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

September 2018

1. APPLICATIONS

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland MBE	Yes	Chair
Dr Rachel L Knowles	Yes	
Mr Andrew Melville	Yes	Lay Member
Mrs Diana Robbins	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Connected Bradford Linked Education and Healthcare Research Database**

CAG reference: **18/CAG/0091 (Previously 17/CAG/0178)**

IRAS project ID: **239924**

REC reference: **18/YH/0200**

Context

Purpose of Application

This application from the Bradford Teaching Hospitals NHS Foundation Trust set out the purpose of medical research which will establish a research database aiming to understand the relationship between child health issues and educational attainment levels within the Bradford and Airedale locality.

The sample to be included within the database will be all individuals within the Bradford and Airedale locality who were born between 01 January 1988 and 01 September 2014. It is proposed that routinely collected data from the following sources will be linked to create the research database:

1. Primary Care data from all 88 GP practices across the Bradford and Airedale region,

2. Secondary care inpatient, outpatient and emergency care data from Bradford Teaching Hospitals NHS Foundation Trust and Airedale NHS Foundation Trust,
3. Community Care data from Bradford District Care Trust,
4. School Education data from Bradford Council and North Yorkshire County Council who receive this information direct from the schools.

Data source four detailed above is out of remit for the CAG, as they do not fall within the definition of confidential patient information as defined in s251(11) of the NHS Act 2006.

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

Patients within the Bradford and Airedale region, born between 01 January 1988 and 01 September 2014. The sample size is estimated to be 220,000 patients.

Confidential patient information will be provided by all healthcare providers participating in the study, in order to facilitate linkage across datasets. The following items of confidential patient information are requested the purposes described:

- Name – linkage
- NHS number - linkage,
- Date of birth – linkage,
- Address (First Line) – linkage,
- Postcode – linkage and analysis,
- Sex – linkage and analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

The Sub-Committee of the CAG considered the applicant's written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. Provide further information around the abuse data which will be included within the database – confirm which organisation would be supplying this, how this would be recorded and what data would be provided.

The applicant confirmed that abuse data would not be requested from any of the participating organisations and would therefore not be included in the database.

The Sub-Committee received the confirmation and no further issues were raised in this area.

2. Confirm whether the linkage would be undertaken on a one-off basis or over time and revise any documentation accordingly.

The applicant confirmed that linkage would be undertaken on a one-off basis only.

The Sub-Committee received the confirmation and no further issues were raised in this area.

3. Provide further information around the assessment and approval process which would be undertaken by the Connected Bradford Research Database Committee when assessing

applications to access the database. Provide copies of any policies/protocols which will support this.

The applicant confirmed that they had developed the Connected Bradford Research Database Committee protocol which provided further information around the assessment and approval process. The protocol included information on the Committee's membership, their responsibilities, frequency of meeting, approval process, and the application form and study protocol requirements. A copy of the document was provided for information purposes.

The Sub-Committee received the information and no further issues were raised in this area.

Recommendation

1. The CAG acknowledged that the patient information materials have been developed in collaboration with patient focus groups and does not require that these are changed. It is recommended that these documents are revised to ensure that the use of confidential patient information in the creation of the pseudonymised research database is correctly explained and to ensure that the documentation is presented in a way using language which would be accessible to wide audience.

The applicant's revised the documentation in line with the CAG's recommendation and revised copies were provided for information purposes.

The Sub-Committee received the revised documentation and no further issues were raised in connection with this point.

Amendment Request

An amendment request was submitted by the applicant for consideration alongside the response to the provisional outcome. The amendment requested removal of the Department for Education's National Pupil Database as a data source with which the patient cohort would be linked. It was explained that, due to delays in the approval of the application, the applicant wanted to remove this data source due to an ongoing issue in relation to the Department for Education's NHS Information Governance Toolkit submission, to prevent further delays. The applicant confirmed that educational data would only be provided via the established Local Authority links.

The Sub-Committee were content to provide a recommendation of support to the amendment to remove this data source in order to enable the project to get underway. Members commented that patient-facing materials should be reviewed to ensure that all references to the Department for Education's National Pupil Database were removed.

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. All patient-facing materials should be reviewed to ensure that all references to linkage with the Department for Education's National Pupil Database have been removed.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 03 August 2018**).

3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Confirmed – published satisfactory reviewed grade on V14.1, 2017/18 for the following organisations:**

- Bradford Teaching Hospitals NHS Foundation Trust (Org Code: RAE),
- Bradford District Care Trust (Org Code: TAD),
- Airedale NHS Trust (Org Code: RCF),
- City of Bradford Metropolitan District Council (Org Code: 209),
- Apollo Medical Software Solutions Ltd. (Org Code: 8HH66).

