Appendix 1. Confidentiality Advisory Group Sub Committee Minutes (approved 08/09/2016)

Correction made to conditions of support for CAG 8-06 (b)/2013 on 21.12.16

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

August 2016

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Ms Natasha Dunkley	Confidentiality Advice Team

1. NEW AMENDMENTS: ECC 1-06 (c/2011 National oesophago-gastric cancer audit

Amendment request

A valid amendment, signed off by the data controller, HQIP, was received on 01 August 2016. The amendment documentation confirmed that a change to the approved data flows was requested. In particular, support was requested to share fact of death of a patient with the Trust and individual surgeon who operated on that patient.

The amendment confirmed that NHS Digital had been commissioned by HQIP, as part of the audit programme, to publish clinical outcomes at consultant and organisation level. The process for collecting and analysing the data to support this was indicated to be via the existing approvals in place under this reference. The paperwork indicated that publication of results at consultant level is sensitive and is likely to form part of the patient decision and choice as to whom they would wish to be referred for treatment. In light of this, the view was expressed that it would be important for the data quality to be accurate. As part of the Clinical Outcomes Programme process, the results are fed back to Trusts and those consultants who operated on the patients, prior to publication, to allow sufficient time to check and amend any incorrect entries and to submit any missing data. One of the metrics is risk adjusted mortality and ONS data provides the fact of death.

Confidentiality Advisory Group advice

This was reviewed by the chair and agreed this was a reasonable amendment and support should be recommended.

Reviewers:

Name	Capacity
Dr Tony Calland	Vice Chair
Dr Martin Andrew	Reviewer
Ms Hannah Chambers	Reviewer
Dr Harvey Marcovitch	*Reviewer*
Ms Natasha Dunkley	Confidentiality Advice Team

1. 16/CAG/0097 Pathways of Care for young people in secure institutions (national service evaluation) – follow-up to provisional support outcome

A teleconference took place on 24 August 2016 in response to the CAG request to discuss the provisional support outcome. Members had recommended support at the meeting on 04 August 2016 however there were a number of clarifications members thought could be more readily facilitated through a discussion with the applicant. The teleconference was attended by Professor Annie Bartlett on behalf of the applicant.

This application from Central and North West London NHS Foundation Trust had set out the overarching purpose of undertaking a NHS England-funded service evaluation linked to Child and Adolescent Mental Health Services Transformation (see minutes from 04 August 2016 for further detail).

Provisional support had been recommended, subject to clarification as to scope, who would require access, methodology of data extraction, clarification as to the relevant population and further detail on appropriateness as to a mechanism for patient objection.

It was agreed that the applicant would provide a response to the issues raised in line with the discussion, that would be reviewed by those present on the teleconference.

19 July 2016

Reviewers:

Name	Capacity
Dr Tony Calland	Chair
Rachel Heron	Confidentiality Advisor

2. NEW AMENDMENTS

14/CAG/1028 British Childhood Visual Impairment and Blindness Study 2

Context

This application from University College London set out the purpose of the first national epidemiological study to determine the incidence, mode/context of detection, determinants/risk factors, management and short term health and social outcomes of all-cause visual impairment and blindness in childhood (i.e. across the full spectrum of visual disability as per the WHO international classification).
The study would use data only collected from managing ophthalmologists and paediatricians using national active surveillance, including the British Ophthalmological and Paediatric Surveillance Units. There would be no patient contact. The study was supported by the British Childhood Visual Impairment Group.
The study would investigate variations in visual impairment by socio−demographic factors (sex, ethnicity and socio−economic status as measured by deprivation index from postcode). The British Childhood Visual Impairment study (BCVIS; which was limited to severe visual impairment/blindness), undertaken by the research team 10 years ago, reported, for the first time, an association between childhood blindness, socioeconomic status and ethnicity. BCVIS2 would also assess whether there had been an increase in inequality.
A recommendation for class 1, 2, 4, 5 and 6 support was requested to support the extracting and anonymising the information, obtain and use information about past or present geographical location, link patient identifiable information obtained from more than one source, for auditing, monitoring and analysing patient care and treatment and to allow access to an authorised user for one or more of these purposes.

