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

August 2017

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor

Application title:	**A feasibility randomised controlled trial of mechanical chest compression devices for in-hospital cardiac arrest**
CAG reference:	**16/CAG/0088**
IRAS project ID:	**204160**
REC reference:	**16/WM/0299**

Context

Purpose of Application

In the UK, 35,000 patients have a cardiac arrest in hospital each year. Less than one in five of these patients survive to leave hospital. Chest compressions are an essential treatment for cardiac arrest patients, but are often difficult for a person to deliver to a high standard (manual chest compressions). A mechanical chest compression device can be used to deliver chest compressions (mechanical chest compressions) instead of a person. Small studies suggest using these devices may improve patient survival when used as part of treatment for cardiac arrest patients in hospital.

This application from the University of Warwick set out the purpose of conducting a feasibility study over a period of two years. 330 patients that have a cardiac arrest will participate. After initial treatment has been started (including manual chest compressions), patients will either continue to receive manual chest compressions or they will receive mechanical chest compressions. The treatment will be decided randomly. All patients will receive all other necessary treatments.

CAG support is requested for the following activities:

1) To continue to collect data, post-mortem, for those participants who die before consent or advice can be obtained from the patient or their consultee (as appropriate).
2) To use data collected under the emergency provisions of the MCA, as approved by the REC. In patients who survive, to collect data relating to baseline characteristics, treatment, safety data and outcomes from the end of the emergency situation to the point that the participant or their consultee is approached regarding consent to ongoing data collection. This includes participants who are discharged from hospital before consent or advice can be obtained from the patient or their consultee (as appropriate). The site research team will make attempts to contact these patients.
3) To transfer anonymised data collected prior to the point that the participant or their consultee is approached to Warwick Clinical Trials Unit for analysis.

A recommendation for class 1, 3, 5, and 6 support was requested to cover access to on baseline characteristics, treatment, safety data and outcomes to death for the participants in this trial who fall into the two groups set out above.

Amendment Request

The amendment request was for the addition of a site which would also process identifiable data, as above.

The site named was South Warwickshire NHS Foundation Trust.

Confidentiality Advice Team advice

The amendment request was considered by the Confidentiality Advice Team, who noted that there were no changes to the purposes, data sources, data items or data flows (CAT). The amendment would be considered to be a non-substantial amendment by the REC and would not require review.

The security arrangements were confirmed to be suitable.

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 Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – NHS Digital email received 24/08/2017).**
2. Confirmation of a favourable opinion from a Research Ethics Committee**. Favourable opinion in place for the application, review of the amendment not required.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Application title:	**A feasibility randomised controlled trial of mechanical chest compression devices for in-hospital cardiac arrest**
CAG reference:	**16/CAG/0088**
IRAS project ID:	**204160**
REC reference:	**16/WM/0299**

Context

Purpose of Application

In the UK, 35,000 patients have a cardiac arrest in hospital each year. Less than one in five of these patients survive to leave hospital. Chest compressions are an essential treatment for cardiac arrest patients, but are often difficult for a person to deliver to a high standard (manual chest compressions). A mechanical chest compression device can be used to deliver chest compressions (mechanical chest compressions) instead of a person. Small studies suggest using these devices may improve patient survival when used as part of treatment for cardiac arrest patients in hospital.

This application from the University of Warwick set out the purpose of conducting a feasibility study over a period of two years. 330 patients that have a cardiac arrest will participate. After initial treatment has been started (including manual chest compressions), patients will either continue to receive manual chest compressions or they will receive mechanical chest compressions. The treatment will be decided randomly. All patients will receive all other necessary treatments.

CAG support is requested for the following activities:

4) To continue to collect data, post-mortem, for those participants who die before consent or advice can be obtained from the patient or their consultee (as appropriate).
5) To use data collected under the emergency provisions of the MCA, as approved by the REC. In patients who survive, to collect data relating to baseline characteristics, treatment, safety data and outcomes from the end of the emergency situation to the point that the participant or their consultee is approached regarding consent to ongoing data collection. This includes participants who are discharged from hospital before consent or advice can be obtained from the patient or their consultee (as appropriate). The site research team will make attempts to contact these patients.
6) To transfer anonymised data collected prior to the point that the participant or their consultee is approached to Warwick Clinical Trials Unit for analysis.

