Health Research Authority

Minutes of the meeting of the Confidentiality Advisory Group

05 July 2018 at Skipton House, SE1 6LH

Present:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Dr Malcolm Booth	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Professor Barry Evans	Yes	
Mr. David Evans	Yes	
Dr Lorna Fraser	Yes	
Mr Anthony Kane	Yes	Lay Member
Dr. Simon Kolstoe	Yes	
Dr Harvey Marcovitch	Yes	
Dr Murat Soncul	Yes	Alternate Vice-Chair
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Natasha Dunkley	Head of Confidentiality Advice Service
Miss Kathryn Murray	Senior Confidentiality Advisor

1. INTRODUCTION, APOLOGIES AND DECLARATIONS OF INTEREST

Mr David Evans, a newly appointed member of the CAG was welcomed to the meeting.

No apologies for absence were recorded.

The following declarations of interest were made in relation to the business:

Agenda Item 3.a: 15/CAG/0119

It was recognised that the main applicant, Professor Jennifer Kurinczuk, was a current member of the Confidentiality Advisory Group. Whilst Professor Kurinczuk was not present at the meeting and was not involved in any deliberations or the final recommendation, this interest would be declared within the CAG minutes published on the HRA website.

Agenda Item 4.a: 18/CAG/0112

It was recognised in advance of the meeting that Dr Murat Soncul, CAG Alternate Vice-Chair, was referenced within the application as having provided advice to the applicants under his role as Head of Information Governance at the South London and Maudsley NHS Foundation Trust. Arrangements were made to ensure that Dr Soncul did not receive any papers in connection with the application. Dr Soncul was asked to leave the meeting during the consideration of this item and did not participate in the discussion or recommendation for the application.

Agenda Item 4.b: 18/CAG/0109

Dr Harvey Marcovitch noted that the Caldicott Guardian supporting the project, Dr Christopher Bunch, was a previous colleague. Dr Marcovitch confirmed that this was a historic connection and did not present a conflict of interest for the review of the application. It was agreed that the declaration would be noted within the minutes in the interests of transparency.

Agenda Item 4.e: 18/CAG/0113

Dr Simon Kolstoe noted that one of the named co-investigators on the application had been involved in the care of his children. Dr Kolstoe confirmed that he had no knowledge or involvement with the application. It was agreed that this did not constitute a true conflict of interest so no further action was required; however, a note would be made in the minutes in the interests of transparency.

2. APPROVAL DECISIONS

Secretary of State for Health and Social Care Approval Decisions

The CAG did not consider any non-research applications at the meeting held on 07 June 2018.

Health Research Authority Decisions

The HRA agreed with the advice provided by the CAG in relation to the 07 June 2018 meeting applications.

3. AMENDMENTS

a. 15/CAG/0119 - Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)

Context

This Healthcare Quality Improvement Partnership (HQIP) commissioned application from University of Oxford set out the purpose of the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) which is a national programme that aims to assess quality and stimulate improvement in safety and effectiveness in maternal, newborn and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events.

A recommendation for class 2, 4 and 6 support was requested to cover access to confidential patient information from the Office for National Statistics (ONS) and NHS Trusts to achieve the purposes set out in the original application.

Background to Amendment

The Confidentiality Advice Team undertook an assessment of the 2018 annual review for the application, which was received in April 2018. A query was raised around the retention of an administrative data set which held confidential patient information in relation to all reported maternal deaths since 01/01/2009, as it was unclear whether the existing support extended to retention of this data.

It was clarified that the original application had specified that this information would be retained; however, it was explained that a trusted third party, NHS Digital, would be approached for this retention. This retention arrangement had not yet been secured with NHS Digital which prompted the applicant to submit the proposed amendment to extend the scope of support so that the MBRRACE-UK collaboration could retain this data set on a long-term basis.

Amendment Request

This amendment application sought support to enable the MBRRACE-UK collaboration to retain the administrative database which holds confidential patient information in relation to all maternal deaths which have been recorded since 01/01/2009.

The applicant proposed ongoing retention on a long-term basis, but is currently seeking support up to 30 September 2021 in line with the current funding of the overarching MBRRACE-UK programme.

Confidentiality Advisory Group Advice

The CAG was assured that there was an ongoing medical purpose in the retention of the maternal deaths dataset, which would assist in the management of health and social care services. Members were satisfied that there was a significant public interest in the retention of this information, as it was recognised that this was the only complete dataset available which contained details on all maternal deaths since 2009.

