Minutes of the meeting of the Precedent Set Sub Committees of the Confidentiality Advisory Group

August 2015

Reviewers:

Name	Capacity	Items
Dr Kambiz Boomla		1a, 1f
Mr Anthony Kane		1a
Dr Tony Calland MBE	Chair	1a, 1d, 2a.
Dr Miranda Wolpert		2a, 1e
Mr C. Marc Taylor		2a, 1e, 1f
Dr Murat Soncul		1b, 1c
Dr Mark Taylor	Chair	1b, 1c, 1e, 1f, 1g
Professor Barry Evans		1b, 1c
Professor Julia Hippisley-Cox		1d, 1g
Ms Hannah Chambers		1d, 1g
Ms Clare Sanderson		1f

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) Retrospective study to predict adverse outcome in monochorionic twins-OMMIT-1-15/CAG/0142

This application from a student at the University of Birmingham aims to predict adverse outcome in monochorionic twins from first trimester ultrasound scan and maternal serum samples. All women with monochorionic twin pregnancy will be identified from the K2 electronic database which contains all delivery information for patients at Birmingham Women's Foundation Trust. The ultrasound measurements will be pulled off the electronic database that stores this information by the Informatics Department at Birmingham Women's NHS Foundation Trust and laboratory staff will identify relevant samples in storage. Data will be stored on an encrypted database for 6-12 months and the main analysis performed on an anonymised database.

A recommendation for class 1, 4 and 6 support was requested for the process of extracting and anonymising the information, to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to hospital unit no, date of birth and NHS number.

Confidentiality Advisory Group advice

Public interest

Members noted that this was a very valuable and important study which should be supported. It was considered whether the applicant could be seen as part of the clinical care of the patient despite the data being used for aspects other than direct clinical care. Members concluded that patients would not be surprised that those accessing their records could do so, were part of their care team and therefore had a legal basis to access the identifiable data. However it was clearly seen as good practice to anonymise the data for analysis.

Justification of identifiers

The members recommended that the full postcode information be destroyed as soon as the deprivation scores had been calculated. It was noted that Hospital number and NHS number should not be retained on the anonymised dataset as this would constitute identifiable information.

Additional points

The members recommended that the identifiable information is held for 6 months at most and that this limit apply to one-off data linkage and the total data extraction process.

Confidentiality Advisory Group advice conclusion

The CAG recommended that support under the Regulations did not appear to be required as there will be no disclosure of patient identifiable data without consent outside of the clinical care team.

b) Diabetic retinopathy in type 1 diabetes: the Winchester Cohort-15/CAG/0151

This application from University Hospital Southampton NHS Foundation Trust set out the purpose of conducting an epidemiological cohort study to investigate diabetic eye disease in patients with type 1 diabetes. The applicant would review how the prevalence relate to the duration of the type 1 diabetes, how the prevalence relate to other risk factors such as smoking, blood pressure and renal function and also the risk of progression of diabetic retinopathy in this type 1 diabetic cohort over period the period of the study. The applicant confirmed that the Winchester cohort includes 750 patients with type 1 diabetes who attended the specialist diabetes clinic service provided by former Winchester and Eastleigh Healthcare Trust and were registered on the Diamond Diabetes Database. The applicant was seeking s251 support in order to collect further data on this cohort from Southampton Diabetic Eye Screening Programme (SDESP) and health records from University Hospital Southampton NHS Foundation Trust.

A recommendation for class 1, 4 and 6 support was requested to allow access to an authorised user for the purpose of linking patient identifiable information obtained from one or more source and also for the purpose of extracting and anonymising the information.

Confidential patient information requested

Access was requested to NHS number. The applicant would be required access to following data classes:

- Gender
- Truncated Postcode
- Age
- Age at death

Access would also be required to age at diagnosis, smoking status, blood pressure, HbA1C, diabetic retinopathy screening dates, age at screening, retinopathy grade, maculopathy grade, visual acuity, laser treatment, presence of cataract and outcomes of screening visits.