Group Members:

Name	*Present*	*Notes*
Dr Harvey Marcovitch	Yes	
Dr Murat Soncul	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **BPSU survey of severe Chronic Fatigue Syndrome/Myalgic Encephalopathy**

CAG reference: **18/CAG/0052**

IRAS project ID: **223838**

REC reference: **18/SW/0051**

Purpose of Application

This application from the University of Bristol sets out the purpose of medical research focusing on children with Chronic Fatigue Syndrome or Myalgic Encephalitis (CFS/ME), who had persistent disabling fatigue for at least 3 months. The fatigue and symptoms are made worse by activity (post exertional malaise) and are not relived by rest. Children with CFS/ME have other symptoms including muscle aches, headaches, and poor concentration. Children with severe chronic fatigue syndrome or ME are only able to leave their house occasionally (if at all). They have severe fatigue and often severe pain and many require help with daily activities such as eating and washing. Currently, it is unknown how often children develop severe CFS/ME or what treatment they receive.

The proposed study will follow the agreed BPSU methodology, in order to receive reporting via the orange card system of every child with severe CFS/ME. A follow up one year later will be conducted to understand the progression of the illness.

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

Confidential Patient Information Requested

Cohort

Data from reporting clinicians in relation to identification of cases of Chronic Fatigue Syndrome in Children will be collated over a one year reporting period. It is estimated that around 33 cases will be identified in this duration.

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

- NHS number – linkage,
- DOB month and year only – linkage and analysis,
- Gender – linkage and analysis,
- Ethnicity – analysis,
- Partial postcode – linkage.

Confidentiality Advisory Group advice

The Sub-Committee considered the applicant's response to the request for further information as detailed in the provisionally supported outcome in correspondence.

1. **The CAG encouraged the applicant to consider how to share the outcomes of the research with the affected families. Confirmation that a process for this dissemination is in place should be provided.**

The applicant agreed that dissemination of research findings with affected families was important and provided a communication strategy for consideration.

The Sub-Committee received the document and no issues were raised in this area.

The following point was appended to the CAG's advice on the guidance of the decision- maker:

1. **The applicants should consider ways to strengthen the patient and public involvement and engagement as the project progressed, due to the potential wider interest in children with Chronic Fatigue Syndrome or Myalgic Encephalitis. It was noted that this was a recommendation only and not a formal condition of support; however, feedback should be provided at the time of annual review around any action which has been undertaken in this area.**

The applicant advised that the communication plan detailed ways in which the study team planned to work with and disseminate information to patients and the public. It was advised that a CFS/ME young person's advisory group was held approximately every six months. This Group will be kept informed about the progress of the study, and their advice would be sought around how information about the study can be disseminated to other young people with CFS/ME.

The Sub-Committee received the response and issues were raised in this area.

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. Favourable opinion from a Research Ethics Committee. **(Confirmed – issued 20/03/2018)**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – University of Bristol, Bristol Medical School, Sever Paediatric CFS/ME Surveillance Study, shows a reviewed satisfactory grade of Version 14.1, 2017/18).**

Group Members:

Name	*Present*	*Notes*
Professor William Bernal	Yes	
Dr Malcolm Booth	Yes	
Mr. David Evans	Yes	
Dr Lorna Fraser	Yes	
Dr Murat Soncul	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Detection Dementia from Retinal Morphology: a Big Data Machine Learning based Retrospective Case-Control Study**

CAG reference: **18/CAG/0111**

IRAS project ID: **233974**

REC reference: **18/LO/1163**

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

1. Confirm the source of the wider clinical information that will be used for analysis.

The applicant noted that the query related to the clinical information referenced in question 14 of the application form, which included wider clinical information to be included in the analysis dataset, such as Mini Mental State Examination. The applicant confirmed that they had removed these additional pieces of information. It was clarified that only ICD codes of neurodegenerative disease and covariates, as detailed in Table 1 and 2 of the protocol, would be requested from NHS Digital.

The Sub-Committee received the response and raised no further issues.

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.

The applicant confirmed that there was currently no plan to undertake a data refresh.

The Sub-Committee received the response and raised no further issues.

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.

The applicant submitted a revised document to address the points raised. It was explained that further revisions had been made in line with conditions attached the favourable opinion provided by the Research Ethics Committee.

