Minutes of the meeting of the Confidentiality Advisory Group

03 September 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr Malcolm Booth	Yes	CAG Member
Ms Sophie Brannan	Yes	CAG Member
Dr Patrick Coyle	Yes	CAG Vice-Chair
Professor Barry Evans	Yes	CAG Member
Mr David Evans	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor

Ms Nicole Mather	Observing

1. Introduction, apologies and declarations of interest

Any declarations of interest are detailed for each application below

2. Consideration Items

a. 20/CAG/0084 - PIONEER: The UK Health Data Research Hub for Acute Care

Context

Purpose of application

This application from University Hospitals Birmingham NHS Foundation Trust set out the purpose of medical research which aims to create and manage the PIONEER database, which will be used to understand and inform acute healthcare processes and long-term consequences for patients admitted to hospital which can inform current and future patient health care and health processes.

Acute care traditionally has not been the subject of research or innovation, despite its scale and the costs involved, and acute care records are traditionally siloed within individual NHS organisations. Linking records at a population level and allowing use of this data for research purposes could provide significant benefits. PIONEER will gather and link data from across acute care providers to become the first such research database to combine routine acute care provision. Using linked organisation level data, rather than national level data will provide a greater granularity of data and greater utility.

The PIONEER database will be managed within University Hospitals Birmingham NHS Foundation Trust. Initially, routinely collected acute care data from University Hospitals Birmingham NHS Foundation Trust data will be linked with routinely collected data from West Midlands Ambulance Service NHS Foundation Trust. It is expected that the database will expand the number of NHS organisations submitting routine clinical care data over time, although future unspecified organisations were not considered within this application.

Processing elements requiring support

The application indicated that, in most instances, the data to be transferred from participating organisations to University Hospitals Birmingham NHS Foundation Trust will be in a pseudonymised format. Upon receipt University Hospitals Birmingham NHS Foundation Trust will process this data through briefly reidentifying three identifiable fields (NHS number, postcode and date of birth) in order to link the data to that of other organisations. This element of processing for the purpose of linkage would require a lawful basis.

Where participating organisations do not have the capacity to pseudonymise the data prior to transfer, they would send the data in an identifiable format to University Hospitals Birmingham NHS Foundation Trust to undertake the pseudonymisation. A lawful basis would be required for this sub-set of organisations to disclose this identifiable information to University Hospitals Birmingham NHS Foundation Trust for this purpose.

Researchers can apply for data extracts for specific research projects, which will undergo a defined application process, including scrutiny by lay members, before released in an anonymised form (for example, only age will be provided, not date of birth). Support would be required to process and render relevant information fully anonymous prior to disclosure.

A recommendation for class 1, 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	Patients who have undergone an acute care contact, within University Hospitals Birmingham NHS Foundation Trust or West Midlands Ambulance NHS Trust. Data will be collected retrospectively (from 01 January 2000 at the earliest) and prospectively.

Data sources	1. University Hospitals Birmingham NHS Foundation Trust 2. West Midlands Ambulance NHS Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode
Identifiers required for analysis purposes	1. Postcode 2. Date of birth 3. Gender 4. Ethnicity 5. Diagnosis information (including rare diseases)
Additional information	Postcode is not provided to researchers. Instead, a less specific geographical unit such as the Lower layer Super Output Area (LSOA), or the associated data of interest such as the Index of Multiple Deprivation score will be provided. Date of birth is not provided to researchers. It will be used to calculate the age of the patient at the time of interest to the researcher.

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by the CAG.

Provide a letter from West Midlands Ambulance NHS Foundation Trust, as data controller, to confirm their support for this application and to confirm that 'section 251' support is required to enable this transfer for this purpose.

A letter of support from West Midlands Ambulance NHS Foundation Trust was provided to confirm that support was required for the transfer of information to University Hospitals Birmingham NHS Foundation Trust.

Members were content with this letter.

Provide firm examples of the research questions that the database will initially be used to answer.

The applicants provided three examples of initial uses of the data in the fields of sepsis, diabetes and cancer therapy, with full details of the research question and how PIONEER will be used to address the question.

The group noted these examples and raised no issue.

Provide considerations as to why, if a common pseudonymisation process was used, the linkage could not be undertaken on pseudonyms.

The applicants provided detail that is as become standard practice at University Hospitals Birmingham NHS Foundation Trust to quality check data by re-identifying the NHS number, postcode and date of birth of patient to quality check linkage. Using three identifiers to do this gives a negligible error rate, compare to a 1% error rate when only using one identifier. This is undertaken using a code applied to the data and checked automatically and is not a manual process.

The group considered this point, and concerns remained about the need to undertake this reidentification, whilst noting this is automated, and felt that the justification for pseudonymisation at source with a common pseudonym (which would remove the need for reidentification) had not been fully explained. There were also concerns that, whilst it may be justifiable to undertake on a small scale with West Midlands Ambulance NHS Foundation Trust, reidentification on a larger scale across the country has not been justified in the response

As such, a meeting between the CAG chair team and the applicant was arranged to fully discuss the remaining concerns, with the applicants providing an options appraisal paper to supplement the conversation. The applicants fully detailed their approach to this, and the methodology used to automatically reidentify patient data to match across datasets. Where there are discrepancies the match will be rejected. The advantage for this method over using a common pseudonym is the ability to be able to quality control the data.

