on the CHIG website lets parents and children know how to contact the study team in order to opt out if they wish, and the applicant has worked to develop how the local opt out mechanism would will work with GOSH. The CAG raised no issued with the proposed opt out mechanisms.

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 worked with the British Thyroid Foundation (BTF) in developing this research.

The PI has spoken to 7 parents whose children have CH about the study, who got in contact after seeing details about the study advertised through the BTF. The applicants have also spoken to People's Advisory Group and the Parents' and Carers' Advisory Group of the Great Ormond Street Hospital Biomedical Research Centre in September 2018. Presentations and feedback have been provided, and detailed information regarding the future Patient and Public Involvement plan has been provided.

The applicant states all were very supportive of the research methodology, and were informed that the linkages would be unconsented.

The CAG were content that the applicant had undertaken appropriate Patient and Public Involvement regarding the targeted patient group. However, due to the disproportionate number of controls used, they did not feel that enough Patient and Public Involvement had been conducted with all of the groups of people potentially involved in this study. The Group asked that further Patient and Public Involvement be carried out with mothers and children who do not have congenital hypothyroidism regarding the use of their confidential patient information without consent for the purposes of this research study.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which

addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Provide much more clarity on the scope of activities that require support, particularly regarding if this application is supporting the proposed research question, or if this application is supporting a research database.

2. Regarding the answer to the above question, please consider if an application for a research database is required.

3. Consider whether this application can be undertaken in an alternative manner, in order to minimise the disproportionate number of controls proposed.

4. If the applicants do not propose to alter the number of controls required, please provide a clear justification as to why 2.2million controls are required.

5. Please develop a layered approach to patient notification, including a separated simple patient notification, and a more detailed privacy notice.

6. Consider getting feedback from Patient and Public involvement groups about the suitability of notification materials.

7. Consider on which other websites the patient notification materials could be displayed.

8. Please undertake further patient and public involvement with control mothers and children to ensure proportionality of patient and public involvement and to ensure this is conducted with all groups of people that are potentially involved in the research. Please consider specifically the acceptability of using their confidential patient information without consent.

9. Security assurances are required to be in place for 2019/20 in order for the application to be supported after 12 December 2020. This relates only to Great Ormond Street Hospital for Children NHS Foundation Trust, and Public Health England (X25), all other security assurances are in place.

Declarations of Interest

There were no declarations of interest.

5. New applications – Non-Research

a. 20/CAG/0151 - NHS Digital and BAD: Dermatology Intervention Service and Clinical Registries

Context

Purpose of application

This application from the British Association of Dermatologists set out the purpose of creating a national audit of the NICE Service Guidance on the organisation and delivery of dermatology healthcare services, which will provide the national NHS dermatology service with clinical outcomes for benchmarking by individual consultants, their trusts, Clinical Commissioning Groups and patients in England.

The dermatology specialty is largely outpatient-based, and diagnostic data is not routinely collected to identify patients' skin disease and co-morbidities. Trusts also have historically under recorded outpatient procedural data. This has made it difficult to undertake qualitative and quantitative data analysis to audit and benchmark services. The applicants will create a national audit intended to address these deficiencies and support quality improvement activities, local clinical audit processes and to deliver improved, measurable patient care. The data will also be used to help dermatology departments to achieve some of the areas for improvement identified in the It Right First Time (GIRFT) programme.

The applicants seek support to allow the disclose of confidential patient information from participating NHS trusts to NHS Digital. The confidential patient information will be entered into the NHS Digital Clinical Audit Platform (CAP) system by staff at participating NHS trusts in England. An extract of identifiable and sensitive data will be taken for statistical analysis by NHS Digital, and reports created of de-identified aggregate data. Reports with identifiable data will be made available within CAP for individual organisations to access their own results for local audit. There will be no linkage to other datasets. The data collection is prospective and will be undertaken on a yearly basis to provide the comparative analysis needed to inform on patient demographics, skin disease rates and efficacy of treatments.

A recommendation for class 1, 5 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	All (child and adult) dermatology patients receiving phototherapy treatment and/or cutaneous allergy testing, seen in outpatient secondary care departments and tertiary dermatology centres in NHS trusts in England. Approximately 600,000 attendances for dermatological treatment occurred in 2019.
Data sources	1. Clinical data for eligible patients at participating trusts, input into the NHS Digital Clinical Audit Platform (CAP) system.
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – district level 4. Sex 5. Ethnicity 6. Consultant GMC code
Identifiers required for analysis purposes	1. NHS Number 2. Date of birth 3. Postcode – district level 4. Sex 5. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

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 agreed that the application was in the public interest and had a clear medical purpose.

