Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

21 March 2019 at Barlow House, M1 3DZ

Present:

Name	*Present*	*Notes*
Dr Malcolm Booth	No	Apologies received
Ms Sophie Brannan	Yes	Lay Member
Dr Tony Calland MBE	Yes	Chair
Dr. Liliane Field	Yes	
Dr Lorna Fraser	Yes	
Professor Jennifer Kurinczuk	Yes	Agenda Items 3.a, 7.a and 8.b. only – by telephone
Dr Harvey Marcovitch	Yes	
Ms Clare Sanderson	Yes	Alternate Vice Chair
Dr Murat Soncul	Yes	Alternate Vice Chair
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	Confidentiality Advisor
Mr Jonathan Fennelly-Barnwell	HRA, Deputy Director of Approvals Service
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Introductions

The Chair welcomed Mr Jonathan Fennelly-Barnwell, Deputy Director of the Approvals Service within the Health Research Authority to the meeting. Mr Fennelly-Barnwell was in attendance to observe the practice of the CAG, following appointment to his new role within the HRA.

Apologies

Dr Malcolm Booth submitted apologies for the meeting.

Dr Jennifer Kurinczuk was unable to attend the meeting in person; however, dialled in via teleconferencing facilities for specific items.

Declarations of Interest

- 19/CAG/0043 (Agenda Item 4.c)

Dr Lorna Fraser advised in advance of the meeting that the main applicant for the item was a professional colleague; however, confirmed that she had no involvement with the proposal. The CAG agreed that Dr Fraser could remain in the meeting, but could contribute to the discussion or recommendation for the item.

2. SUPPORT DECISIONS

Secretary of State for Health and Social Care support decisions

The Department for Health and Social Care senior civil servant on behalf of the Secretary of State for Health and Social Care agreed with the advice provided by the CAG in relation to the 21 February 2019 meeting applications.

Health Research Authority (HRA) support decisions

The HRA agreed with the advice provided by the CAG in relation to the 21 February 2019 meeting applications.

3. CAG ADVICE UNDER CARE ACT

The CAG considered a request for advice under its function in the Care Act 2014. Minutes in relation to this item will be published at the separate appointed place in line with the agreed publication cycle.

4. CONSIDERATION ITEMS

a. ECC 1-04 (b)/2010 Age-X Trial – annual review

Context

This annual review was presented to CAG for information and comment. While a relatively typical annual review, this was escalated for Member consideration due an incident referred to within the documentation around the patient invitation process for the trial. CAG agreed that they should consider this item at a full meeting.

The annual review explained that in July 2016 new Public Health England software was introduced. In addition to inviting birth-year age 50-70 it provided the option (used in about two thirds of cases) of also inviting women of birth-year age 71 who had not yet reached their 71st birthday. The annual review documentation indicated that the software should have ensured that use of this option would exclude such women from the trial (as half would get no invitation), but it did not.

From July 2016 to January 2018 approximately 60,000 women of birthday age 70 were randomised into the trial, of whom about two thirds might otherwise have been invited for screening; instead, half were which amounted to approximately 10,000 fewer. The applicant confirmed that this was the only relevant IT error and that there was no error in 2009 when the trial began.

Confidentiality Advisory Group advice

The CAG reviewed the annual review and agreed that this had been appropriately escalated for consideration due to the incident report which had been attached.

Members recognised that patients of the incorrect age had been invited to participate in the trial due to an error with the IT software at Public Health England, which was out of the applicant's direct responsibility to control. The CAG was assured by the applicant description of the handling of the issue and appreciated the transparency under which this had been reported.

Members did note that it was unclear from the information provided whether the confidential patient information that had been disclosed, in error, in relation to woman aged 71 years, had been destroyed by the applicant. Members noted that assurance would be sought from the applicant around this point.

The Group recognised the wider study progress which had been reported and raised no further queries around the annual review.

Confidentiality Advisory Group conclusion

As a whole, it was recommended that the support in place for the purposes set out in the application should continue, subject to the existing conditions of support.

Request for Further Information

The following point was raised by the Confidentiality Advisory Group in consideration of the item.

1. Provide assurance that the confidential patient information which was disclosed in error in relation to patients aged 71 years has been appropriately destroyed.

5. REVISED APPLICATIONS – National Joint Registry

a. 18/CAG/0146 (PIAG 2-05(j)/2006) – Non-Research Audit Activity

Context

Purpose of application

The National Joint Registry, commissioned by the Healthcare Quality Improvement Partnership, was originally granted Section 60 support in June 2006. Support has been ongoing since this time.

Support under the Regulations currently extends to the following three specific purposes:

1. To collect confidential patient information where a patient record indicates 'Not recorded' for consent.

2. To use patient identifiers to link procedures recorded on the NJR to other healthcare datasets where patient consent is recorded as 'yes' and 'unknown'. The third-party datasets include data from HES, PROMs and ONS data provided to the NJR by NHS Digital in relation to the relevant OPCS4 codes for the reporting periods from 2014 up to and including 2017. Confidential patient information is disclosed from NHS Digital to Northgate Public Services for linkage with the NJR records.

3. To retrospectively obtain confidential patient information without first gaining patient consent where there is a specific and clear issue with regards to patient safety.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

The National Joint Registry collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards. The CAG remit extends to those patients whose consent status is unknown within the registry.

The following items of confidential patient information were requested for the purposes set out below:

Surname – for data linkage,
Forename – for data linkage,
Date of Birth – for data linkage and analysis,
Home address including postcode – for data linkage and analysis,
NHS Number or national identifier – for data linkage,
Gender – for data linkage,
Date of death – data for linkage and analysis.

Confidentiality Advisory Group advice

Public interest

The CAG recognised that the application established an appropriate medical purpose through the management of health and social care services. Members were assured of the ongoing public interest in the work of the National Joint Registry and raised no queries in this area.

Purpose of the Application

The Group acknowledged that support under the Regulations had been in place to support the National Joint Registry had been ongoing since June 2006, in which time several amendments had been made to the scope of support. The applicant was asked to provide a refreshed application submission which consolidated the existing scope of support into a single application to ensure an accurate and up-to-date record was available and to bring the application in line with current standards.

