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

June 2017

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **TRIPHIC (Translation Research in Pulmonary Hypertension at Imperial College)**

CAG reference: **CAG 4-09(a)/2013**

Protocol number: **1.0**

IRAS Project ID: **99940**

REC number: **13/LO/0695**

Context

Purpose of Application

This application from Imperial College Healthcare NHS Trust detailed the establishment of a research database for use in research projects into pulmonary vascular disease. Data from established datasets within Imperial College and at the HSCIC would be linked and pseudonymised to be used for research purposes. Approximately 2000 patients had been referred to the National Pulmonary Hypertension Service at Imperial over the last decade and the database would include all these patients.

The application detailed linking the following datasets:

1) The Integrated Computerised Hospital Information System (ICHIS)
2) Internal Communication Environment (ICE)
3) The cardiopulmonary exercise testing data
4) Lung function database
5) The National Pulmonary Hypertension Audit (NPHA) database

A recommendation for class 1 and 4 support was requested to allow the Database Manager access to all retrospective information held in local databases and from the NPHA database. NPHA data would be accessed via the Health and Social Care Information Centre (HSCIC) and linked to mortality data from ONS.

Amendment Request

The amendment was submitted to clarify the data items and specific flow of confidential patient information into TRIPHIC, both indirectly from the PHDATA database (used by the

clinical service) and directly from the dedicated Pulmonary Hypertension Biobank and Trust's Pathology server. The amendment documentation also detailed a reduced number of pathology data items required.

The amendment also responded to previous query raised by the CAG around how the applicants would reduce the need to access confidential patient information without consent.

Data Flows and Data Items

The Chair agreed that the proposed changes outlined to data flows and data items to be held in TRIPHIC were sensible and did not pose any additional risk to patient privacy. Support was recommended for the changes as outlined within the amendment form.

Prospective Consent

The applicants identified within the amendment submission that they would be moving away from the requirement for support under the Regulations as they will be prospectively seeking patient consent. However, it was confirmed that continued support was required for those existing patients that were no longer being treated and therefore won't be seen in clinic to obtain their consent together with deceased patients. Further clarification was sought from the applicants in respect of this point – the following clarification was provided:

The applicants would ideally approach all patients for donation of blood/urine samples and their consent to use data in TRIPHIC. However, this was not possible due to the time constraints at clinical appointments and limited number of staff available to undertake consent and collect/process samples.

In the prospective study, the applicants intended to focus efforts on enrolling new referrals to the service and the follow up of incident cases and long-term survivors who already donated samples. Regarding other individuals with data in TRIPHIC, the applicants intended to enrol as many as possible in the prospective study while also informing all patients (via the one page flyer – Use of patient information for research, version 1.0 09/12/2016) that their information had been collected for research. Patients would then have the opportunity to withdraw, should they object to the TRIPHIC system, or be approached for their informed consent.

The Alternate Vice-Chair considered the response and reminded that once a patient had been approached for consent and either declined to provide this or did not respond to the request it was no longer possible to access this individual's data via support under the Regulations.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Alternate Vice-Chair who noted that this amendment did not involve further access to identifiable information and that the amendment would result in a richer pseudonymised resource.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Support does not extend to those patient who are approached for consent and to provide samples and either decline or do not respond.
2. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14, 2015-16 at 66% satisfactory)**
   Confirmation of a favourable opinion from a Research Ethics Committee.
   (Confirmed – 21/02/2017).

Reviewers:

Name	Capacity
Ms Sophie Brannan	CAG Member
Dr Tony Calland	Vice Chair
Dr Patrick Coyle	Vice Chair
Ms Clare Sanderson	Alternate Vice Chair
Dr Murat Soncul	Alternate Vice Chair
Dr Mark Taylor	Chair
Ms Rachel Heron	Confidentiality Advisor

Application title:	**Long term follow up of asymptomatic carotid surgery trial (acst-1)**
CAG reference:	**16/CAG/0122**
IRAS project ID:	**194088**

Context

This application from the University of Oxford set out the purpose of ascertaining whether the risks of dementia were reduced in patients with narrowing of the carotid artery (a blood vessel in the neck) who underwent carotid endarctectomy (an operation to reduce this narrowing), compared with those allocated to treatment as usual.

