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

July 2015

Reviewers: 22 May 2015

Name	Capacity	Items
Dr Patrick Coyle	Chair	1a, 1b, 1c, 1d
Professor Jennifer Kurinczuk		1a, 1b,
Ms Hannah Chambers		1a, 1b,
Dr Murat Soncul		1c, 1d
Clare Sanderson		1c, 1d

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) Pierre Robin Sequence national surveillance study- 15/CAG/0141

Context

This application from NHS Lothian NHS Foundation Trust set out the purpose of utilising the BPSU surveillance methodology and notifications to members of the Royal College for Paediatrics and Child Health (RCPCH), to provide a dataset to assess the epidemiology of Pierre Robin Sequence (PRS) within the UK and Ireland and how these cases are managed within hospitals. The study will involve inclusion of PRS on the "Orange Card" for a 13 month period. Clinicians participating within the BPSU reporting mechanism will be informing cases of incidence to the BPSU office. The BPSU office notify the lead investigator and the research team will send a questionnaire consisting of specified identifiers and associated clinical data to the clinicians to complete and return. A second questionnaire will be sent to clinicians 1 year after the initial report to collect clinical information about each child's progress and health over the first year of life. The identifiers will be kept separately from the clinical data for case verification and to de-duplicate the dataset.

Patient initials, date of birth, hospital number and postcode will be requested to allow for identification of case duplication, calculation of regional incidences of PRS and accurate ages of affected infants. In order to protect confidentiality, data collection questionnaires are structured so that the front page, which contains information only essential for case verification and deduplication, can be separated from the remaining pages that contain clinical research data.

A recommendation for class 1, 2, 4, 5, and 6 support was requested to cover access to an authorised user for the process of extracting and anonymising data, to obtain and use information about past or present geographical area, for linking patient identifiable

information obtained from more than one source and also for auditing, monitoring and analysing patient care and treatment.

Confidential patient information requested

Access was requested to patient initials, date of birth, hospital number and postcode.

Confidentiality Advisory Group advice

Public interest

Members noted that given its rarity there was scarcity of data and thus limited understanding of the epidemiology of the disease, particularly how these cases were managed and especially how the vulnerable airway are managed.

Justification of identifiers

It was noted that the identifiers requested were standard for a BPSU study and would be required in order to identify region, age of child and to enable de-duplication.

Additional points

It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the Data Protection Act 1998 (DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data.

It was noted by the committee that REC approval required the applicants to indicate in patient information how parents/carers could object to the use of their child's data. The committee sought reassurance that this patient information would be going on the website prior to approval.

The applicant should be clear that support would apply to England and Wales only, not Scotland, Northern Ireland or the Republic of Ireland.

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. The committee requested view of the text to be displayed on the web site,
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. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-security-review-arrangements/ and contact Exeter.helpdesk@nhs.net with any queries.

b) Geographic and socioeconomic mapping of hepatocellular carcinoma (HCC)- 15/CAG/0147

Context

This application from Hull and East Yorkshire Hospitals NHS Trust set out the purpose to build on an existing database of incidence of Heptocellular Carcinoma (HCC) in Hull and East Yorkshire to map geographical/postcode incidence of the disease and examine possible socioeconomic factors associated with the variation. Cases will be identified by searching the Hull and East Yorkshire hepatobiliary cancer electronic registry and case note numbers supplied to the study team. The patient records of people diagnosed with liver cancer held by the trust will then be reviewed for clinical information and postcode and a unique identifier assigned to each. Where there is some clinical information missing the patients GP will be contacted to ask for a copy of their summary GP record, this will be the minority of cases. Researchers at the University of Hull will map the data but only partial postcode and a sequential study number will be retained for analysis.

A recommendation for class 2, 5 and 6 support was requested to cover access to Hospital ID no, date of birth and postcode.

Confidential patient information requested

Access was requested to Hospital ID no, date of birth and postcode.