Amendment request

The request was for the research team to assist some consultants in completing the data collection forms on their behalf, to reduce the workload for the consultants. The research team would travel to the hospital in question and transcribe data from the routinely collected ophthalmology notes to the data collection forms. This would be arranged under the supervision and with assistance from their clinical teams. This would ensure

that there was no missing data, which would have an impact on the validity of the findings since this was a rare condition of public health importance and national surveillance was the only means of achieving an unbiased dataset.
The amendment would not involve gaining access to any data other than those which the clinicians would themselves have returned had they completed the data collections forms solely by themselves.
In addition to this the research team requested support to use NHS numbers retained for governance purposes in order to carry out follow-up in order to ascertain longer-term outcomes of visual impairment. This would be subject to approvals for each use of the data.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who was of the opinion that it was reasonable for the research team to collect data from hospital notes, to reduce the calls on clinician time. This would not involve the collection of any additional data to that already approved.
The Chair observed that the data that had support to be kept for governance purposes was now required for follow-up studies. This could lead to findings which would benefit patients with visual impairment and would not involve the collection of any additional data.

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.

21 July 2016

Reviewers:

Name	Capacity
Dr Tony Calland	Chair
Mr David Smallacombe	Committee member
Ms Gillian Wells	Committee member
Ms Rachel Heron	Confidentiality Advisor

3. NEW AMENDMENTS

ECC 3-04(f)/2011

Context

This research application from the South London & Maudsley NHS Foundation Trust set out the purpose of investigating the associations between specific mental disorders in secondary mental health care (schizophrenia, schizoaffective disorder, bipolar disorder and dementia) and physical illness. This would use a new linked dataset containing health records for patients with these disorders from the SLAM BRC Case Register Interactive Search (CRIS) and general hospital records from the English national Hospital Episode Statistics (HES) database. Review of this application was sought so as to provide a legitimate basis for the processing of this patient identifiable information; to effectively test this 'honest broker' capability and to permit the linkage and subsequent anonymisation.

Confidential patient information requested

Access was requested to name, date of birth, sex, address, postcode and NHS Number.

Amendment request

This application was to use the HES data already linked to CRIS to investigate presentations to hospital due to suicidality and self-harm by young people. It extended the scope of the original application by requesting to use data relating to children under the age of 18 whereas the original application only covered adults. A previous amendment dated 28/11/2013 had extended permission to allow the use of under 18s data for a project looking at epilepsy outcomes in children with autistic spectrum disorder treated with psychotropic medication.
The planned project would use HES A&E data for patients known to SLaM to ascertain A&E attendances, with linked clinical record data being used to get information about the reason for attendance. It would also use HES inpatient data to ascertain admissions

coded as due to self-harm, and physical health co-morbidities in those presenting with self-harm and suicidal behaviour. It would use HES data on all residents in the area covered by SLaM to provide a comparison population.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair, who determined that as the amendment involved both mental health data and the use of health care data relating to minors, it required review by Sub-Committee.
The Sub-Committee noted that the amendment involved the use of a control group, who would not directly benefit from this use of their data. However, it was agreed that there was a strong public interest in this research, which the Confidentiality Advisory Group had already supported for a different (and potentially less relevant) group of patients.
The Sub-Committee considered the patient information provided, which had been previously approved by the Confidentiality Advisory Group for children and young people. It was deemed adequate for this project.

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.

Reviewers:

Name	Capacity
Ms Clare Sanderson	Chair
Ms Rachel Knowles	Committee member
Dr Murat Soncul	Committee member
Rachel Heron	Confidentiality Advisor

4. NEW AMENDMENTS

CAG 8-06(b)/2013 National Chronic Obstructive Pulmonary Disease (COPD) Audit Programe – Secondary Care Clinical Audit

Context

This audit application from the Royal College of Physicians of London (RCP) followed a successful secondary care audit feasibility pilot (CAG 5-07(a)/2013) and sought support for the full secondary care audit element of the programme. A recommendation for class 1, 4, 5 and 6 support was requested to collect data via a web-based audit tool from every eligible organisation in relation to consecutive cases identified prospectively from February 2014 to May 2014, comprising approximately 200 NHS Trusts.

Amendment request

The amendment proposed a change in data processing methodology, and data processor. The new data processor – Crown Informatics - could enable data to be collected continuously, replacing the current system of snapshot audits at set time periods. Crown Informatics would enter the data into a bespoke web based audit tool, and transfer it to HSCIC, DARS and NWIS. The data would be linked and returned to Crown Informatics, still in identifiable form.

Crown Informatics requested support to combine and pseudonymise the data (this function was previously carried out by HSCIC). Support was also requested for Crown Informatics to share the data with other bodies including researchers, and to provide identifiable data on the behalf of researchers or auditors for linkage.