It was recognised that the privacy notice, a requirement in relation data protection legislation, was also being used to achieve the patient notification requirement under the common law duty of confidentiality. Members commented that the revised text was unclear in places and further revision was required to ensure the use of confidential patient information within the project was clear. Within the opening paragraph entitled 'What will the study involve?' the final two sentences should be revised to explain that confidential patient information would be disclosed to NHS Digital for the purposes of linkage only and once this had been achieved identifiers would be deleted prior to disclose of the linked data set to the research team. Within the section entitled 'What are the data protection measures in place for this project?' the opening sentence should be revised to explain that confidential patient information would only be used to facilitate linkage and would not be used in any analysis. The Group agreed that as the

required revisions were minor, support was recommended for the application; however, the revised documentation would need to be provided within two months 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 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. Revise the text of the patient notification material in line with comments made by the CAG around the use of confidential patient information within the project. Revised documentation should be provided within two months of the date of this outcome letter.
2. 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.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 01 August 2018**).
4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital facilitating linkage**).

Group Members:

Name	*Present*	*Notes*
Dr Patrick Coyle	Yes	Vice Chair
Mr. David Evans	Yes	
Dr Lorna Fraser	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **THE INCIDENCE, MANAGEMENT AND EARLY OUTCOME OF CONGENITAL ICHTHYOSIS**

CAG reference: **18/CAG/0105**

IRAS project ID: **243183**

REC reference: **18/WM/0211**

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

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.**

The applicant explained that the rationale for the linkage with NCARDRS was that this BPSU study aimed to identify all cases of severe congenital ichthyosis born in the UK and Ireland within a two year period, but it was anticipated that data could be missed for the following reasons:

- not all paediatricians engage with BPSU,

- not all new-born babies are seen by a paediatrician, eg if they are delivered in a midwife-led unit,
- still-born babies are rarely seen by a paediatrician.

NCARDRS is a facilitated by Public Health England and aims to identify all babies born with any congenital anomaly, whether live or still-born. It had been established that NCARDRS coding was able to identify congenital ichthyosis by ICD10 code and the applicant had discussed with NCARDRS how the approaches may complement each other. By collecting comprehensive data under section 251 it was likely that NCARDRS will identify cases that the study reporting has missed; conversely it is possible, although unlikely, that the study reporting would identify cases that NCARDRS had missed. Therefore, following discussion with NCARDRS team, the applicant proposed to disclose the study list of cases with minimal identifiers, to enable comparison to be undertaken by NCARDRS data, in order to identify cases that had not be reported.

a. The data flows to support this linkage would be as follows: a list of patients would be sent to NCARDRS over NHS secure file transfer (SFT). The data would be held in the NCARDRS secure safe haven and matched against records held by NCARDRS. Any additional cases of congenital ichthyosis missed by BPSU would be identified. These cases would be sent over NHS SFT to the BPSU study team. If any cases were missing from the NCARDRS database, these would be added, in line with the NCARDRS s251 approval.
b. Regarding which data flows within the linkage required a recommendation of support under the Regulations to legitimise the data processing within the scope of this application: the flow to NCARDRS did not require support as this was already covered under NCARDRS s251 approval. Support was requested to legitimise the transfer of data from NCARDRS to the BPSU study team.

c. Regarding which items of confidential patient information would be transferred between the research team and PHE, NCARDRS advised the following was required: NHS number, name, date of birth and diagnosis of congenital ichthyosis. The three identifiers are the minimum required as there are often errors with NHS number, so this cannot be relied upon as a sole identifier.

d. Regarding what data would be disclosed from PHE to the research team: a list of patients would be provided, containing the following data items: name, NHS number, DOB, diagnosis of congenital ichthyosis and hospital.

The Sub-Committee received the response and no further issues were raised.

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.**

The applicant confirmed that the SANDS charity had reviewed the study information and patient information leaflet. The feedback provided was incorporated into the documentation. It was confirmed that continued liaison would be undertaken with the Ichthyosis Support Group, providing updates at their meetings and for their newsletter. It was also confirmed that a poster would also be displayed in maternity units as requested as part of the REC review.

The Sub-Committee received the response and no further issues were raised.

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.**

The revised document was provided for consideration – it was confirmed that this had been reviewed by the Ichthyosis Support Group as recommended.

The Sub-Committee received the response and no further 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. Favourable opinion from a Research Ethics Committee (**Pending**).
   Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed –Birmingham Women's And Children's NHS Foundation Trust shows a published satisfactory reviewed grade on V14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Ms Sophie Brannan	Yes	Lay
Dr Patrick Coyle	Yes	Vice-Chair
Mr Andrew Melville	Yes	Lay
Mrs Diana Robbins	Yes	Lay

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **HPS-4/TIMI 65/ORION-4: A double-blind randomized placebo-controlled trial assessing the effects of inclisiran on clinical outcomes among people with atherosclerotic cardiovascular disease**

CAG reference: **18/CAG/0100**

IRAS project ID: **240684**

REC reference: **18/SC/0243**

Purpose of Application

This application from the University of Oxford set out the purpose of medical research which is a Clinical trial of an Investigational Medicine Product (CTIMP Study) which is assessing a new cholesterol lowering treatment, which if shown to be effective, could have a major impact on the number of people dying of vascular disease or suffering strokes or heart attacks in the UK. The application has been submitted to the CAG under the Precedent Set criteria one – participant identification studies, to enable a large sample of potentially eligible patients to be identified and invited to participate in the study. The UK sample size is estimated at 12,000 patients, which will be randomised on a 50/50 basis to receive the experimental drug versus placebo. The CAG is only required to consider participant identification and recruitment element of the study – after which, patients will provide informed consent for their involvement in the study.