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. The committee would like to see consultation with a HCC patient/carer group if such exists. Evidence of support from British Liver Trust provided
2. Favourable opinion from a Research Ethics Committee. Confirmed 16/06/2015
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Confirmed 16/06/2015

c) Breast-Screening After Radiotherapy Database - Questionnaire (BARD-Q)- 15/CAG/0149

Context

This application from the University of Manchester and The Christie NHS Foundation Trust set out the purpose of a study to investigate into women who have had radiotherapy to the upper chest under the age of thirty-six years as treatment for Hodgkin Lymphoma are at a higher risk of developing secondary breast cancer. The study would also include a review into women who may be at a higher risk are attending breast screening in accordance to the national breast screening protocol and the likely deviations from the protocol. The applicant would like to invite and obtain consent from participants of a previous similar study to complete a questionnaire.

A recommendation for class 3 and 6 support was requested to cover access to allow an authorised user for the purpose of selecting and contacting patients to seek their consent.

Confidential Patient Information Requested

Access was requested to obtain current contact details from Cancer Registry North West, Public Health England (PHE) for individuals who were consented participants of the previous questionnaire but for whom contact information is no longer accurate.

The applicant was also seeking for support in order for PHE to extract date of death from the Cancer Analysis System (CAS) to ensure that the questionnaire and associate materials are not sent through the post to deceased patients and to also complete the overall study. The applicant would need to submit a list of the previous participant's NHS numbers to Cancer Registry North West, PHE and the applicant would receive name, NHS number, Hospital ID number, date of birth, date of death and patient full address and postcode.

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 requested clarification as to how long the applicant was intending to retain the Date of Birth identifier and the justification for the retention period. Applicant confirmed Date of Birth identifier will only be used to extract correct patient and up to date address. Once this activity had been completed, the applicant will destroy the identifier.
2. Favourable opinion from a Research Ethics Committee. Confirmed 8th June 2015
3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Health and Social Care Information Centre (HSCIC) confirmed 23rd March 2015.

d) ERIC-PPCI-15/CAG/0150

Purpose of Application

This application from University College London Hospitals NHS Foundation Trust (UCH) set out the purpose of a study to investigate whether remote ischaemic conditioning (RIC) can increase survival and prevent the onset of heart failure in patients undergoing a specific type of heart attack known as ST elevation MI or STEMI. The study would also review whether RIC will reduce the amount of damage to the heart muscle during the heart attack thereby, preserving the pump action of the heart. The applicant confirmed that the direct clinical care team will identify eligible patients for the study and will enter month and year of birth against a study ID number within the study database. The clinical care team would provide the patient with information materials and seek to obtain consent or note dissent to take part within the study on behalf of the research team to access confidential patient information.

A recommendation for class 1 and 6 support was requested to permit access to an authorised user to extract and anonymise confidential patient information.

Confidential patient information requested

The applicant was seeking s251 support to access medical records of the deceased patients who had not consented, to extract and anonymise confidential patient information. The applicant would require access to date of birth, date of death, gender and ethnicity.

Confidentiality Advisory Group advice

Security Measures

Members noted the issue of information security and governance is complex within multi-centre trials. It is difficult to be assured that each of the participating institutions have achieved a sufficient Information Governance (IG) Toolkit compliance score. Members noted that little information had been provided on all participating sites and requested the applicant to provide a list of sites where confidential patient information is to be processed. Members noted that it was unclear within the application what the roles of University College London Hospitals NHS Foundation Trust (UCH) and the London School of Hygiene and Tropical Medicine (LSHTM) are and requested further clarification as to which institution is data controller and which data processor.

The applicant responded to the request for clarification by providing a list of participating organisations and confirmed that University College London Hospitals NHS Foundation Trust was the data controller and London School of Hygiene and Tropical Medicine was the data processor. The Chair confirmed that the applicant provided a satisfactory response to the request of further information and content to advise support subject to the specific conditions.

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. Favourable opinion from a Research Ethics Committee.