Following this meeting the CAG chair team agreed to support the use of reidentification of NHS number, postcode and data of birth of data provided by West Midlands Ambulance NHS Foundation Trust to link to University Hospitals Birmingham NHS Foundation Trust data, on the following conditions:

a. The applicants, alongside this, pilot the use of a common pseudonym to link data between the West Midlands Ambulance NHS Foundation Trust and University Hospitals Birmingham NHS Foundation Trust.
b. The applicants explore returning rejected pseudonymised linkages back to West Midlands Ambulance NHS Foundation Trust, in order for the Trust to identify and correct the error, before returning back to University Hospitals Birmingham NHS Foundation Trust.
c. The applicants record the percentages of mismatch from linkage through reidentification, linkage through a common pseudonym, and the impact of returning pseudonymised rejected linkages to the original Trust. A report on the effectiveness of each method, and as well as a summary of the benefits and challenges encountered with each should be provided to the CAG prior to any request to add further organisations.

Clarify the understanding of pseudonymisation within the application in terms of what is transferred to Birmingham and the Pioneer database.

The applicants detailed that pseudonymisation is the form of deidentification which will be used within PIONEER, to replace or remove information in any data set that identifies an individual. The data that will be transferred to Birmingham and the PIONEER database that will need pseudonymisation are personal data, for example NHS number, date of birth and postcode. The applicants further explained how this will be undertaken.

Whilst noting the previous point, the CAG raised no issues on this description.

Specify, in absolute clarity, the exact relationship between the four hospitals of University Hospitals Birmingham NHS Foundation Trust and the PIONEER database team who may access confidential patient information of these hospitals, providing confirmation where 'section 251' support is or is not required.

a. On what common law duty of confidentiality basis are the PIONEER team accessing this data, for research purposes, considering the processing relates to a different purpose.

b. Detail the medical system infrastructure within University Hospitals Birmingham NHS Foundation Trust. Are the systems of each hospital linked, or separate?

The applicants confirmed that the four hospitals that make up University Hospitals Birmingham NHS Foundation Trust are one legal entity, and that health data from all four hospitals is held and processed for its primary purpose under a single and joint UHB

informatics service, using a linked system. This team have access to patient data from University Hospitals Birmingham NHS Foundation Trust as part of the provision of healthcare. Given the team have access as part of clinical care 'section 251' support is not required for this element.

This was confirmed in an email from the Data Protection Officer dated 29 June 2020

Members were content with this response.

Detail the ultimate ambition, in terms of geographical scope, of the PIONEER database.

It was clarified that the intention is to initially expand PIONEER across the West Midlands, and then nationally, to enable PIONEER to address important research questions arising from differing geographical areas and populations.

Members raised concerns about providing blanket support for this expansion without further oversight to ensure that the systems in place were secure, and ensuring that, when expanding to areas outside the West Midlands that appropriate patient notification is undertaken to ensure that patients are made aware of the uses of their data in PIONEER. Whilst this does not need to be addressed immediately, the CAG will expect this to be addressed when submitting any future amendment to widen the geographical scope of PIONEER.

Provide, separate to the privacy notice, further patient notification materials. This should include:

a. **Information, in Plain English, for service users to understand the work of PIONEER**
b. **Details of how service users may use the local opt out for PIONEER, including contact details.**
c. **Supplementary information on where the provided patient notification materials will be used.**

The applicants provided template text for the PIONEER website (the website is currently under construction). As well, two ethically approved blogs for CAG to see and a series of "frequently asked questions" were provided that will be used on the PIONEER website.

It was explained that patient opt out information will be included in all patient facing material, with the template text provided. Patient materials will be displayed in a number of ways:

- The University Hospitals Birmingham NHS Foundation Trust privacy notice will contain a link to the PIONEER website
- The PIONEER website itself
- Facebook and twitter, using the text provided
- At public facing events, webinars and public "You ask and we answer" sessions
- The PIONEER specific text within the UHB privacy notice will be incorporated into the West Midlands Ambulance NHS Foundation Trust privacy notice.

The group noted these and no issues were raised, though noting the provisional support letter condition of support to provide the CAG with a comprehensive media and communications strategy.

Confidentiality Advisory Group advice conclusion

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

1. Support is limited to the involvement of West Midland Ambulance Trust initially. Prior to the addition of subsequent external organisations, a report should be sent to the CAG for consideration on the success of the processes with this Trust, detailing any issues that have arisen in the initiation of the database, and how these have been resolved.
    a. This report should include details of the percentages of mismatch using linkage through reidentification, linkage through a common pseudonym, and the impact of returning pseudonymised rejected linkages to the original Trust. The effectiveness of each method, and as well as a summary of the benefits and challenges encountered with each should be included.