Confidentiality Advisory Group advice

Public interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a significant public interest due to the need to examine diabetic retinopathy within patients with type 1 diabetes.

Practicable alternatives

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

Members agreed that consent was not practicable due to the retrospective nature of the cohort as patients may be deceased. Members noted that maximum ascertainment was important, and agreed that to pursue a consent based approach would lead to research bias due to small numbers involved in a study. Members noted that once the collection of data and subsequent data linkage activity had been completed, the NHS number will be replaced by the unique study ID.

Justification of identifiers

Members agreed that the specified identifier was necessary for the purpose of this research and to complete the data linkage activity. However, members queried the justification to retain the identifiable master index for up to three years. Members requested clarification regarding the retention of the NHS number and justification for the period specified.

Patient notification and opportunity to opt-out

Members noted that was no patient notification or mechanism to provide patients with the opportunity to opt-out. The applicant noted that as the patients had previously consented to their data being used for audit, there was no need to notify the individuals or provide opportunity to opt-out. However, members advised that efforts should be made in order to notify patients and provide local mechanisms for patients

to opt-out of the study. Members requested clarification that information about the project will appear on local website and any objections received from patients would be respected.

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

1. Clarification regarding the retention of the NHS number and justification for the period specified.
2. Clarification that information about the project will appear on local website and any objections received from patients would be respected.
3. Favourable opinion from a Research Ethics Committee.
4. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed by the HSCIC on 26th June 2015.**

c) FILTR Study - Field triage tool for ruptured aneurysms

This application from St George's Hospital NHS Trust sets out the purpose of conducting a prospective study to test the Field Triage tool for Ruptured Abdominal Aortic Aneurysms (rAAA). Abdominal Aortic Aneurysms leads to 8000 deaths per year and there was 41% of misdiagnosis, which would have an impact on number of deaths. The research team at St George's Hospital NHS Trust was proposing to introduce software on mobile phones of paramedics and by entering certain types of information, the paramedics would be able to identify increased risk of rAAA to support the diagnosis process. The application is for the pilot to test the accuracy of the software.

The study will assess how practical it is to utilise the scoring system software in practice, enable feedback from paramedics and allow modelling of excess treatment costs and the impact on vascular and non-vascular A&E Workload. The study will also assess how accurately the ambulance computer software, which had been developed for this purpose, can correctly identify those patients who have a rAAA. The applicant was seeking s251 support in order for London Ambulance Service to obtain discharge summaries containing confidential patient information, from hospitals where the patient, who meets the inclusion criteria, was conveyed. The applicant appreciates that London Ambulance Service (LAS) regularly process confidential patient information as part of the patient's direct care pathway; however, LAS currently do not obtain discharge summaries. The applicant also confirms that the research team will only receive pseudonymised data from LAS.

A recommendation for class 5 and 6 support was requested to allow access to an authorised user for the purpose of auditing, monitoring and analysing patient care and treatment.

<u>Confidential patient information requested</u>

Access was requested to NHS number, name, date of birth and postcode

Confidentiality Advisory Group Advice

Public Interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a significant public interest due to the need to identify the increased risk of ruptured Aortic Aneurysms to support the diagnosis process.

Practical Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006. Members agreed that consent was not practicable due to the emergency nature of LAS interventions and attending an emergency. Members noted that once the data linkage activity had been completed, LAS will remove the identifiers and forward the pseudonymised linked dataset to the St George's Hospital NHS Trust research team. Members agreed the appropriate use of the pseudonymised data and noted that St George's Hospital NHS Trust would not receive confidential patient information.

Justification and Retention of Identifiers

Members agreed that the limited number of identifiers were necessary to identify the location where the patients were conveyed, in order to request discharge summaries and to link the data with LAS diagnosis of ruptured Aortic Aneurysms. Members advised that the activity of linking LAS data to the receiving Hospital NHS Trust discharge summaries, the removal of the identifiers should be completed within six to twelve months.