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission for University College London Hospitals NHS Foundation Trust. Please see security review requirement section of the HRA website: http://www.hra.nhs.uk/resources/confidentiality-advisory-group/confidentiality-advisory-group-cag-application-advice/ and contact Exeter.helpdesk@nhs.net with any queries.

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

Amendments July 2015

Reviewers:

Name	Capacity	Items
Dr Mark Taylor	Chair	2a
Dr Tony Calland	Chair	1a
Dr Murat Soncul		1a
Dr Miranda Wolpert		1a
Mr Anthony Kane		2a
Ms Clare Sanderson		2a

2. AMENDMENT –RESEARCH

a) BINOCAR PIAG 2-08(e)/2002

Context

This application from the British Isles Network of Congenital Anomaly Registers set out the purpose of a study to provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies by means of national, regional and disease specific registers of congenital anomalies. A recommendation for class 1, 4, 5 and 6 support was requested to cover access to congenital anomaly registers.
Confidential patient information requested

Access was requested to mother's name, address, postcode, hospital number, NHS number and date of birth, and to baby's name, address, postcode, hospital number, NHS number, date of birth, date of death and address at conception.

The following registers were included:

• East Midlands and South Yorkshire Congenital Anomalies Register – University of Leicester
• Wessex Antenatally Detected Anomalies Register – University Hospital Southampton NHS Foundation Trust
• Congenital Anomaly Register for Oxfordshire, Berkshire and Buckinghamshire – University of Oxford

• South West Congenital Anomaly Register – University Hospitals Bristol NHS Foundation Trust
• National Down Syndrome Cytogenetic Register – Queen Mary University London
• Yorkshire and the Humber Congenital Anomalies Register – University of Leeds

Amendment request

Background

From 1 April 2015 responsibility for providing the surveillance function undertaken by the BINOCAR registers transferred to Public Health England (PHE), as part of this transfer a number of staff previously delivering the registers had been transferred to PHE under TUPE arrangements. PHE had requested support in order to collect prospective data and transfer legacy data held by BINOCAR registers to PHE. Joint letters had been submitted to CAG from PHE and BINOCAR which confirmed the approach for the transfer of this legacy data.

Current request

An amendment request was submitted from BINOCAR in May 2015 which requested an extension to the current support given until 20 June 2016 and linkages to ONS mortality and HES data from the Health and Social Care Information Centre (HSCIC). This request was to ensure that the research programme currently delivered by the BINOCAR registers could be continued, noting that the PHE application detailed surveillance purposes only.

The amendment detailed that once the linkages were complete the applicant intended to identify a third party (potentially the HSCIC) to retain identifiable data so that future linkages could be carried out without the applicant needing access to identifiable data items.

Confidentiality Advisory Group advice

The amendment was forwarded to a sub-committee of members who requested a discussion with the applicant to clarify the request and next steps. This meeting took place on 12 June 2015 and a brief summary is outlined below.

Members advised that whilst they recognised that an urgent extension would be required, a new application would be required in order to ensure that CAG had sufficient information to consider the request. It was noted that this whilst this was a time extension and additional data source request only, the potential alternatives had changed since the transfer of responsibilities to PHE and further information was required in relation to the specific purposes to be covered by the amendment.

In particular it was advised that the new application should detail the following:

1. Details of the research programme and activities supported by the BINOCAR registers.
2. Evidence in relation to considerations of practicable alternatives. For example whether the required information could be provided by PHE for the research programmes.
3. Further information in relation to the proposed exit strategy and timescales for this. The applicant was asked to consider the time extension outlined within their

request to ensure that this was sufficient and to provide further specific details in relation to the exit strategy.

Separately to the meeting, it was noted that the BINOCAR outcome letter dated 11 September 2014 following the 2014 annual review had requested the following:

1. Members advised that where patient information was to be obtained without consent, greater efforts should be made to engage with the public and queried whether further efforts could be made in relation to this application to engage with patients and the public.
2. Members noted limited information in relation to fair processing had been provided within the annual review and requested further information in relation to how it was ensured that patients were made aware of the registries and the processing of confidential patient information.