Acute Hospital Trusts and NHS Digital will undertake a search to identify potentially patients based on the inclusion criteria. This information will be shared with the Clinical Trial Service Unit at the University of Oxford to enable the establishment of a pre-screening database. List screening will be undertaken via NHS Digital prior to invitation letters being issued to potentially eligible patients.

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

Confidential Patient Information Requested

Cohort

- All patients aged 55 years and over, with a history or evidence of cardiovascular disease through at least one of the following: myocardial infarction, ischaemic stroke or peripheral arterial disease (evident by lower extremity artery revascularisation or aortic aneurysm repair.
- It is estimated that 400,000 patients will be invited across England, Wales and Scotland in order to recruit the required patient cohort of 12,000 patients.
- Alternative arrangements are being made via the Public Benefit and Privacy Panel for the recruitment of Scottish patients.

The following items of confidential patient information will be disclosed by Acute Hospital Trusts and NHS Digital in relation to potentially eligible patients to the Clinical Trial Service Unit at the University of Oxford, for the purposes as set out below:

- Full name and title – to facilitate invitation,
- Full latest address and postcode – to facilitate invitation,
- Date of birth – to ensure eligibility and sample validation,
- NHS number – to facilitate invitation and sample validation,
- Hospital number – to facilitate invitation and sample validation,
- GP Registration – to facilitate invitation,
- Sex – sample validation,
- ICD-10 or other diagnostic or procedure codes – to ensure eligibility
- Fact of death – sample validation

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Clarify whether both NHS Number and Hospital ID are required to facilitate the invitation process. If so, provide further justification to support the requirement for both data fields.**

The applicant explained that having the NHS number was important in identifying duplicate patient records and facilitating the NHS list cleaning process. The Hospital ID would be useful in facilitating the linkage to hospital laboratory data. As outlined in the application, identifying patients with low historic total cholesterol values in the Hospital Trust laboratory records would avoid inviting those who are unlikely to be eligible for the study. Wherever possible, NHS and hospital numbers will be sent securely to the Acute NHS Hospital Trust where the ORION-4 clinic is located (which is the same Trust which recorded the qualifying admission code data for those patients) so that the most recent total cholesterol value can be securely transferred to the ORION-4 team. In some NHS Hospital Trusts having the hospital ID would facilitate this step.

The Sub-Committee received the response and no further issues were raised in this area.

2. **Further information is required to understand why NHS Digital and Acute Trusts would be providing confidential patient information in relation to potentially eligible patients to be invited to the trial – provide further justification to support this proposed methodology, based on evidence from the previous trials which have been facilitated via similar recruitment processes.**

The applicant explained that the intention was that confidential patient information would be sought from NHS Digital for patients in England and from the NHS Wales Informatics Service for patients in Wales.

Data would only be sought direct from NHS Acute Hospital Trusts in the event of a substantial delay in processing the application by NHS Digital or the NHS Wales Informatics Service. Obtaining the data directly from NHS Digital, or the NHS Wales Informatics Service, has advantages in terms of efficiency since one standard data format would be used and would avoid delays waiting for data analysts at local Hospital Trusts. The applicant confirmed that this was the preferred approach and discussions with NHS Digital suggested that it can be achieved within the appropriate time-frame. The proposal to obtain the data direct from individual NHS Acute Hospital Trusts would only be implemented in the event of a substantial delay in obtaining the data from NHS Digital or the NHS Wales Informatics Service.

The Sub-Committee received the response and was assured by the rationale provided to support the two proposed recruitment strategies. No further issues were raised in this area.

3. **Clarify whether NHS Wales Informatics Service have been approached about the study in order to access information from the Patient Episodes Database Wales (PEDW) in relation to Welsh patients.**

The applicant confirmed that the intended recruitment strategy was to obtain details of potentially eligible patients in Wales from NHS Wales Informatics Service and confirmed that NHS Wales Informatics Service had been approached to initiate this application. As with NHS Digital, it is anticipated the this application can be processed by NHS Wales Informatics Service within the necessary timeframe and the data would only be requested from individual NHS Acute Hospital Trusts if there is an unexpected delay in processing the application.