2. Support is limited to the use of structured data and unstructured medical image data only.

3. Support is not provided for the use of unstructured free text data. Where the applicants wish to use this form of data in the future, a detailed amendment/paper should be submitted to the CAG, providing information on how the applicants have considered the pseudonymisation methods of free text data at source, and how they demonstrate its effectiveness in deidentification.

4. Support is not currently provided for participating organisations to transfer identifiable information to University Hospitals Birmingham NHS Foundation Trust to undertake the pseudonymisation process. Where this situation is expected to occur, an amendment should be submitted to the CAG, providing assurances on the minimisation of identifiable information and the further detail on the processes that will be used.

5. Within three months of the final outcome letter date, provide the CAG with a comprehensive media and communications strategy. This should include details on how the applicants will maintain patient notification to the wider public throughout the lifetime of this project, and how the applicants will handle media enquiries.

6. Support is given for the use of data for medical research purposes only.

7. Favourable opinion from REC **Confirmed 21 August 2020.**

8. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT review for West Midlands Ambulance Service NHS Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 29 June 2020).**

   The NHS Digital DSPT review for University Hospitals Birmingham NHS Foundation Trust was confirmed as 'Standards Not Fully Met (Plan Agreed)' on the NHS DSPT Tracker (checked 29 June 2020). Support is conditional upon organisation meeting the action plan, as agreed with NHS Digital, and maintaining the agreed standard for the duration of support. All University Hospitals Birmingham staff handling information under this support must act in accordance with all details specified in the application.

Declarations of Interest

There were no declarations of interest.

3. Revised Applications - Research

a. 19/CAG/0152 - Royal Free HIV Cohort Study (RFHCS)

Context

Purpose of application

This application from University College London set out the purpose of medical research to address critical questions regarding the natural history and prognosis of HIV through the ongoing retention and addition of data to the established research database.

The Royal Free HIV Cohort Study (RFHCS) is an ongoing study of people with diagnosed HIV attending the Royal Free Hospital HIV clinic, also known as the Ian Charleson Day Unit. The RFHCS has been running since 1995 and information is currently held on patients until 31 January 2018. In this application support is sought for the ongoing retention of previous information collected to date, where public interest had been relied upon as the legal basis for processing. Support is also sought for the ongoing prospective collection of data in relation to newly diagnosed patients. Confidential patient information would be transferred from the Royal Free Hospital to the UCL Data Safe Haven in order to enable creation of a non-identifiable analysis dataset. The applicants are also seeking support to prospectively enrol all new patients who attend the HIV clinic.

The database includes all individuals who have ever attended the Ian Charleson Day Unit, unless they have opted out. Data relating to individuals that have since died or have stopped attending the clinic are included, up until the date of their last Royal Free clinic visit. The RFHCS only includes data from the individual's Royal Free Hospital clinical record already collected as part of routine care, and data is not collected from other hospitals or other sources.

A recommendation for class 1, 4 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 individuals who attended the Ian Charleson Day Centre between 01/01/1991 and 31/01/2018, unless they have opted

	out. This includes those individuals that have since died or have stopped attending the clinic. The number of patients included in the database is 6833.
Data sources	1. Royal Free HIV outpatient clinic (Ian Charleson Day Centre)
Identifiers required for linkage purposes	1. NHS Number 2. Hospital ID Number 3. Date of birth 4. Postcode – unit level 5. Soundex
Identifiers required for analysis purposes	1. Date of death 2. Postcode – unit level 3. Gender 4. Ethnicity
Additional information	

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 accepted that there was a clear public interest in the creating the research database and recognised the importance of retaining the data already collected.

Scope

The database had previously relied on public interest as the legal basis for processing data in relation to the common law duty of confidence. The applicants were now seeking Section 251 support to retain data already collected and to prospectively enrol all new patients attending the clinic. Members were clear that, should a recommendation of support be provided for the proposal, this could not be retrospectively applied to legitimise past practice. However, it was noted that support could be prospectively recommended to legitimise the ongoing retention of this established database.

The database currently contained data on patients followed-up until 31 January 2018. The CAG requested clarification over whether data had continued to be collected between 31 January 2018 and the CAG discussion of the application in September 2019.

Members noted that support was required for the transfer of confidential patient information to the UCL Data Safe Haven, where it was pseudonymised, but it was not clear whether support was needed for the collection of data within the Royal Free London NHS Foundation Trust. The Group requested clarification on whether the data collection within the Royal Free London NHS Foundation Trust was undertaken by members of the direct care team, as the data flow and access were unclear.

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 advised that consent was not feasible due to the difficulties in recruiting large numbers of patients into observational research studies. The applicant also noted that HIV disproportionately affected marginalised and socially disadvantaged people, who may be difficult to recruit. The purpose of the research was to study and improve the health outcomes of this patient group, and the applicant noted the importance that the database accurately reflected the health and outcomes of this population.

The CAG considered if the applicants could undertake the prospective data collection on a consented basis. Support under Section 251 would therefore only be needed to retain the data already collected. The information provided in the application suggested that all patients were informed of the database when attending their first clinic appointment and the CAG suggested that consent was sought at this point. The applicant was asked to confirm that all patients included in the database would have attended the clinic at least once and provide justification for not seeking consent during patients' clinic appointments.