A recommendation for class 1, 3, 5, and 6 support was requested to cover access to on baseline characteristics, treatment, safety data and outcomes to death for the participants in this trial who fall into the two groups set out above.

Amendment request

The amendment request was for the addition of a site which would also process identifiable data, as above.

The site named was Blackpool Teaching Hospitals NHS Foundation Trust.

Confidentiality Advice Team advice

The amendment request was considered by the Confidentiality Advice Team, who noted that there were no changes to the purposes, data sources, data items or data flows (CAT). The amendment would be considered to be a minor amendment by the REC and would not require review.

The security arrangements were confirmed to be suitable.

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 Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Confirmed published and reviewed.**
2. Confirmation of a favourable opinion from a Research Ethics Committee**. Favourable opinion in place for the application, review of the amendment not required.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor
Dr Patrick Coyle	Chair
Dr Lorna Fraser	
Dr Barry Evans	

Application title: **Incidence of JLSE in CYP and their access to care in the UK and ROI**

CAG reference: **17/CAG/0075**

IRAS project ID: **211962**

REC reference: **17/NW/0095**

Context

Purpose of application

This research application from the University of Liverppol set out the purpose of determining the incidence of Juvenile-onset Systemic Lupus Erythematosus (JSLE) or 'childhood lupus' – a rare disease where the immune system attacks the body.

This disease was difficult to diagnose and its effects could vary from mild to severe. The study aimed to increase knowledge of the number of cases, how long it took to diagnose, the impact of new diagnostic criteria, the severity of the disease effects, and treatments used within the first year.

The study would use the BPSU 'orange card' reporting system, a compulsory reporting system which enabled study of rare conditions. Paediatricians in the UK would be obliged to report to the BPSU whether or not they had come across a case of the condition listed (in this case JSLE). The clinician details would be passed from the BPSU to the research team, who would send a questionnaire to the clinician, requesting minimally identifiable, clinical information on the patient.

For this particular study the researcher would also identify other clinicians who might see patients with JSLE, through the British Society for Paediatric Dermatology (BSPD), the British Association for Paediatric Nephrologists (BAPN), the British Isles Lupus Assessment Group (BILAG) and the Barbara Ansell National Network for Adolescent Rheumatology (BANNAR) group. These clinicians would be asked to report all new cases meeting the surveillance case definition directly to the study team, who would proceed to send the questionnaire as above.

A recommendation for class 1, 2, 4 and 6 support was requested for the process of extracting and anonymising the information, to obtain and use information about past or

present geographical location, to link patient identifiable information obtained from more than one source and to allow access to an authorised user for one or more of the above purposes

Confidential patient information requested

Access was requested to data from clinicians in relation to children identified by clinicians as having Juvenile-onset Systemic Lupus Erythematosus (JSLE) or 'childhood lupus'.

The application would collect the following data items:

Partial date of birth (month/year), date of death, NHS number and partial postcode (first part only).

Amendment Request

The applicant had stated during the application process that they would not need to process full date of birth. Although date of birth would be reduced to month and year of birth before being stored for analysis, the applicant later realised that they would require complete date of birth to act as a back-up for the NHS number (in case of transcription error etc.) to allow them to remove case duplications. They would also need to store NHS numbers and full date of birth in order to follow up participants. This data would be stored separately to the dataset for analysis.

Confidentiality Advisory Group advice

The original application was reviewed via the Precedent Set pathway. This change had originally been reported to the Sub-Committee during the submission of requested further information in response to Provisional outcome.

At the time the CAG noted that both the full NHS number and the full date of birth were collected as standard in BPSU studies for the above reasons, and there was established precedent for this to be approved via Precedent Set.

However, as changes could not be made to the application until final approval had been given, the applicant was advised to submit an amendment once approval was obtained. Members stated that they were content to approve the amendment.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Sub-Committee of the CAG 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.