The Sub-Committee received the response and no further issues were raised in this area.

4. **Provide further information around the timelines of the invitation process, clarifying how long following the data cleaning process by NHS Digital invitations will be sent.**

After the initial data was received, list cleaning would be undertaken on a monthly basis to ensure that addresses are accurate and up-to-date, expressed opt-outs are respected and to minimise the risk of writing to individuals who are deceased.

The Sub-Committee received the response and no further issues were raised.

5. **The website text should be revised, with input from the trial's patient and public panel to address the following points:**
    a. **To make this text more accessible to a wider audience,**
    b. **Include clearer information around the patient's right to object,**
    c. **Confirm that historically registered dissent would be respected prior to the invitation process,**
    d. **Provide information around the co-sponsorship arrangements for the study.**

The applicant provided a revised copy of the website text which had addressed the issues raised. It was confirmed that the patient panel had reviewed the revised text and were supportive of the approach.

The Sub-Committee received the document and no further issues were raised in this area.

6. **A copy of the participant invitation letter is required for review.**

A copy of the participant invitation letter was provided.

The Sub-Committee received the document and no further issues were raised.

7. The patient information sheet should be revised to include clearer information around the patient's right to dissent.

A copy of the revised Patient Information Sheet was provided which included information about the identification and invitation process and to provide information about how potential participants can exercise their rights. Some wording had also been added to provide more information about the processing of data in order to comply with GDPR.

The Sub-Committee received the revised document and no further issues were raised in this area.

8. Provide confirmation that, should a patient request the removal of their data from the trial recruitment database, the potential for future invitations to the trial would be explained to the individual, but the objection respected and data destroyed if this is requested.

It was confirmed that if a patient requested the removal of their data, understanding the potential for future invitations, the applicant would comply with their request and destroy the data.

The clarification was received and no further issues were raised in this area.

9. Revised patient-facing documentation should be submitted to enable an assessment to be undertaken around whether the revisions require further review by the CAG.

Revised documentation was provided.

The Sub-Committee received the documentation and no further issues were raised in this area.

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 – alternative arrangements should be made via the Public Benefit and Privacy Panel for the recruitment process within Scotland.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 31 May 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – University of Oxford – Medical Sciences Division – Nuffield Department of Population Health – Clinical Trial Service Unit, Version 14.1, 2017/18**).

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Patrick Coyle	Yes	Vice Chair
Mr Anthony Kane	Yes	Lay Member
Professor Jennifer Kurinczuk	Yes	
Mr Marc Taylor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Mechanisms of Change in Psychological Therapy**

CAG reference: **18/CAG/0014**

IRAS project ID: **225649**

REC reference: **17/SC/0204**

Purpose of Application

This application from Royal Holloway University of London sets out the purpose of medical research to examine the relationship between cognitive change and symptom change during psychological therapy for people with symptoms of depressive and anxiety disorders. It is expected that the study will find that a change in a client's attitudes and beliefs will be associated with symptom change during psychological therapy, and that changes in cognition will occur before changes in symptoms. Data will be collected from clients receiving individual psychological therapy in City & Hackney Improving Access to Psychological Therapies (IAPT) service and the 'Let's Talk' IAPT service, Barnet, Enfield and Haringey Mental Health NHS Trust and Whittington Hospital NHS Trust. Data from 200 participants will be required to examine the relationship between cognitive change and symptom change.

The project had originally been designed in such a manner that the IAPT therapists (direct care team) would identify potential participants; however, issues with recruitment were encountered which led to eligible patients not being invited to participate. The revised process proposes the main applicant review's patient medical records to identify potential participants and provide details to the team administrators, to enable participant information materials to be passed to the patients when they attend for their appointment or posted to them with their assessment letter.

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

Confidential Patient Information Requested

Cohort

- Male/Female patients over 18 years of age,
- Clients who are receiving individual psychological therapy from City and Hackney IAPT service and the 'Let's Talk' IAPT service, Barnet, Enfield and Haringey Mental Health NHS Trust and Whittington Hospital NHS Trust ,
- There will be 120 patients recruited to the study (33 have already been successfully recruited, 87 further participants are required). It is estimated that access to 380-400 patient records will be required in order to achieve this recruitment target.

The applicant will need access to the full patient record in order to determine which patients are eligible for inclusion in the study. The following data items are required for the purposes as set out below:

- Patient Name – to allow invitation to participate to be provided,
- Therapist's Name – to allow invitation to participate to be provided,
- Date of Appointment – to allow invitation to participate to be provided,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group Advice

A Sub-Committee of the main CAG considered the written response to the request for further information detailed within the provisionally supported outcome in correspondence. This response was supported by an amendment request, which sought to change the main applicant (Chief Investigator) for the project – it was agreed that this amendment request would be considered together with the response to the provisionally supported outcome.