A change in data items was also proposed. The following items would be removed: cause of death, ethnicity, Hospital Unit Identifier, and time of discharge. The following additional items would be collected: gender, date and time of admission, date and time of arrival and date of discharge. Other data items to be collected remained the same as in the original application.

Confidentiality Advisory Group advice

The amendment was considered by a Sub-Committee.

The Committee considered whether the change to continuous data collection would significantly increase the numbers of patients included in the audit or would simply increase the turnaround time for the audit. It was agreed that clarification would be sought from the applicant.

The provision of data to other organisations was discussed. The Committee noted that the data flow diagram signified that the data transferred would be aggregate data, rather than patient level pseudonymised data. Confirmation was sought that this would be the case.

The Committee noted that organisations receiving data would be approved by Patient Voices and HQIP. It was recommended that further information about data sharing with other organisations be placed on the website, for transparency.

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.
2. Clarification to be provided with regards to whether the number of patients included in the audit will increase
3. Confirmation that only aggregate data will be provided to other organisations
4. Updated patient information leaflets and posters to be provided, with clear information on how to opt out of this use of patient data.
5. It was recommended that information about the sharing of data with other organisations is provided, for example on a website, in the interests of transparency.

12 August 2016

Reviewers:

Name	Capacity
Ms Clare Sanderson	Chair
Ms Rachel Heron	Confidentiality Advisor

5. NEW AMENDMENTS

16/CAG/0009 Risk of Malignancy after Gamma Knife Stereotactic Radiosurgery, Ten Years On

Context

This application from the National Centre for Stereotactic surgery at Sheffield teaching hospital NHS Trust set out the purpose of evaluating the risk of malignant transformation by matching their treated patient population with national cancer register statistics and evaluating survival data. An earlier study was completed by in 2005 and assessed the risks in the initial 5014 UK patients, with 30,000 years of follow-up. The applicant was now re-running the study to strengthen the data by including further follow-up for the original 5014 patients and all UK patients treated by them in the last ten years.

Amendment request

The initial application requested approval to send the NHS number to HSCIC for linkage. However the applicant had been informed that the minimum required for HSCIC linkage purposes was the NHS number and the Date of Birth. The request was therefore for 1 additional data item (DOB) to be sent to HSCIC.

Confidentiality Advisory Group advice

The amendment request was sent to the Chair who was happy to support the request, subject to confirmation that this was the only change to the application. The application form had also stated that there would be a change to data flows.

The applicant confirmed that only this additional data item was being requested and that she had checked ‘change to data flow’ in error.

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.

12 August 2016

Reviewers:

Name	Capacity	Items
Dr Murat Soncul	Chair	1
Rachel Heron	Confidentiality Advisor	1

6. NEW AMENDMENTS

16/CAG/0068 Cancer Research UK (CRUK) bowel cancer screening endorsement mailing

Context

This application from Cancer Research UK set out the purpose of this request to facilitate two mailings of a targeted CRUK and NHS branded personalised bowel cancer screening endorsement direct mailings The overarching aim of the project was to increase participation of the Guaiac Faecal Occult Blood Test (gFOBT) i.e. the bowel cancer screening programme by raising awareness of the Bowel Cancer Screening Programme (BCSP) amongst the eligible population and reduce barriers to participation.

This project sets out to test the effectiveness of introducing an additional step in the bowel cancer screening programme call process (when combined with a supporting advertising campaign) on increasing participation in the BCSP.

The project was informed by 2 previous pilots in London and Wales. These found that advertising combined with direct mail (London pilot) and a highly targeted and personalised version of direct mail (Wales pilot), were effective methods of improving uptake. This project will apply learning from both previous pilot projects, and has the potential to increase uptake beyond 9% in some groups. Each of the four participating bowel cancer screening hubs has confirmed their support for the project.

A recommendation for class 4 and 6 support was requested to allow the disclosure of confidential patient information from 4 NHS Bowel Cancer Screening programme hubs to a third party data processor, Real Digital International, on a daily basis (week days only) between Monday 21 March 2016 to Friday 22 April (25 days).

Amendment request

A number of changes were proposed:

The launch of the original mail-out was delayed, so an extension to the time limit was requested to allow it to be completed. Only 1 Bowel Screening Cancer hub would participate, rather than 4 as originally suggested.

Based on evidence that males were less likely to participate in the bowel screening programme than females, and that males may respond better to literature targeted specifically to them, new gender-specific letters had been produced.