Members requested an update in relation to these points within the new application.

Members advised that a recommendation of support until 20 September 2015 should be provided to ensure that BINOCAR could continue to process the legacy data whilst a submission to CAG was made. It was advised that the applicant should submit to the August CAG meeting at the latest, and whilst consideration would be given as to whether this could be reviewed by a sub-committee, it was likely that this would need to be reviewed at a full CAG meeting. The applicant was asked to submit the application by 5pm on 21 July 2015.

Confidentiality Advisory Group conclusion

In line with the considerations above, members agreed that the minimum criteria under the Regulations appeared to have been met and advised recommending support to the Health Research Authority to allow the retention of data in the interim whilst a new application was submitted. The support should be provided until 20 September 2015 and a new application should be submitted by 5pm on 21 July 2015.

3. AMENDMENT –NON- RESEARCH

a) Inflammatory Bowel Disease Registry - CAG 6-07(d)/2013

Context

This application from Public Health England set out the purpose of the establishment of a national registry to provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies and rare diseases for the population of England.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to confidential patient information.

Confidential patient information requested

Access was requested to a variety of sources including cytogenetic laboratories, post mortem laboratories, ultrasound departments, delivery suites, computerised obstetric notes, ONS data, Personal Demographics Service and other outcome datasets. Name, postcode, NHS number and data of death were requested in order to carry out linkages, collect follow up data and to ensure the correct individual was identified. Legacy data from BINOCAR registers was also requested.

Confidentiality Advisory Group advice conclusion

National Registration Service Data

In relation to the prospective data collection from 1 April 2015 only, 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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support to be met or agreed to prior to final support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. V12 confirmed 01 April 2015

2. Submission of a final draft of the patient information leaflet. Provided by applicant 26 March 2015

3. Confirmation of how patient information would be disseminated to parents/patients. Provided by applicant 26 March 2015

4. Support extends only to the cohort specified within the application, suspected and diagnosed cases of congenital anomaly and rare diseases in England as defined within the application. Provided by application 26 March 2015

Specific conditions of support to be reported on at annual review stage

1. Continued exploration of options for adoption of a pseudonymised approach or consent as an exit strategy.

2. Further information in relation to the development of a web portal and how it is anticipated this will be implemented and managed.

3. Report on progress and effectiveness of fair processing plan, in particular in relation to informing patients reaching the age where they are able to provide consent themselves.

As the above conditions have been accepted or met this letter provides confirmation of final approval for the collection of prospective data as outlined with the application. I will arrange for the register of approvals on the HRA website to be updated with this information.

Legacy data

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided in relation to the legacy datasets. The following information should be provided prior to a recommendation being confirmed:

1. A joint letter from PHE and BINOCAR confirming the agreed approach to the management of legacy data.

A joint letter was received on 25 March 2015 which confirmed that the existing registers had all agreed to transfer data collected since 1 April 2013 to NCARDRS. It was confirmed that the existing BINCOAR data controllers would put in place measures to transfer, anonymise or destroy any datasets or an application would be made to CAG to continue processing following the expiration of their current approval at the end of June. Following this it was confirmed that the approval was extended to cover the legacy data collected since 01 April 2013.

A further joint letter was received on 11 May 2015 which confirmed that all existing registers had agreed to transfer all legacy data to the applicant.

4. Public Health England National Congenital Anomaly and Rare Disease Registration Service- CAG 10-02(d)/2015

Context

This application from Public Health England set out the purpose of the establishment of a national registry to provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies and rare diseases for the population of England.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to confidential patient information.

Confidential patient information requested

Access was requested to a variety of sources including cytogenetic laboratories, post mortem laboratories, ultrasound departments, delivery suites, computerised obstetric notes, ONS data, Personal Demographics Service and other outcome datasets. Name, postcode, NHS number and data of death were requested in order to carry out linkages, collect follow up data and to ensure the correct individual was identified. Legacy data from BINOCAR registers was also requested.

