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14 March 2016

Dear Dr Mason

Study title: **National Confidential Enquiry into Patient Outcome and Death (NCEPOD)**
CAG reference: **PIAG 4-08(b)/2003**

Thank you for the provision of an annual review report for your 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 Secretary of State for Health on whether an application should be approved, and if so, any relevant conditions. The purpose of the annual review is to provide an update against the conditions of approval where applicable, confirm progress of the study, review the need to process confidential patient information, and ensure the minimum amount of identifiable information is being used.

Secretary of State for Health approval decision

1. The Secretary of State for Health, having considered the advice from the Confidentiality Advisory Group as set out below, has approved the continued processing of this application for the specified purposes for a further 12 months from the anniversary of your original final approval outcome letter, therefore until the 9 December 2016.

Context

Purpose of application

This application from the NCEPOD set out the purpose of reviewing clinical practice and identifying potentially remediable factors in the practice of medical and surgical care. NCEPOD examines the quality of the delivery of care, not specifically cause of death; this is done by reviewing the provision of care and treatment and the management of health services. The commentary and recommendations made in each report are based on peer

review of the data submitted to them. A recommendation for class 1, 4, 5 and 6 support was requested to achieve the purposes set out in the application.

Confidential patient information requested

Information would be obtained from case notes. This included: NHS Number, hospital number, date of birth, gender, date of admission, source of admission, name of admitting clinician/operating clinician, date of discharge/death (if appropriate), date of procedure, type of procedure (OPCS code), diagnosis (ICD10 code (if relevant)). In addition, name and postcode where required (for ONS/HES outcome linkage only).

Confidentiality Advice Team advice

Security arrangements

A satisfactory Information Governance Toolkit score of 98% for version 12 (2014—15) was noted.

Study Progress

The applicant confirmed that there were no specific conditions of approval set at the time of amendment in 2013.

It was noted that two new studies were added this year:

1. Non-invasive ventilation, and
2. Cancer in young people.

It was confirmed that these will follow the standard retrospective case note review method and the applicant will submit the protocols when they are developed for approval and addition to the Register.

The Confidentiality Advice Team noted that the amendment for non-invasive ventilation has been received.

Project changes

The applicant confirmed that there have been no changes to the main application.

Access to identifiers

The applicant confirmed that patient identifiers continued to be required for linkage purposes. It was confirmed that once the linkages are performed, identifiers are deleted and case notes are anonymised as soon as possible after receipt and no later than two months afterwards. Trusts are encouraged to remove patient identifiable data prior to sending notes to the applicant and the secure electronic transfer by nhs.net of case notes is available to Trusts.

Practicable alternatives or exit strategies

The applicant noted that their methodology requires them to collect copied extracts of case notes, and that, while the preference is for hospitals to anonymise these prior to sending them (as some do) this would be an additional burden. As such, whilst their questionnaires are pseudonymised, the case notes mean that they cannot yet receive completely anonymised or pseudonymised data.

The applicant advised that there is presently no alternative to the continuing need to receive notes containing patient identifiers due to the additional burden that this would otherwise place on Trusts.

It was agreed that the response to this seemed reasonable and proportionate.

Projected end date

The applicants have provided a timetable listing when the data for the various projects will be destroyed by. No projected end date for NCEPOD itself was provided.

User feedback and involvement

The applicant noted that NCEPOD had received high profile media coverage for their reports of the previous year, and that patient representatives attended the launch of the GI bleed study.

Patient representatives are involved in the study design groups for all studies and NCEPOD's Steering Groups, Independent Advisory Group, and Board of Trustees. They are currently advertising for lay representatives to sit on their study advisory groups and to become advocates for their work.

The user involvement was noted and requested that impact of this involvement and an update on the recruitment of lay representatives should be provided at time of next annual review.

Confidentiality Advice Team advice conclusion

Following assessment, it was agreed that there was still a continued need to access confidential patient information as specified within the original application. As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter (to 09 December 2016).

However, this was subject to receiving satisfactory responses to the following clarification requests.

Clarification requests:

1. What information could reasonably be provided to this cohort to inform them (or the relevant third party) of this activity. **Received, 14 March 2016.**
2. What mechanism is in place to manage any objections, if they are raised. **Received, 14 March 2016.**

Please respond within 20 working days.

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 4 weeks before the date indicated above.

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

Yours sincerely

Christopher Ward,
Senior Confidentiality Advisor.

On behalf of the Secretary of State for Health

Email: HRA.CAG@nhs.net

Enclosures: Standard conditions of approval

Standard conditions of approval

The approval provided by the Secretary of State 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.