Scope of Support

The CAG recognised that an amendment had received a recommendation of support in June 2017 which provided support under the Regulations for the disclosure of confidential patient information from NHS Digital to the NJR in relation to all relevant OPCS4 codes for the reporting periods from 2014 up to and including 2017. A condition had been added to the scope of this support to explore the potential for data linkage to be undertaken by NHS Digital. However, following receipt of an appeal from the applicant, this condition was waived in February 2019.

The refreshed application had requested ongoing support under the Regulations for this disclosure and linkage of confidential patient information; however, Members noted that the patient facing information materials and consent form provided clear information around this data linkage. The information leaflet was dated June 2018 which suggested that this had been updated in the intervening period; however, the consent form provided was dated August 2014.

The CAG recognised support under the Regulations could not be recommended where a practicable alternative was already in place, in relation to the common law duty of confidentiality, to legitimise the processing. Members were of the opinion that the consent taken from patients included in the Registry on this basis provided a legal basis to legitimise this data linkage. It was agreed that further information was required from the applicant to understand why the revised application had requested ongoing support for this data flow, when there appeared to be a practicable alternative of valid consent already in place.

The Group was content to provide continued support to this disclosure and data linkage in relation to the sub-cohort of patients for whom consent status was unknown or recorded as no.

Practicable alternatives

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

- Feasibility of consent

The Group acknowledged that data collection for the National Joint Registry was undertaken in most cases with patient consent. The latest annual consent rates recorded were reported as: 'Yes' - 92.3%; 'No' - 1.4%; 'Unknown' - 6%, which was recognised as high attrition rate.

Members were also considering an associated application for use of data collected for audit purposes within the NJR for research purposes. This application had raised questions around how inclusion within the registry was being managed for patients who lacked capacity to consent for themselves. The CAG agreed that the implications of these queries carried over into the audit application on the basis that initial consent approach related to the non-research purposes. It was agreed that further clarity was required from the applicant in this area.

- Use of anonymised/pseudonymised data

The CAG recognised that confidential patient information was required for sample verification and linkage with wider NHS datasets which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The Group were assured that the items of confidential patient information requested continued to be appropriate and proportionate to achieve the aims of the audit and raised no queries in this area.

Patient Notification and 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. The Group considered the patient facing information and consenting documentation which had been provided to support the application. It was noted that the documentation did not made it clear that confidential patient information would be recorded for those patients who did not provide an active consent or dissent to their inclusion on the Registry.

Members commented that in the consent form, it was specifically noted that personal information would only be recorded if consent was provided, which did not accurately reflect that support under the Regulations was in place to collect confidential patient information for patients whose consent status was unknown. It was agreed that the patient facing information and consent materials should be updated to provide a clear overview of what information would be collected in the event that consent is not actively recorded or dissented.

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 ongoing support for the Registry 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.

Further Information Required

The CAG had identified some areas requiring further clarification when considering the refreshed application which required further response from the applicant.

Request for further information (Summary)

1. Explain why support under the Regulations has been requested to legitimise the disclosure of confidential patient information from NHS Digital to the National Joint Registry in relation to patients who were included in the Registry on a consented basis.

2. Clarify what protocol is in place to include patients on the Registry who lack capacity to consent for themselves.

3. The patient information and consent materials should be updated to include clear information around the collection of confidential patient information with support under the Regulations for those patients whose consent status is unknown. Revised documentation should be provided for consideration together with an overview of the plan to disseminate this amongst participating Trusts and Health Boards.

Specific conditions of support

1. All pre-existing conditions of support related to PIAG 2-05(j)/2006 remain applicable.
2. The pre-existing annual review cycle remains applicable, with the next annual review to be received 4 weeks before 12 November 2019, and then on an annual basis to this schedule.
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: Northgate Public Services has a satisfactory reviewed score for IGT v14.1 2017-18)**

b. Amendment Request (Sub-Reference: 19/CAG/0066) – Extension to Data Collection for Audit Purposes

Amendment request

The amendment requests that support under the Regulations is extended to include the disclosure of confidential patient information from the local PAS (Patient Administration Systems) at participating Trusts and Health Boards to Northgate Public Services as processor for the National Joint Registry (NJR), in relation to all patients who have undergone a specified joint replacement, to facilitate auditing of the data submitted to the NJR.

As submission to the NJR was mandated in England in Wales in 2011, the purpose of the audit is to identify procedures in local systems that have not been submitted to the NJR and ensure that this omitted information is subsequently provided.

The amendment request reflects the scope of support which is currently in place for the flow of confidential patient information from NHS Digital and NHS Wales Informatics Service, for HES, PROMS, ONS and PEDW information in that procedures may be reported which do

not have a corresponding record in the NJR database. It was further acknowledged that this flow of confidential patient information may also include patients who have actively refused consent for the use of their data within the registry. The applicant confirmed the same handling processes would be operated in relation to audit data, in that there would be no attempts to match any data where the NJR record has an indicated 'No' for consent.

Confidentiality Advisory Group advice

Public Interest

The CAG was assured that there was a significant public interest in undertaking an audit of the data included in the National Joint Registry, as it was recognised that the value and benefit of the audit could would only be fully realised with accurate and complete data. It was further commented that there was potential for significant patient safety issues surrounding those procedures which were being omitted from the mandatory return to the NJR.

However, Members were unclear how the proposed additional data flow would improve the quality and completeness of the data within the NJR. The Group noted that the existing support extended to the disclosure of information relating to the relevant procedures (identified by OPSC4 codes) within the HES dataset at NHS Digital and the PEDW dataset at NHS Wales Informatics Service. These datasets were created from local Trust and Health Board PAS and SUS returns. On this basis, the CAG confirmed that whilst supportive of the principle of auditing the NJR, it was unclear how the additional and significant flow of confidential patient information directly from local PAS systems to the NJR would achieve anything further than the existing methodology.

The Group agreed that further information would be required from the applicant to understand the intended value of the proposed additional data flow before a recommendation of support under the Regulations could be considered.

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 an unconsented activity should go ahead. Whilst Members recognised that two patient representatives sat on the NJR steering committee and there was wider involvement in the HQIP user group, it was unclear whether any specific activity had been undertaken to test the acceptability of the proposed additional flow of confidential patient information as detailed in the amendment request.