Amendment Request

The amendment sought to change the main applicant detailed on the project. Ms Iona Symington would become named Chief Investigator on the proposal and would be supported by Ms Justine Kinney. Dr Dorothy King, previously named main applicant, had completed her aspect of the overarching research project and provided a letter confirming she was relinquishing her duties in relation to the proposed application.

The Sub-Committee considered the amendment to the application. It was acknowledged that the reviewing Research Ethics Committee had undertaken an assessment of the suitability of the proposed replacing Chief Investigator to take forward the proposal. Confirmation of the REC Favourable Opinion in relation to the change of Chief Investigator was confirmed on 01 June 2018.

The Sub-Committee agreed that consideration the proposed amendment alongside the written response to the provisionally supported outcome was the most appropriate handling route and was content to provide a recommendation of support to the amendment and change to main applicant.

The below response was provided by the newly appointed main applicant to the request for further information detailed in the provisionally supported outcome.

1. **Provide confirmation of which organisation is acting as controller for the project.**

It was confirmed that Royal Holloway, University of London was the controller for the application activity. The Doctoral Thesis associated with the application activity was taking place at this institution.

The Sub-Committee received the clarification and no further issues were raised in this area.

2. Patient and Public Involvement and Engagement – further information is required in this area to address the following points:

a. Provide details around the service group attendance to discuss the revised recruitment strategy, including an overview of how many people attended,

b. Provide details of the feedback provided by the attendees in relation to the proposed change to the project's recruitment strategy,

c. If the responses given were negative, the CAG would take this into account when considering whether support should continue, or whether further actions are necessary.

It was explained that individuals associated with the proposal had attended three service user meetings at City and Hackney IAPT. Four service users attended the first meeting, with one service user being present at the following two attendances.

The general sense is that the service user feedback falls into two categories: (1) those who do not wish anyone but their therapist to have access to any identifying information and (2) those who accept limited use of identifying information insofar as it is necessary to facilitate data collection, once this has been explained.

Furthermore, in the final service user meeting, the relevance of GDPR regarding service-related research was discussed. The service user who attended explained that she did not see a problem with DClinPsych trainee staff having access to patient's name and problem descriptor in order to identify clients who may be interested in relevant research. It was explained that this is required due to clinician staff being very busy. It was also highlighted that this is all the data that the trainee staff would be able to access, and attendee agreed to this.

The Sub-Committee received the response and no further issues were raised in this area.

3. Patient Notifications and Dissent – further information is required in this area to address the following points:

a. Provide a copy if the letter which will be included by the Trust in routine appointment letters to inform patients of potential access to medical records outside the direct care team to facilitate research activities for consideration,

b. Confirm why it is not possible to check patient records for evidence of historic dissent.

It was explained that patient notification was not routinely provided within the participating sites at present. The applicant advised that they were working on the process of implementation of this procedure in co-ordination with the services involved. It was proposed that a slip of coloured paper within appointment letters which stated: "This service is actively involved in research to improve services provided. This can sometimes involve temporary and restricted access to personally identifying information. If you do not wish for your information to be accessed in this way, please tick this box and return this slip to the service". It was further explained that as historically the services involved with the proposal, did not have an established system to enable patient objections to be raised, this had not been previously recorded so there were no historic records to be checked.

The Sub-Committee received the response and agreed that the proposed system to enable patient dissenting was proportionate to the proposed activity and no further issues were raised in this area.

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.

Specific Conditions of Support (Final)

1. Favourable opinion from a Research Ethics Committee **(Confirmed – initial approval issued 20/04/2017, Change in Methodology 22/11/2017 and Change of Chief Investigator 01/06/2018).**
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed - Barnet, Enfield and Haringey Mental Health NHS Trust and Homerton University Hospital NHS Foundation Trust, V14.1, 2017/18 by email 16 August 2018. Additional Site: Whittington Hospital NHS Trust – confirmed by email on 13 September 2018).**

Group Members:

Name	*Present*	*Notes*
Professor Barry Evans	Yes	
Mr Andrew Melville	Yes	Lay Member
Dr Murat Soncul	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Automated Cancer Diagnosis and Prognosis Using Digital Images**

CAG reference: **18/CAG/0124**

IRAS project ID: **231039**

REC reference: **18/WA/0222**

Purpose of Application

This application from the University of Leeds set out the medical purpose of medical research which aims to validate a machine learning algorithm (a computer-based processing system) which has been developed to identify a range of cancers without human input. The algorithm extracts morphological features from images which is uses to achieve a diagnosis.