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

5. The removal of the identifiers should be completed within twelve months.
6. Favourable opinion from a Research Ethics Committee. **Confirmed 20th January 2015**
7. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

d) MERIDIAN- 15/CAG/0155

This application from the Academic Unit of Radiology in Sheffield outlines the purpose of the Meridian study and its 2-3 year follow up to find out if magnetic resonance imaging (MRI) improves the accuracy of diagnosis of fetal brain abnormalities. The study had recruited 750 pregnant women identified during routine second trimester ultrasound screening (i.e. between 18+0 and 21+6 weeks gestation). The sociological aspects of the research will examine patients' views of care, including overall satisfaction with care, acceptability of in utero Magnetic Resonance in the process of prenatal diagnosis, and the impact of in utero MR on decision making. The inclusion of an in-depth qualitative study of health professional perspectives alongside patient perspectives will also allow for a more comprehensive understanding of the utility of in utero MR in this setting. All participants had been provided with a patient information sheet describing the study and the consent form to be signed.

The 2-3 year follow up study will follow up the children of the MERIDIAN cohort when they are aged 2- 3 years. The research team have prior consent to contact the families regarding future studies about their child's development. However to avoid causing emotional upset the HSCIC patient tracking system will be used to check that the child is still alive before the parents are approached. NHS number and, for verification purposes, date of birth will be provided to the HSCIC to allow them to link the cohort with the Patient Tracking service. The date of death and cause of death of the children born from the Meridian study will be returned to the research team, allowing bereaved parents to be excluded from further contact and providing valuable information for the prognostic aspect of the follow-up study, particularly where the cause of death is related to brain development.

Confidential patient information requested

Access was requested to an authorised user for the process of extracting and anonymising data, to select and contact patients to seek their consent, to link patient identifiable data obtained from more than one source.

Confidentiality Advisory Group advice

Retention of identifiers

It was noted that the applicant intended to retain consent forms, CRFs, questionnaires and interview transcripts in a locked filing cabinet in a secured area at each relevant participating site for at least 5 years after study completion. Members requested greater clarity on retention of identifiers and why they need to be retained for five years.

Purpose of application

Members noted that the application was not clear on the purposes that support was required for given that the study was originally consented. However, subsequent information indicated that the original consent form did not include the need for linkage to HSCIC to check whether any of the subjects would be deceased before further contact was made and getting further consent retrospectively would be disproportionately difficult. Members agreed that obtaining further retrospective consent would be impractical.

The applicant was requested as a condition of approval that the application be amended to make clear why support is required. Because of the longer follow up, which may include assessment of children, Q6 should also be answered to include participants who are children.

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

8. The application should be amended to make clear why S251 support is required and Q6 should be ticked to include participants who are children.
9. Members requested greater clarity on the need to retain identifiers for 5 years
10. Favourable opinion from a Research Ethics Committee.
11. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

e) Life course pathways to ageing in the MRC National Survey of Health and Development - 15/CAG/0139

This application from The Medical Research Council (MRC), Unit for Lifelong Health and ageing at University College London (UCL) sets out the purpose of support to allow continued data flows in relation to cancer registry and mortality data from the Health and Social Care Information Centre (HSCIC).

A recommendation for class 4 and 6 support was requested to cover access to cancer registry, mortality and HES data from the HSCIC.

Confidentiality Advisory Group advice

Public interest

Members noted that this was a valuable long term study cohort permitting study of ageing. Previous follow-up was covered by support which the applicant had been advised by the HSCIC was no longer valid because of organisational change.

Justification of identifiers

It was noted by the committee that as a long term study of individuals alive and deceased these identifiers were required by the applicant.

Patient Objection

Members noted that whereas the Patient Information Sheet requesting a home visit was entirely clear that participation is voluntary, the newsletter did not mention that participants had a choice whether to withdraw from the study or to object to the continuing use of the study data set.

Members queried what provisions had been made to allow objection and agreed that reassurances in relation to how this would be managed should be provided. The committee suggested that the applicant amend patient information about objection to continuing participation in the study and provide reasons other than not wishing to undergo further tests, such as objecting to any further data being collected.

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

1. Members queried what provisions had been made to allow objection and agreed that reassurances in relation to how this would be managed should be provided.