The applicant had provided a strong rationale to support the ongoing retention of this information. Whilst it was explained that, once the confidential enquiries were completed, there was no specific need for further analysis or reporting of this data for MBRRACE-UK to retain the confidential patient information for women and their babies, there were wider reasons to support the ongoing retention. The applicant provided the example of the retrospective care review which was undertaken as part of the Morecambe Bay inquiry to evidence the importance of the ongoing retention of information about maternal deaths. It was explained that the provider of the audit programme at that time had destroyed all confidential patient information once the programme findings had been reported. As such, support could not be given to retrospective review of care undertaken as part of the inquiry as the relevant women could not be identified from the dataset retained by the audit programme.

Assurance had also been provided that access to the confidential patient information retained in this dataset would require the approval of the Health Quality Improvement Partnership (HQIP), as data controller for the programme, and the establishment of an appropriate legal basis, which would involve making an application to the CAG.

The Group was in agreement that the dataset should be retained in the long-term; however, it was queried whether the applying organisation was the most appropriate place for this dataset to be retained as it was recognised that the rationale and purpose for the ongoing retention of this information differed from the overall purpose of the MBRRACE-UK programme. Members agreed that support would be recommended for the amendment for a one year period, during which time HQIP, in their capacity of data controller, and the applicant would be expected to robustly explore and confirm a more appropriate arrangement for the ongoing retention of this data. The applicant would be expected to provide a report back at the time of next annual review around the progress which has been made.

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.

Specific Conditions of Support

1. Support is recommended for the ongoing retention, by the University of Oxford (on behalf of HQIP), of the maternal deaths dataset for a period of one year from date of this letter. During this time HQIP and the applicant are required to explore and establish a more appropriate arrangement/organisational location for the ongoing retention of this data. A report is required by the time of next annual review, at the latest, on the substantive progress which has been made to achieve this.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University of Oxford – National Perinatal Epidemiology Unit shows a satisfactory reviewed reported grade, V14.1, 2017/18**).

4. NEW APPLICATIONS – Research

a. 18/CAG/0112 – Mental health needs of mothers involved in family court cases

Context

Purpose of Application

This application from South London and Maudsley NHS Foundation Trust / King's College London Institute of Psychiatry set out the purpose of medical research through the establishment of a research database which intends to generate evidence about the health needs of mothers who are involved in care proceedings (including recurrent care proceedings). Care proceedings are family court cases where the local authority applies to the court to have a child removed from parental supervision because they believe a child is risk of significant harm.

The application proposes to link information from Children and Family Court Advisory and Support Service (Cafcass) around care proceedings to patient records held in the Clinical Research Interactive Search (CRIS) database, which holds information on mental health service users at the South London and Maudsley (SLaM) NHS Foundation Trust. Health data for women who link to mental health records within the CRIS database will be compared against the records of women who do not.

The three objectives which have been cited for the research database are as follows:

1. Evaluate linkage success between Cafcass and mental health service data held by CRIS,
2. Describe the frequency, type and timing of mental health service use among mothers involved in care proceedings,
3. Evaluate risk factors (such as live birth interval) for involvement in care proceedings for women using mental health services.

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

Confidential Patient Information Requested

Cohort

- Cohort One: Women involved in care proceedings who were resident in one of the Local Authorities between 01/04/2007 and 31/03/2017 as identified from the Children and Family Court Advisory and

Support Service (Cafcass) dataset. This consists of 3,396 mothers who will be included within the cohort regardless of whether successful linkage is achieved with mental health records within the South London and Maudsley NHS Trust CRIS database. This cohort will be used to answer the questions set out in objectives one and two.

- Cohort Two: The CRIS database will provide information in relation to women accessing mental health treatments within the four Local Authority Areas which SLAM Covers (Lambeth, Southwark, Lewisham and Croydon) and information in relation to women accessing supplementary addiction services for an additional three local authorities (Wandsworth, Greenwich and Bexley). Women will be aged 16 – 55 years accessing mental health services from 01/04/2007 – 31/03/2017. The sample size for this cohort has not yet been established; however, the applicants have estimated, based on previously published information, that the CRIS cohort will include 399,630 women aged 20-59 years, so it is expected that the target cohort will contain similar numbers, based on a slightly different age range. This cohort would be used to answer the questions posed in objective three.

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

- Name – linkage,
- Date of birth – linkage,
- Postcode – linkage and analysis,
- Gender – 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 noted that the applicants had provided a number of sound justifications which supported the requirement for research in order to gain a better understanding of the mental health needs of mothers who were involved in care proceedings.

The Group considered the three main objectives which had been cited within the application. Members were unclear how the project could be classified as the establishment of a research database, when the primary objective was focussed on the methodological success of the proposed linkage. It was noted that the recording of data within the Cafcass dataset ceased at the conclusion of the care proceeding so there was potential that the data provided from this source would be outdated, particularly when considering the mobile nature of the target patient population. As the target patient cohort was being identified via a non-NHS dataset, the proposed linkage would not involve NHS number, which Members agreed had the potential to impact the success.