Confidentiality Advisory Group advice conclusion

National Registration Service Data

In relation to the prospective data collection from 1 April 2015 only, 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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support to be met or agreed to prior to final support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **V12 confirmed 01 April 2015**

2. Submission of a final draft of the patient information leaflet. **Provided by applicant 26 March 2015**

3. Confirmation of how patient information would be disseminated to parents/patients. **Provided by applicant 26 March 2015**

4. Support extends only to the cohort specified within the application, suspected and diagnosed cases of congenital anomaly and rare diseases in England as defined within the application. **Provided by application 26 March 2015**

Specific conditions of support to be reported on at annual review stage

1. Continued exploration of options for adoption of a pseudonymised approach or consent as an exit strategy.

2. Further information in relation to the development of a web portal and how it is anticipated this will be implemented and managed.

3. Report on progress and effectiveness of fair processing plan, in particular in relation to informing patients reaching the age where they are able to provide consent themselves.

As the above conditions have been accepted or met this letter provides confirmation of final approval for the collection of prospective data as outlined with the application. I will arrange for the register of approvals on the HRA website to be updated with this information.

<u>Legacy data</u>

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided in relation to the legacy datasets. The following information should be provided prior to a recommendation being confirmed:

1. A joint letter from PHE and BINOCAR confirming the agreed approach to the management of legacy data.

A joint letter was received on 25 March 2015 which confirmed that the existing registers had all agreed to transfer data collected since 1 April 2013 to NCARDRS. It was confirmed that the existing BINCOAR data controllers would put in place measures to transfer, anonymise or destroy any datasets or an application would be made to CAG to continue processing following the expiration of their current

approval at the end of June. Following this it was confirmed that the approval was extended to cover the legacy data collected since 01 April 2013.

A further joint letter was received on 11 May 2015 which confirmed that all existing registers had agreed to transfer all legacy data to the applicant.

This response was forwarded to a sub-committee of members who noted that the request had been satisfied and that final support for all legacy data could now be recommended.

Annual review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should therefore be provided no later than 1 April 2016 and preferably 4 weeks before this date.

5. Longitudinal Study of Young People in England (LSYPE)- CAG 1-03(PR3)/2014

Context

This application from Centre for Longitudinal Studies at the Institute for Education, University of London, sets out the purpose of a longitudinal study, previously managed and funded by the Department of Education (DfE) from 2004 until 2012. In 2013, the Economic and Social Research Council (ESRC) took over the funding of the study and management transferred to the Centre for Longitudinal Studies (CLS).

The aim of the study is to examine how health, wealth, education, employment and attitudes are linked, how they change over time and how they can vary between different people, at different points in time.

A recommendation for class 2, 3, 4 and 6 support was requested to cover access to:

1) GP registrations and addresses from the Health and Social Care Information Centre (HSCIC) so that individuals could be contacted and invited to continue participating in the study.
2) Notification from the HSCIC of deaths, embarkations (i.e. emigrations) and exits/entry from the NHS

Amendment request

It was noted that one external supplier had been appointed as Data Processor to carry out the survey fieldwork and associated mailings for the LSYPE Age 25 survey. The National Centre for Social Research (NatCen) had been contracted to

carry out: (1) Email and postal mailings to LSYPE cohort members about the study. (2) Interviews with LSYPE cohort members. Upon completion of these activities, the data files will be securely deleted from NatCen systems. Note: These activities were covered in the original application, but the Data Processor had not been appointed at that time.

An amendment was submitted to request an additional data processor (NatCen) with no change to the purposes, data sources, data items or data flows.

Confidentiality Advice Team advice

The amendment requested was forwarded to the CAT who noted the submission of a satisfactory IG toolkit for this application.

Confidentiality Advice Team 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.