- **Use of anonymised/pseudonymised data**

The applicants advised that the confidential patient information collected was continually reviewed in order to ensure that the minimum required was collected. The data stored in the UCL Data Safe Haven was limited to Hospital Number, date of birth, NHS number and soundex, which was the minimum required for the data merging, management and cleaning processes required. The Group raised no queries in this area.

'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.

Information about the study would be displayed on the Royal Free HIV cohort study website. This information included a list of publications and conference presentations, and links to access this material. The website would also be updated with lay summaries of important findings from the research. Posters, with details of the study and a link to the website, would also be displayed in the outpatient clinic. A downloadable patient information document was also included on the RFHCS website, and this was highlighted on the front page of the website. The Group noted that the poster and website information had not been included in the application and asked that these were provided.

Patients were informed about the database by their treating clinician when attending for their first clinic appointment and were given the opportunity to dissent. If a patient opted out, this was noted in their clinical notes and on the NHS live clinical database. Information on patients who had opted out was not included in RFHCS.

Patients who had not attended their booked appointments at the clinic within the last year would be sent the patient information sheet, if they had consented to such letters being sent. The applicants would also engage with the community health nurses, whose role targeted the hard to reach population, to convey this information to patients.

The Group noted that the Patient Information Sheet gave brief information about the study and did not explain how patients could opt-out. Patients with queries were told to contact their doctor. If the applicant opted not to proceed with the prospective data collection on a consented basis, then more comprehensive information needed to be provided to patients about how they could opt-out.

Patient and Public Involvement and Engagement

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

The Royal Free HIV Cohort Study Steering Committee met every 6-12 months. This Committee provided feedback into study policies and procedures, the research agenda, patient perspective and dissemination of results. One patient representative was currently included, and the applicants were in the process of recruiting at least two community representatives to the RFHCS Steering Committee. At least one patient representative needed to attend a meeting for the Committee to be quorate.

The Chief Investigator attended the HIV Clinic Patient User Group (PUG) meeting in 2014, to explain the purpose and procedures of the RFHCS, including data security. Seven patients attended, who were not asked for their demographic characteristics. No concerns regarding the RFHCS or the procedures in place had been raised. The applicant noted that participants had raised a number of research ideas, which were then incorporated into the research agenda. The minutes for this meeting had been provided with the application.

The applicants aimed to attend the PUG every five years, and planned to visit before the end of 2019, where they will re-discuss and review the study procedures, including; the confidentiality procedures in place, the acceptability of the opt-out approach, the best way to communicate study findings and the real-life issues of living with HIV in this patient group, which will help to inform the RFHCS research agenda. They also planned to increase the frequency of visits to every three years. The applicant advised that no patient and public

involvement had been undertaken more recently. The activity previously undertaken had involved explicit explanation of the collection of clinical data without individual consent.

The CAG requested that further information about the PUG was provided, including details of the membership of the group. Members asked if the transfer of data from the Royal Free to the Data Safe Haven at UCL had been discussed at these meetings. The CAG also asked if the applicants could attend these meetings more regularly and suggested that this could be annually.

The applicants also planned to arrange a further meeting before the end of 2019 in order to discuss HIV research taking place at the Royal Free. The lead HIV clinicians at the Royal Free will be invited attend this, alongside clinical research staff, the applicant and other members of the RFHCS team from UCL. This will also be advertised and open to all clinic patients. As part of the meeting, the applicants will give a presentation on the RFHCS. Views on the research topic and the acceptability of using confidential patient information without consent will be sought.

The Group agreed that further effort needed to be made to increase the patient and public involvement carried out in line with the above recommendations. The applicants needed to discuss how information about the database is collected and what is done with the information with a patient and public involvement group. Feedback from this activity should be provided as part of the revised submission to evidence that there is support from this patient group for the use of confidential patient information without consent for the application activities. A number of patient groups existed for those with HIV, and the CAG suggested that the applicants also made contact with these.

Exit Strategy

The applicant explained that a number of exit strategies for the RFHCS had been considered. The proposed exit strategy was to use a source pseudonymisation process within the NHS system, so that data transferred from the Royal Free London NHS Foundation Trust to the UCL Data Safe Haven only included non-identifiable information. A five-year timescale had been set for developing and implementing this process.

Members noted that this technology was already in use in primary care, but not widely used in tertiary care, and queried whether it was possible to start using this technology sooner than the five years anticipated. The Group asked that further information about this proposed exit strategy was provided.

Governance and access arrangements for the database

The CAG noted that further information would be required from the applicant to explain the ongoing governance arrangements for the research database. This should include an overview of planned uses for the data, the governance arrangements together with details of the application process and access arrangements for researchers wishing to use the database. Documentation to support these processes should also be provided for consideration.

Confidentiality Advisory Group advice conclusion

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

Further information required

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

1. Consider whether the prospective data collection can be conducted on a consented basis. Also, provide clarification on whether all patients included in the data base will have attended at least one clinic appointment.