   It was noted that the IG Toolkit for Alder Hey Children's NHS Foundation Trust had been reviewed as 'Satisfactory with Improvement Plan' by NHS Digital.

   The Improvement Plan was provided to the Sub-Committee for review. It was noted that data flows were not clearly mapped and a request had been made for a flow mapping exercise to be undertaken in order to meet the following criteria:

'All transfers of hardcopy and digital person identifiable and sensitive information have been identified, mapped and risk assessed; technical and organisational measures adequately secure these transfers'. This would enable NHS Digital to assess the legal basis for all data flows.

The applicant undertook to complete this action by December 2017, and further training of staff would be complete by March 2018.

The Sub-Committee was happy with the applicant's response and agreed to recommend support, subject to confirmation at annual review that all outstanding actions for the Improvement Plan had been complied with.

2. Confirmation of a favourable opinion from a Research Ethics Committee. (**Confirmed 22 February 2017).**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor

Application title: **Genetic mechanisms in polyposis of the bowel.**

CAG reference: **17/CAG/0011**

IRAS project ID: **87399**

REC reference: **12/WA/0071**

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research into colorectal cancer (CRC), which is one of the most common cancers worldwide, with over one million new cases diagnosed each year. There is a considerable heritable component which is important for correct diagnosis on the basis of a family pedigree or through molecular characterisation. This study will employ 'next generation' sequencing methodologies to identify mutations that may clarify the genetic mechanisms involved in polyposis of the bowel. The study involves both living and deceased patients - **the application for support only relates to the deceased patient cohort**, the living patients will be consented.

The submission had been made to CAG for consideration of arrangements in relation to the deceased patient cohort. From original approval of the research project in 2012, the applicants were accessing the data of deceased patients with consent from the next of kin. The project had received the relevant ethical and R&D approvals on this basis. It was brought to light in January 2016; the Access to Health Records Act 1990 does not provide a legal basis for next of kin to consent to the review of medical information of deceased patients. Upon receipt of this confirmation, the applicants halted recruitment of deceased patients in order to make amendments to the procedures for accessing this information. A substantial amendment was submitted to the REC to establish legal basis to access the deceased patient's information, which was approved. The application to CAG followed this REC approval.

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

Amendment request

The amendment request was for an extension to the timescale for the study until 31 August 2017. The extension was required in order to meet the recruitment target and complete data collection.

Confidentiality Advice Team advice

The amendment requested was considered by the CAT, who queried whether this amendment was necessary under the terms of the Section 251 support, which covered data from deceased patients only, and asked for further information in relation to the recruitment of deceased patients. .

The applicant submitted the following response by email dated 4 August 2017:

1. *'The timeline of the study was extended until 31.08.18, in which time more participants will be recruited. Excluding deceased participants from further recruitment could bias the outcome of the study.*

2. *The original time period would have given recruitment centres only 7 months (CAG approval was received in January) to check their records for eligible deceased patients and provide the data needed for the study. The extension will ensure that all necessary data is collected.*

3. *The 7 month period to include deceased patients is too short to ensure the appropriate next of kin could be identified and contacted. Particularly because we specify that next of kin will not be contacted within the first 12 months after a patient had passed away, and also not around the anniversary of the day of death, to prevent causing emotional distress'*

The CAT accepted that the extension to the time period for the study was necessary and justified according to the first two points. The third point relating to obtaining consent from relatives was considered irrelevant to the Section 251 support, as it had already been established that consent from relatives in relation to use of the data of a deceased person had no legal basis.

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.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **Cardiff University - v14 confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed that REC approval not required.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor
Dr Tony Calland	Chair
Dr Lorna Fraser	Member
Dr Rachel Knowles	Member

Application title:	**Feasibility of an impact analysis of a clinical prediction tool to estimate the probability of abusive head trauma in children less than three years of age**
CAG reference:	**16/CAG/0022**
IRAS project ID:	**167217**
REC reference:	**16/WA/0003**

Context

Purpose of application

This application from Cardiff University set out the purpose of assessing the Feasibility of using an impact analysis tool to predict abuse. Abusive Head Trauma is the leading cause of death and disability in young children who have suffered abuse; however it can be difficult to tell if a head injury is the result of abuse. The researchers have created a tool to facilitate clinicians in this judgement. They will collect:

1. The probability assessment provided by the tool;
2. The probability assessment of the clinician pre and post use of the tool [with consent of the clinician];
3. The child protection decisions of the clinician pre and post use of the tool [with consent of the clinician, s251 is not sought for this]; and
4. Whether the child was deemed abused or not.