5. Hip Fracture Audit – CAG 8-03(PR11)/2013

Context

This audit application was originally submitted by the Health and Social Care Information Centre and received approval by the Secretary of State for Health on 11 April 2011. The application set out aims to use case-mix, process and outcome data together with quality standards to improve the quality of care. A recommendation for class 1, 3, 4, 5 and 6 was requested to cover linkage with Hospital Episode Statistics (HES) data. Access was requested to NHS number, date of birth, date of death and postcode.

An amendment request to the original application ECC 3-04(s)/2011 was received on 30 August 2013, following prior discussions with the Confidentiality Advice Team, to change the data processor for this application to the Royal College of Physicians of London. The Healthcare Quality Improvement Partnership (HQIP) would remain data controller. An amended application and details of resultant changes to data flows were provided.

A further amendment request was submitted for the purpose of converting the date of death identifier to life status at thirty days and the return of the data to the submitting hospitals to perform root cause analysis of all deaths within thirty days. The amendment request also included to extend the user base to clinical teams within trusts for direct care purposes and also for secondary use of anonymised data for the purposed of audit, service evaluation and research. The applicant would only share anonymised data with credible third party applicants however; the amendment request was to allow the flow of confidential patient information to the HSCIC for the purposes of data linkage of HES data with subsequent flow of a linked (anonymised) dataset to the third party applicant organisation. A further

additional amendment was submitted in order to seek support for the purpose of submitting confidential patient information to the NHS Wales Informatics Service (NWIS) for linkage with PEDW and forwarding anonymised data to the relevant third party applicants.

Amendment request

The applicant had submitted an amendment request to match date of death received from Office for National Statistics (ONS) against the National Hip Fracture Database (NHFD). The amendment also incorporated the required changed to data flow, whereby, data including the only identifier date of death, to be flowed securely to the Royal College of Surgeons Clinical Effectiveness Unit (RCS-CEU) to perform case-mix adjusted mortality analysis.

Within the previous amendment request, the applicant included utilising an alternative method of converting date of death to life status at thirty days prior to release to RCS-CEU. The applicant had reported that the specified alternative method had been rejected for the following reasons:

1. Date of death enabled the applicant to ensure the outcome data are accurate by cross-referencing the date of death with other dates about the admission. The applicant had found that the ONS data can be erroneously linked to patients.
2. The applicant specified that alive at 30-days is not the only outcome of relevance to the NHFD. Both 90-day and 1-year mortality are valuable indicators of performance, and the original tender award for the Falls and Fragility Fracture Audit Programme by HQIP recommended introducing these outcomes at some point.
3. The analysis of survival could involve analysing data on patients who will not have completed the whole follow-up period and so their data will be censored. The applicant would need to know actual time of survival rather than a flag in order to accurately measure mortality rates. Ignoring patients with censored data will lead to biased estimates of mortality.

The applicant requested for the amendments requested to be in place until 31st March 2017, which is the end of the project.

Confidentiality Advisory Group Advice

The amendment request had been forwarded to the chair for review and it was noted that the purpose of the overall application was to record and review outcomes from hip fracture. The chair noted that date of death and associated data flow to the Royal College of Surgeons Clinical Effectiveness Unit was necessary and an important part of the dataset.

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 Secretary of State for Health.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. HSCIC Confirmed satisfactory IG Toolkit submission for Crown Informatics Limited on 3rd March 2015. HSCIC confirmed satisfactory IG Toolkit submission for Royal College of Physicians on 12th May 2015.

Chair's Action Report

July 2015

Officer:

Name	Capacity	Items
Dr Mark Taylor	Chair	1a
Dr Tony Calland	Chair	1b
Dr Patrick Coyle	Chair	2b

5. AMENDMENTS –NON-RESEARCH

b) MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) 15/CAG/0119 and ECC 5-05 (f)/2012

Context

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

A recommendation for class 2, 4 and 6 support was requested to cover access to confidential patient information from ONS and NHS Trusts. Patients treated between 1 Jan 2009 and 31 March 2017 would be included.