Members raised concerns around the third project objective as it was acknowledged that the patient cohort that would be established to address this was considerably larger. It was further commented that the success of the linkage between Cafcass and CRIS would need to be evaluated to understand if this dataset provided a viable source for comparison prior to moving forward to establish the second patient cohort required to address the third objective. The CAG considered this and it was agreed it was supportive of activity progressing to enable objectives one and two of the project to be undertaken; however, Members agreed that an evaluation would need to be carried out at this point to ensure that there was public interest in the additional processing of confidential patient information required to create the second patient cohort and proceeding to objective three.

The Group was content to provide a recommendation of support to the initial linkage between the Cafcass dataset and mental health records held within the SLaM CRIS database, in order to create cohort one which was required to answer the questions proposed in objectives one and two. Feedback would be required from the applicant around the outcomes of the first two objectives for consideration by the CAG. An amendment would need to be submitted in connection to the data linkage required to establish the dataset necessary for the third objective if it is determined, following analysis of the outputs of the first two objectives, that this element of the project should proceed.

Scope of Support

In advance of the meeting, correspondence had been undertaken between the Confidentiality Advice Team and the applicants in order to establish which elements of the application activity fell within the scope of the Health Service (Control of Patient Information) Regulations 2002.

An alternative legal basis had been established to support the disclosure of information from the Children and Family Court Advisory and Support Service (Cafcass) dataset to South London and Maudsley NHS Trust. This was via Practice Direction 12G of the Family Procedure Rules. The applicants provided confirmation that the project had been approved by the Cafcass Research Governance Committee. It was confirmed that the disclosure from Cafcass was out of remit for the CAG consideration.

The applicants were only seeking support under the Regulations for the processing of confidential patient information generated by SLaM in order to facilitate the linkage of mental health care records within the data which had been released by Cafcass into the SLaM CRIS environment.

Controller – Project Activity

Queries had been raised in advance of the meeting to clarify which of the named organisations was acting as controller for the purposes of the application activity; however, this remained unclear from the responses provided. The controller was the organisation which was determining the purpose and means of processing personal data for the specified activity. The applicants would be asked to confirm which organisation(s) was taking this responsibility in relation to the application activity to ensure the controller was accurately referenced.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data 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, due to the retrospective nature and size of the patient cohort to be included within the project, consent was not feasible for this proposal.

- Use of anonymised/pseudonymised data

It was recognised that confidential patient information was required in order to facilitate the linkage between the two datasets, which could not be otherwise achieved.

Justification of Identifiers

The CAG was assured that the patient identifiers requested were appropriate and proportionate to the proposed linkage. It was recognised that, as the patient cohort was being generated from data held by Cafcass, which was not an NHS organisation, NHS numbers were not available from this data source.

CRIS - Proposed Linkage

The CAG recognised that the SLaM CRIS database had support under the Regulations to link with a wide range of external datasets, including HES. It was acknowledged that the application stated that in relation to the third objective, data from the established CRIS-HES linkage would be used. Members acknowledged that support was not being recommended for this element of the overall application at this stage; however, it was commented that clear confirmation would be required within any future amendment submission that linkage was limited to CRIS-HES data only and there was no intention to link more widely to the additional datasets within the CRIS database.

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 applicants had clarified that confidential patient information would only be accessible to SLaM employees. It was confirmed that, once linkage is completed, all items of confidential patient information would be destroyed as records would be linked via a pseudonym only. Analysis would be undertaken on an anonymous dataset. No further issues were raised 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. Members noted that the activity which had been undertaken to date in this area was via the Maudsley Biomedical Research Centre (BRC) Data Linkage Service User and Carer Advisory Group, which focussed on mental health. Whilst the disclosure of information from Cafcass was out of scope for the CAG recommendation, the Group recognised the sensitivities of this dataset.

The applicants had advised that they intended to explore the project with women who had been involved in care proceedings; however, had not yet been able to establish connection with a specific group for these purposes. The CAG stated that the Cafcass website provided links to support networks which may be able to facilitate involvement and engagement activity with an appropriate cohort of women who have experience with family court proceedings. Members agreed that these links should be explored and details of planned activity with an appropriate patient group would need to be provided before any recommendation of support would come into effect. Feedback from the planned activity would also need to be reported to understand the views of this cohort in relation to the proposal. If the responses given are negative, the CAG would take this into account when considering whether support should continue, 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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of current data protection legislation. The project was relying on the established communications strategy for the CRIS database within SLaM as the project notification and dissent mechanism. Members agreed that, due to the sensitivities around the information which would be linked for the project, specific information should be displayed on the CRIS website, to enable a project-specific objection mechanism to be operated. It was noted that there was a specific section of the CRIS website which displayed information about the wider data linkages which had been undertaken. The Group recognised that information would need to be displayed with a lead-in time in order to operate a meaningful project specific-objection. Sight of the text would be required together with an overview of how the dissenting mechanism would be operated.

