Health Research Authority

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28 September 2016

Dr Daniel Martin
Royal Free London NHS Foundation Trust
Department of Anaesthesia
Royal Free Hospital
London
NW3 2QG

Dear Dr Martin

| | |
|---|---|
| **Application title:** | **Intraoperative hypotension in elder patients** |
| **CAG reference:** | **16/CAG/0126** |
| **IRAS project ID:** | **186097** |
| **REC reference:** | **16/LO/1154** |

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. HRA approval covers England and Wales only.

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 precedent set CAG meeting held on 09 September 2016. The application was considered via the Precedent Set process under criteria 4 – time limited access to undertake record linkage/validation and to pseudonymise the data

**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 approved, subject to compliance with the standard and specific conditions of approval.

This letter should be read in conjunction with the outcome letter dated 23 September 2016.

## Context

Purpose of application

This application from University College London set out the purpose of preventing avoidable harm to patients over 65 years as a result of low blood pressure during operations. The study would record how often low blood pressure occurs in older patients having surgery, how long it persists for and how anaesthetists treat the problem.

Patients would be identified by local investigators who were NHS anaesthetic department staff, and therefore able to access operating theatre lists as part of their clinical role. All patients over 65 undergoing surgery would be identified from the list and included in the study, unless they had expressed dissent as a result of posters in the department explaining the study. Consent would not be sought in order to avoid excluding those who were severely ill and unable to consent, which would bias the results given that this group was most at risk from complications due to low blood pressure. Data would be recorded by the local investigator on a paper case report form and anonymised apart from the retention of the patient's gender and hospital ID number. The hospital ID number would be kept with the form on site for 30 days and used to identify the patient after surgery, when surgery outcome data would be recorded. The hospital ID number would then be removed, but gender retained. The data set would be transferred from the paper case report form to a secure encrypted online portal (REDCap) which is managed by RAFT and hosted by NHS Scotland. Local sites would be asked to retain a link between the study number and the hospital number. Once collated, the anonymised data from each site would be transferred to UCL data safe haven for final analysis and data storage.

A recommendation for class 1, 5 and 6 support was requested for the process of extracting and anonymising the information, for auditing, monitoring and analysing patient care and treatment and to allow access to an authorised user for one or more of the above purposes.

Confidential patient information requested

Access was requested to the anaesthetic record.

## 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. Further to the letter of 23 September 2016, the CAT team clarified that support from CAG was given for access to the anaesthetic record and surgery outcome data only. The information transferred from hospital sites via the REDCap system did not come under CAG approval as the only identifier to be retained was gender, which was not considered to be identifiable data in this context.
2. Favourable opinion from a Research Ethics Committee. **Confirmed 20 July 2016**

3. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Condition rescinded.**

   Support is here provided for local data processing. Due to the volume of sites and different locations, IG toolkits have not been assessed. To mitigate against this, the expectation is that the local data entry will conform to local IG requirements

   CAG support only applies to data generated in England and Wales, and does not apply to data generated in Scotland, or data transferred via REDCap to Scotland (again, to confirm the CAG does not consider gender to be identifiable in this context therefore does not consider that any identifiable data is being transferred).

As the above conditions have been accepted and/or met, this letter provides confirmation of final approval. I will arrange for the register of approved applications on the HRA website to be updated with this information.

**Annual review**

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report on the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements. An annual review should be provided no later than 28 September 2017 and preferably 4 weeks before this date. If at any stage you no longer require support under the Regulations as you will cease processing confidential patient information without consent you should inform the Confidentiality Advice Team of this in writing as soon as possible.

**Reviewed documents**

The documents reviewed at the meeting were:

| *Document* | *Version* | *Date* |
|---|---|---|
| CAG application from (signed/authorised) | | 17 July 2016 |
| Data Protection Registration [UCL DP Registration] | | |
| Data Protection Registration [NSS SHOW DP Registration] | | |
| Patient Information Materials [Information Sheet Anaesthetists] | 2.1 | 14 July 2016 |
| Patient Information Materials [Information Sheet Patients] | 2.1 | 14 July 2016 |
| REC favourable opinion letter and all correspondence [REC 1 Application letter] | | 08 June 2016 |
| REC favourable opinion letter and all correspondence [REC 2 Provisional opinion] | | 17 June 2016 |
| REC favourable opinion letter and all correspondence [REC 3 Response to Committee] | | 14 August 2016 |
| REC favourable opinion letter and all correspondence [REC 4 Approval] | | 20 June 2016 |
| Research protocol or project proposal [iHypE Protocol ] | 5.2 | 10 January 2015 |
| Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [UCL Letter of recommendation] | | 18 August 2016 |

**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.

**User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

**HRA Training**

We are pleased to welcome researchers and R & D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Yours sincerely

Rachel Heron
Confidentiality Advisor

Email: HRA.CAG@nhs.net

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

## Confidentiality Advisory Group sub-committee meeting 09 September 2016

## Group Members:

| *Name* | *Profession* | *Present* | *Notes* |
|---|---|---|---|
| Mr Anthony Kane | | Yes | |
| Dr Rachel Knowles | | Yes | |
| Dr Mark Taylor | | Yes | |

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**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.