Health Research Authority
Confidentiality Advisory Group
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Dear Dr Moonesinghe

Application title:	**Epidemiology of Critical Care provision after Surgery (EpiCCS)**
CAG reference:	**16/CAG/0087**
IRAS project ID:	**154486**
REC reference:	**TBC**

Thank you for your research application, submitted for approval under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 to process patient identifiable information without consent. Approved applications enable the data controller to provide specified information to the applicant for the purposes of the relevant activity, without being in breach of the common law duty of confidentiality, although other relevant legislative provisions will still be applicable.

The role of the Confidentiality Advisory Group (CAG) is to review applications submitted under these Regulations and to provide advice to the Health Research Authority on whether an application should be approved, and if so, any relevant conditions. This application was considered at the CAG meeting held on 13 July 2016.

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is conditionally approved, subject to compliance with the standard and specific conditions of approval outlined below.

Support does not come into effect until a letter from CAG has been issued confirming that the conditions set out below have been met.

Context

Purpose of application

This pilot study is to explore how clinicians determine the risk of death in clinical practice and whether these risk estimates are accurate.

Data will be collected on all patients undergoing surgery requiring overnight stay in hospital in participating UK hospitals for one week. The researchers will measure complications in these patients.

In a sub-group of patients, the quality of recovery after surgery (e.g. ability to self-care, mobility etc) will also be recorded on day 3. The researchers will learn about if and when patients die after surgery through linkage to national databases held by the Department of Health.

This application from University College London set out the purpose of describing the rates and reasons for patients being admitted to critical care after inpatient surgery in the UK. A secondary aim is to estimate whether postoperative critical care admission is associated with patient benefit (a reduction in postoperative complications).

A recommendation for class 4 and 6 support was requested to support the processing of identifiable data for the purpose of data-linkage.

Confidential patient information requested

Access was requested to:

- Patient name
- Date of birth
- NHS number
- Sex
- Postcode

At the time of data-entry onto the EpiCCS webtool, Patient Identifiable Information will be retained and stored securely in their original format within the database, however different database access privileges (dependent on usernames and passwords) will apply to different users of the database:

- Local investigators within NHS Trusts will have access to their own full datasets, including patient identifiable information.
- The central EpiCCS study team will only have access to an anonymised dataset for analysis. Among the patient identifiers, only sex will be used for analysis. In this dataset the NHS number will be replaced by a unique study patient identifier; Date of Birth will be converted to Age on date of surgery, and trimmed to month and year of birth; Postcode will be converted to PCT, SHA of residence, and the Office for National Statistics Lower Super Output Area, which allows the allocation of the Index of Multiple Deprivation.
- The data custodian will extract the required patient identifiable data from the study database onto a password protected Excel spreadsheet, and email this securely to the HSCIC to perform data linkage.

Confidentiality Advisory Group advice

Public interest

Members agreed that studies of this type were potentially in the public interest.

Practicable alternatives

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

- Feasibility of consent

The group was content that seeking consent might introduce bias into the dataset and that would not be reasonably practicable to seek consent from the entire cohort.

- Use of anonymised/pseudonymised data

Members were satisfied that identifiable data was required to perform the linkage requested and for the analyses set out in the application.

Justification of identifiers

The members were unclear exactly which data items were required for linkage. The applicant should provide a justification for each data item required.

Exit strategy

The members noted that identifiable data would be retained within the database, with different levels of access granted; they were unclear how long it was proposed to retain this data and what, if any, exit strategy was proposed.

Patient and public involvement (PPI)

Members felt that much greater efforts could have been made to involve patients and members of the public. In particular, CAG would have liked to have heard the views of patients and the public in relation to whether patient notification and/or opt out was appropriate. The applicant will need to evidence that this has taken place and any suggestions with regards to the study design before CAG can recommend support.

Patient notification and objection

Members were concerned that notification and opt out on the day of the surgery might not be appropriate as patients would be more concerned with impending surgery than the details of the study. They also expressed a concern that this model could, potentially, be coercive, as patients might worry as to whether the decision to opt out would impact on the care they received. Members noted that many of them would attend a pre-op meeting, and questioned whether providing the notification at this point would be more appropriate – subject to the outcomes of the PPI, as above.