The applicants had confirmed that information about the project would be displayed on the Cafcass website within the section around external research supported by Cafcass. Members agreed the information here should also direct interested readers to the notice displayed on the CRIS website, particularly in relation to opt-out. Members also commented that the information should clearly explain the governance arrangements for the project, to ensure that it was clear that identifiable information would only be used to facilitate linkage between the data sources and advise that analysis would be undertaken on an anonymised dataset. It was agreed that sight of this text would also be required prior to any final recommendation coming into effect.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. A copy of the REC's favourable opinion would be required before any final recommendation of support could come into effect.

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. Confirm which organisation is acting as controller for the purposes of the project.
2. Provide an overview of further planned patient and public involvement and engagement activity with a cohort which has been involved in care proceedings. Detail should be provided how and when activity will be undertaken, together with an overview of what will be explored as part of these sessions.
3. Provide a copy of website text which would be displayed on the SLaM-CRIS website around the project for review. This should provide specific details about the project and enable an opt-out facility.
4. Provide a copy of the website text which would be displayed on the Cafcass website around the project for review. This should provide specific details about the project and provide a link to the SLaM-CRIS website in order to inform patients about the opt-out facility.
5. Explain how the project specific opt-out mechanism would be operated. Confirmation is also required around the lead-in duration that information would be displayed ahead of the data linkage being undertaken, in order to allow a specific time period for meaningful opt-out.

Specific Conditions of Support (Provisional)

1. Support is extended to processing of confidential patient information by South London and Maudsley NHS Trust to facilitate linkage with the information disclosed by the Children and Family Court Advisory and Support Service only.
2. Support only extends to the creation of the dataset for cohort one, required to address objectives one and two, at this time. Feedback is required on the findings of these elements of the study before support would be considered in relation to objective three of the overall project.
3. Feedback would be required at the time of first annual review around the outcomes of the planned patient and public involvement and engagement activity. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
4. Favourable opinion from a Research Ethics Committee (**Pending**).
5. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – South London and Maudsley show a satisfactory reviewed grade on V14.1, 2017/18**).

b. 18/CAG/0109 – Non-Contact Monitoring of Older Patients

Context

<u>Purpose of application</u>

This application from Oxford University Hospitals NHS Foundation Trust set out the purpose of medical research which aims to test a 'non-contact' monitoring system's (NCMS) ability to monitor a patient's vital signs without the need to be physically connected to a patient. The NCMS uses a single video camera to monitor vital signs without the need to be physically connected to the patient. Computer software processes

visual information including movement and location data to add 'contextual' information not currently captured by contact monitoring systems. It is unobtrusive and minimises interference with patient care and mobility, while infra-red illumination allows the technology to work in all lighting conditions.

Monitoring vital signs of patients is a basic component of providing healthcare, with most routine systems involving a healthcare worker connecting patients to electronic equipment. It is noted that vulnerable, older and frail patients, who are most likely to benefit from monitoring, are often the patients for whom contact monitoring is unsuitable for undesirable for various reasons. The applicants hypothesise that, in this study, the non-contact monitoring system will be able to accurately detect vital signs and location information for patients in single-occupancy rooms in hospitals and care homes. Non-contact monitoring equipment will be installed on the wall or ceiling of single rooms in an inpatient hospital ward and a nursing home. Patients admitted to these rooms will be enrolled into the study after informed consent (or consultation with consultee if unable to consent). The NCMS will unobtrusively monitor and securely collect video data for 12 hours and additional salient data thereafter. The system's ability to detect if a patient has got out of bed, along with vital sign monitoring, will be assessed.

The purpose of this study is to assess feasibility of non-contact monitoring techniques and to support the further development of the system design and functionality. There will be a screen viewable to staff reporting physiological and positional information (not a continuous live video feed) but it will not be relied on for care decisions or replace treatment as usual.

The study will operate on a consented basis and the relevant steps have been incorporated to follow the requirements of the Mental Capacity Act 2005, should patients not have capacity to consent for themselves. The application has been submitted to the CAG for consideration in the event that the study protocol is not followed and the recording system has been started when a non-consented patient is in the room. This would lead to the recording of identifiable images without an established legal basis.

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

Confidential Patient Information Requested

Cohort

- All patients aged over 18 who are admitted to the rooms at the hospital and care home where the study equipment is installed.
- Patients must have the ability to provide consent or have an appropriate consultee to provide a declaration on their behalf.

The applicants are not seeking access to any confidential patient information; however, the recordings made by the non-contact monitoring system would be identifiable in that they would contain visual images of the patient.

