Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

28 August 2020

Present:

Name	Capacity	Items
Ms Clare Sanderson	Alternative Vice-Chair	1a, 1b, 2a
Dr Lorna Fraser	CAG Member	1a, 1b
Dr Simon Kolstoe	CAG Member	2a
Dr Harvey Marcovitch	CAG Member	1a, 2a
Ms Diana Robbins	CAG Member	1b

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. New Precedent Set Review Applications

a. 20/CAG/0099 - Promoting vision-related quality of life (QoL): first stage development of a model for intervention from the evidence of what matters most to visually impaired children and their families

Context

Purpose of application

This application from the University College London Great Ormond Street Institute of Child Health set out the purpose of medical research that seeks to identify the key 'risk' and 'protective' factors associated with self-perceived quality of life, identify the time points when specific factors exert the greatest influence and propose which factors can be used in an intervention model to improve quality of life for children and young people with visual impairment and their families.

The applicants aim to inform intervention development by identifying risk and protective factors that promote better quality of life by investigating the views and experiences of children and young people with visual impairment and their families, as well as their personal and environmental characteristics. The applicants have developed a suite of validated age-appropriate patient-reported outcome measures (PROMs), which will be used to enable children to self-report their views on the impact of their visual impairment on their everyday lives and the health care they receive. These PROMs will be used in a large-scale survey of children and young people with visual impairment and their parents, in combination with other questionnaires measuring the family environment, levels of support, social-emotional well-being, personal and psychological factors, health and clinical and socio-economic characteristics of the child. In-depth qualitative interviews will also be undertaken with a subset of these participants.

The applicants seek support to allow a research assistant, who is not part of the clinical care team, to access confidential patient records at Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust in order to identify eligible patients. Patients will then be contacted about the study and to seek consent to participate. The applicants also noted that, should it become necessary, patients may also be identified from Moorfields Eye Hospital. An amendment to the CAG will be submitted should this be necessary.

A recommendation for class 3 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged between 8 and 18 years of age who attend Paediatric Ophthalmology services at Great Ormond Street Hospital (GOSH) who are sight impaired/severely sight impaired (defined as corrected visual acuity LogMAR > 0.50) due to any disorder and are able to assent (aged 8-15 years) or consent (aged 16-18 years), but are without significant motor, intellectual, learning/cognitive and other sensory impairments. Also the parents or primary carers of children or young people with visual impairment selected as eligible and able to consent to take part will also be invited to participate. 150 family units will be recruited.
Data sources	1. Patient records held at Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. GP Registration 5. Date of birth 6. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Ethnicity 4. Visual acuity

Confidentiality Advisory Group advice

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

Public interest

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

Practicable alternatives

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

- **Feasibility of consent**

The applicant explained that eligible patients could only be identified from medical records held at the ophthalmology department within GOSH. Members of the direct care team could undertake screening, however this would place a significant burden on these staff. The applicant also advised that it would not be feasible to seek consent from patients attending clinics as a high proportion of those attending would not meet the inclusion and exclusion criteria, requiring the screening of records to identify suitable patients. The CAG noted that it was not feasible for members of the direct care team to screen records for suitable patients and raised no queries in this area.

- **Use of anonymised/pseudonymised data**

Confidential patient information is needed in order for the screening process to be conducted. This cannot be undertaken in any other way. The Group raised no queries in this area.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster will be placed in the clinic and ward waiting areas at GOSH at least two weeks before the process of selection begins and will provide information about the study, and how to contact the study team for further information or to dissent from being contacted about the research. The poster will not be displayed with intention to recruit any participants, but to inform patients at GOSH about their right to opt-out of this research study prior to the start of the study. The poster was provided for review. The CAG noted that the usual recommended time for displaying notification was 6-8 weeks before the start of screening and asked that the applicants followed this.

The applicants explained that any patients whose electronic record states that they have opted-out of taking part in research will also be excluded.

The applicants had advised that the information leaflets would be made available in a format accessible to visually impaired children and young people. Members asked whether the posters would also be made available in an accessible format.

