Health Research Authority

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Professor Jenny Kurinczuk
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9 November 2017

Dear Professor Kurinczuk,

Application title: **BINOCAR**
CAG reference: **PIAG 2-08(e)/2002**

Thank you for your amendment request to the above 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.

Health Research Authority approval decision

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

1. The amendment is approved, subject to compliance with the standard conditions of support.

Context

Purpose of application

The BINOCAR application has support to collect identifiable data on all cases of congenital anomalies within the population of England and Wales. A number of regional and disease specific registers of congenital anomalies provide continuous epidemiological monitoring of the frequency, nature, cause and outcomes of congenital anomalies. Confidential information including mother and baby name, address, postcode, NHS number, date of birth and baby date of death are collected from a number of NHS organisations and other outcome datasets.

Amendment request

The applicant had originally sought permission to hold the identifiable congenital anomalies register (CAR) data until Sept 2017 by which time they had hoped that the data would have been linked to ONS mortality data, hospital episode statistics data (HES) and education data held by the Department for Education to create the de-identified research database.

Due to delays in obtaining Research Ethics Committee approval, an ongoing application to NHS Digital, and difficulties in establishing the legal gateway for linkage with the DfE pupil database, this linkage had not yet begun.

The amendment request was therefore to extend support to enable the applicant to hold the CAR dataset until data linkage could take place. Without the extension, the database could not be set up.

Confidentiality Advice Team advice

The amendment requested was forwarded to the Chair, due to the extension to the time of data processing. The Chair was of the opinion that adequate justification had been provided to hold the data until September 2018.

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. **Details provided and confirmed for each organisation processing data – v14 published and reviewed.**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **REC approval is in place – amendment not required for extension of time period.**

Reviewed documents

Document	*Version*	*Date*
Amendment request form		

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

Rachel Heron
Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

Enclosures: Standard conditions of approval

NHS
Health Research Authority

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.