Confidentiality Advisory Group Advice

Members considered the application and supporting documentation which had been provided in connection with this proposal. It was acknowledged that the remit under which the CAG can advise is defined in section 251 of the NHS Act 2006 and its Regulations. At section 251(4), it is stated that the remit does not extend when there is a practicable alternative to processing confidential patient information without consent.

The applicants had confirmed within the submission that the project will operate on a fully consented basis, with the appropriate arrangements in place to satisfy the requirements of the Mental Capacity Act 2005, for those patients who do not have capacity to consent for themselves.

Members acknowledged that the application had been submitted for review by the CAG to provide a recommendation of support under the Regulations in case the study protocol was not followed and the recording equipment was instigated prior to consent being provided by the patient. The Group stated that

this circumstance should be handled within the standard research governance framework and the incident reported via the established protocol violation or serious breach of Good Clinical Practice procedures.

The CAG noted that support under the Regulations enabled the data controller to provide specified confidential patient information to an applicant for the purposes of a relevant activity, without being in breach of the common law duty of confidentiality. Support was not recommended to provide assurance when there is deviation from the agreed protocol.

The Group agreed that a recommendation of support under the Regulations was not required as the project would proceed on a fully consented basis, which was an established practicable alternative. As there was no remit for the CAG, no wider consideration of the proposal was undertaken.

Confidentiality Advisory Group Advice Conclusion

The CAG recommended that support under the Regulations did not appear to be required as the project would proceed on a fully consented basis, which was an established practicable alternative to seeking support under the Regulations.

c. 18/CAG/0105 – Surveillance of Congenital Ichthyosis in Neonates (SCIN)

Context

Purpose of Application

This application from the Birmingham Women's And Children's NHS Foundation Trust set out the purpose of medical research using the established British Paediatric Surveillance Unit (BPSU) methodology to investigate incidence of Ichthyosis, which is a group of incurable genetic conditions with abnormally thick, scaly skin. The most severe type of ARCI is harlequin ichthyosis (HI) where thick scales (plaques) encase the baby, causing problems with breathing, feeding, movement, eye closure and temperature control. Historically such babies died at birth or in the first month of life (neonatal period) but they can survive with modern treatments. Less extreme ARCI types present with a collodion membrane (CM), where the skin is tight but less rigid. Many of these improve with time, some even resolving completely within weeks.

Babies with HI and CM are very rare. Staff in maternity units recognise them but need help from skin specialists to care for them. There is no proven correct treatment so practice varies; some babies remain in the neonatal intensive care unit for weeks whilst others are nursed within a more normal setting. Babies with CM may suffer from unnecessary medical interventions. Some health professionals express the view that babies with HI should be left to die, unaware that the condition is now treatable.

The BPSU methodology has received support in principle from the CAG.

Through the established BPSU orange card reporting system, paediatricians and neonatologists will report all new cases of harlequin ichthyosis and collodion membrane in their service in the UK and Ireland over a 25 month reporting period. Babies who die soon after birth may not be seen by a paediatrician so the applicants intend to liaise with other bodies to identify perinatal deaths. For each reported case, the reporting clinician will be asked to complete a research questionnaire. For babies still alive at 30 days, a follow-up questionnaire will be sent to be completed at 6 and 12 months.

The project extends to the UK and the Republic of Ireland; however, the CAG support would extend to England and Wales only. The applicant has been advised to seek alternative arrangements for data processing in the wider countries involved in data collection.

This application differs from standard BPSU projects as it has built in sample verification checks via linkage with a wider non-research programme which operates with support under the Regulations, as follows:

- NCARDRS – Public Health England's National Congenital Anomaly and Rare Disease Registration Service (CAG 10-02(d)/2015), to identify stillborn babies that fall within the study cohort.

It is also stated that the main applicant's will also undertake monthly verification checks by contacting reporting clinician's to assess whether the reported cases meet certain diagnostic criteria. This activity does not require support under the Regulations as data would only be disclosed to the treating clinician.

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

- All babies born with harlequin ichthyosis (ICD10 Q80.4) or collodion membrane (ICD10 Q80.2) whose diagnosis evolves into Autosomal Recessive Congenital Ichthyosis (ARCI) across the two year reporting period.
- It is anticipated that there will be 64 cases reported across this period.

The following items of confidential patient information will be supplied by the individual treating clinicians:

- NHS Number – validation,
- Hospital Number – validation and follow-up,
- Date of birth – validation,
- Date of death – analysis,
- Postcode (Sector Level) – analysis,
- Gender – 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, which was within the public interest as gaining any further understanding about this rare condition would improve care in the future.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data 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 recognised that the project would follow the established BSPU methodology and it was agreed that the importance of complete case ascertainment for this project was sufficient justification to support that consent was not feasible. No further issues were raised in this area.

- Use of anonymised/pseudonymised data

It was recognised that confidential patient information was required to facilitate sample validation and create the pseudonymised dataset required for analysis, which could not otherwise be achieved.

