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

04 December 2020

Present:

Name	Capacity	Items
Ms Clare Sanderson	CAG Alternative Vice-Chair	1a, 1b
Dr Malcolm Booth	CAG Member	1a
Prof Barry Evans	CAG Member	1b
Dr Liliane Field	CAG Member	1a
Mr Anthony Kane	CAG Member	1b

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 21/CAG/0004 - Neonatal Complications of Coronavirus Disease (COVID-19) Study

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to determine the incidence of neonatal COVID-19, including hospital acquired infection, and the incidence of transmission from mother to baby during pregnancy, labour and birth by setting up a national surveillance programme.

Coronavirus is a new virus and was first recognised as causing a new infection (COVID-19) in late 2019. Little information is available about how the virus affects mothers and new-born babies and it is not clear how best to care for mothers and babies affected. Little is also known about how babies become infected with Coronavirus and whether it transmits from mothers to their baby(s) while they are still pregnant, during labour and birth, or whether the infection occurs following birth. Recent UK cases raise the concern that vertical transmission is a potential issue, as both mother and baby are infected in at least one case. The virus is known to be contained within most bodily secretions and there are suggestions that faecal oral transmission occurs, raising the possibility of transmission from mother to baby at birth, if not prenatally. Understanding this will mean that better care can be given to mothers and babies and the best advice to pregnant women about the effects of Coronavirus on their baby.

The British Paediatric Surveillance Unit (BPSU) will be used to carry out the study, using standard BPSU methodology to ask for weekly responses regarding any new-born baby with Coronavirus or whose mother has Coronavirus. Wider linkages will also be made to seek data from additional sources. Identifiers will be shared with the national surveillance of maternal and perinatal deaths (MBRRACE-UK) to cross check deaths. Identifiers from MBRRACE-UK cohort are also shared with the University of Oxford to enable cross-checking. Cases meeting the second eligibility criteria will be cross-checked between UKOSS maternal study of COVID-19, to ensure complete ascertainment, and this will be performed by BPSU with no identifiers flowing between this study and UKOSS. Identifiers will be shared with the National Neonatal Research (NNRD) in order to obtain more detailed clinical information. Identifiers will be shared with the Paediatric Intensive Care Audit Network (PICANet) to ensure complete ascertainment and obtain more detailed clinical information. Cross checks will also be undertaken with Public Health England (PHE) and Public Health Wales, to ensure complete

case ascertainment. Confidential Patient information also flows from Public Health England and Public health Wales to University of Oxford to enable cross checking.

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

Confidential patient information requested

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

Cohort	Any child in England and Wales that has a diagnosis of COVID-19, made on a sample taken prior to 29 days of age, who has received inpatient care for COVID-19, and their mother. OR: Any child in England and Wales whose mother had confirmed COVID-19 at the time of birth, or suspected COVID-19 and the diagnosis was later confirmed, and the baby was admitted for neonatal care, and their mother. Aged 0-28 days
Data sources	1. Paediatricians within Trusts who report eligible patients through BPSU 2. National Neonatal Research Database (NNRD): (Chelsea & Westminster Hospital NHS Foundation Trust) 3. Paediatric Intensive Care Audit Network (PICANet): (University of Leeds) 4. The University of Oxford: a. The national surveillance of maternal and perinatal deaths (MBRRACE-UK) b. The UKOSS maternal study 5. Public Health England (PHE) 6. Public Health Wales

Identifiers required for linkage purposes	For the baby: 1. NHS Number 2. Date of Birth 3. Sex 4. Date of Death (if relevant) 5. Postcode – District Level 6. Ethnicity of baby For the mother: 7. NHS Number
Identifiers required for analysis purposes	1. Date of Birth – modified for analysis to age in days 2. Date of Death – modified for analysis to age in days at death 3. Postcode – District Level 4. Gender 5. Ethnicity of baby 6. Sex 7. Unique study ID
Additional information	Duration of follow-up: In this initial phase follow up will be within the month of notification and will consist of: still an inpatient, discharge, transfer, or death
Areas excluded from scope of Regulation 5 support	Data flows from Scotland and Northern Ireland, as detailed in the application, as outside the scope of Regulation 5 support. The applicant should rely on another legal basis for these flows.

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 to transition the study to support under Regulation 5.

