Health Research Authority

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11 December 2018

Professor Jenny Kurinczuk
National Perinatal Epidemiology Unit,
Nuffield Department of Population Health,
University of Oxford,
Old Road Campus, Headington,
Oxford
OX3 7LF

Dear Professor Kurinczuk,

Application title: **BINOCAR**
CAG reference: **PIAG 2-08(e)/2002**
REC Reference: **16/EM/0440**

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 confidential patient 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 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.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

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 amendment requested an extension to the duration of support under the Regulations for a further year, up to 30 September 2019.

Confidentiality Advice Team advice

The amendment requested was considered by the Confidentiality Advice Team. It was acknowledged that the amendment sought an extension to the duration of support only and did not proposed any changes to purpose, data items, sources or flows currently supported. The amendment had been requested due to delays experienced in data linkage via NHS Digital, which was justified. Support was recommended for the amendment.

Confidentiality Advice Team conclusion

In line with the considerations above, the Confidentiality Advice Team 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 a favourable opinion from a Research Ethics Committee (**Confirmed – no requirement to submit a duration extension for REC approval**).
2. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – published satisfactory reviewed grade of Version 14.1, 2017/18 for the following organisations:**

- National Perinatal Epidemiology Unit, University of Oxford,
- TIMMS, University of Leicester,
- Public Health England,
- Newcastle University,
- Wolfson Institute, Queen Mary, University of London,
- Wolfson Institute, Queen Mary, University of London,
- University Hospitals Bristol NHS Foundation Trust

Reviewed documents

Document	*Version*	*Date*
Amendment request form		14 September 2018

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

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

Enclosures: Standard conditions of approval

cc. *NRESCommittee.EastMidlands-Derby@nhs.net*
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Health Research Authority

Standard conditions of support

Support to process confidential patient information without consent, given by the Health Research Authority, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient 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, in addition to other national guidance.

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

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

6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.

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. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.