Justification of Identifiers

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

Linkage with National Congenital Anomaly and Rare Disease Registration Service

Linkage with Public Health England's National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) was referenced within the application; however, Members agreed that further information was required in this area.

It was explained within the application that the purpose of linking with the NCARDRS database was to include stillborn babies with Ichthyosis within the study to ensure accurate incidence reporting. However, in the description provided of the data flows, it appeared that the research team would disclose confidential patient information to the Office of Data Release (ODR) at Public Health England (PHE) to enable linkage with the NCARDRS. It was unclear from the information which was provided whether the information returned from PHE would include confidential patient information.

The Group agreed that a clear articulation of the purpose of linkage with the PHE NCARDRS dataset was required together with a detailed overview of the data flows involved with the linkage and the data items which would be disclosed. Confirmation was also required around what data would be disclosed by PHE as it was unclear whether any supplementary information would be provided in addition to confirmation of babies that were stillborn with Ichthyosis.

Members commented that the detail provided within the application around the elements of the application the CAG was being asked to consider was unclear. Information provided in response to queries, suggested that any disclosure of confidential patient information from the applicants to the ODR-PHE would be covered under the scope of the existing NCARDRS application (reference CAG 10-02(d)/2015). The Group was unclear whether this was accurate as the existing application provided support for non-research purposes only. It was agreed that confirmation would also be required from the applicants around which elements of the proposed linkage process with the NCARDRS database required a recommendation of support under the Regulations for the purposes of this specific research project.

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 Group recognised that the application was supported by the Ichthyosis Support Group, which was a relevant third-sector organisation. Members acknowledged that the proposed application differed from the standard BPSU methodology due to the linkage with the NCARDRS database to enable inclusion of stillborn children within the study. The Group recommended that applicants link with the SANDS (Stillborn and Neonatal Death) charity in order to seek the views of bereaved parents about the project. An overview of planned additional activity in this area would be required prior to any recommendation of support coming into effect.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of current data protection legislation. The Group considered the information leaflet which had been drafted for the project. It was noted that the document followed the standard BSPU template; however, it did not provide information about the linkage with the PHE NCARDRS dataset and the inclusion of stillborn infants within the study. Members agreed that the document required revision to provide a clear overview of the complete project. It was agreed that the document should be reviewed by the Ichthyosis Support Group for suitability prior to resubmission.

Security Assurance

It is the policy position of the Department of Health that all approved applications seeking support under these Regulations must evidence satisfactory Information Governance toolkit compliance. It was noted that a self-assessed score for Birmingham Women's And Children's NHS Foundation Trust had been published in respect of version 14.1 (2017/18) of the toolkit; however, this self-assessment had not yet been reviewed by NHS Digital. In order to complete this element, the CAG must receive confirmation of satisfactory security arrangements directly from NHS Digital, or via population of the 'reviewed grade' field on the IGT website. This would need to be addressed by the applicant.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Confirmation of the favourable ethical opinion was required prior to any recommendation of support coming into effect.

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 a detailed overview of the proposed linkage with the Public Health England's National Congenital Anomaly and Rare Disease Registration Service. The response should address the following points:
    a. The data flows to support this linkage,
    b. Confirm which data flows within the linkage require a recommendation of support under the Regulations to legitimise the data processing within the scope of this application,
    c. Clarify which items of confidential patient information will be transferred between the research team and PHE,
    d. Confirm what data would be disclosed from PHE to the research team.
2. Provide an overview of planned additional patient and public involvement and engagement activity to be undertaken as the study proceeds. It is recommended that the SANDS charity is approached about the study.
3. Revise the information leaflet for the project to ensure the complete project is described, including linkage with the NCARDRS database. The document should be reviewed by the Ichthyosis Support Group prior to submission.

Specific Conditions of Support (Provisional)

1. Favourable opinion from a Research Ethics Committee (**Pending**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Pending – confirmation of NHS Digital's reviewed grade of Birmingham Women's And Children's NHS Foundation Trust**).

d. 18/CAG/0111 – Detecting Dementia in the Retina; a Big Data Machine Learning Approach

Context

Purpose of Application

This application from Moorfields Eye Hospital NHS Foundation Trust set out the purpose of medical research which aims to investigate if there is a link between changes in appearance of the retina, the light detecting structure at the back of the eye, and the onset of Alzheimer's disease.

Moorfields Eye Hospital holds a large database of 'optical coherence tomography' images (OCT images) of patients' retinas. This application seeks to link this database with diagnostic information held by NHS Digital to enable the images of eyes of patients who developed dementia to those who have not. The primary research aim will be to identify on these scans of the patient's retinas, the morphological features associated with a diagnosis of dementia. The secondary research aim will focus on how retinal morphology evolves with time.