If consent was to be sought for the prospective data collection, then a revised application will need to be submitted, specifying that support is only being requested for the retention of data collected up until 31 January 2018.

The following additional points would also need to be addressed in the revised application:

2. Clarification needs to be provided on whether the data collection and collation at the Royal Free London NHS Foundation Trust is undertaken by members of the direct care team.

3. Clarify whether data continued to be collected between 31 January 2018 and September 2019.

4. Further details need to be provided about the continued holding of the data, including the planned uses of the data, governance arrangements, how researchers will access the data and how access will be managed.

5. Further consideration should be given to the planned exit strategy of applying a pseudonymisation at source technology, to clarify how soon it could be implemented.

6. The patient information sheet needs to be revised to contain more information on how patients can opt-out of inclusion in the database.

7. The posters and text of the website information about the study need to be submitted for review.

8. Further patient and public involvement and engagement needs to be carried out prior to resubmission of the revised application to provide assurance that this patient group is supportive of the use of confidential patient information without consent for the application purposes. The following wider points should also be addressed:

    a. Members of the research team should attend meetings of the Patient User Group on a more frequent basis than every five years.

    b. Further information on the composition of membership of the Patient User Group needs to be provided.

    c. Provide information on the topics discussed with the Patient User Group, including whether the transfer to confidential patient information to the UCL safe haven was discussed.

Once received the information will be reviewed at the next available CAG meeting.

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0103 - UK Haemophilia Research Registry

Context

Purpose of application

This application from United Kingdom Haemophilia Doctors Organisation set out the purpose of medical research which aims to use the data collected within the National Haemophilia Database as a research registry.

The UK National Haemophilia Database (NHD) is a long running national database that was established in 1968. Whilst the database maybe used for direct clinical care, it is also used extensively for national audit purposes. The database has a long history of working with national bodies to further patient care by assisting continuity of care and monitoring safety through the provision of accurate data, and this information informs and shapes national policy. This activity is working under support (20/CAG/0102).

The applicants request support for using the National Haemophilia (NHD) as a research registry. Given the data held by the NHD dates back over 50 years, the registry can play an important role in the research of bleeding disorders. Applications for use of the data for research purposes will be reviewed by the Data Analysis Group (DAG), a sub-committee of the Data Management Working Party (DMWP) within the National Haemphilia Database. The DMWP includes a number of stakeholders including a patient representative. Once approved, the data will be released in a pseudonymised or anonymised format and is generally accessed directly from the N3 servers and is not transferred.

A recommendation for class 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 with a bleeding disorder in England and Wales

Data sources	1. National Haemophilia Database
Identifiers required for linkage purposes	
Identifiers required for analysis purposes	1. Gender 2. Postcode 3. Ethnicity 4. Date of Death

Confidentiality Advisory Group advice

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

Public interest

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

The CAG noted the high public interest in this application, and the benefits that using the data in the National Haemophilia Database for research purposes will bring to Haemophilia patients

Legal Basis

The group noted previous applications for using the NHD as a research registry were deferred, due to the lack of a legal basis under the common law duty of confidentiality for the existing holding of data. However, the applicants have sought to rectify this moving forwards with the related application (20/CAG/0102) to provide a legal basis for holding of the confidential patient information for non-research purposes, which underpins the legal basis for using the data for research purposes in this application.

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 group noted the attempts that the applicants had made to consent patients for the research registry, and that approximately 2000 patients had consented. These patients would be outside the scope of this support. Members were also aware that that a small number had declined consent and agreed that the data of these patients would not be able to used under this support.

The CAG understood however that has been difficult to achieve the aspirations of a fully consented model, exacerbated by the COVID-19 pandemic and reduced interactions with patients. The CAG agreed that a consented model will be difficult to achieve and were content to support this position.

- **Use of anonymised/pseudonymised data**

The applicants will minimise the data in order that research applicants will not access any confidential patient information, instead using anonymised data only. The CAG were content with this position.

'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 CAG reviewed the patient privacy notice and the patient broadcasts supplied with the application. Whilst the group understood the need to meet the legal requirements of GDPR (as the privacy notice does), it felt that the application would benefit from further patient notification materials which were short and in an accessible format for patients. The patient

broadcasts would also benefit from a patient review to ensure that they are in a format suitable for patients.

The group agreed that, as a condition of support, updated patient notification materials should be provided to the CAG within six months of the final support letter being issued.

The CAG noted that a dissent mechanism will be in place via the patient's clinician. The CAG were content with this, but advised that in developing the patient notification materials these should contain a central telephone and email contact for patients to opt out.