Public interest

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

Practicable alternatives

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

- **Feasibility of consent**

The applicant explained that it is not practicable to seek consent from individual patients due to the urgent need to collect information and the necessity that information about all affected babies was collected. The CAG agreed that it was not feasible to seek consent.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to enable cross checking with other datasets to ensure that a complete picture of the impact of COVID-19 on all affected mothers and babies is carried out and to prevent de-duplication of cases. The CAG agreed that this could not be done in any other way without the use of identifiers.

'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, information leaflet, website text and privacy notice were provided with the application. Posters will be displayed on neonatal units and paediatrics intensive care units (PICUs), and leaflets left in locations where parents can find them.

The Group noted in March as part of informal advice, that the BPSU public information leaflet did not offer the option of opting out by contacting the research team, as is offered on the

poster, and that certain telephone numbers were not consistent across the documents. Members asked that these were revised and the applicant has subsequently updated these with the same opt out options for all patient notification materials and ensuring the contact details are consistent. The Sub-Committee were content with these updated documents.

All patient notification materials have a clear option to opt out, and it is understood and noted that the National Data Opt Out will apply under Regulation 5 support. The applicant noted that parents could not opt-out of the notification being sent via BPSU, but could opt-out of the data collection. This can be done by letting their baby's doctor know or by contacting the study team by email, telephone or written contact. If the research team are notified that a parent wishes to remove their child's data, then any information already received will be deleted and will not be included in the study. The applicants will retain the fact that there was an eligible baby, to ensure that the incidence estimates produced are as accurate as possible.

The applicant also explained that If somebody has opted out of the study then applicants will not do the linkage checks; However they may get sent information from the other sources about them as part of a bulk transfer of data – for example SARS-CoV2 test results from PHE. However, if this happens then the applicants will delete that information.

The CAG were content with the patient notification and opt out options provided.

Patient and Public Involvement

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 applicant acknowledged that the patient and public involvement carried out prior to March was limited due to the urgent nature of the application. However the Group commended the applicants on the patient and public information and engagement they had undertaken during the pandemic.

The Policy Research Unit PPI co-leads reviewed the application and parent facing information. The MBRRACE-UK stakeholder group, an established group who represent relevant baby charities and service users, reviewed the poster and privacy notice. Feedback was supportive of the aims of the study and the processing of confidential patient information without consent.

Feedback was also sought, and comments received from AIMS (for better births), Sands (Stillbirth and neonatal death charity), BLISS, the multiple birth foundation (MBF), ICP support, Action against Pre-eclampsia APEC, Birthrights, the Birth Trauma Association, and Action against medical accident AvMA. Feedback was supportive and examples of the comments received were included in the application. The comments received on the parent-facing materials were incorporated into the materials. Additional information was also added to the protocol, in line with the feedback received.

The Sub-Committee wishes to state that the patient and public involvement carried out is noteworthy.

Exit Strategy

This application is for 13 months surveillance with 6 months follow-up to ensure ascertainment of all outcomes, from the end of March 2020 until the end of April 2021. An amendment will be submitted if any further follow up is required. The identifiable data will be held in until 31 October 2021.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

1. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

2. The National Data Opt Out will apply to processing of Confidential Patient Information under Regulation 5.

3. Favourable opinion from REC
   Received 30 March 2020

4. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be

provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for Chelsea & Westminster Hospital NHS Foundation Trust, University of Leeds (PICANET), The University of Oxford, Public Health England are in place once support under Regulation 5 is active, as well as a CPiP for Public Health Wales.**

Declarations of Interest

There were no declarations of interest.

b. 20/CAG/0157 - The Oxford Risk Factors And Non-invasive imaging Study: ORFAN

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to develop and validate novel imaging biomarkers to predict future heart attacks and other cardiovascular complications. This is a multi-arm study, with arm 4 only relevant to this application. Following the COVID-19 pandemic, the ORFAN study will additionally ascertain COVID-19 status (suspected or confirmed). The influence of COVID-19 infection on the outcome measures of the study will be explored.