Confidential patient information requested

Access was requested to name, postcode, NHS number, date of birth and date of death in relation to maternal deaths, maternal morbidity, late fetal losses, late terminations of pregnancy, stillbirths, neonatal deaths and perinatal morbidity and mortality.

Amendment request

The amendment request detailed accessing confidential patient information from the National Confidential Enquiry into Suicide and Homicide (NCISH) at the University of Manchester, rather than directly from Mental Health Trusts, due a number of difficulties accessing the required information from Trusts. It was noted that there was now limited time for the inclusion of the cases in the confidential enquiries which were currently underway and for which the applicant was reaching the reporting stage. Whilst NCISH could provide questionnaires only, rather than case notes, the applicant confirmed that receiving copies of the questionnaires relating to these specific cases would allow the case assessors access to at some information about the perinatal mental health care of the patients to review and ensure that any additional lessons for improvements in care were not missed.

Confidentiality Advisory Group advice

This application was forwarded to the Chair who noted that the amendment was a change in data source, rather than extent of information requested. It was agreed that the amendment should be supported to ensure that these cases were not missed.

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 Secretary of State for Health.

c) NCEPOD- PIAG 4-08(b)/2003

Context

This audit application from the National Confidential Enquiry into Patient Outcome and Death set out the purpose of a study to review clinical practice and identify potentially remediable factors in the practice of anaesthesia, surgery and other invasive medical procedures including primary care. A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to patient data.

Amendment request

The applicant submitted an amendment request to inform that two studies were specified as starting this year, the first was Acute Pancreatitis and Mental Health in Acute Trusts. The amendment request was in relation to Mental Health in Acute Trusts. The original application and that of the applicant's annual review is an approval of the methods adopted to undertake confidential enquiries. The applicant was commissioned to start two topics each year and the method follows the standard retrospective identification case note review.

Confidentiality Advisory Group Advice

The amendment request was forwarded to the chair for review and consideration. The Chair noted that the request was for an extension to apply the same method that had been previously used and for which the applicant already has support to two new studies. The Chair agreed that the request was likely to be in the public interest and that no new issues had arisen.

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 Secretary of State for Health.

Specific conditions of support

a) Confirmation of suitable security arrangements via IG Toolkit submission. Confirmed by the Health and Social Care Information Centre (HSCIC) on 13th May 2015.

6. AMENDMENTS -RESEARCH

a) An ongoing case-control to evaluate the NHS Breast Screening Programme (NHSBSP)- ECC 6-05 (e)/2012

This research application from Queen Mary University of London (QMUL) detailed a case control study to evaluate the impact of the National Breast Screening Programme. The study would incorporate the following four case control comparisons:

- Breast cancer deaths with living controls to assess impact on mortality;
- All breast cancer cases with disease-free controls to assess the effect on breast cancer incidence;
- Late stage breast cancer cases with controls to assess the effect on incidence of late stage disease;
- Breast cancer deaths with surviving breast cancer cases to assess the interplay of early detection, tumour attributes and treatment on mortality from breast cancer

A recommendation for class 1, 4 and 5 support was requested to cover disclosure of MRIS and cancer registry data to NHS Connecting for Health. NHS Connecting for Health would then link MRIS, cancer registry and NHAIS screening data and identify controls. A linked dataset including NHS number, date of birth and date of death would be transferred to QMUL for analysis purposes.

Confidential patient information requested

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

Amendment request

An amendment to the approval was requested for a change to data items following the pilot phase of the study. Ethnicity was no longer requested. Month and year of treatments was added.

Confidentiality Advisory Group advice

The amendment was forwarded to the chair who agreed that support should be recommended for a change to the data items requested. It was noted that this amendment was justified on the basis that it was a minor change to the data items that had no impact on identifiability.

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.
2. Confirmation of a favourable opinion from a Research Ethics Committee.