Patient and Public Involvement and Engagement

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

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 group noted the patient and public involvement work undertaken to date, primarily consisting of patient representation in the Data Management Working Group that is run by the NHD. Members were content with the involvement that has been undertaken, but suggested that the updated patient notification materials should be reviewed by an appropriate patient group.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Provide, within six months of the final support letter, updated patient notification materials that have undergone review by a patient group.
    a. These materials should include a central telephone and email address for patients to opt out of their use of data.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 15 April 2019**

3. 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. **The NHS Digital DSPT review for Manchester University NHS Foundation Trust was confirmed as 'Qualified Assurance – Trust has not achieved 95% staff undertaking security awareness training' on the NHS Digital DSPT Tracker (checked 14 August 2020). All staff at Manchester University NHS Foundation Trust that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support.**

   The NHS Digital DSPT review for the National Haemophilia was confirmed as 'standards met' (by email from NHS Digital 18 September 2020).

Declarations of Interest

There were no declarations of interest.

4. Revised Applications – Non-Research

a. 20/CAG/0102 - National Haemophilia Database (NHD)

Context

Purpose of application

This application from United Kingdom Haemophilia Doctors Organisation set out the purpose of the management of health and social care services to enable reporting of outcomes regarding Haemophilia.

The UK National Haemophilia Database (NHD) is a long running national database that was established in 1968. Whilst the database maybe used for direct clinical care, it is also used extensively for national audit purposes. The database has a long history of working with national bodies to further patient care by assisting continuity of care and monitoring safety through the provision of accurate data, and this information informs and shapes national policy.

National Haemophilia centres provide confidential information to the NHD through an encrypted transfer. Haemtrak data (an application in which patients input medication usage etc) is also transferred to the NHD in an encrypted format. However, it is noted that the existing held database has historically not had a proper legal basis under the common law duty of confidentiality for transfer confidential patient information and subsequent processing. As such, the applicants request support for the continued prospective holding and processing of existing data in the NHD, and well as the continued collection of prospective data from Haemophilia Centres.

Additionally, the applicants also request support to transfer confidential patient information to NHS Digital to enable linkage to mortality data, which will contribute to safety (provision of care and treatment), cost reduction (management of health and social care services), improved knowledge and therefore care (provision of care and treatment), and provision of a firmer evidence base to inform public policy (Serve the wider public interest).

A recommendation for class 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 with a bleeding disorder in England and Wales
Data sources	1. Haemophila Centres 2. Haemtrak Application 3. NHS Digital

Identifiers required for linkage purposes	1. NHS Number 2. Name 3. Date of birth
Identifiers required for analysis purposes	1. Gender 2. Postcode 3. Ethnicity 4. Date of Death

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 the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The CAG noted the high public interest in this application, and the ongoing benefits that the NHD has to Haemophilia care.

Legal Basis

The group noted that, whilst the NHD has been ongoing since 1968 and is a long-standing database, there has been no sound legal basis under the common law duty of confidentiality for its maintenance, and this has been the primary reason for previous deferrals of research applications by CAG.

The group noted that this application sought to provide a legal basis for both the existing holdings and continued collection of data in the NHD for non-research purposes. Whilst it was understood that there may be some direct care uses of the NHD data (which would not require support as a legal basis exists), there was also significant non-research uses outside of direct care, for which no legal basis exists currently. Members were content

to support this position, but reaffirmed that this support applies only prospectively, not to retrospectively.

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 group noted that there have been some attempts for using a consented model for the NHD. However, it has been difficult to achieve the aspirations of a fully consented model, exacerbated by the COVID-19 pandemic and reduced interactions with patients.

The CAG agreed that a consented model will be difficult to achieve and were content to support this position.

- **Use of anonymised/pseudonymised data**

It was agreed that achieving the aims of the NHD was not possible using only anonymised/pseudonymised data.

'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 CAG reviewed the patient privacy notice and the patient broadcasts supplied with the application. Whilst the group understood the need to meet the legal requirements of GDPR

(as the privacy notice does), it felt that the application would benefit from further patient notification materials which were short and in an accessible format for patients. The patient broadcasts would also benefit from a patient review to ensure that they are in a format suitable for patients.

The group agreed that, as a condition of support, updated patient notification materials should be provided to the CAG within six months of the final support letter being issued.

The CAG noted that a dissent mechanism will be in place via the patient's clinician. The CAG were content with this, but advised that in developing the patient notification materials these should contain a central telephone and email contact for patients to opt out.

Patient and Public Involvement and Engagement

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

The group noted the patient and public involvement work undertaken to date, primarily consisting of patient representation in the Data Management Working Group that is run by the NHD. Members were content with the involvement that has been undertaken, but suggested that the updated patient notification materials should be reviewed by an appropriate patient group.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Provide, within six months of the final support letter, updated patient notification materials that have undergone review by a patient group.

a. These materials should include a central telephone and email address for patients to opt out of their use of data.

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. **The NHS Digital DSPT review for Manchester University NHS Foundation Trust was confirmed as 'Qualified Assurance – Trust has not achieved 95% staff undertaking security awareness training' on the NHS Digital DSPT Tracker (checked 14 August 2020). All staff at Manchester University NHS Foundation Trust that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support.**

   The NHS Digital DSPT review for the National Haemophilia was confirmed as 'standards met' (by email from NHS Digital 18 September 2020).

Declarations of Interest

There were no declarations of interest.