Support for activities 2 and 3, above, was not requested.

The researchers will identify cases by attending child protection and radiology peer review meetings. The notes will then be consulted to discover the six clinical indicators the tool uses as the basis for its prediction (seizure, apnoea, long-bone fracture, rib fracture. Head/neck bruising, and retinal haemorrhages). These cases will be given a study identifier and the link between study identifier and NHS number will be retained separately by the CI to allow data-linkage for follow-up.

Clinicians will then be approached to take part in the study. If they agree they will be asked to make an assessment pre and post use of the tool, and what their child protection decisions are pre and post use of the tool.

The research student will follow up each case to determine abuse/non-abuse. This will be determined by the decision of the multidisciplinary assessment conducted by the clinicians, social workers, police, and other relevant agencies at a strategy meeting, case conference,

or child death case review meeting. These outcomes will be determined from the children's case notes or child protection peer review meeting. Abuse will also be confirmed if witnessed or admitted to. Where abuse is not suspected (and therefore no multidisciplinary assessment meeting is held), the clinician will be followed up after six months to determine if they have any child protection concerns – unless there is an independently witnessed accidental injury or confirmed underlying organic disease. Follow up data will be obtained from health visitor records.

In addition, they will collect quantitative process data (e.g. the number of eligible patients) and qualitative process data (e.g. researcher observations, structured field notes arising from informal conversations and stakeholder organisations.)

A recommendation for class 1 and 6 support was requested to cover the activity specified in the application.

Confidential patient information requested

Access was requested to access case note data (NHS number, name, and date of birth) relating to head trauma in fifty 0—3 year olds presenting with head injury; from Bristol Royal Hospital for Children and University Hospital Wales.

Amendment request

Researchers now wished to address the issue that not all children with abusive head trauma would receive neuroimaging due to radiation concerns, resulting in these cases being missed – conversely, some children may undergo neuroimaging where this is not clinically indicated, exposing them to unnecessary radiation. New guidelines had recently been put in place at the study site regarding which children should undergo CT scan. The researcher wished to evaluate the guidelines looking at previous records for children who had undergone neuroimaging.

The researcher therefore requested additional access to medical notes in order to identify children who had undergone a CT scan, and to review the CT scan to establish whether the scan would have been recommended by the guidelines and whether they were clinically indicated.

Confidentiality Advisory Group advice

The amendment requested was forwarded to a Sub-Committee who considered it to have demonstrated a medical purpose and to be of clinical importance; however it was not clear why this constituted an extension from the previous study. Taking into account the fact that this request was to evaluate new guidelines rather than the tool that they had already assessed, and therefore could be seen as a new study entirely, members requested further clarification from the researcher on this point.

The following response was received by email dated 1 August 2017:

'The original project is a PhD research programme that I am supervising. The project is looking at validating the 'Feasibility of an impact analysis of a clinical prediction tool to estimate the probability of abusive head trauma in children less than three years of age'.

One of the related research findings has been that within routine clinical practice there are two populations of children

a. Children who have neuroimaging unnecessarily and are therefore at unnecessary risk of cranial irradiation

b. Children who probably should have had neuro imaging based upon their clinical features but did not do so, and thus at risk of missing intracranial injury.

Thus an extension of the project proposed is to explore the clinical records of these children to identify the determinants of abnormal neuroimaging. This is an extension of the PhD research programme.

As this research question relied upon the same methodological approach namely examining the same clinical records for an extended population of children (children in Cardiff and Vale UHB < 2 years of age) and extracting the same clinical dataset from the notes that has been applied within Laura's PhD we thought it reasonable to submit a substantial amendment to the ethics committee for approval using the same methodological approach. As you are aware from the email 28/07/17, the amendment has now received ethical approval.
We are therefore now seeking CAG approval to undertake the retrospective analysis of hospital case notes.'