2. Favourable opinion from a Research Ethics Committee.

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission.

f) Small area, geodemographic profiling of health needs - 15/CAG/0159

Purpose of application

This application from University College London set out the purpose of an application for a PhD project which aimed to build on a previous study that used extracts from Hospital Episode Statistics (HES) data to assess health needs based on small area information in relation to the location of service providers. The current study aimed to assess local health needs more comprehensively by means of population profiling. A recommendation for class 1, 4 and 6 support was requested.

The Health and Social Care Information Centre (HSCIC) would link HES data to Personal Demographics Service (PDS) data. The HSCIC would then apply the classification tool on the dataset and provide the applicant with an HES data extract including lower super output area (LSOA) linked to the classification data. The dataset would therefore by anonymised when disclosed to the applicant.

Background

This application was considered at the CAG meeting on the 19 February 2015 and it was advised that the application was deferred pending further information in relation to the following:

1. Details of how it is anticipated the results of the application will be used to improve patient care.

2. The applicant should explore the potential to use the HSCIC Secure Data Facility and confirm when this will be available.

3. Confirmation in relation to what information will be publically available about the study including the agreed process for respecting patient objection.

The applicant responded with further information on 8 June 2015, this was forwarded to a sub-committee of members for review and the advice provided is outlined below.

Confidentiality Advisory Group advice

Potential to improve patient care

It was noted that the applicant confirmed that the potential to improve patient care were; (a) advanced knowledge of the contribution of different kinds of ethnicity-related risk factors alongside other risk factors such as inequality, (b) testing limits and possibilities of a method to measure population structure without cost-intensive genotyping of patients, (c) improve patient health through targeted health screening, informed prevention and personalised care based on the findings of this research. It was asserted that the research would generate direct recommendations for health needs assessments at a strategic level and optimised patient care at the provider level.

HSCIC Secure Data Facility

The HSCIC confirmed on the 4 March 2015 that it would not be possible for the researcher to use the Secure Data Facility. However, it was confirmed that the HSCIC had confirmed that they were able to run the researcher software within HSCIC, thus allowing a dataset to be released that did not include names, but rather the coding of individuals into a form of ethnic classification. The letter and note from Professor Longley stated that the classification algorithm could be applied within HSCIC without direct involvement of the researcher. Members agreed that this was a positive step and it now appeared that anonymised data only would be received by the applicant and therefore there would be no disclosure of confidential patient information without consent.

Members confirmed that if there was any disclosure of patient information that was considered to be identifiable, this would require support and the applicant should inform CAG of this.

Patient notification and opt out

It was confirmed that the HSCIC would publish information about the HES application on their website and that information would also be made public on the UCL Department of Geography website. Both publications would include a link to the HSCIC and the administrative office of UCL Geography and patients could use these to raise questions, concerns and objections.

Confidentiality Advisory Group advice conclusion

The sub-committee of members noted the potential to improve patient care and were pleased that the methodology had been adapted so that confidential patient information would not need to be disclosed to the applicant and therefore support under the Regulations would not be required.

g) Retrospective case note review of enteral tube related issues [15/CAG/0154]

This application was promoted to full review at the August CAG Meeting.

2. NEW PRECEDENT SET REVIEW APPLICATIONS –NON RESEARCH

a) Improving care in the NHS- 15/CAG/0148

This application from The Royal College of Surgeons set out the purpose of linking Hospital Episode Statistics (HES), Office for National Statistics (ONS) mortality and clinical outcomes from previous audits to support a programme of national clinical audits and service evaluations that examine the quality of care delivered by the NHS in England. The information would be produced at an appropriate aggregate level to support quality assurance activities within these organisations, such as benchmarking, as well as at a national and regional level to support policy makers and commissioners.

The applicant would utilise the Health and Social Care Information Centre (HSCIC) data linkage service to link the dataset and return a pseudonymised dataset to the applicant containing no identifiers.