The CAG noted that the amendment was seeking to include a substantial additional flow of confidential patient information, which the applicant acknowledged may also include information relating to patients who had actively declined consent to their inclusion in the NJR. Members agreed that some specific engagement activity around this proposal with a wider group of relevant patients would be helpful to evidence that patients and the public were supportive of this additional processing of confidential patient information for the purpose of auditing the registry. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further actions are necessary.

Patient Notification and 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. Members noted that the patient-facing information materials which had been provided did not appear to cover this supplementary data flow. As such, the CAG was unclear how patients would be informed about this additional use of their data, particularly those who had declined consent for inclusion on the Registry.

The Group agreed that any revised submission of the amendment should include a clearer overview of the communications mechanism which would be used to inform patients about this specific data flow.

Confidentiality Advisory Group 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.

Further information required (Summary)

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

1. Provide further information to explain what additional value the flow of confidential patient information directly from the local Trust and Health Board PAS system will provide, in terms of auditing the Registry, that cannot already be achieved with the information supplied from the HES and PEDW datasets.

2. Feedback from patient and public involvement and engagement activity should be provided to explain how the acceptability of including this additional data flow has been tested, together with an overview of the views expressed by attendees. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended, or whether further action is required.

3. A clear overview of how the communications mechanism for the National Joint Registry would be updated to reflect this additional data flow should be provided, to include clear information to all sub-cohorts of patients, including those who actively declined consent to the use of their data within the registry. Copies of any revised documents should be provided for information purposes.

c. 19/CAG/0057 – Research Activity

Context

<u>Purpose of application</u>

This application from the Healthcare Quality Improvement Partnership set out the purpose of medical research through the secondary use of information collated for audit purpose by the National Joint Registry, under reference 18/CAG/0146, for research purposes.

The CAG's remit only extends to the secondary use of data for research purposes for those patients, within England and Wales, whose consent status is not known within the National Joint Registry. This currently extends to approximately 6% of records within the NJR. Those patients who have consented to the use of their information within the National Joint Registry have provided consent in relation to research purposes. The latest consent rate states 92.3% of patients have provided consent to their inclusion. Those patients who have declined consent would not be included in the research database.

Background to the Application

The National Joint Registry has had ongoing support under the Regulations since June 2006. When the application was initially supported, research and non-research activities were handled via the same review pathway.

The applicant was requested to submit refreshed applications to ensure that an accurate and up-to-date record was in place which reflected the current scope of support. As such, a separate research application was provided which sets out how the information which is collected with support under the Regulations for non-research audit purposes is also used for research purposes.

The research database is a pseudonymised version of the NJR audit dataset, following linkage with wider NHS administrative datasets. Confidential patient information is not disclosed for research purposes.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

The National Joint Registry collects data on all hip, knee, ankle, elbow and shoulder replacement operations carried out in NHS and independent sector hospitals and treatment centres in England and Wales from 1 April 2003 onwards.

The following items of confidential patient information are held within the National Joint Registry; however, only pseudonymised information is made available for research purposes. Direct identifiers are removed and other data items

Full Name (Forename and Surname),
Date of Birth,
Home address including postcode,
NHS Number or national identifier,
Gender,
Date of death.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. It was recognised that there was public interest in the wider use of information collated for the purposes of audit under the National Joint Registry for research

purposes, as this was an incredibly rich dataset which could be used to inform improvements in patient care and treatment.

Practicable alternatives

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

- Cohort – Adults Lacking Capacity to Consent for themselves

At Q7 of the application filter page, it had been stated that patients who lacked capacity to consent for themselves would not be included within the study. However, Members queried whether this was accurate as, due to the nature of the procedures which the National Joint Registry collated information around, it would be expected that a proportion of the patients undergoing surgery of these types would lack capacity to consent for themselves.

Members raised concerns that the sub-cohort of patients for whom the consent status in relation to inclusion within the NJR and subsequent use of data for research purposes was unknown may include some patients who lacked capacity to provide this consent. The CAG recognised that support under the Regulations could not be recommended where a practicable alternative to processing confidential patient information without consent existed. The best practice methodology for inclusion of patients within the NJR was via the established consenting mechanism, which also extended to the use of information for research purposes. The CAG queried whether there was a requirement to make necessary provisions as set out within the Mental Capacity Act 2005 in relation to this sub-cohort of patients for both research and non-research purposes.

It was further noted that as the application had not been flagged to include patients who lacked capacity, it could not be confirmed that review would be undertaken by an appropriately flagged NHS Research Ethics Committee to consider these points.

The CAG agreed that, due to the lack of clarity in this area, the recommendation in relation to the research database application would be deferred, pending further information from the applicant, to ensure that appropriate provisions had been made in relation to patients who lacked capacity to consent for themselves.

- Feasibility of consent

The CAG recognised that the majority of patients were included within the NJR and the resulting research database on the basis of consent. The Group noted that the remit of the CAG, within the scope of this research application, extended only to those patients whose consent status was unknown. All other patients had either consented to the use of their data, including research purposes, or declined inclusion in the National Joint Registry.

Members commented that the scope of the CAG remit was not clearly described within the application. It was agreed that the revised application should clearly set out what legal basis is being relied upon, in relation to the common law duty of confidentiality, for the supplementary research purposes, for each sub-cohort of patients included within the Registry.

- Use of anonymised/pseudonymised data

The Group recognised that confidential patient information was not utilised or released for research purposes. However, for the sub-cohort of patients for whom the consent status was unknown, support under the Regulations was required to legitimise the wider use of information collated with support for audit purposes under reference 18/CAG/0146, for research purposes. No issues were raised in this area.

Access and Governance Arrangements

Members noted at Q24 of the application form that reference was made to the disclosure of information from the research database to applicants outside the EEA. The Group agreed that further assurance was required in this area that any data disclosures would meet the appropriate requirements in relation to the General Data Protection Regulation 2018. The GDPR makes clear that pseudonymising data does not changes its status as personal data. The applicant would be asked to provide further information in this area to ensure that an appropriate process was in place to manage data releases to ensure compliance with the requirements of the GDPR. Further assurance was also required that any disclosures would be subject to a clear data sharing agreement and would only be made to countries which are recognised to meet the required security assurance standards.