The aim of the project is collect a large database of images which will be used to refine and validate the developed algorithm so it can be used to diagnose a wider range of cancers of the breast, skin, digestive system, liver, female reproductive tract, lung, urinary tract and hormonal system. This will involve scanning 12,000 cases of both malignant and benign diagnoses from records held at the Leeds Teaching Hospitals NHS Trust. The scanned images will be linked with clinical and demographic patient information. The resulting database will be anonymised prior to release to the University of Leeds for analysis.

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

Confidential Patient Information Requested

Cohort

- Patients aged between 18 and 115 years, who were diagnosed with cancer on biopsy or resection specimens at Leeds Teaching Hospitals NHS Trust, where there is archival tissue that has been sectioned and H&E stained.

- Both malignant and benign cases will be included.
- Patients will be excluded if samples are still in use for current diagnosis or prior case review.
- 12,000 patients will be included in the sample.

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

- NHS Number – linkage and validation,
- Date of birth – to calculate age for analysis,
- Date of death – to calculate survival time,
- Gender – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

1. **Provide a copy of the information which will be displayed on the Trust website for consideration.**

The applicant provided a copy of this document for consideration which allowed patients to learn more about the study as well as having an accessible framework for expressing any dissent for their data to be used of research studies. It was confirmed that arrangements had been made with both the Communication and Marketing and the Information Governance teams at Leeds Teaching Hospitals Trust to arrange uploading a copy of this document in a location accessible to patients on the Trust website.

The applicant noted comments made by the CAG about the complexity of the text to be displayed on the study registration site. A revised copy of this information was also provided.

The Sub-Committee received the response and supporting documentation and no further issues were raised.

2. **Explain how the study-specific objection mechanism would be operated, providing an overview of how and where this would be promoted and confirmation of how any registered dissent would be respected.**

The applicant confirmed that they would compile a register of any patients who come forward to raise an objection to the use of their data in the study. Any patient who raised an objection would receive individual personal confirmation that their data would not be used in the study at the point the contact was made. The applicant would keep a record of the patient's details and store these securely on the NHS IT system with restricted access to the individual(s) collecting data. Each accessed case will then be cross-referenced to this register before information is collected such that relevant cases can be excluded.

The Sub-Committee received the response – clarify was sought from the applicant around the understanding of how the dissenting mechanism would be managed to ensure this had been understood. The applicant confirmed Members understanding and no further issues were raised.

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. Further activity should be undertaken with the Leeds Patient and Public Involvement Group to seek views around how the study results can be disseminated to patients and the public. Feedback is required at the time of the first annual review around the activity which has been undertaken in this area together with an overview of the feedback which was provided.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 30 August 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Leeds Teaching Hospitals NHS Trust shows a reviewed satisfactory grade on Version 14.1, 2017/18**).

2. AMENDMENTS

Group Members:

Name	*Present*	*Notes*
Dr Patrick Coyle	Yes	Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Effectiveness and Cost-effectiveness of 'Usual Care' versus 'Specialist Integrated Care': A Comparative Study of Hospital Discharge Arrangements for Homeless People in England**

CAG reference: **16/CAG/0021**

IRAS project ID: **166237**

REC reference: **16/EE/0018**

Purpose of Application

This application from University College London set out the purpose of establishing the ways in which Specialist Integrated Homeless Health and Care (SIHHC) services are being developed and used to facilitate hospital discharge in England. The study also aims to examine the impact this is having on quality of care for homeless people admitted to hospital and whether this care can help prevent readmission to hospital shortly afterwards.

The first work package (WP1 –for which support is not requested) seeks to gain an informed understanding of the ways in which SIHHC services are being developed and implemented to facilitate hospital discharge in England and the impact this is having on quality of care and organisational outcomes such as the prevention of readmission to hospital. For this work package, local service providers will be asked to identify and nominate potential participants.

The second work package (WP2, for which support is requested for datasets 1, 3, 4, and 5) is a data linkage and health economic analysis work package that will work with twenty sites across England where homeless patients have been admitted to hospital. A cohort of homeless people who have used specialist discharge scheme will be compared to a cohort of homeless people who have not used such provision. The study will also compare patient's hospitalisation history before and after engagement with specialist services. Analysis will also be undertaken to understand whether the outcomes are a factor of homelessness specifically or are tied to deprivation.

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover the activity specified in the application for work package 2, datasets 1, 3, 4, and 5.