Subject to the same provisos with regards to patient notification, members recommended that, in drafting such materials, the applicant refer to the HRA style guide (http://www.hra-decisiontools.org.uk/consent/) & the ICO notifications guidance (https://ico.org.uk/media/for-organisations/documents/1610/privacy_notices_cop.pdf).

Members also noted that the information provided was unclear at points. The data processors should be set out, and the reference being unable to link an individual to their data would be clearer were it rephrased to say that none of the data would be identifiable.

The group did not consider it reasonable to provide opt out via e-mail for patients who would be confined to a hospital bed. Alternatives, such as being able to express dissent to their clinicians, should be explored. If no other alternatives are reasonably practicable, a full justification should be provided.

Finally, and also subject to the outcomes of the PPI, members agreed that opt out should be arranged so that the data did not leave the trust in which care was provided. Justification should be provided if this is not reasonably practicable.

Additional points

Members queried whether, as described in the application, the patients would, in every instance, be seen by the anaesthetist on discharge, or whether in some cases this would be performed by another individual.

The group wished to stress that any recommendation of support would extend only to the pilot study and that a new full application would need to be submitted for any subsequent studies. The applicant should note that CAG's remit extends only as far as England and Wales and that an alternative legal basis would need to be found for any processing conducted outside these regions.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Justification of each data item required for linkage.
2. Provision of a clarification and justification of the exit strategy proposed.
3. Clarification as to whether the patients would, in every instance, be seen by the anaesthetist on discharge.
4. Provision of the outcomes of PPI, as set out above.
5. Subject to the outcomes of the PPI and taking due note of the CAG deliberations, as set out above, provision of suitable patient notification materials together with a description of how these will be disseminated.
6. Favourable opinion from a Research Ethics Committee.
7. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. Please contact Exeter.helpdesk@nhs.net with any queries.

Please provide confirmation and/or evidence that the above conditions have been accepted and/or met. Once provided, the response will be reviewed by the Chair and original reviewers and if satisfactory, the HRA will confirm final approval. Support only comes into effect once this final approval letter has been received.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from		29 June 2016
Covering letter on headed paper		
Data Protection Registration		
CAG Checklist		
Information Governance		
Registration details		
Sponsorship confirmation		
Therapeutic Assessment FU protocol		
Information sheet, parent/guardian	4	06/02/15
Information sheet, child	6	17/12/07
Consent, child		
Assent, parent/guardian		

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

Yours sincerely

On behalf of the Health Research Authority

Christopher Ward
Senior Confidentiality Advisor
Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*
Standard conditions of approval

Confidentiality Advisory Group meeting 13 July 2016

Name	*Present*
Dr Mark Taylor	Yes
Dr Patrick Coyle	Yes
Ms Claire Sanderson	Yes
Mr Anthony Kane	Yes
Dr Miranda Wolpert	Yes
Ms Hanna Chambers	Yes
Dr Martin Andrew	Yes
Mr Andrew Melville	Yes
Ms Diana Robbins	Yes
Ms Sophie Brennan	Yes

Standard conditions of approval

The approval provided by the Health Research Authority is subject to the following standard conditions.

The applicant will ensure that:

1. The specified patient identifiable information is only used for the purpose(s) set out in the application.

2. Confidentiality is preserved and there are no disclosures of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.

3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication when relevant.

4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities are consistent with the Data Protection Act 1998.

7. Audit of data processing by a designated agent is facilitated and supported.

8. The wishes of patients who have withheld or withdrawn their consent are respected.

9. The Confidentiality Advice Team is notified of any significant changes (purpose, data flows, data items, security arrangements) prior to the change occurring.

10. An annual report is provided no later than 12 months from the date of your final confirmation letter.

11. Any breaches of confidentiality / security around this particular flow of data should be reported to CAG within 10 working days, along with remedial actions taken / to be taken.