The Group further noted at Q21 of the application form that reference had been made to the breach of data sharing agreements and unauthorised release of data. The applicant was reminded that the reporting of any breach of confidentiality around the supported flows of information was a standard condition of support for all activities being carried out with support under the Regulations and would need to be reported to the CAG in line with this condition.

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.

Request for further information (Summary)

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

1. Consideration should be given to the provisions of the Mental Capacity Act 2005 and the inclusion of patients who lacked capacity to consent for themselves within the research database.

    a. A revised application form would be required for both the CAG and REC, which identifies that adults lacking capacity to consent for themselves may be included within the research database.
    b. Appropriate supporting documentation would need to be developed to support the inclusion of patients who lack capacity to consent for themselves.

2. The application form should be revised to clearly set out the scope of the CAG's remit in relation to the research activity. This should set out the legal basis, in relation to the common law duty of confidentiality, being relied upon for each sub-cohort of patients for the use of data collected within the NJR for research purposes.

3. Provide further information around the access and governance arrangements for researchers based outside the EEA who wish to use the research database. Assurance is required that data releases would be subject to a clear data sharing agreement and would only be made to countries which are recognised to meet the required security assurance standards.

4. Provide further assurance that any data releases which would be made from the research database would be compliant with standards under the GDPR around pseudonymised data.

6. AMENDMENTS – Non-Research

a. 17/CAG/0100 – Tower Hamlets Together (Duration Extension Amendment Request Sub-Reference: 19/CAG/0066)

Amendment request

This amendment request has been submitted to seek an extension to the duration of support under the Regulations to 31 July 2019 to enable the completion of the project analysis, described as zone two of the application activity.

The amendment document explained that due to delays experienced in accessing data, the applicants were only able to begin the data linkage processes in July 2018. This delay in the initial stages of the project had carried forward into the further linkage and analysis stages.

Confidentiality Advisory Group advice

The CAG acknowledged the delays which had been experienced in the receipt of and subsequent linkage of the data sets requested to support the project analysis. Members recognised the complexity of this process and were assured by the overarching public interest which could be achieved from the resulting analysis of the linked database.

The Group received the detailed summary of the project activity and commended the applicants on the achievements to date, which were strongly supported by ongoing patient and public engagement activities.

It was stated within the amendment application form that following the completion of the linkage work, referenced by the applicant as zone one activity, all confidential patient information was destroyed, leaving a pseudonymised dataset for analysis. However, elsewhere in the documentation it was suggested that data from the local Commissioning Support Unit (CSU) was still to be linked, which implied that a mechanism to facilitate linkage remained.

The CAG agreed that further information was required from the applicant in this area as if confidential patient information had been destroyed, this would suggest that the proposed exit strategy from requiring support under the Regulations had been enacted and the project could be expired. However, if confidential patient information had been retained to facilitate the linkage with information provided by the CSU, ongoing support was required. It was further noted that, due to the richness of the linked database, the applicant may be concerned that the risk of re-identification was so significant that support under the Regulations continued to be required.

Members recognised that support under the Regulations was due to expire and wanted to avoid the applicant being in a situation whereby the legal basis, in relation to the common law duty of confidentiality, for the ongoing retention of information was unclear. As such, the Group agreed that support under the Regulations would be recommended on a conditional basis, with a rapid response required from the applicants to confirm the ongoing requirement for this to be in place.

A request had also been detailed within the amendment application to extend the submission date of the annual review. The Group commented that submission of the annual review was required every year in line with the anniversary of support coming into effect. This was a standard condition of support which was attached to all activities supported under the Regulations and this requirement and the timeframe for submission could not be amended.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care subject to standard and specific conditions of support detailed below.

Further Information Required

Support is recommended for the amendment on a conditional basis pending further information from the applicant to address the below points. A detailed covering letter is required to address the below points.

1. Clarify whether all items of confidential patient information used to facilitate the linkage activity described in zone one has all been destroyed.

2. If so, clarify if there is any requirement for support under the Regulations to remain ongoing to support the data analysis activity described in zone two.

3. If there is no ongoing requirement for support, provide confirmation that the application can be expired.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission **(Confirmed: Clinical Effectiveness Group within Queen Mary University of London, 8HPQ2 has a confirmed satisfactory score for IGT v14.1)**

7. NEW APPLICATIONS – Non-Research

a. 19/CAG/0051 – Piloting a new questionnaire to understand patient experiences of liver transplant services

Context

<u>Purpose of application</u>

This application from the Picker Institute Europe set out the purpose of undertaking a pilot assessment of patient experiences of Liver Transplant Services in England. The aim of the study is to conduct a pilot survey of adults who have received a liver transplant within the last three years, but more than three months ago, to:

1. Increase understanding of the views, preferences and experiences of people who have received liver transplants in England and Scotland.
2. Develop and pilot a national Patient Reported Experience Measure (PREM) as a tool for future assessment of patient experience of liver transplant services in England and Scotland
3. Gather comparative evidence of patient experience of liver transplant as a basis for improving transplant services across England.

The patient cohort will be identified from seven specialist NHS Transplant centres within England as follows: Royal Free Hospital, King's College Hospital, University Hospitals Birmingham, Cambridge University Hospitals, Leeds Teaching Hospitals and Newcastle Hospitals. A further site will be located in Edinburgh; however, this is out of scope for the CAG application. Participants will be sent a paper questionnaire surveying their experiences of pre-transplant, transplant, and post-transplant care.

Picker runs and coordinates the NHS Patient Survey Programme (NPSP) under the title of the Survey Coordination Centre. In addition, Picker is an approved NHS contractor. The patient experience of Liver transplant services in England survey, will adopt a similar methodology to the NHS Patient Survey Programme (NPSP) – alterations to this methodology will be described below, mainly:

- Picker will be addressing and mailing out the survey packs to avoid patient identifiable information being shared with sub-contractors.
- Picker will have access to the mailing data in order to circulate the survey packs,
- Data files will be password protected and saved on a non-network drive with restricted access to necessary staff,
- The mailing file will be kept separate to the response file, linked by a unique reference, to ensure that survey responses are pseudonymised and there is no risk of linkage between the two files.

A recommendation for class 5, and 6 support was requested to cover activities as described in the application.