Members considered this response, and agreed that there was a high public interest in this work. The CAG had already recommended support to test the accuracy and efficiency of the clinical prediction tool designed to help clinicians to take decisions in relation to presenting risk factors for child abuse, some of which would come after CT scanning. It was recognised that investigating whether there were clinical indicators which would help determine whether CT scanning was appropriate was aligned with the original purpose of the application. The clarification that this activity was part of the same PhD study was also considered useful to the Sub-Committee decision.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Sub-Committee 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. **Cardiff University – v14 confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 28 July 2017.**

Reviewers:

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

Study title: **Building Blocks 2-6: parenting support to reduce maltreatment**

CAG reference: **CAG 10-08(b)/2014**

Protocol number: **1**

IRAS Project ID: **140682/558642/4/487**

Context

Purpose of Application

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

This amendment was submitted to clarify the details of an amendment request which had previously been submitted in April 2015, for which a recommendation of support was issued in June 2015. The amendment concerned a sub-cohort of 110 patients who had left before the conclusion of the original trial. The applicants had identified a risk that they may not hold up-to-date information in relation to this cohort, including mortality information. The previous amendment requested support to trace this patient cohort via NHS Digital or NHS Shared Services, before further follow-up information was issued to them, to ensure that the mother and child were still eligible for inclusion in the follow-up study. It was stated that if the mother or child had subsequently died, or the child had been adopted, they would no longer be eligible for follow-up in the study and would not be followed up.

The applicants specified that the remainder of the cohort which remained eligible for inclusion in the follow-up would be contacted in the same manner as other participants as per the protocol described in the original application. These individuals would be contacted by letter, text and email and provided with the opportunity to opt-out of the follow-on study should they wish.

It had not been made clear in the historic amendment review that, following the trace of patients carried out via NHS Digital or NHS Shared Services, data would be transferred back to the applicants at Cardiff University to enable contact to be made about the follow-on study.

This amendment submitted clarification of the proposed data flows in relation to the tracing of the sub-cohort of participants as follows:

1. Cardiff University will send a list of identifiers in relation to the 110 participants to the data provider (either NHS Digital or NHS Shared Services). This will include the following data items: name, date of birth (or estimated delivery date), NHS Number, contact address and gender.
2. The data provider (NHS Digital or NHS Shared Services) will trace the individuals and provide an updated list to include the following data items: name, date of birth, NHS Number, most recent contact address and gender.
3. The list will be flagged with any individuals who have died in the interim.
4. The list of updated identifiers would be returned from the data provider (NHS Digital or NHS Shared Services) to the applicants at Cardiff University.
5. The applicants will remove those patients who no longer meet the eligibility criteria from the list. Remaining patients will be followed up as per the agreed protocol.

Confidentiality Advisory Group advice

The amendment was reviewed by the Vice Chair, and it was noted that whilst the previously reviewed documentation had implied that updated contact information would be returned to the applicants, this was not explicit. The Vice Chair confirmed that the data flow was clearly described in this revised submission.

Previous assurance had been sought and confirmed by the applicant that removal of consent to use any of their data was an explicit option that was offered to all patients who withdrew from the study. This was confirmed in an email dated 15 April 2015 from the applicants, which clarified that the withdrawal standard operating procedures specified that the research "must also ask the participant if data already collected from them can still be used", therefore this requirement was met. Those patients who had indicated that no further information should be used would not be included in the follow up. It was noted that the collection of follow up data in relation to these patients had been specified within the original application.

Confidentiality Advisory Group Conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – V14, confirmation received via email from NHS Digital 30 August 2017).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Received – REC Approval issued on 14 December 2014, prior to review of previous amendment).**

Reviewers:

Name	Capacity
Ms Kathryn Murray	Senior Confidentiality Advisor
Dr Tony Calland	Chair

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

This amendment seeks permission for the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH) to securely link Welsh NCISH cases and enhanced questionnaire data within the Suicide Information Database Wales (SID-Cymru).