The applicants will share confidential patient information, with a unique study ID, from records held at Moorfields Eye Hospital with NHS Digital to facilitate linkage with HES. Pseudonymised OCT images will be shared with the UCL Institute of Ophthamology. NHS Digital will also release pseudonymised HES information to UCL, to enable linkage with the OCT images for analysis.

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

Confidential Patient Information Requested

Cohort

- All patients aged 40 years old and older who have had an OCT scan in the Moorfields Trust from 01/01/2008 to 01/06/2018.
- It is confirmed that there will be 257,450 patients included within the sample.

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

- Study ID – for further linkage,
- NHS Number – linkage,
- Date of Birth – linkage,
- Sex – linkage and 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 the activity proceeding as any advancement in detecting the onset of dementia had the potential for significant wider benefit.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data 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 due to the size of the retrospective cohort which would be included within the project data set. The applicants had provided an overview of the staff and time requirements which would be necessary to undertake the consenting process to support this rationale which Members agreed provided clear assurance that this was not feasible.

- Use of anonymised/pseudonymised data

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

Justification of Identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to enable the proposed linkage to be undertaken. No issues were raised in this area.

Data Sources

Linkage with the Hospital Episodes Database held by NHS Digital had been described; however, it was noted at question 14 of the application form a wider range of clinical information would be included in the analysis dataset, including MMSE (Mini Mental State Examination) scores, wider clinical diagnoses and medication usage. The Group was unclear of the source of this wider information and it was agreed that clarification would be required from the applicants. It was recognised that NHS Digital may be undertaking linkage with wider datasets, which would need to be confirmed for the scope of the project. Alternatively, it was queried whether, if this wider clinical data was already held by the applicants, there was scope to further minimise the data flows.

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. It was clarified within the application that confidential patient information would only be required for the purposes of linkage and would be retained by NHS Digital for a period of up to three months, following which it would be destroyed.

Members queried whether there would be any requirement for the applicants to undertake a data refresh via NHS Digital at a later stage, as it was unclear what the level of data would be provided for those patients who had undergone the OCT scan more recently. It was agreed that the applicants would be asked to consider this point and revise the proposed exit strategy should a data refresh be required in future.

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. Members acknowledged that the activity which had been undertaken to date had focussed on the use of anonymised data for research purposes; however, the applicants explained that the introductory paragraph which supported the survey provided the context to the proposed research and it was hoped that this conveyed that use of confidential patient information was necessary. Wider patient and public involvement was achieved via the charity peer review of the project which were supportive. The applicants provided an overview of the planned activity in this area which would be undertaken as the project progressed and it was also confirmed that two members of the public will sit on the project working group. Members were assured that the project was engaged with patients and public; however, it was agreed that the acceptability of using confidential patient information without consent for the application purposes should be tested as part of these forthcoming activities. Feedback around these wider activities would be required at the time of first annual review.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of current data protection legislation. The Group recognised that the applicants had established a communications strategy for the project which linked with wider appropriate charities and had an established dissenting mechanism. Members were satisfied that the established process was proportionate and sufficient to support the activity.

The CAG commented that the lead-in time offered for patients to raise an objection to the use of their data for these purposes would require revision, as it was currently stated that dissent had to be registered before 1 September 2018, which would not allow sufficient time to offer a meaningful period for dissent once all study approvals were in place. Members further noted that the notification material would require further revision to ensure it was clear that confidential patient information would be shared with NHS Digital to facilitate the linkage process. Sight of the revised document was required for consideration prior to any support coming into effect.

Research Ethics Committee Favourable Opinion

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority (following advice from the CAG), and providing a favourable ethical opinion is in place. Confirmation of the REC favourable opinion was required prior to support coming into effect for the project.

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

1. Confirm the source of the wider clinical information that will be used for analysis.
2. Consider whether there would be any requirement for a data refresh via NHS Digital in future. If this would be required, provide an overview of when this would be undertaken and also the revised exit strategy for the project.
3. Submit a revised patient notification document to address the following points:
   a. Explain that confidential patient information will be disclosed to NHS Digital to facilitate the linkage,
   b. Revise the cut-off date for patient's to raise an objection to the use of their data.

Specific Conditions of Support (Provisional)

1. Feedback should be provided at the time of first annual review around the wider patient and public involvement and engagement activity which has been undertaken. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Favourable opinion from a Research Ethics Committee (**Pending**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital facilitating linkage**).

e. 18/CAG/0113 – Food Protein Induced Enterocolitis Syndrome (FPIES)

Context

Purpose of Application

This application from University Hospitals of Leicester NHS Trust set out the purpose of medical research using the established British Paediatric Surveillance Unit (BPSU) methodology to investigate Food Protein Induced Enterocolitis Syndrome (FPIES), a delayed type of food allergy in infants, which leads to repeated vomiting and other gut symptoms several hours after a trigger food (or baby formula) is eaten. It can lead to rapid dehydration and shock.