A recommendation for class 4, 5 and 6 support was requested to allow access to an authorised user for the purpose of linking patient identifiable information obtained from one or more source and also for the purpose of auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to:

- Demographic data: HES generated unique identifier, age at admission, month and year of birth, postcode district of residence, sex, ethnicity, measures of socio-economic deprivation, dates of admission, and discharge, elective/urgent admission, discharge destination including in-hospital death).
- Diagnostic Data: diagnostic codes based on the ICD-10 classification
- Procedure Data: procedure codes and corresponding dates
- Geographical Data: NHS Trust, NHS region and current electoral ward
- Critical Care Data: dates of start and end of high dependency/ITU care, type of care
- Maternity data: baby's date of birth, birth weight, and gestational age, baby's sex, place of delivery, number of previous pregnancies.
- HES data and ONS Morality data linkage: event and date of death after discharge from hospital, cause of death based on ICD-10 classification

Public Interest

Members agreed that this was a medical purpose as defined within the s251 (1) NHS Act 2006. Members agreed that the activity carried out would likely to provide a significant public interest due to the need to audit and examine the quality of care delivered by the NHS in England.

Practicable Alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006. Members noted that the Royal College of Surgeons receives pseudonymised HES data for linkage with data from clinical audits and with ONS data on deaths. Members noted that practical alternatives to s251 support were not available for the processing of confidential patient information for this application as the members agreed that the data flows were too large for consent to be a feasible approach.

Identifiers

Members agreed that the specified use of identifiers appears to be appropriate and not excessive for the processing and pseudonymisation of the data by the HSCIC. Members noted that the date of birth would be converted to age at admission. Members advised that the identifiers should be retained for a maximum of three years in order to check data prior to publication of findings.

Security Measures

Members noted that the Royal College of Surgeons security policy appears to be outdated and also noted that the applicant stated security audits are regularly undertaken by an independent company. Members advised that an update on when security audits had been undertaken and for a full report to be included within the annual review submission.

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

1. Update on security audits and full report to be included within annual review submission.
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 27th April 2015.**

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

Amendments August 2015

Reviewers:

Name	Capacity	Items
Dr Mark Taylor	Chair	1a
Professor Jennifer Kurinczuk		1a
Mr C. Marc Taylor		1a

3. AMENDMENTS –RESEARCH

a) Small Area Health Statistics Unit-14/CAG/1039

This application from Imperial College London set out a request for continued support for a research database covering England and Wales, the database would be mainly used by studies focusing on environmental health risks. The original application specified that support would be required for the funding period of 5 years, as the funding period had been extended the application requested an extension to the initial support provided.
A recommendation for class 1, 2, 3, 4, 5 and 6 support was requested to cover access to the following datasets:

- ONS Births and Still births
- ONS Cancer Incidence
- Welsh Cancer Intelligence and Surveillance Unit.
- ONS Mortality
- National Congenital Anomaly Register (NCAR from ONS)
- Local Congenital Anomaly registries affiliated with BINOCAR [CARIS (Wales), Glasgow Register of Congenital Anomalies, Merseyside and Cheshire Congenital Anomaly Survey, North Thames (West) Congenital Malformation Register, Northern Congenital Abnormality Survey (NORCAS), Oxfordshire Congenital Anomaly Register (OXCAR), Scottish Congenital Anomaly Register (SCAR), East Midlands & South Yorkshire Congenital Anomaly Register (formerly Trent), West Midlands Congenital Anomaly Register, Wessex Antenatally Detected Anomalies Register (WANDA), National Downs Syndrome Cytogenetic Register (NDSCR)

- Terminations grounds “E” (that there is a substantial risk that if the child were born it would suffer from such physical
- or mental abnormalities as to be seriously handicapped)
- NN4B – currently expecting data for 20062011
- (data arrival expected November 2014).
- HES Inpatients

- HES A+E – current holdings
- HES ONS mortality link – current holdings
- NCCHD (National Community Child Health Database)

Confidential patient information requested

Access was requested to address, postcode, NHS number, date of birth and date of death.

Amendment request

CAG original approval had covered the SAHSU application but not unlimited data linkages. The applicant had been asked to come back when undertaking specific projects which required additional linkages. It was noted that the applicant confirmed that they will be using the approved methodology agreed at the CAG meeting.

