Health Research Authority

Confidentiality Advisory Group

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Mr Ian Seccombe
NHS Patient Surveys Lead
Care Quality Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

29 April 2013

Dear Mr Seccombe

Study title: CQC 2013 Maternity Survey
Project CAG reference: ECC 6-02(FT16)/2012

Thank you for your research application, submitted for approval under 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 Ethics and Confidentiality Committee meeting on the 05 December 2012.

Secretary of State approval decision

The application was considered by the Confidentiality Advisory Group's predecessor, the Ethics and Confidentiality Committee. The Secretary of State provided provisional approval for this application which was confirmed in the outcome letter dated 10 January 2013. It was agreed that when the conditions outlined below had been met final approval would be provided.

As these conditions have been met, final approval can be confirmed.

This letter should be read in conjunction with the outcome letter dated 10 January 2013.

Context

This application from the Care Quality Commission (CQC) was for a recommendation of support for the transfer of patient identifiable data from acute trusts to an approved survey contractor (Over 250 patients would be identified from each trust who had had a live birth prior to the 28 February 2013), for the purpose of mailing out questionnaires for the 2013 maternity survey. The application indicated that the list of survey contractors was yet to be confirmed but the vast majority trusts involved would probably opt to use either: Picker Institute Europe, Quality Health or Patient Perspective. Picker Institute Europe would act as the survey coordination centre for the survey.

Two files would be created, a mailing file and sampling file. These would both be sent to the approved survey contractor, and the sampling file would be sent to the coordination centre for further analysis purposes and to identify women who had received antenatal and postnatal care from the trust. The mailing file would include; full name, address and postcode. The sampling file would include; mother's year of birth, ethnicity, date of delivery, place of delivery, GP practice code, sector level postcode and trust held provider information.

Specific conditions of support

1. Confirmation of a favourable REC opinion. **Received.**

2. It should be ensured that the survey and use of information is explained to all patients under the age of 18 by NHS trust staff prior to the disclosure of information and patients should be given adequate opportunity to opt out.

3. Please forward a copy of the amended questionnaire to the NIGB office. **Received.**

4. Confirmation of satisfactory security assurance. **Confirmed.**

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 this 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 6 weeks prior to 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.

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

Yours sincerely

Claire Edgeworth
Deputy Confidentiality Advice Manager

Email: HRA.CAG@nhs.net

Enclosures: Standard conditions of approval

Copy to: NRES North West – Haydock, nrescommittee.northwest-haydock@nhs.net

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.