In order to do this the applicant proposed to follow up participants from a large, randomised controlled trial, which took place in the UK and Sweden between 1993 and 2008, comparing these two groups for risk of stroke (ACST-1). At the time this trial demonstrated a small reduction of the risk of stroke following endarctectomy in the 5 to 10 years after the operation. To study longer term effects, the applicant would link the UK participants from ACST-1 with data from HSCIC/NHS Digital. Name, NHS number and date of birth would be sent to NHS Digital in order to obtain HES data and ONS mortality data. Date of death, gender, and date of birth would be returned and retained by the study team in order to link participants back to the original study record.

Although consent was given for researchers to access medical notes for audit purposes, consent was not given for the purpose of this study.

A recommendation for class 4 and 6 support was requested 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.

Amendment Request

The application described the data required in order to answer the research question, however due to a recent restructuring of patient records resulting from a re-classification of dementia, this data was now located in the Minimum Mental Health Dataset. The application had not specified that access to this dataset would be required. They also wished to link to the National Dementia and Antipsychotic Prescribing Audit dataset.

Linkage to the Mental Health Minimum dataset and the Dementia Prescribing audit would enrich this study significantly since dementia may actually be more commonly reported in these datasets than HES or death certificates. The amendment therefore requested access to this dataset.

Confidentiality Advisory Group advice

The application was originally approved via the Precedent Set pathway, which usually excludes applications requesting access to mental health data.

The amendment request was forwarded to the Chair, who was of the opinion that this deviation from the usual process should be considered by the CAG Chair team.

The amendment was forwarded to all CAG Chairs for discussion. It was agreed that amendments relating to the re-classification of dementia data would be considered by the CAG on a case by case basis. In this instance, the Chair team agreed that this access to the mental health dataset did not raise significant concerns and a review by the CAG was not warranted.

It was recognised that dementia data had only recently fallen within the Minimum Mental Health Dataset, and that the access to this data was in line with the original approval. The Chair team was satisfied that support could be given in this case via Chair's Action.

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. **V14 confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed January 2017.**

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Ms Rachel Heron	Confidentiality Advisor

Study title: **National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme**

CAG reference: **CAG 8-06(b)/2013**

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

This audit covered the collection of audit data for all admissions to hospital for acute exacerbation of COPD in England and Wales, on a continuous basis. Identifiable secondary care data was entered into a bespoke web-based audit tool provided by Crown Informatics, which carried out linkage with HES, ONS and PEDW data via NHS Digital and NWIS. The data was returned to Crown informatics, who then transferred the data to Royal College of Physicians (RCP) for analysis. This data was identifiable (the applicant referred to it as 'pseudonymised + date of death').

The amendment requested the addition of Imperial College London as an additional data processor, as they would be sub-contracted to lead on statistical analysis of audit data. The linked dataset would therefore be returned by Crown Informatics to ICL as well as to RCP.

Updated patient materials included the phrase 'Imperial College London will work with the National COPD Audit Programme to analyse the data'.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair, who requested further information. The applicant provided responses (in italics) via email on the 24 May 2017, as outlined below:

Please provide a justification as to why it is not possible for Imperial to conduct the analysis remotely on the RCP data so that a further copy isn't necessary.

The reasons why it is not possible for Imperial to conduct the analysis remotely on the RCP data are outlined below:

- *Data analysis by Imperial will require complex statistical analyses using software and code that is not routinely available on RCP systems.*
- *Installation of software such as STATA on 'virtual' PCs for remote access is currently impractical for reasons of licensing.*

- *Data analysis by Imperial will require complex statistical analyses which are likely to require more processor capacity than is available on the RCPs virtual computers.*
- *In line with RCP information system policies, access to RCP 'virtual PCs' is limited to staff with a contract of employment with the RCP.*

The Chair reviewed the response and was happy with the justification provided.

The dataset returned to RCP and ICL is described in the amendment form as 'pseudonymised + date of death', however the data flow diagram states the Date of Death is translated to survival days by Crown Informatics and not included in this dataset – please clarify which is correct?

Apologies for this oversight, the data-flow diagram is correct (i.e. date of death will be translated to survival days by Crown Informatics and not included in the dataset). I have amended the form to reflect this – please find attached.

The Chair reviewed and approved this response.

Please further clarify the new data flow diagram as follows: - please clarify the data flow from the web-tool to ICL as well as from Crown Informatics, and also the statement that ICL will be providing data instead of Crown Informatics, but the data flow diagram illustrates a data flow from Crown to other parties.

The data-flow diagram has been updated to reflect the fact that ICL do not receive data directly from the web-tool, but only receive it once it has been processed by Crown Informatics.