Confidential Patient Information Requested

Access was requested to:

- Dataset 1: Data from homeless healthcare users, as outlined in SIHHC data variables in the 'Data Flow Diagram' document, including forename, surname, aliases, date of birth, sex, address, contact number(s), hospital of admission, date of hospital admission, nationality, ethnicity, and NHS number; from study fieldwork sites: November 2013 to a maximum of November 2016
- At each site the research team will create a unique study identifier for each record for the service provider. The data requested for the study will then be securely uploaded and processed at University College London (UCL). The data will be stored and cleaned. Identifiable information required by the Health and Social Care Information Centre (HSCIC) for the linkage to Hospital Episode Statistics/Office for National Statistics (HES/ONS) will at this point be transferred to HSCIC.
- When HSCIC have confirmed that the list is clean, and linkage to HES has been completed, the researchers will de-identify all data.

- Dataset 3: Data from homeless healthcare users, as outlined in SIHHC data variables in the 'Data Flow Diagram' document, including forename, surname, aliases, sex, address, and contact number(s); from Find and Treat Service: November 2008 to November 2016.
- The data requested for the study will then be securely uploaded and processed on the data safe haven at UCL. The data will be stored and cleaned. Identifiable information required by HSCIC for the linkage to HES/ONS will at this point be transferred to HSCIC.
- When HSCIC have confirmed that the list is clean, and linkage to HES has been completed, the researchers will de-identify all data.

- Dataset 4: Personal Demographics Service (PDS) data from homeless healthcare users, including date of hospital admission, date of hospital discharge, date of hospital appointment, and date of death: November 2008 to November 2016.
- The HSCIC will use data within PDS to provide missing NHS numbers for the two previous datasets. The research team will not at any point have access to these NHS numbers, which will be used to improve the linkage of data to HES.

- Dataset 5: HES ONS mortality data from homeless healthcare users and a geographically comparable and representative sample of lowest quintile of deprivation population in HES (based upon the index of multiple deprivation) equal in size to the Find and Treat dataset during the hospital admission study period: November 2008 to November 2016. This data will have already been de-identified by the HSCIC.

Amendment Request

The amendment request set out the following three changes to the project:

1. To extend the duration of support to the end of March 2019,
2. To revise the variables included within the analysis dataset, with the addition of four new variables and to exchange one item previously listed,
3. To revise the primary and secondary outcomes for the study.

Confidentiality Advisory Group Advice

The amendment requested was considered by the Vice-Chair, who recognised the delays experienced by the applicant in the receipt of data from NHS Digital which had led to the request to extend the duration of support required under the Regulations. The Vice-Chair was content to provide a

recommendation to the extended duration of support. The Vice-Chair recognised that the wider amendments described did not impact on the scope of the support provided under the Regulations as the additional analysis variables were not considered items of confidential patient information.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Vice-Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – UCL School of Life and Medical Sciences; published satisfactory reviewed grade at 66% on Version 14.1, 2017/18).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed).**

Group Members:

Name	*Present*	*Notes*
Dr Tony Calland	Yes	Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Avoidable mortality from in-hospital cardiac arrest: Have interventions aimed at recognising and rescuing deteriorating patients made an impact on incidence and outcomes?**

CAG reference: **15/CAG/0113**

IRAS project ID: **139667**

REC reference: **15/SW/0151**

Purpose of application

This application from London School of Hygiene and Tropical Medicine set out the purpose of study which aims to determine the association between different services aimed at identification of patients at risk of deterioration and their subsequent management and ward-based cardiac arrest rates and outcomes. The applicant will investigate on the implementation and effectiveness of services and the differentiation of arrests and outcomes within hospitals as new services had been introduced. It is the objective of the study to improve outcomes for all patients and to reduce avoidable mortality. This study will also involve carrying out a staff survey with consent.

The application of support was requested to permit the disclosure of confidential personal information from Intensive Care National Audit and Research Centre (ICNARC) to the Health and Social Care Information Centre (HSCIC) in order to carry out linkage with Hospital Episode Statistics (HES) and Office for National Statistics (ONS) Mortality and outcome data.

A recommendation for class 4 and 6 support was requested to cover access to allow access to an authorised user for the purpose of linking patient identifiable information obtained from one or more source.

Confidential patient information requested

Access was requested to link NHS number, date of death and postcode in order to carry out the linkages specified above.

Amendment Request

The amendment requested an extension to the end date of the study, which was now identified as 30 September 2019, in order to facilitate completion of the final analysis for the study.

Confidentiality Advisory Group Advice

The Chair considered the amendment to be in line with the principles of the original approval, and noted that it concerned the extension of the end date of the project, which appeared to be justified. The applicants confirmed that the extension to the end date was required due to delays experienced in receipt of data from NHS Digital.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Chair agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – London School of Hygiene and Tropical Medicine reviewed satisfactory grade on Version 14.1, 2017-18).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Amendment Type considered minor by REC – no longer requires review).**