SID-Cymru links routinely collected data about all persons in Wales over 10 years of age, who were recorded to have died by suicide between the 1st January 2001 and the 31st December 2015. SID-Cymru is hosted within the Secure Anonymised Information Linkage (SAIL) Databank which links together a wide range of person-based data (such as primary care, emergency department attendance and hospital admissions) using robust anonymisation techniques for health related research.

The applicants clarified that the data linkage would be facilitated by transfer of two datasets (i) a demographic component comprising the following identifiers: NHS number, name, date of birth and address and (ii) a clinical component (NCISH questionnaire data). It was explained that a 'join key' would be assigned to every record within each of these two datasets. The key has no meaning of its own but is used in order to enable the two datasets to be recombined in the SAIL Databank. The demographic component will be transported to NWIS, whilst the clinical component will go to the SAIL Databank. NWIS will anonymise and encrypt the demographic data and assign each individual record with an Anonymous Linking Field (ALF). These anonymised demographic elements are then sent to SAIL Databank and recombined with the clinical component making them ready for linkage to other datasets. The NHS Number will be used as the primary method of linkage, however if this is not available or is incorrect, the name, date of birth and address will be used. The ALF is the key to linking different anonymised datasets together.

Confidentiality Advisory Group Advice

The amendment requested was forwarded to the Vice Chair who acknowledged that the linkage processes described between NWIS and SAIL were standard. It was recognised that in recommending support for the amendment, the applicants would gain a more comprehensive picture of patients who have died by suicide which supported the ongoing public interest in the project.

Confidentiality Advisory Group Conclusion

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

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – Version 14, 2016-17, Satisfactory Reviewed Grade at 77%).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – Favourable Opinion issued 17/07/17.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor
Dr Patrick Coyle	Chair
Dr Lorna Fraser	Member
Dr Barry Evans	Member

Study title: **National Bowel Cancer Audit**

CAG reference: **ECC 1-03(d)/2012**

Context

Purpose of application

NHS Digital and The Royal College of Surgeons (RCS) have been commissioned to undertake work as part of the National Bowel Cancer audit program which forms one of the HQIP commissioned national clinical audits.

The National Bowel Cancer audit is undertaken with the intention of informing patients and the public about the prevention, diagnosis, treatment and care of this disease and the outcomes. Every trust in England and Wales fully participates in the audit and due to the high standard of data quality, it is possible to focus on trying to understand the variation seen by using case-mix adjustment and to work with organisations to improve the standard of care offered. The audit has demonstrated that many more patients are now receiving appropriate care and the amount of variation seen between trusts has reduced

Amendment request

The amendment request was for a change in purpose. The NBCA has been asked to enable the sharing of the audit data with Third Party Researchers as part of HQIP's Data Access processes.

This would entail the transfer of identifiable data from NBCA to NHS Digital for the purposes of linkage between the audit data and HES and ONS data. Anonymised patient level data would then be shared with approved researchers.

Confidentiality Advisory Group advice

The amendment requested was forwarded to the Chair and two Sub-Committee members.

It was noted that written confirmation of approval for the amendment was provided from HQIP.

The applicant advised that patient notifications would be updated accordingly.

Members were satisfied that all appropriate procedures had been followed and raised no concerns in relation to the sharing of anonymous data for research purposes, as outlined above.

Confidentiality Advisory Group conclusion

In line with the considerations above, the Sub-Committee 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. **NHS Digital confirmed published and reviewed as satisfactory.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed that REC approval is not required for this amendment.**

Reviewers:

Name	Capacity
Ms Rachel Heron	Confidentiality Advisor
Dr Mark Taylor	Chair
Mr Anthony Kane	Member
Dr Jennifer Kurinczuk	Member

Study title: **UK Transplant Potential Donor Audit**

CAG reference: **PIAG 4-05 (e)/2008**

Context

Purpose of application

This application from NHS Blood and Transplant set out the purpose of utilising donor referral information in an identifiable format to allow audit activities to take place using the data. The application enhanced the Potential Donor Audit System (PDA), PIAG 4-05(e)/2008, which received support to allow collection of data in relation to potential donors attending emergency departments. The current application requested an extension to the amount of information collected and requested access to data in relation to all patients referred for possible donation.