5. New Applications – Research

a. 20/CAG/0097 - Breast Cancer Metastasis

Context

Purpose of application

This application from the Institute of cancer Research sets out the purpose of medical research which aims to use tissue samples to identify molecular mechanisms driving breast cancer metastasis.

Breast cancer is a leading cause of cancer death in women. However, invariably death does not result from the primary tumour in the breast, rather it is caused by secondary (metastatic) tumours which spread to, and colonise, secondary sites in the body. The applicant's laboratory-based research is focussed towards understanding how primary breast tumours acquire the additional properties which allow them to invade into the surrounding tissue, enter the circulation, and establish themselves at metastatic sites. The long-term aim is to identify suitable targets for therapeutic intervention and/or prognostic screening in breast cancer metastasis. Advances in molecular technologies now provide the applicants with an opportunity to interrogate the genetic changes associated with breast cancer metastasis, and in the response and resistance to therapy.

The applicants previously collected 19 samples between 2002 and 2004 from women with metastatic breast cancer, under consent. The Institute of Cancer Research (ICR) hold the identifiable data these women in a pseudonymised form. Support is requested for the applicant to deidentify the personal information and transfer the name, hospital ID and date of birth to a clinical fellow at the Royal Marsden NHS Foundation Trust. The clinical fellow at the Royal Marsden:

- will collect age at diagnosis, original tumour diagnosis, burden of disease – primary and site of metastatic disease, details of prior breast cancer treatment including systemic treatment, surgery and radiotherapy, histological tumour type, size, grade, hormone receptor status, HER2 status) and provide this data in a pseudonymised format (using laboratory ID) to the applicants.
- Will return the identifiable data to the applicant in a pseudonymised format (using the laboratory ID). This is to enable the data held at the ICR to be linked with the data held at the Royal Marsden NHS Foundation Trust and the archival tissue samples.
- Will request that the archival tissue blocks from the histopathology department(s) of the relevant NHS Trust(s) be sent to the CI in secure post. These Trusts will not be able to be identified until this point.

The identifiable information will be deidentified once the sampled and data are collected.

The applicants also note that the existing holding of confidential patient information since 2002 does not have a legal basis under the common law duty of confidentiality. As such, the applicants also request support for the holding of the confidential patient information prospectively in order to allow the above activities to be undertaken legally.

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	Nineteen women with breast cancer metastasis that originally provided sample between 2002-2004 under consent.
Data sources	1. Institute of Cancer Research 2. Royal Marsden NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. Hospital Number 3. Date of Birth
Identifiers required for analysis purposes	No identifiers are required for analysis purposes
Additional information	

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 agreed that there is a clear medical purpose to the application and felt that the research had a high public interest. It was also noted by the group that this work can only now be undertaken given the development in technologies and were content with this.

Scope

It was noted that the initial application did not request 'section 251' support for the existing holding of confidential patient information. However, discussions with the Confidentiality Advice Team highlighted that there may not be a legal basis, under the common law duty of confidentiality, for the applicants to have retained the identifiable information since 2002-2004, given the original consent form did not make this clear. Without a legal basis for the existing data, the CAG would be unable to advise support for the proposed activities.

This was further considered by the applicants, who subsequently requested 'section 251' support for the existing holding of confidential patient information prospectively. This was discussed with the Institute of Cancer Research Data Protection Officer who agreed this approach and provided a letter of support.

The group considered this point and were content to additionally provide support for the existing holding of confidential patient information. However, it should be noted that this support is prospective only and does not provide a legal basis for holding of the data retrospectively.

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 described the flows of identifiable information and noted that once all data and samples are retrieved that all identifiers will be destroyed and the remaining data will be anonymised.

The group were content with this proposal.

- **Feasibility of consent**

Members noted that it is highly likely that all women from the original study will now be deceased. The group also agreed that collecting new samples from a different set of women under consent was not reasonable, given the historical work already undertaken on the women in this study

- **Use of anonymised/pseudonymised data**

Members agreed that this work could not be undertaken using only anonymised or pseudonymised data but noted that the data collected will be anonymised at the earliest possible opportunity.

'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.

Whilst the CAG expects patient notification to be undertaken with the opportunity to opt out included, it also understands that the cohort of patients is expected to be deceased. As such, the group agreed that patient notification and an opt out mechanism were not necessary for this application.

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 group wishes to commend the applicants on the thoughtful and thorough patient and public involvement work that has been undertaken for this research study. Given that the patients are deceased it may have been easy for the applicants to regard this as a tick box

exercise, especially with the COVID-19 restrictions. However, it is clear that the applicants were thorough in their Patient and Public Involvement and Engagement work, which members praised.

Confidentiality Advisory Group advice conclusion

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

1. Favourable opinion from REC **Received 23 March 2020**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT review for the Institute of Cancer research and the Royal Marsden NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 18 August 2020)**

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0100 - Study of lung transplant in cystic fibrosis through linkage between the UK Cystic Fibrosis Registry and the UK Cardiothoracic Transplant Registry

Context

Purpose of application

This application, from London School of Hygiene & Tropical Medicine, sets out the medical purpose to undertake data linkage and research into lung transplants in Cystic Fibrosis.