ICL will be responsible for securely transferring the cleaned, de-identified audit data (either patient-level or aggregated) to credible applicants (i.e. those whose request has been approved by both HQIP (as data controller) and the RCP). However, if the applicant organisation require both audit data and outcome data (i.e. linked data), the data flows will be as per the previously approved (in 2016) amendment:

Should the applicant organisation require both audit data and outcome data (i.e. linked data), permission is sought to allow the flow of identifiable data to NHS Digital and NWIS (from Crown Informatics) for the purposes of data linkage (e.g. with HES, ONS or SUS) with subsequent flow of a linked (anonymised) dataset from NHS Digital to the applicant organisation.

This is because Crown Informatics are the only organisation which has access to the identifiers and, therefore, would be able to facilitate these requests. Please note, these requests are rare and in the majority of cases (i.e. which are requests for unlinked data) it would be more appropriate for applicant organisations to access cleaned data. I have updated the data-flow diagram to make this more clear – please let me know if more is required or if I misunderstood the request.

The Chair was satisfied with this explanation.

The applicant was asked to provide a letter from HQIP confirming that they approved the amendment, as data controller. This was provided on 24 May 2017.

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. **Checked and confirmed published and reviewed, for RCP, ICL and Crown Informatics.**

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Ms Rachel Heron	Confidentiality Advisor

Study title: **National Prostate Cancer Audit**

CAG reference: **CAG 8-03(PR9)/2013**

Context

Purpose of application

This application refers to a collaborative prostate cancer audit which is part of the Healthcare Quality Improvement Partnership programme looking at treatment and outcomes for all patients. The application detailed the linkage of the HES dataset already held by the Royal College of Surgeons (PIAG 2-07(i)/2004 Audit of outcomes after surgical procedures using linked HES data and ONS mortality data) to cancer registry data held by Public Health England using the Health and Social Care Information Centre's date linkage service.

Amendment request

This amendment request was for the data flow, data items and duration, as follows:

- Data flow - The Wales Cancer Network, Public Health Wales, will supply a pseudonymised NPCA data extract direct to the CEU containing information for men diagnosed from April 2015 onwards (for the duration of the NPCA) linked to corresponding PEDW and ONS records (data flow diagram was attached).
- Data items - Additional data items have been added to the NPCA Prospective Audit minimal dataset (items were listed in attached appendix)
- Duration - An extension to duration until March 2018.

Confidentiality Advisory Group advice

The amendment request was forwarded to the Chair, who made the observation that the changes were consequent upon organisational changes in Wales. The data sources were the same, and there was no real change in the flow of identifiers: - the Clinical Effectiveness Unit at the Royal College of Surgeons still only received pseudonymised 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 Secretary of State for Health.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **V14 confirmed published and reviewed as Satisfactory.**

Reviewers:

Name	Capacity
Dr Patrick Coyle	Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Context

This audit application 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. The audit was administered by the Royal College of Physicians (RCP) as data processor on behalf of HQIP.

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.

Amendment Request

This amendment is to add Clinical Practice Research Datalink (CPRD) to the list of NHS Digital held datasets that National Hip Fracture Audit database data may be linked to. There amendment request did not involve any additional data flows as linkage would be facilitated by NHS Digital with whom support was already in place to facilitate linkage.

Confidentiality Advisory Group Advice

The amendment was considered by the Vice Chair, who acknowledged that there was no requirement for the use of any additional identifiers to facilitate the additional data linkage. The Vice Chair advised that the link to the CPRD would allow a much better understanding of the influence of co-morbidities and possible confounding factors for the 9% of the National Hip Fracture Audit patient population which are held within the CPRD and help inform decisions around which other fields need to be collected for the whole database.

Confidentiality Advisory Group Advice 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 Secretary of State for Health.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed - Royal College of Physicians (8J008-CSD), Version 14 confirmed published and reviewed as satisfactory at 97%, Crown Informatics (8J157) Version 14 confirmed published and reviewed as satisfactory at 97%).**

Reviewers:

Name	Capacity
Ms Clare Sanderson	Alternate Vice Chair
Ms Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Confidential Inquiry into Suicide and Homicide by People with Mental Illness**

CAG reference: **PIAG 4-08(d)/2003**

Context

The original application considered by PIAG in 2003 detailed a national study of adverse incidents within the NHS psychiatric services which aimed to improve the clinical care provided.

Amendment Request

The amendment requests changes to the questionnaires which are completed by clinicians in relation to patients who are included within the NCISH database. Copies of the revised questionnaires were submitted for consideration. The applicants advised that the questionnaires are subject to ongoing review to ensure that the data collected remains relevant and complete to enable the aims of the Inquiry to be achieved.