An amendment was requested in order to link between the ONS births registrations (enhanced with NN4B variables) and ONS mortality records to be able to analyse infant mortality as an outcome for two studies (12/LO/0566 and 12/LO/0567) covered by HRA - 14/CAG/1039 – Section 251 support; (supersedes NIGB - ECC 2-06(a)/2009). The applicant confirmed that approval would be sought from NRES and ONS (the data provider) before carrying out any linkage**.**

Confidentiality Advisory Group advice

The amendment requested was forwarded to the members who agreed that the study had a clear medical purpose, with potential findings of significant public interest, with no practicable alternative to support.

Confidentiality Advisory Group conclusion

In line with the considerations above, the sub-group 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
2. Confirmation of a favourable opinion from a Research Ethics Committee

Chair's Action Report

August 2015

Officer:

Name	Capacity	Items
Dr Patrick Coyle	Chair	1a, 1b

4. AMENDMENTS RESEARCH

b) 1970 British Cohort Study - CAG 2-03(PR4)/2014

This application is for the 1970 British Cohort Study, which is the third of Britain's world renowned national longitudinal birth cohort studies. It follows all those born in a particular week in 1970 throughout their lives, charting the effects of events and circumstances in early life on outcomes and achievements later on. The study is run by the Centre for Longitudinal Studies (CLS), at the Institute of Education, University of London and funded by the Economic and Social Research Council.

Since 1970 there have been eight attempts to gather information from the whole cohort. Over time, the scope of enquiry has broadened from a medical focus at birth, to encompass physical and educational development at the age of five, physical, educational and social development at the ages of ten and sixteen, and then to include economic development and other wider factors at ages 26, 30, 34, 38 and 42. Future sweeps of the study will take place every 45 years.

The ongoing success of the study depends on maintaining contact with as many study members as possible. The purpose of the original application was to request Section 251 support for two activities which will support this endeavour.

1) To supply the HSCIC with lists of 'untraced' cohort members in order that they can be matched with GP registrations and new addresses supplied. These matched individual would then be contacted and invited to continue their participation in the study.
2) Receive notifications from the HSCIC which inform us of deaths, embarkations (i.e. emigrations) and exits/entry from the NHS which are used for both tracing and research purposes.

A recommendation for class 2, 3, 4 and 6 support was requested to cover access to HSCIC data for the above purposes.

<u>Confidential patient information requested</u>

Access was requested to name, NHS number, date of birth, full address and postcode.

Amendment request

The applicant submitted an amendment request to advise of a change in data controller and that the invitation letters to the patient cohort will be sent by an external contractor which had been appointed since the original application was submitted.

The applicant noted that as of the 2nd December 2014, the Institute of Education (IOE) joined with University College London (UCL) as a single faculty school, to be known as the UCL Institute of Education. The applicant confirmed that the data controller for the 1970 British Cohort Study was UCL.

The applicant confirmed that the original application did not state who would send the invitations but had now contracted an external supplier as a Data Processor to carry out the survey fieldwork for the Age 46 survey. Invitations will be sent to study members (including those who have been traced via the NHSCR) asking them to participate in the Age 46 survey – these invitations will be sent via letter and email and will be sent by National Centre for Social Research (NatCen).

The applicant also confirmed that Nurse Interviewers working for NatCen would visit consenting study members in their home in order to conduct an interview and a range of assessments and measurements.

Confidentiality Advice Group Advice

The amendment requested was forwarded to the Chair who agreed that the change in data controller was a merger of academic institutions of high repute and that the organisation's Information Governance Toolkit is of satisfactory compliance. The Chair noted that the data processor is an organisation that is experienced in this work and the organisation's Information Governance Toolkit is also of satisfactory compliance. The Chair noted that the patients will be informed of the change and the data processor will seek consent from patients prior to being approached by the nurse assessor, which will enable an opportunity for patient objection at that point, should the patients wish to no longer participate.