Cystic fibrosis (CF) is one of the most common inherited diseases and affects around 10,500 people in the UK. The most seriously affected organ in CF is the lung and people with CF experience long-term deterioration in lung function. Lung transplantation is a treatment option for people with CF who have end-stage lung disease, with the aim being to improve both quality and quantity of life.

The applicants wish to link data held within the Cystic Fibrosis Registry and NHS Blood and Transplant (Cardiothoracic Transplant Registry). Identifiers, without clinical data, from each registry will be sent to NHS Digital to enable common pseudonyms to be generated. The pseudonymised IDs will be transferred to London School of Hygiene & Tropical Medicine from NHS Digital, as will the clinical data from each registry, where the data from each registry will be linked. The actions of Cystic Fibrosis Registry is undertaken through participant consent, whereas section 251 support will be required for the actions of NHS Blood and Transplant.

The resultant data will be used for research purposes by the team to investigate how people with CF progress along the transplant pathway from joining the waiting list to transplant and to death on the waiting list or post-transplant, the impact of lung transplantation on life expectancy for people with CF, how patient characteristics are associated with the risks and benefits of lung transplant and how patient and donor characteristics affect post-transplant outcomes.

A recommendation for class 4 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	People with CF in the UK who have data recorded in the UK Cardiothoracic Transplant Registry up to and including 2019. People without CF and lung transplant donor who have data recorded in the UK Cardiothoracic Transplant Registry, up

	to and including 2019.
Data sources	1. NHS Blood and Transplant 2. NHS Digital
Identifiers required for linkage purposes	1. NHS Number 2. Date of Birth 3. Gender
Identifiers required for analysis purposes	1. Date of Death
Additional information	The applicants state that The Cystic Fibrosis Registry data is collected under consent, and so is not part of this support.

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 noted that the application will have a high public interest in people with CF and their journey along the ling transplant pathway

Scope

Members noted that the application relates to only the information shared from NHS Blood and Transplant, given that the information from the Cystic Fibrosis Registry can be shared under a consented model.

It was unclear whether the UK Cardiothoracic Transplant Registry includes patients from Northern Ireland and/or Scotland, and whether there is the potential for their data to be used in this study. The applicants are reminded that support can only be provided for England and Wales, and the applicants should seek further advice if there may be patients from Northern Ireland and/or Scotland.

Whilst members noted some representative numbers of patients for each registry, it was unclear on the potential total numbers of patients that will be included in the UK Cardiothoracic Transplant Registry. The group requested clarification on the number of patients that will be included in the data linkage.

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 group noted that no single organisation will have sight of full clinical information and identifiers, with appropriate minimisation procedures in place to limit the identifiability of the data.

- **Feasibility of consent**

Given that the patients in the UK Cardiothoracic Transplant Registry are retrospective, and some patients may have died the applicants state consent would be impracticable to gain consent as this would involve the use of more identifiable data and the information may not be correct. The members accepted this position that consent was impracticable.

- **Use of anonymised/pseudonymised data**

The use of confidential patient information is necessary for the linkages of the datasets. As above, members noted that procedures are in place to limit the use of identifiable 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.

The group noted the patient notification statement that will be placed on the NHS Blood and Transplant website. Whilst generally content with the information, members felt that the information around the opt out procedure could be clearer. The contact details to opt out should be separated from contact details for further information.

Members also queried how the applicants will communicate and provide opt out information for the non-CF patients, and requested further information on this aspect.

The CAG commented that the registries will include children under the age of 16. The group requested further details on how the applicant will provide age appropriate patient notification materials for children, and how the applicants will address patient notification and opt out mechanisms for when children reach the age of majority.

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 Research Group on the Impact of Lung Transplant in Cystic Fibrosis at London School of Hygiene & Tropical Medicine includes an expert patient representative with Cystic Fibrosis who has undergone a lung transplant and has contributed to the development of this work. The research team also distributed a lay summary to Cystic Fibrosis lung transplant recipients and received five supportive responses.

The group were content with the patient and public involvement and engagement that had been 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 would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, within one month.

Request for further information

1. Clarify the size of the patient cohort from the UK Cardiothoracic Transplant Registry for which data will be processed under support.

2. Revise the patient notification statement to clearly detail the procedure for patients to opt out of the use of their data.

3. Clarify how patient notification materials will reach the non-CF patients.

4. Detail how patient notification materials and opt out mechanisms for when children reach the age of majority will be addressed.

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 16 September 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. **The NHS Digital 18/19 DSPT review for NHS Digital and NHS Blood and Transplant were confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 19 August 2020).**

   The NHS Digital 18/19 DSPT review for London School of Hygiene and Tropical Medicine has not been met. Support therefore cannot be provided until a satisfactory NHS Digital review of the 19/20 London School of Hygiene and Tropical Medicine DSPT submission. The applicants are advised to follow the procedure to gain a satisfactory NHS Digital review of the 19/20 DSPT submission.

Declarations of Interest

There were no declarations of interest.

6. 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