The study will operate via the approved BPSU methodology: the BPSU 'orange card' reporting system, which is approved in principle by the CAG. All UK and Ireland paediatricians participate the compulsory reporting system over a 13 month period, where they are asked to return a card to BPSU stating whether or not they have observed a case of the disease under observation (in this case FPIES). BPSU then provides details of clinicians who have reported a case of the disease to the research team, who send a questionnaire for the clinician to fill in.

The applicants are also seeking to supplement reporting by the BPSU orange card methodology by contacting regional children's allergy centres to encourage reporting at centres where several new cases of FPIES may be seen each month. These centres will act as sentinel sites and will be contacted at 3, 6 and at 13 months at the end of prospective surveillance to ensure completeness of reporting. Sentinel sites will be self-selecting. The applicants intend to recruit these sites by emailing the Paediatric Allergy Group membership of the British Society of Allergy and Clinical Immunology at the start of the BPSU study asking for expressions of interest to act as sentinel sites. In addition sentinel sites will also be sites where co-investigators work.

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

Confidential Patient Information Requested

Cohort

- All children aged up to two years at the time of initial Food Protein Induced Enterocolitis Syndrome (FPIES) reaction, where there was a history of vomiting within four hours of eating where removal of this food resulted in resolution of symptoms.
- It is estimated that 300 patients would be identified over the 13 month reporting period.

The following items of confidential patient information are requested from the reporting clinicians for the purposes specified:

- NHS Number – sample validation/remove duplicates,
- Date of birth – sample validation/remove duplicates and to calculate age at presentation for analysis,
- Postcode (District Level) – sample validation/remove duplicates and to calculate distance travelled to secure diagnosis/deprivation scoring for 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 the public interest in the activity proceeding as FPIES was often misdiagnosed and the proposed study will aid understanding of the incidence, clinical presentation and management of the syndrome.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data 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 recognised that the project would follow the established BSPU methodology and it was agreed that the importance of complete case ascertainment for this project was sufficient justification to support that consent was not feasible. No further issues were raised in this area.

- Use of anonymised/pseudonymised data

It was recognised that confidential patient information was required to facilitate sample validation and create the pseudonymised dataset required for analysis, which could not otherwise be achieved.

Justification of Identifiers

The CAG was assured that the items of confidential patient information requested were appropriate and proportionate to achieve the proposed activity. No issues were raised 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 Group recognised that the applicants had sought patient and public involvement with the study via two appropriate charities, Allergy UK and FPIES UK. It was also acknowledged that lay review of the study protocol had been undertaken as part of the standard BPSU approval process. The applicants had provided an overview of planned activity in this area as the project moves forward. The CAG was assured that the activity which had been undertaken and planned in this area was appropriate and proportionate to the proposed activity and no issues were raised.

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 and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of current data protection legislation. The Group considered the information leaflet which had been drafted for the project. It was noted that the document followed the standard BSPU template; and appropriate arrangements had been made to display the information on the supporting charity websites, as well as the BSPU site. Members were satisfied with the content of the document and the proposed communications strategy and no issues were raised.

Confidentiality Advisory Group Advice Conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific Conditions of Support (Final)

1. Support extends to England and Wales only.
2. Favourable opinion from a Research Ethics Committee (**Confirmed 20/06/2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission **(Confirmed – University Hospitals of Leicester NHS Trust shows a reviewed satisfactory grade on Version 14.1, 2017/18).**

5. MINUTES OF THE MEETING HELD ON 07 JUNE 2018

The minutes were received and agreed as an accurate record of proceedings. A minor administrative error was noted within the declaration of interest references which would be revised before publication.

6. CAG CHAIR REPORT

The report from the Chairman was received and noted by the Group.

7. ANY OTHER BUSINESS

Public Health England Annual Review PIAG 03 (a)/2001

The Confidentiality Advice Team informed members that Public Health England, under reference PIAG 03 (a)/2001 (cancer registration), had a number of conditions of support to meet by 25 May 2018 following their annual review in January 2018. Members noted this was the annual review where the SofS for Health and Care had strengthened the CAG initial recommendation to include specific deadlines in light of the media interest at that time and lack of clarity regarding anonymised disclosures.

Members were advised that Public Health England had failed to respond to the conditions of support and had not provided evidence they had complied with the conditions. The rationale given was work to undertake GDPR compliance. Members noted that PHE had been given a 10 working day window in which to submit the overdue evidence to demonstrate compliance with the support. It was advised that unless PHE met their conditions of support then the matter would be escalated directly to the decision-maker in the Department of Health as it was that legal decision that was not being complied with. The Advice Team would update the CAG if the outstanding response was not received.

No further business was raised.

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