Obesity is a known risk factor for cardiovascular disease (CVD). Body fat accumulation is associated with increased metabolic risk and it is now recognised that not only body fat quantity but also adipose tissue (AT) quality determines increased CVD risk. CT scans provide a reliable, accurate and non-invasive way to assess body adiposity. Increased volume of AT as measured by CT is independently associated with increased CVD risk in large clinical cohorts; similarly, increased epicardial AT volume is an independent predictor of cardiovascular event in subjects undergoing coronary CTA. Developing imaging biomarkers for assessing body adiposity could potentially provide a useful screening tool for the primary or secondary prevention of CVD.

A substantial proportion of Covid-19 patients have suffered adverse cardiovascular outcomes. If applicants can identify patients at risk for rapid deterioration during acute Covid-19 infection by quantifying the background vascular inflammation and the tendency of micro-thromboses, this will enable deployment of appropriate therapeutic measures (e.g. anticoagulation) and guide allocation of NHS resources.

NHS Trust direct care teams will identify retrospective patients with eligible scans. They are assigned a unique study ID, and the minimum required identifiers extracted alongside this ID are sent to;

- NHS Digital, for the purposes of linkage with HES, ONS, and other datasets as detailed below, including the emergency care dataset, medicines dispensed in primary care, and covid-19 hospitalisations,
- Barts Health NHS Trust, on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR), for the purposes of linkage with clinical outcomes, such as heart attack
- Kings College London, on behalf of the Sentinel Stroke National Audit Programme (SSNAP), for the purposes of linkage with clinical outcomes, such as stroke,
- Participating NIHR Biomedical Research Centres (BRC's) for the purposes of linking with baseline clinical data extracted from the Electronic Patient record (EPR) of associated participating trust.

The above parties will perform the data linkage, will modify date of birth and date of death and will delete identifiable data, with only the unique study ID remaining. The linked datasets will be sent to the ORFAN study team, at University of Oxford. The third parties that performed the data linkage will keep the linkage file for 10 years to update the relevant outcomes on an annual basis, to avoid individual NHS Trusts having to send identifiers to the third parties multiple times.

The scans are pseudonymised with the unique study ID by the direct care team and securely sent to University of Oxford. The direct care team will also screen electronic health records for health outcomes. Participating trusts also send health outcomes alongside the unique study ID to the ORFAN study team, at university of Oxford. The ORFAN team will link the datasets received from NHS Digital, NICOR, SSNAP and the NIHR BRCs, with the clinical data including the scans from the participating Trusts.

75,000 retrospective patients data will be collected over a 2 year period from when CAG support is provided. The data collected will span different time points as each participating Trust, as they commenced CT services at different times. However no patient with a scan prior to 2010 will be included.

A recommendation for class 1, 4 & 6 support was requested to cover 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	75,000 retrospective patients in the UK (England and wales only for the purposes of CAG) who have undergone clinical CTA's or unenhanced CT chest, abdomen and pelvis scans at participating NHS Trusts. The timescale for inclusion in the ORFAN study Arm 4 is different for each collaborating NHS Trust, however no patient with a scan before 2010 will be included in the study. Inclusion criteria detailed in the application
Data sources	1. NHS Digital; (HES, ONS, Medicines dispensed in primary care, Emergency care dataset, Covid-19 hospitalisations – datastes as detailed below) a. Hospital Episode Statistics (HES) – Accident and Emergency dataset b. HES – Admitted patient care dataset c. HES - Outpatients d. HES – Critical care e. Emergency Care Data Set (ECDS) f. Medicines dispensed in Primary Care (NHSBSA data) g. Civil Registration (Deaths) - Secondary Care Cut h. COVID-19 Hospitalization in England Surveillance Syste i. HES:Civil Registration (Deaths) bridge HQIP is the data controller for the below datasets, however the legal entities where identifiers are sent are; 2. Barts health NHS Trust (on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR) 3. Kings College London, on behalf of the Sentinel Stroke National Audit Programme (SSNAP) 4. NHS Trusts participating – PACS radiology systems and electronic patient records at;