<u>Confidential patient information requested</u>

<u>Cohort</u>

Liver transplant patients aged over 18 years who have had a liver transplant between three months and three years prior to extraction of the patient sample at one of the following sites: Royal Free Hospital, King's College Hospital, University Hospitals Birmingham, Cambridge University Hospitals, Leeds Teaching Hospitals and Newcastle Hospitals. It is estimated that 3,000 patients would be included in the study.

The following items of confidential patient information are requested in order to facilitate the distribution of the survey and no analysis purposes:

- Full name and title,

- Full address and postcode,
- Date of transplant,
- Treatment centre code,
- Study specific ID,
- Year of birth,
- Sex.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, through the management of health and social care services. Members were assured that there was public interest in undertaking an evaluation of liver transplant services to gain an understanding of patient satisfaction with the care provided and it was recognised that the proposal covered a pilot of the patient survey.

Practicable alternatives

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

Justification of identifiers

- Feasibility of consent

Whilst the proposed patient survey was not part of the NHS National Patient Survey Programme, this was being undertaken by the Picker Institute following the same methodology for which prior consent was not taken. The justification provided by the applicant to support the determination that consent was not feasible for this proposal was the potential burden on the NHS treatment centres which would need to facilitate the consent process, the potential for this to introduce bias and that the survey would not benefit from the expertise of the survey coordination centre. The CAG was assured by the justification provided and was content to provide a recommendation of support to the activity proceeding under the Regulations.

- Use of anonymised/pseudonymised data

Confidential patient information was required to undertake sample validation and to facilitate the survey distribution process which could not be otherwise achieved. No issues were raised in this area.

Justification of Identifiers

Members were assured that the items of confidential patient information requested were appropriate and proportionate to achieve the survey pilot, with the exception of year of birth. As it was recognised that patients must be aged 18 and over to be eligible to participate in the pilot, the Group recommended that month and year of birth was requested to ensure only eligible patients were approached about the survey. The applicant would be asked to confirm the inclusion of this additional data item.

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 an unconsented activity should go ahead. It was explained that this project was being conducted in collaboration with patient representatives recruited via the British Liver Trust and patient groups supporting people undergoing liver transplants, for example PSC Support and LIVErNORTH, acting in an advisory capacity.

The applicant confirmed that patients were and continued to be involved at the cognitive testing stage of the questionnaire. Picker had also previously consulted with liver transplants patients in the UK through in-depth interviews to inform the broad topics and themes for the questionnaire. These patients were recruited through a range of channels - including the British Liver Trust and Picker's website.

The draft survey questions had also been reviewed and commented on by Picker's Patient and Public involvement advisory group composed of the patient representatives and clinical advisors mentioned above.

The CAG was assured that the activity undertaken in this area was appropriate and proportionate to the proposed activity and raised no concerns in this area.

Patient Notification and 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. Site-specific posters had been created to promote the survey within the specialist liver transplant centres.

The dissenting mechanism which had been described involved contacting the generic PALS service at site to be excluded from the survey. The applicant had provided assurance that the PALS staff would be fully informed about the project to enable management of this objection process.

The Group was not assured that this was the most appropriate contact for project objections. It was commented that in informing the PALS service of the survey they wished to dissent from, the patient was having to disclose their personal details together with their health status, which did not appear appropriate. Members agreed that a nominated person within the liver transplant team should be provided at each site to facilitate the objection methodology. Care should be taken so that wherever possible the nominated person is at a distance from the patient's care. The applicant would be asked to provide confirmation to this point before any final recommendation of support would come into effect.

Members recognised the potential that raising a dissent with a member of the wider treatment team may cause anxiety amongst patients. To provide additional reassurance, it was agreed the poster should be revised to include a standard statement to advise that the patient's care would not be affected should they wish to opt-out of participation in the survey. The revised poster would be required prior to support coming into effect.

Other Points

The CAG agreed that copies of the covering letter and patient questionnaire should be provided for completeness of the application file.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Secretary of State for Health and Social Care, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information (Summary)

1. Confirm that month and year of patient birth would be requested to ensure that patient's eligibility could be assessed prior to invitation.

2. A nominated individual within the liver transplant care team at each site should be appointed to manage the patient objection mechanism. Provide confirmation to this point.

3. Revise the poster to include a statement advising that patient's care would not be affected by a decision to opt-out of participation in the survey.

4. Provide copies of the covering letter and questionnaire which would be used for the project.

Specific conditions of support (Provisional)

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: Picker Institute Europe has a satisfactory reviewed grade on V14.1, 2018/18)**

8. NEW APPLICATIONS – Research

a. 19/CAG/0053 – Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis: Mascot Registry

Context

Purpose of application

This application from the University College Hospitals London NHS Trust set out the purpose of medical research which aims to establish a research database of patients with Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis (MPN-SVT) to use this to investigate demographics, clinical features, co-morbidities, outcomes & UK treatment practices for MPN-SVT enable future clinical trial design and facilitate regulatory approval decision-making. MPN-SVT is rare. It is life-long, affects young people, especially women and comprises three separate but connected set of problems occurring more or less simultaneously: bone marrow cancer, severe thrombosis, liver plus intestinal damage. The database will enable documentation of the prevailing situation and prospective information in UK and can help improve care pathways in UK for these patients.

Data will be collected from participating sites in England and Wales and entered directly into an online data platform hosted by Dendrite Clinical Systems Ltd. Information from the research database would only be released in an anonymised format to any applying researchers.

A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

Patients, aged 18 years and over, treated at participating Trusts throughout England and Wales, who have the relevant clinical characteristics to confirm a Myeloproliferative neoplasms Associated SplanChnic vein Thrombosis (MPN-SVT) diagnosis. Patients will be included both retrospectively and prospectively for newly diagnosed patients.

The following items of confidential patient information will be disclosed by treating clinicians to Dendrite Clinical Systems Ltd for inclusion in the research database. The items of information are required for the purposes set out below:

- NHS Number – sample validation and linkage,
- Hospital ID – sample validation and linkage,
- Date of birth – sample validation, linkage and analysis,
- Date of death – analysis,
- Postcode (District Level) – analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members recognised that the focus condition was rare and life-long and it was accepted that creating a centralised resource to support research was within the public interest.