Patient and Public Involvement and Engagement

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

The applicants advised that this research had been designed in response to patient feedback given during previous research. The applicants have sought the advice of the GOSH Young Person’s Advisory Group and Parent and Carers Advisory Group, particularly around the proposed method of recruitment and the development of patient information, the privacy notice and consent forms. The applicants will also seek feedback from the GOSH Young Visionaries Group on the questionnaires. The CAG noted this information and raised no queries.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Confirm that the study poster will be displayed 6-8 weeks before the start of screening. If not, please justify why this is not possible.

2. Clarify if the posters will also be made available in an accessible format.

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

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – Great Ormond Street Hospital (GOSH) for Children NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT**

submission 2018/19 by check of the NHS Digital DSPT Tracker on 09 September 2020).

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0106 - The SUFFICE CoV-Study

Context

Purpose of application

This application from the Oxford University Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to develop understanding and identify the clinical success factors contributing to Covid-19 negative and positive patients being detected as deteriorating and rescued within the clinical ward area.

Up to 40,000 hospital patients yearly suffer a preventable death due to staff failing to recognise patient illness or delays in medical review, leading to a delay in the escalation of care. This problem has been identified in NHS care reviews and current research is focused on the reasons why escalation of care does not always happen. Further reduction in patient death may be possible by examining the care of unwell hospital patients who are successful managed and identifying success factors in the escalation of care. The applicants noted that the Covid-19 pandemic presented an opportunity to examine care escalation in two distinct patient groups, those who are Covid-19 positive and those who are Covid-19 negative, as the NHS has had to modify care delivery models meaning that success factors may now be evident.

The application is formed of 4 Stages:

Stage 1 – Staff observations during escalation events. 200-400 care escalation events will be observed, detailing staff interactions for Covid-19 positive and negative patients.

Stage 2 – Care record reviews. 200-400 records of Covid-19 positive and negative patients who deteriorated, improved and were not admitted to ICU.

Stage 3 – Staff interviews. The applicant will interview 30 doctors and nurses to identify escalation success factors, how these could be applied effectively and the impact of pandemic care models.

Stage 4 – Data integration phase. The study will use a 'coding buddy' who will ensure confirmability in qualitative data findings. The advice of a qualified statistician will be sought for the quantitative data analysis.

The applicants are seeking support for Stage 2 of the study, to extract and anonymise data from patients who are unable to consent or for whom an approach to seek consent is impracticable. Records for 200 – 350 patients who deteriorated to the point where an intensive care review was triggered but did not require admission to ICU. Up to 50 notes will be reviewed for patients who became unwell while on the ward, were admitted to ICU and then died. The purpose of the notes review is to develop understanding of the care of patients with Covid-19, such as the recognition and presentation of their deterioration, how current care processes support or hinder their deterioration events, their illness patterns, care delivered and management.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 18 years and over, both Covid-19 positive and negative. 830 patients in total will be included, however the records of up to 400 patients will be examined for Stage 2, for which support is sought. 2 - 400 escalation events will also be observed.
Data sources	1. Hospital electronic and paper patient records, held at Oxford University Hospital NHS Foundation Trust

Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. Date of birth
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. ward location and movement throughout the admission episode if relevant to escalation of care episode 4. Gender

Confidentiality Advisory Group advice

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

Public interest

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

Scope of Support

The CAG agreed that support was also required for Stage 1, due to incidental disclosures of confidential patient information that may be made during observations of escalation events. In the CAT advice form responses, the applicant had asserted that support was not required as it was likely that the observations will be centred around the ward's nursing stations or offices. While the researcher will be exposed to confidential patient information during these observations, no information will be recorded in the fieldnotes. The applicant also stated that the researcher in question is a Critical Care Outreach Practitioner by background, and managed clinical care escalations similar to the ones being observed during the research. The researcher is well rehearsed in dealing with sensitive and confidential clinical information for both research and clinical duties. The CAG asked that assurances were sought from the appropriate persons within Oxford University Hospital NHS Foundation Trust that the researcher had an existing legal basis for this processing of confidential patient information without being in breach of the Common Law Duty of Confidence, or whether support under s251 was needed to provide an alternative legal basis. If support was needed, this would be under Precedent Set Category 10.