In light of a recent directive from the Secretary of State, the Health and Social Care Information Centre (HSCIC) is required to establish and operate a system to process and uphold Type 2 Objections, and in accordance with the principles outlined. In light of this, the applicant was required to make an adjustment to the way in which data was extracted from the bowel screening programme, to ensure that Type 2 objections were upheld and that nobody who had registered an objection would receive a mail out. This would involve a small change to the data flow.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair who was of the opinion that the change to data flows was in line with the original approval.

The gender specific letters appeared to have been adequately justified.

It was commented that the mail out appeared to be planned for a specific time period during the year. The reduction in screening hubs was seen as a welcome change.

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.

<u>Specific conditions of support</u>

1. Confirmation of suitable security arrangements via IG Toolkit submission.

15 August 2016

Reviewers:

Name	Capacity
Dr Patrick Coyle	Chair
Dr Kambiz Boomla	Committee member
Mr Anthony Kane	Committee member
Ms Rachel Heron	Confidentiality Advisor

2. NEW AMENDMENTS

PIAG 3-06(i)/2004 Does long-term use of aspirin reduce the risk of colon cancer?

Context

In 2004, the University of Oxford gained ethical approval and support under the Regulations to collect the cancer registrations from a historical cohort of patients recruited to a completed clinical trial on the effectiveness of treatment with aspirin after transient ischaemic attack conducted in the 1980s. The results of this study together with two other trials showed aspirin significantly reduced the risk of developing colon cancer.

Amendment request

Bayer, the marketing authorisation holder of aspirin, had sought advice from the European Medicines Agency (EMA)about the possibility of gaining regulatory approval for the use of aspirin in the primary prevention of colorectal cancer (ie change of indication). They were advised that source data verification by an independent clinical trials organisation would be required for an application to be considered.

The amendment sought support to re-request the data, which included identifiable data, to allow source data verification to be carried out.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair who advised that this amendment should be reviewed by Sub-Committee.

The Sub-Committee noted that source data verification would take place on site under the supervision of the Chief Investigator of the original study, and that no patient identifiable information would be removed from the site.

The Sub-Committee agreed that this application had demonstrated public interest, in its aim of enabling Bayer to market aspirin as a drug to prevent bowel cancer, which could save lives.

It was agreed that it would be impracticable to attempt new patient notifications given that the data had been collected in the 1980s when patients were in their 30s and had been diagnosed with bowel cancer, therefore many of the patients would be deceased.

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

3. Confirmation of suitable security arrangements via IG Toolkit submission.
4. Confirmation of a favourable opinion from a Research Ethics Committee.

16 August 2016

Reviewers:

Name	Capacity
Dr Patrick Coyle	Chair
Ms Rachel Heron	Confidentiality Advisor

3. NEW AMENDMENTS

CAG 10-08 (b)/2014 Building Blocks 2-6: parenting support to reduce maltreatment

Context

This application from Cardiff University set out the purpose of following up a cohort of 1562 women and children until the child reached age of 6 in order to assess whether Family Nurse Partnership (FNP) reduced maltreatment of children.

A recommendation for class 4 and 6 support was requested in order to carry out linkage of Hospital Episode Statistics data to assess BB 0- 2 data which includes FNP data. Cardiff University would provide demographic data only to the Health and Social Care Information Centre (HSCIC) who would use this data to select relevant clinical records. Clinical data including the unique ID would be passed to Health Information Research Centre (HIRU) and linked using Secure Anonymised Information Linkage (SAIL). Cardiff University will provide the BB trial data to HIRU with the same unique ID. The linked dataset will be stored at HIRU.

Follow up data would be extracted at the child's 4th and 6th birthday.

Amendment request

The amendment request consisted of two aspects:

In response to the HSCIC requirements for fair processing, the applicant had produced a new letter for participants to better inform them what would happen to their data. This was to be published on the website and sent to withdrawn participants. The letter was provided for review, and approval requested to enable the applicant to access HSCIC data.

In order to fully answer the secondary outcome set out in the Protocol – to assess subsequent pregnancies in trial participants – abortion data was to be requested from the DoH. This would enable subsequent pregnancies to be calculated using self-report, HES data and abortion data, allowing an important outcome to be measured.

Confidentiality Advisory Group advice

The amendment was reviewed by the Chair, who noted that the data requested was sensitive. However the matter of the abortion data was being dealt with appropriately. The data flows were observed to be the minimum necessary for linkage and the clinical data released was pseudonymised.

No issues were raised in relation to the amended information for participants.

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.