Scope

The CAG assumed that the input of confidential patient information into the database was undertaken by the clinical care team and that support was required for the transfer of confidential patient information from the participating trusts to NHS Digital. Members requested confirmation that staff from the clinical care team in all trusts would undertake the data input, or whether support under s251 was also needed for those outside of the direct care team to input confidential patient information into the database.

Data controllership

The British Association of Dermatologists and NHS Digital were listed as joint data controllers. The CAG queried whether this was correct or whether the British Association of Dermatologists only were data controllers. A data controller is a person, company, or other body that determines the purpose and means of personal data processing, which appears to be the role of the British Association of Dermatologists in this application, with NHS Digital and the participating trusts as data processors, as they will process data on behalf of the data controller.

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.

- **Feasibility of consent**

The applicants' justification for not seeking consent was that consent was not feasible due to the potential size of the cohort and the number of treatments received by each patient. This implied that the applicant thought that consent was needed every time that patient data was

recorded, however consent would only need to be sought at patients' first visit. Patients were given an information leaflet. The CAG requested that further justification was given on why consent could not be sought.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to identify and remove any duplicate records within the database. The CAG accepted that this could not be undertaken in any other way.

'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 objection 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.

A patient handout and poster were provided with the application. This handout will be given to patients at the start of their treatment and at appointments throughout the patient's journey. This was a generic document about the National Data Opt-Out.

The National Data Opt-Out will be applied at trust level before the data is submitted to NHS Digital. An opt out record will be held in patients' files in the clinical intervention registry, this will prevent data being uploaded into the audit throughout the patient pathway. Patients will be allowed to object to data that has already been collected being processed and details of how they can do this will be included in the patient information handout.

No project-specific local opt-out is in place. The CAG asked that a local patient notification and dissent mechanism was created, and the materials provided to the CAG. These comments are made on the assumption that it can be demonstrated consent is impractical.

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 BAD service guidance and clinical guidelines have been developed with patients and patient specialty groups. The Phototherapy Working Party Group (WPG) and the Cutaneous Allergy Working Group will continue to be part of the development of the database and registry for their specialty specific clinical intervention area. They meet yearly as part of the service standards review process and will form the test group for the relevant database.

The BAD uses a NICE accredited framework and standard response framework to formally record and answer all feedback received as part of this process. The BAD will continue to use this process as part of the development of the audits. The information collected from the audits will have patient specific outcomes as part of the reporting functions. For example, the phototherapy patient will be able to receive a cumulative treatment summary for their records.

The Group asked that further details were provided on the patient and public involvement conducted, including clarifying the involvement of lay representation.

Exit strategy

The CAG requested clarification on whether the identifiable dataset was held within participating trusts only for 5 years after the close of the audit or whether confidential patient information would also be held by NHS Digital.

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 Secretary of State for Health and Social Care 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, the applicant was required to respond back to all of the requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please confirm that staff from the clinical care team in all participating trusts will undertake the input of confidential patient information, or whether support under s251 was also needed for those outside of the direct care team to input confidential patient information into the database.

2. Provide further justification needs to be given on why consent cannot be sought at the time of providing patients with the information sheet.

3. Clarify if the British Association of Dermatologists only are the data controllers for this application, with NHS Digital and the participating trusts as data processors.

4. A local patient notification and dissent mechanism needs to be created and the materials provided to the CAG.

5. Further details need to be provided on the patient and public involvement conducted, including clarifying the involvement of lay representation.

6. Clarify whether the identifiable dataset will be held within participating trusts only for 5 years after the close of the audit or whether confidential patient information would also be held by NHS Digital.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

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. Confirmation provided from the IG Delivery Team at NHS Digital 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.

- **NHS Digital has a confirmed 'Standards Met' grade on DSPT submission 2019/20 by check of the NHS Digital DSPT tracker on 07 December 2020.**

- **The British Association of Dermatologists – DSPT pending for 2019/20**

- **Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.**

Declarations of Interest

There were no declarations of interest.

6. Office Report

A report from the office was received for December 2020 and was shared with members.

7. Chair's Report

A report from the CAG Chair was received for December 2020 and was shared with members.

8. Any other business

No other business was raised.

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

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date