For Stage 2, the applicant will access patient records in order to extract an anonymised dataset. The CAG requested further clarification on how the list of records to be accessed would be obtained.

Practicable alternatives

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

- **Feasibility of consent**

Stage 2 is comprised of a Retrospective Care Records Review. The applicants advised that many patients will no longer be in hospital and it may not be possible to seek consent.

- **Use of anonymised/pseudonymised data**

For Stage 2, the applicants require access to confidential patient information in order to extract an anonymised dataset. The Group accepted that this could not be done in any other way.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicants advised that, due to the Covid-19 pandemic, they have opted not to use leaflets to promote the study. A website will be created, hosted by the Trust, and this will contain contact details for the research group and a mechanism for patients to dissent.

Posters created to recruit staff will also be displayed and the applicants advise that these will be displayed in in-patient areas, and will also serve the purpose of promoting the study to patients.

Patients who make contact with the applicants will be able to request that their records are removed from the study, up to the point that the study is closed, and the ledgers held by individual sites are deleted.

The CAG asked that a separate public-facing poster and also a leaflet were provided. These needed to include a description of the dissent mechanism and contact details, including telephone and email contacts, for the study team. The wording to be used on the Trust websites also needed to be provided.

Patient and Public Involvement and Engagement

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

The application was discussed at a SUFFICE PPI Advisory Group meeting in March 2019. The applicants discussed the study aims, plain English summary and any ethical concerns. The issue of processing confidential patient information without consent has been discussed with the SUFFICE-CoV PPI group, who raised no concerns, but did note that care should be taken when extracting the data, what devices will be utilised within this process, and that this was discussed with hospital IT and Data Protection Services. The PPI group consists of a patient and public representative. The issue was also discussed with the Oxford University Hospital NHS Foundation Trust R&D Department.

Feedback from a patient and public involvement representative, which was sought in April 2020, was provided.

The CAG noted that the bulk of the patient and public involvement had been undertaken when the study was focused on investigating flu. Members asked that further attempts were made to undertake patient and public involvement around the use of confidential patient information to investigate Covid-19. The CAG suggested that the applicants utilise the resources available through Oxford University Hospital NHS Foundation Trust and NIHR.

Exit strategy

The applicant explained that only anonymised data will be needed for analyses. The CAG asked that the list of patients whose records will be examined by the researcher was destroyed once the data extraction was complete. If this could not be done, justification for retaining the list needed to be provided.

Patients' date of birth and date of death will be retained for analysis. The CAG noted that retaining the of date of birth would mean the dataset was not anonymised and asked whether these dates will be converted into less identifiable formats, such as month and year of birth and age at death.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Assurances need to be sought from the appropriate persons within Oxford University Hospital NHS Foundation Trust that the researcher has an existing legal basis for this processing of confidential patient information without being in breach of the Common Law Duty of Confidence, or whether support under s251 was needed to provide an alternative legal basis.

2. Clarify how the list of records to be accessed in Stage 2 will be obtained.

3. A public-facing poster and leaflet need to be provided for review. These need to include a description of the dissent mechanism and contact details, including telephone and email contacts, for the study team.

4. The wording to be used on the Trust websites needs to be provided for review.

5. Further attempts were to be made to undertake patient and public involvement around the use of confidential patient information to investigate Covid-19. The CAG suggested that the applicants utilise the resources available through Oxford University Hospital NHS Foundation Trust and NIHR.

6. Clarify whether the date of birth and date of death for patients will be retained or whether these dates will be converted into less identifiable formats, such as month and year of birth and age at death.

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

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **(Confirmed – Oxford University Hospital NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 17 September 2019).**

Declarations of Interest

There were no declarations of interest.