The Chair advised that the Confidentiality Advice Team would require evidence of REC approval in relation to Age 46 Survey fieldwork prior to advising s251 support.

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. **Centre for longitudinal studies IG Toolkit was confirmed by HSCIC on 16th April 2015 and NatCen IG Toolkit confirmed by HSCIC on 2nd April 2015.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed NHSCR 8th April 2014.** REC favourable opinion required for Age 46 Survey.

Improving Outcomes from Out of Hospital Cardiac Arrest: The Cardiac Arrest Individual Registry and Outcomes (CAIRO) Programme (Work Package A) - 14/CAG/1003

This application from University Hospitals Bristol NHS Trust detailed a research programme designed to monitor and improve patient care from initial ambulance response to cardiac arrest through to hospital discharge and beyond. A comprehensive patient registry, the CAIRO database, would be established to allow linkages to be made from different data sources and to track each cardiac arrest patient from initial collapse through to hospital discharge.

The aim of this specific application was to evaluate the feasibility of setting up the CAIRO database.

Confidential patient information requested

Support under class 1, 4 and 6 was requested to access name, NHS number, hospital ID, date of birth and date of death. NHS number, date of birth and postcode would be retained if a patient died prior to consent being sought to carry out data linkage. Patients would be identified through South Western Ambulance Service NHS Foundation Trust, consent would be sought from surviving patients whilst still in hospital where possible and mortality data obtained from the HSCIC prior to writing to patients to seek consent once discharged from hospital.

Amendment to the CAG form:

The applicant submitted an amendment request to change details specified within the application, in particular question 45. The applicant requested to add further details to note that it should not be stated that the data stored on University computers will be encrypted, as these data are stored securely on the University server, and will have had all identifiers removed apart from study ID, age, date of death and postcode of OHCA. The applicant added that it should not be possible to identify patients from this data in this context. Data at rest is unencrypted; however, all data in motion is encrypted using SSL.

Amendments to the protocol (these changes also impact upon various questions within the CAG form)

Section 4.3.2

The applicant submitted an amendment to the text for the fourth exclusion criteria to clarify what the applicant would do if it is not possible to identify whether or not the OHCA definitely occurred within the North Division of SWAST for example, if a postcode was not available for the incident.

Sections 4.5.2, 5.6, 9.2, 9.5

The applicant submitted an amendment to the text within these sections to clarify that the applicant would only approach survivors that were admitted to one of the 3 hospitals that will be participating in this feasibility study (Bristol Royal Infirmary, Royal United Hospital Bath or Southmead Hospital). The resources would not be available to assess capacity, approach and carry out follow-up for patients who have an OHCA within the eligible geographical area but are subsequently admitted to a different hospital. The initial data collected for these patients will be retained, but no follow-up data will be collected.

Section 5.3.1 – Table 2 and 5.6

The applicant submitted an amendment to provide clarification regarding which data will be collected for patients that are deceased prior to the study team being able to approach them.

Section 5.6

The applicant submitted an amendment to include a clause regarding patients who are discharged for palliation. These patients (or their consultees) would not be approached about the study; and again, the initial data collected for these patients would be retained, but no follow-up data would be collected. The applicant considers that it would unnecessary and potentially distressing for the patient and/or their family/friends at an already difficult time.

Section 11.2.1

The applicant submitted an amendment to add a sentence to clarify that age on day of OHCA, date of death and postcode of OHCA would be transferred to the University of Bristol IT system for analysis, but it should not be possible to identify patients from this data in this context.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Vice-Chair who noted that with regard to question 45 on the application form, the chair was concerned with the transfer of date of death unencrypted to the university server for those subjects whose data were covered within regulation 5 support. The Chair also noted that the Confidentiality Advice Group had previously been assured that no identifiers would be transferred to the University. The Chair advised that in some contexts date of death may be considered identifiable and requested further clarification to specify the reason and the period it would be retained at the University.

The applicant provided clarification that the research team would calculate the survival time, which was required for analysis, prior to the data being transferred to the University server. The applicant confirmed that the survival time would be transferred instead of date of death.

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.