The amendment also clarified that the recent pilot of a secure online website to capture our questionnaire data had been successful. The pilot was covered by a historic REC and CAG approved amendment to the National Confidential Inquiry. As such the questionnaire changes would be applied to the online questionnaire and the paper version of the questionnaire that will be retained for those clinicians that request this format.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Alternate Vice Chair who agreed that the proposed amendment was fully justified as this ongoing confidential enquiry was in the public interest as suicide prevention remains a high priority. The Chair agreed that the proposed amendment would assist the applicants in ensuring they had complete data.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14, 2015-16, Satisfactory Reviewed Grade at 80%)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – Favourable Opinion issued 01/06/17.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Context

This application from the National Cancer Services Analysis Team (NATCANSAT) set out a study which would establish a central data collection on patients receiving radiotherapy treatment in the UK.

The collection of the Radiotherapy Dataset transferred to Public Health England (PHE) on the 1 April 2016. NATCANSAT continued to hold historic data until receiving confirmation from PHE that the data now held by PHE was complete and adequate. After this the data held by NATCANSAT would be destroyed.

Amendment request

Confirmation from PHE that the data held by NATCANSAT could be destroyed was not received until 24 March 2017, which meant that the data could not be destroyed by the specified date of 31 March 2017. Therefore the request was for an extension of the time period of support until the 31 August 2017, to allow time to destroy the data.

Confidentiality Advice Team advice

The CAT observed that the extension was requested in order to allow data processing for an extended time period, in order to delete the data. This was in line with previous correspondence.

The amendment form referenced other activities carried out by NATCANSAT for which there was an existing legal basis (CAG 1-06 (FT2)/2013 for which s251 support was ongoing, and the provision of radiotherapy data to the Head and Neck 5000 clinical trial with explicit patient consent. To continue with these activities, some previously collected data from the Radiotherapy Dataset would be retained.

On the understanding that all data held under s251 support for PIAG 3-09(g)/2003 would be destroyed by 31 August 2017, the CAT recommended support for this amendment.

Confidentiality Advice Team conclusion

In line with the considerations above, the CAT 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. **V14 published and reviewed as satisfactory.**

Reviewers:

Name	Capacity
Dr Tony Calland	Vice Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **SABRE (Southall and Brent Revisited)**

CAG reference: **ECC 8-02(FT5)/2010**

IRAS Project ID: **61089**

REC number: **07/H0712/109**

Context

Purpose of application

This project is a follow-up of a unique cohort of 4,858 people of South Asian, African Caribbean and European origin who were aged 40 to 69 and living in northwest and west London when first studied. The South Asian and African Caribbean participants are all first generation migrants to the UK. The study set out to examine the association between insulin resistance and cardiovascular risk in people of European, South Asian and African Caribbean origins who were living in West London.

The 3,400 surviving participants are now aged between 65 and 98. They underwent very detailed clinic profiling at baseline, at 20 years and a third wave of follow-up is currently in progress at 25 years.

Support was sought in order to permit access to cancer registration and mortality data in order to link to mortality data. A recommendation for class 1, 2, 4 and 6 support was requested to cover access to these datasets.

Amendment Request

Support was requested for a further HES extract to April 2017 in order to bring the hospital admission data up to date for this study's long-standing cohort.

An amendment had previously been submitted for HES data to be released up to April 2016, for which support was recommended in May 2016. The applicants advised that it had taken some time for the review process with NHS Digital; however, they were now in a position to approve the data release. This amendment request would enable release of the additional year of follow-up data together with this historically approved request.

Participants who have asked to be removed from the study or who have indicated that they do not wish for data linkage to their records will be excluded (by pseudonymised study ID) from the requested dataset.

Confidentiality Advisory Group Advice

The amendment request was by the Vice Chair and it was agreed that support was recommended for the amendment. It was acknowledged that the linked amendment which had been provided support in May 2016 had included detailed around a pilot study which had recently been conducted. This pilot included consent for data linkage, in order to assess loss to follow-up and non-response.

The Vice Chair acknowledged that the conditions which had previously been applied to the linked amendment would remain pertinent to patients captured within this additional year of data. IGARD had also attached conditions to the amendment in relation to patients within this cohort.

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 subject to a response to the conditions below.

Specific Conditions of Support

1. The data-linkage set out in the amendment does not apply to those participants who have already been approached for consent as part of the pilot.
2. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14, 2016/17, satisfactory reviewed grade at 66%).**
3. Confirmation of a favourable opinion from a Research Ethics Committee for the amended documentation. **(Confirmed – 17/07/2017).**