	• Oxford University Hospitals • Royal United Hospitals Bath • Milton Keynes University Hospital • University Hospitals of Leicester • Barts Health • Royal Brompton and Harefield • Leeds Teaching Hospitals • Royal Papworth Hospital • Cambridge University Hospitals • Guy's and St Thomas' NHS Foundation Trust • New Cross Hospital • Royal Wolverhampton NHS Trust • Sandwell & West Birmingham Hospitals • Queen Elizabeth Hospital Birmingham • University Hospitals Birmingham NHS Foundation Trust • University Hospital of Manchester Foundation Trust 5. NIHR Biomedical Research Centres (BRCs) that operate at Trusts with collaborating clinical teams – data extracted from electronic patient record (EPR) of the associated local trust • Oxford • Royal Brompton and Harefield • Leicester • Leeds • Cambridge • Barts
Identifiers required for linkage purposes **Minimum required as confirmed with each data processor**	**NHS Digital** 1) NHS Number 2) Date of birth 3) Postcode (if NHS Number is not available) 4) Name (if NHS Number is not available) **NICOR** 1) NHS Number 2) Date of birth 3) Postcode **SSNAP** 1) NHS Number 2) Date of birth 3) Postcode (if NHS Number is not available)

	4) Name (if NHS Number is not available) **NIHR BRCs** 1) NHS Number 2) Date of birth 3) Local hospital number (MRN) 4) Date of relevant CT scan
Identifiers required for analysis purposes	1. Ethnicity 2. Unique study ID 3. Covid-19 status 4. Gender 5. date of death in the following format MM/YYYY. 6. Date of birth in the following format MM/YYYY This dataset can be considered anonymous as the applicants will not be able to re-identify any patient.
Additional information	The third party that performed the data linkage will keep linkage files to enable yearly outcome updates for 10 years.

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 has 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 applicants reason that obtaining consent from such a large number of patients is not practicable as it would pose a significant burden on busy clinical staff. The applicant has also provided some estimates of numbers of people who would have to be contacted if a postal consent system was implemented to take into account non-response, and the high numbers required render this option not feasible.

The CAG agreed with the rationale given for not seeking consent.

- **Use of anonymised/pseudonymised data**

Confidential patient data is required for linkage from CT and/or CTA scans of patients from participating NHS Trusts to relevant clinical and health outcomes held by NHS Digital, HQIP, and NIHR BRCs. The CAG were content that this could not be performed in any other way that would reduce the use of identifiers.

Patient Notification' and mechanism for managing dissent

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

The applicant has described a layered approach of a patient notification, providing a poster and website text to be displayed on the study website, followed by an extended privacy notice. Posters will be displayed in various languages in radiology departments and main receptions of participating study sites.

This poster, website text, and privacy notice all provide a local opt out mechanism and the National Data Opt Out will apply from data received back from NHS Digital, and any opt out from other registries will be respected.

The CAG were content with these materials, however the Sub-Committee reflected that as these patients selected will be a retrospective group, it was their understanding that the posters might not be seen by everyone that will be included in the study. As the data collection period will span two years from CAG support it is possible in some Trusts that patients who had scans in 2021 and 2022 could be included retrospectively, and this group may have seen the study posters and opted out if they wished. However if a patient who had a scan in 2010 was included, but had since not been back to the hospital, it is likely that this patient would not see any notification. The Group encouraged applicants to place the study notification on additional websites, however this is a suggestion not a requirement.

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 applicant asked 25 patients having CT scans to fill in a questionnaire to understand their attitude towards the use of their CT images and the proposed transfer of confidential patient identifiable information to organisations in order to enable linkage with relevant databases and subsequent pseudonymisation. The answers were generally supportive. Both the questions asked and answers were provided with the application.

The CAG were content with the patient and public involvement undertaken.

Exit strategy

The ORFAN study has been running since 2015, however this support is only for arm 4. The data collection for arm 4 is expected to be complete within 2 years from the date CAG provide support. Applicants explained that as participants will be followed up for 10 years after this date, and support is requested for the trusted third parties to retain the linkage keys for this time period, support is expected to end 12 years after support under Regulation 5 is provided.

Confidentiality Advisory Group advice conclusion

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

In order to complete the processing of this application, the applicant was required to respond back to the request for further information, which regards the REC Favourable Opinion, within one month.

Request for further information

1. Please provide REC Favourable Opinion regarding substantial amendment 6.

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 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 REC. This application is relevant to substantial amendment 6 - **Favourable Opinion Pending**

2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.

   All organisations processing confidential patient information, including the Trusts where patients are identified will be required to have security assurances in place. However, as there are more than five organisations, the CAT team will

not check each one individually; it is the responsibility of the applicant to ensure these are in place.

Declarations of Interest

There were no declarations of interest.

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date