2. Resubmitted Applications – Research

a. 20/CAG/0104 - POST-BOX: Consensus-building a post-partum haemorrhage kit using citizen science (Workpackage 1)

Context

Purpose of application

This application from the THIS Institute at the University of Cambridge set out the purpose of medical research that seeks to inform the design and use of post-partum haemorrhage (PPH) kits used in UK maternity units.

Post-partum haemorrhage is a rare complication where a woman experiences heavy bleeding after the birth of their baby. PPH kits are kits used on maternity units which bring together the equipment needed to manage PPH effectively and rapidly. The content, form and packing of PPH kits varies widely across Trusts. The applicants intend to investigate how the design of PPH kits can be optimised in order to ensure that patients are offered the best care.

The applicants plan to visit 3-5 maternity units in England and Wales to observe practice and interview a sample of healthcare professionals who use or stock PPH kits, in order to develop understanding of current practice. Maidstone and Tunbridge Wells (MTW) NHS Trust has been identified as a participating trust. The applicants are in the process of recruiting the other sites and will submit amendments to include additional trusts as data processors. The applicants will also explore the practicalities of uploading photographs of PPH kits and their contents to the study platform to be used for following work packages, the Thiscovery platform. Patients will not be involved directly, but the applicants may be incidentally exposed to confidential patient information when carrying out the observations and interviews with staff, therefore support under s251 is sought.

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

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form

and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	The cohort involved are NHS staff working in clinical roles in maternity units or in a procurement function. No patients will be recruited into the study.
Data sources	Interviews and observations carried out in participating Trusts. 3-5 trusts will be involved, but only one has been identified at this point: 1. Maidstone and Tunbridge Wells (MTW) NHS Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected for analysis purposes

Confidentiality Advisory Group advice

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

Public interest

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

Practicable alternatives

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

- **Feasibility of consent**

Staff participants will be consented into the study. Confidential patient information may be incidentally disclosed during observations of and interviews with staff. The CAG agreed that it was not feasible to seek consent from patients, as it was not possible to predict the information that may be disclosed or which patients it would relate to.

- **Use of anonymised/pseudonymised data**

No items of confidential patient information will be collected or recorded by the researchers. The only disclosures of confidential patient information will be made incidentally during observations of and interviews with staff. The CAG raised no queries.

Exit Strategy

The protocol states the recordings of the staff interviews will be transcribed verbatim by a company with whom the academic department has a data sharing agreement. It was possible that these recordings would include items of incidentally disclosed confidential patient information. The field researchers will anonymise the transcribed data and store what remains on the University of Cambridge secure data holding service. The CAG requested clarification on how long the applicants anticipated it would take for the recordings to be transcribed and fully anonymised.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster and information brochure for women and their partners were provided. The information brochure advised patients to let the researchers or hospital staff know if they do not want to be observed and want the researcher to leave during observations.

The CAG requested that a poster was displayed on doors or elsewhere in the department, advising patients that the researchers were present, providing a brief description of the project and advising patients that the researchers can be asked to leave. Members also asked that a more simplified information sheet was provided, containing a brief outline of the 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 the unconsented activity should go ahead.

This work package will be supported by a multi-disciplinary Expert Collaborative Group (ECG), which will include representation from women who have experienced post-partum haemorrhage, and their partners, alongside NHS staff and researchers. The ECG will provide advice as the study progresses and ensure that all stakeholder perspectives are considered. Opportunities have also been identified in the dissemination of the study's results, where broader involvement of stakeholders, including women, their partners and advocacy organisations can play a meaningful role.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The poster needs to be displayed on doors, or elsewhere in the department, advising patients that the researchers were present, providing a brief description of the project and advising patients that the researchers can be asked to leave.
2. Members also asked that a simplified information sheet was provided, containing a brief outline of the project.

3. Clarify how long it is anticipated it will take for the recordings to be transcribed and fully anonymised.

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

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 18 June 2020.**

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

- **Confirmed – University of Cambridge has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital DSPT tracker on 09 September 2020.**
- **Pending for Maidstone and Tunbridge Wells NHS Trust**

Declarations of Interest

There were no declarations of interest.

Signed – Chair	Date

Signed – Confidentiality Advice Team	Date