A recommendation for class 4, 5 and 6 support was requested to cover access to referral information in relation to all patients referred for possible donation and linkage to ACORN data using postcode.

Confidential patient information requested

Access was requested to date of death and postcode.

Amendment request

The amendment request was to waive the following condition of approval from the original recommendation of support: postcode must be pseudonymised (reduced to first four digits) after 2 years.

The applicant argued that the full postcode was required for a number of activities covered by the original approval, which aimed to use the audit data to increase the number of transplants. This included analysing socio-economic scores to understand donation trends and prioritise promotion of organ donation, comparing the postcodes of potential donors with transplant waiting lists in the same areas, and identifying any areas where NHSBT should focus on improving family consent rates for organ donation.

Confidentiality Advisory Group advice

While members were satisfied that there was public interest in the purpose of the amendment – to analyse local donation potential and improve family response rate to donation requests – it was not clear to them how keeping the full postcode would assist in this aim.

Members acknowledged that granular analysis of data across a variety of data sources was possible using proprietary software like Acorn. However, localised analysis would only be of benefit if planning localised interventions: the amendment refers to intervention at 'borough, constituency or council' level.

Given these two points, the applicant was asked to provide further explanation as to why the pseudonymised postcode was not adequate for the purpose of the application.

The applicant was also asked whether the consent by an individual to donate could be updated to include the use of their data for non-direct medical purposes as an exit strategy.

The applicant responded in an email dated 4 August 2017:

'For analysis purposes, having full postcodes means we can join the data more accurately to other datasets such as census geodemographic data, grid references or social deprivation scores etc. This full postcode mapping allows greater accuracy in understanding our potential donor pool and analysing why certain donors do not proceed to be actual donors. For example, our analysis to date has indicated that social deprivation (Acorn score) is statistically significantly associated with family consent rates (families are more likely to agree to donation in certain groups). This granular level of detail enabled by full postcode mapping helps us to improve and adapt our approaches to different families to try to ensure an outcome supportive of organ donation and which will save multiple lives.

There are many reasons why potential donors do not proceed to donate organs and our nurse workforce sees many more potential donors who do not proceed than those who do. Any intelligence that helps us understand which potential donors are not likely to go ahead means that we can tailor our valuable resource effectively and modify practice to ensure that we deliver a quality service that is effective to benefit the thousands of patients awaiting an organ transplant.

It is important to retain postcode rather than just postcode derived measures to future proof ourselves. We currently have a licence for Acorn but it may be that financial pressures mean we cannot retain this in the future in which case we would rely on postcode to map to some other (free) index of deprivation. It is important to have as much historical data as possible to give power to our statistical analysis and to look at trends over time.

Finally, we will look to add consent from families for postcode retention for non-direct medical purposes as part of our consent process at the next review to ensure that we have appropriate consent for this in the longer term'.

Members reviewed this response, which was perceived to imply that the data would be used on an individual level by staff approaching families of potential donors. It appeared that the individual's deprivation score could be used to predict how likely they would be to consent to organ donation. As such the data would be required for an operational purpose, which would not be consistent with the Section 251 recommendation of support for audit purposes.

An alternative interpretation was that the deprivation score was used to understand the characteristics of the donor pool, and their predisposition to donate, and to plan communications in these areas accordingly. Members agreed that this aligned with the purpose of using audit data to increase transplants; it would indirectly affect the way that individuals were approached, but only as a result of the promotional strategies used locally. On this understanding, members agreed that they would be content to recommend support.

Members noted that the applicant response included an undertaking to update the consent process at the next review, as requested. This updated consent would include the use of

data for non-direct medical purposes, thus avoiding future reliance upon Section 251 support.

Confidentiality Advisory Group conclusion

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

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **NHS Blood and Transplant – v14 confirmed published and reviewed as satisfactory.**