Scope of Support

The application proposed the establishment of the research database, but also described the intention to undertake future linkages with wider NHS administrative datasets to enhance this data provided by the treating Trusts. The CAG noted that these wider future linkages had not been fully described within the application and would not be considered within scope of this initial proposal. Should the research database receive a recommendation of support under the Regulations, an amendment would subsequently be required to extend the scope of support to these wider linkages.

Practicable alternatives

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

- Background to the Application – Pilot Exercise

Within the application, information had been provided around a pilot exercise which had been carried out in 2018 to collect information on 41 patients which had been treated across six hospitals. The Group agreed that further information was required around this pilot exercise to understand on what basis, in relation to the common law duty of confidentiality, this pilot study had been operated to understand whether this presented a practicable alternative to seeking support under the Regulations.

- Feasibility of consent

Stronger justification had been requested from the applicant by the Confidentiality Advice Team in advance of the CAG meeting to explain why it was not feasible to operate the database on a consented basis. It was explained that the introduction of a consenting process would lead to a burden on both busy clinicians and patients, as this would need to be conducted outside of a standard clinical appointment. The requirement for complete case ascertainment was described due to the rarity of the focus condition, which was supported by the argument that a consenting model also had the potential to introduce a bias into the database.

The CAG agreed that a clearer articulation would be required to explain why consent was not feasible for the two sub-cohorts of patients, those retrospectively and prospectively identified, which would be included in the database.

It was recognised that a proportion of the retrospective cohort would be deceased and the Group was content to provide a recommendation of support under the Regulations to collate information for this group as consent was not feasible.

For the retrospective cohort of living patients, Members queried whether this group would continue to be under active follow-up to enable an approach for consent to be made. It was agreed that further information would be required from the applicant to justify why it was not feasible to take consent from this group.

Members commented that the requirement for full case ascertainment did not appear to justify the data collection proceeding without consent as there was a limited number of sites acting as data sources for the database. Due to the limited scope of the participating sites, the Group commented that the scope for data collection potential was already limited, which made it difficult to accept the requirement for complete case ascertainment as justification for recommending support under the Regulations.

The application explained that patients would be provided with a verbal overview of the registry. The CAG was unclear how, given the rarity of the disease and thus limited patient numbers, this did not present an opportunity for consent to be taken from patients.

Whilst it was recognised that there was past precedence in establishing research databases for rare conditions, the Group required further assurance to justify why consent was not feasible for retrospective living and prospectively identified patients.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate sample validation and linkage with wider data sources which could not be otherwise achieved. No issues were raised in this area.

Data Flows

The CAG agreed that further information was required from the applicant around the data flows which would support the creation of the research database. There was some discrepancy within the application around what items of confidential patient information would be stored locally at the Trust which entered the data and what information would be transferred for centralised storage by Dendrite. Further information would be requested in this area.

Justification of identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to achieve to facilitate the establishment of the database and raised no queries in this area.

Exit Strategy

Support was being sought on an ongoing basis to support future linkages with wider administrative datasets. As such, no exit strategy from support under the Regulations was described. Members recognised that the ongoing retention of confidential patient information was required to support this future linkage and raised no issues in this area at this stage. However, it was commented that the applicant would be required to reassess the ongoing requirement for confidential patient information each year as part of the annual review submission, if the activity was supported, which will provide an opportunity to audit this ongoing retention.

Database – Access Governance Arrangements

The protocol for applications to access the database and subsequent review and approval process had not yet been finalised. The CAG agreed that submission of these documents was required before any recommendation of support under the Regulations could come into effect to ensure an appropriate review mechanism and security assurance were in place for disclosed information.

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 an unconsented activity should go ahead. The applicant provided an overview of patient and public involvement and engagement activity which had been carried out over a number of years and led to the development of this application. Two focus groups were held in 2016 with MPN-SVT patients to seek views about their disease – patients were invited to participate via the MPN Voice website, a disease-specific UK charity, together with a postal survey which identified some key conclusions around the patient cohort.

The applicant had also explained that the establishment of the research database had been made possible through patients' donations, which evidenced a key engagement from the patient cohort.

It was further explained that the Registry Review Committee (RRC) included patient members, who had reviewed the protocol and also consulted with fellow patients about the collection of confidential patient information without consent. The feedback from this activity was supportive for the project.

The CAG agreed that the activity which had been carried out in this area was appropriate and proportionate to the proposal and recognised that the patient population was engaged with the proposal.

Patient Notification and 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. The Group considered the drafted text which had been provided to fulfil both the fair processing and transparency requirements in relation to the GDPR and the patient notification requirements under the common law.

Members commented that whilst the text was quite long and detailed, it did provide a clear overview of the purpose of the research database and no issues were raised around the content. It was however commented that additional contact details should be provided to support the objection mechanism. It was further noted that the reference to the CAG application was inaccurate and would require revision.

The Group also noted that the formatting, including the font and text colours, made the documents difficult to read and would benefit from revision. Sight of these revised documents would be required prior to any final recommendation of support coming into effect.

Data Protection Compliance

Confirmation was required from the applicant that the legal basis being relied upon for processing special category data in relation to the GDPR was Article 9(1)(J) – research purposes.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information (Summary)

1. Provide further information around the pilot exercise which was undertaken in 2018, clarifying what basis, in relation to the common law duty of confidentiality had been relied upon to support the disclosure of confidential patient information.

2. Provide a stronger justification to support why consent is not feasible for the retrospective living cohort and those patients who are prospectively included. Clear articulation is required to explain why consent cannot be taken for each sub-cohort of patients.

3. A clear overview of the data flows to support the creation of the research database is required, including clarification of the items of confidential patient information which would be stored locally at Trust sites and those which would be transferred to the centralised database held by Dendrite.

4. Patient-facing information materials should be revised to address the following points:

    a. A postal address and telephone number should be added for the purposes of patient objection,
    b. Reference to the review by the CAG should be amended to read: 'The Health Research Authority has supported the application to process confidential patient information without consent for the purposes of the project, following guidance from the Confidentiality Advisory Group'.
    c. It is recommended that the formatting and style of the documents be reconsidered to ensure this is readable and accessible to a wider audience.

5. The protocol for applications to access the database and subsequent review and approval process should be finalised and submitted for consideration.

6. Confirm that the legal basis being relied upon for processing special category data in relation to the GDPR was Article 9(1)(J) – research purposes.

Specific conditions of support (Provisional)

1. Support extends to data generated in England and Wales only.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – Dendrite Clinical Systems Ltd. has a published satisfactory reviewed grade on V14.1, 2017/18)**

b. 19/CAG/0046 – Deciphering AMD by deep phenotyping and machine learning - PINNACLE retrospective study

Context

Purpose of application

This application from the University of Southampton set out the purpose of medical research which aims to use retrospective medical imaging and clinical data understand whether machine learning computer algorithms can be used to discover imaging markers of retinal aging and to predict individual progression and conversion to late Age-Related Macular Degeneration. This is a collaborative project which involves sites in Vienna and Switzerland combining anonymised patient images and information to test computer software.

University Hospital Southampton Foundation Trust and Moorfields Eye Hospital will be providing patient images and data in England. Optical Coherent imaging tomograms (OCT) images will be extracted from clinical databases on site the company which created the imaging software. The images will include confidential patient information which cannot be removed prior to extraction. The research team will use the confidential patient information

present on the OCT images to wider clinical information within the patient's hospital record. Once linked, all items of confidential patient information will be removed from the dataset which will be used in the study analysis. A linkage file will be created and held onsite by a member of the clinical care team.

The study will also request supplementary information and samples from the UK Biobank; however, this information will be released to the applicant in an anonymised format and is out of scope of the CAG application.

Support is requested to allow the extraction of confidential patient information from patient records at University Hospital Southampton Foundation Trust and Moorfields Eye Hospital by the software company which designed the OCT imaging software. Support is also required to enable the research team to use specified items of confidential patient information to facilitate the linkage of OCT images and wider clinical data held within patient's medical records.

A recommendation for class 1, 4, and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

Patients aged over 50 years who underwent OCT imaging at University Hospital Southampton Foundation Trust and Moorfields Eye Hospital. It is estimated that 13,000 scans will be included from these sites. The time frame for patient inclusion is 01/01/08-31/12/19.

The following items of confidential patient information are requested for the purposes described:

- Name – present on extracted OCT images,
- Hospital ID – to facilitate linkage,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members commented that this was an interesting proposal with considerable potential for patient benefit if an algorithm can be developed and were assured that there was public interest in this proceeding.

Cohort

The applicant had stated that the inclusion timeframe for the study would extend to December 2019. The Group agreed that clarification was required that this was a typographical error and the cohort sample would run to 31/12/2018 only, as it was specified that this was a retrospective cohort only.

It was agreed that further clarification was required around the sample. This had been specified as 13,000 scans; however, the CAG was unclear how many patients this amounted to. Clarification would be sought to understand the scope of support which was being recommended.

Practicable alternatives

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

- Feasibility of consent

The Group was assured that consent was not feasible for the project due to the volume of retrospective retinal scans and individuals to be included. No concerns were raised in this area.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage between the patient scans and wider clinical information which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

Members noted discrepancies between the CAG application form, the protocol and the data sharing plan around the items of confidential patient information which would be used to facilitate the linkage process. It was assumed that the protocol and data sharing plan would also be utilised in the international study sites, which may explain the additional data items included here, which were not referenced in the CAG application. However, the Group agreed that assurance was required from the applicant around the patient identifiers which would be used within the English sites.

Data Linkage Process

It had been clarified that the extraction of OCT images would be undertaken by the data manager who was appointed by the study collaborators at the Vienna Reading Centre. Medisoft, the organisation which operates and maintains the electronic medical record system, would be extracting the wider clinical information. Members were unclear who would be facilitating the subsequent linkage between the scans and clinical data. Clarification was required around this point to understand the scope of data access.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. Support was requested on a time limited basis to facilitate the data extraction and linkage processes. Whilst a linkage file will be retained, this would be held by a member of the clinical care team at the specific site and did not require ongoing support under the Regulations for its retention. The CAG raised no concerns in this area.

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 an unconsented activity should go ahead. The applicant explained that service user groups from University Hospital Southampton Foundation Trust and Moorfields Eye Hospital would be involved in the study. It was further explained that a Retinal Patient service user group had been established at Moorfields which would also be involved, together with the INVOLVE group and the patient group at University Hospital Southampton Foundation Trust.

The project was also supported by the Macular Society and the Gift of Sight charities, which were relevant third section organisations.

A poll had been undertaken with members of the Macular Society around the use of confidential patient information to achieve the study aims. The applicant confirmed that of the 288 respondents, 89% had confirmed support for the project. The Group expressed surprise that support for the project was not higher amongst members of the Macular Society, which it was presumed would be an interested cohort. However, it was further commented that the feedback from the poll did not clarify that the remaining 11% were not supportive of the study progressing. The Group acknowledged that a significant majority of patients were supportive of the study and raised no further concerns.

The CAG was assured that the activity which had been carried out in this area was appropriate and proportionate to the proposed activity and it was acknowledged that feedback was largely supportive of this study. No queries were raised in this area.

Patient Notification and 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.

The applicant had confirmed that a patient-facing study website had been established to support the project. It was further confirmed that information would also be displayed on the University and Trust websites. Finalised versions of this website text were not yet available; however, the applicant had provided draft text for consideration. It was confirmed that any historic recorded dissent would be respected.

Members agreed that sight of the final documentation which would be displayed on the Trust and University websites was required prior to any final recommendation of support coming into effect. It was commented that within the drafted text only an email address had been provided to support patient objections, which it was agreed should be supported by a telephone number and postal address to make this more widely accessible.

The Group agreed that assurance was also required that information would be displayed on the Moorfields Eye Hospital website to raise the profile of the study.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to

the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information (Summary)

1. Confirm the start and end date of the patient inclusion timeframe.

2. Provide further information around the cohort size to explain how many patients would be included in the overarching sample of 13,000 scans.

3. Clarify discrepancies between the items of confidential patient information cited as required for linkage between the CAG application form, the protocol and the data sharing plan. Confirmation is required of the specific data items which would be used to facilitate linkage within the English sites.

4. Confirm who would facilitate the linkage between OCT scans and wider clinical information which would be used for analysis.

5. Provide finalised drafts of website text which would be displayed on the Southampton University and Hospitals Trust websites for consideration. It is noted a telephone number and postal address should be provided to facilitate dissent.

6. Confirm that patient notification information would also be displayed on the Moorfields Eye Hospital website.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee **(Confirmed 20 March 2019)**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: University Hospital Southampton Foundation Trust and Moorfields Eye Hospital both have published satisfactory reviewed grades on V14.1, 2018/18.)**

c. 19/CAG/0043 – Telephone triage of critical illness using NHS Pathways

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research which aims to investigate whether NHS Pathways, the decision support system from NHS Digital used for telephone triage by NHS 111 and five 999 Ambulance Trusts in England introduced in 2018, can identify cases of potential critical illness with enough sensitivity and specificity, measured by equivalence with the National Early Warning Score (NEWS) acuity. This will help to understand if the new triage algorithms can identify persons at risk of clinical deterioration from an illness and in need of emergency care without over-triage to the finite resources of the emergency ambulance service.

The study will use a retrospective patient cohort who was triaged using the new algorithms following a 111 or 999 call received by the North East Ambulance Service NHS Foundation Trust and treated at James Cook University Hospital. The study will compare NHS Pathways triage to an ambulance response against the initial NEWS recorded by the attending NEAS

clinician and to non-ambulance care disposition against any subsequent attendance or admission at James Cook University Hospital within 12 hours of the first 111/999 call and the initial NEWS recorded by the hospital.

Support is requested to allow the processing of confidential patient information by a Senior Information Analyst at North East Ambulance Service in order to identify the eligible patient cohort to be included in the study. North East Ambulance Service will link information for patients who received an ambulance to the electronic patient care records in order to extract relevant clinical information for analysis. This linked dataset will be anonymised by NEAS prior to disclosure to the applicant.

Support is also requested to allow the disclosure of specified items of confidential patient information from NEAS to James Cook University Hospital in order to facilitate linkage with wider clinical information required for analysis for the sub-cohort of patients who received non-emergency triage disposition. An anonymised dataset would then be disclosed to the applicant for analysis.

A recommendation for class 1, 4, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

Patients aged 16 or over, residing at a postcode covered by the South Tees CCG, who were triaged by a non-clinical 111/999 call handler using one of 24 pre-defined NHS Pathways illness symptom groups to receive either emergency ambulance or non-ambulance care. Patient sample is estimated at 7,400 patients. The planned period of retrospective data collection is a six-month period, between 25/05/18 and 23/11/18.

The following items of confidential patient information are requested for the purposes set out below:

- Surname – sample validation and linkage,
- NHS number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Postcode (Unit Level) – sample validation and linkage,
- Sex – analysis.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was medical research. Members agreed that there was a strong public interest in researching the effectiveness of the emergency service call algorithms. The application had been submitted by a student applicant and the Group commended the detailed and clear proposal which had been provided.

Practicable alternatives

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

- Feasibility of consent

The applicant explained that consent was not feasible due to the size of the retrospective patient cohort which would be included within the study. It was further explained as the patients would only have a one-time contact with a random member of the NEAS team which handled their 999/111 call, they were not considered to have an ongoing patient-provider relationship to enable any further contact to be made for consent. The CAG was assured by the rationale which was provided and was content to provide a recommendation of support under the Regulations.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage between the data sources which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The Group was assured that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed data linkage. No issues were raised in this area.

Exit Strategy

It is generally a principle that steps should be taken to move away from this potential support; such as through the seeking of consent or removing identifiable information once completed. The applicant had stated that confidential patient information would be retained for a short timeframe, estimating that the linkage and destruction of patient identifiers would be completed within the working week at each site.

Whilst the CAG recognised that the duration of support under the Regulations should be kept to the minimum time required to undertake the proposed activity, assurance was required that sufficient time had been built into the methodology to undertake audit checks on the accuracy of the linked data to prevent any requirement to repeat the data extraction and linkage process. The applicant would be asked to consider this point and provide a revised timescale for the exit strategy to be implemented which accounted for time to check the data.

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 an unconsented activity should go ahead. The applicant had engaged with a patient and public involvement group, the ‘Sheffield Emergency Care Forum’ as well as the previous representative to the NHS Pathways’ National Clinical Governance Group.

It was explained that the project was presented to the SECF group in December 2018. The group was supportive of the project and provided a letter confirming this as part of the wider study documentation. It was explained that the group had particular input in the communication strategy for the study, in order to raise the profile of the activity in the South Tees area.

The CAG agreed that the activity carried out in this area was appropriate and proportionate to the proposal and commended the scope of this activity for a student project.

Patient Notification and 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. A project-specific objection mechanism had been established which would involve display of a poster/leaflet online via the NEAS website and Twitter profile, together with posters made available in local NHS waiting rooms within GP practices, as example. The Group agreed that the information should also be disseminated via the hospital Trust, displaying in outpatients waiting rooms and the website.

Objection can be raised via telephone or email contact with a named individual at NEAS. It was also confirmed that NEAS and the Trust would be respecting any known historic objections. The applicant had suggested a two-week lead in time for patient objections to be raised. The CAG agreed that this did not allow sufficient time for meaningful objections to be raised and advise that at least four weeks should be provided. Confirmation would be required from the applicant to adhere to this extended objection timeframe.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, however further information would be required prior to confirming that the minimum criteria under the Regulations had been met and therefore advised recommending provisional support to the Health Research Authority, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Request for further information (Summary)

1. Provide assurance that sufficient time has been built into the linkage process to allow for data accuracy checks to be undertaken prior to the destruction of confidential patient information.

2. Confirm that at least four weeks lead in time will be allowed for patient objections to be raised.

Specific conditions of support (Provisional)

1. Favourable opinion from a Research Ethics Committee **(Pending)**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed: North East Ambulance Service NHS Foundation Trust and South Tees Hospital NHS Trust have self-assessed grades on V14.1, 2017/18. Depending on the timing of final recommendation, these will need to be reviewed by NHS Digital, or confirmation of the Data Security and Protection Toolkit assurance will need to be requested)**

9. MINUTES OF THE MEETING HELD ON 21 FEBRUARY 2019

The minutes of the meeting held on 21 February 2019 were received and accepted as a true record of proceedings with no required revisions.

10. ANY OTHER BUSINESS

No other business was raised. The Chair thanked Members for their attendance and the meeting was closed.