NHS
Health Research Authority

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Dear Professor Kurinczuk

Study title: **Linked de-identified research database for congenital anomaly outcomes**
CAG reference: **PIAG 2-08(e)/2002**
REC reference: **09/H0405/48**

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 Advisory Group as set out below, has determined the following:

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

Context

Purpose of application

The purpose of this research application from the University of Oxford on behalf of the British and Irish Network of Congenital Anomaly Researchers was to request support to allow the following regional/national registers to continue processing existing BINOCAR identifiable congenital anomaly information for a 2 year period in order to enable linkage to health, mortality and education data to create a congenital anomaly outcomes research database resource. Following the establishment of the linked database the registers would anonymise the data held. The following registers would be maintained; Congenital Anomaly Register for Oxfordshire, Berkshire and Buckinghamshire, East Midlands and South Yorkshire Congenital Anomaly Register, South West Congenital Anomaly Register, Wessex Antenatally Detected Anomalies Register, the National Down Syndrome Cytogenetic Register and the Congenital Anomaly

Register and Information Service. The relevant data controllers are outlined below in appendix 1.

Confidential patient information requested

Continued access to historical BINOCAR data and to Hospital Episode Statistics (HES) and ONS mortality data from the Health and Social Care Information Centre (HSCIC) and Patient Episode Database Wales (PEDW) was requested.

Identifiable data items detailed to allow linkage to take place were full name, address, NHS number, Hospital ID, date of birth, date of death and postcode.

Confidentiality Advisory Group advice

Following agreement at the August 2015 CAG meeting the application was forwarded to a sub-committee of members for consideration.

Public interest

It was agreed that the stated projects in this application were for a medical purpose that are in the public interest.

Practicable alternatives

Members had previously requested confirmation why it would not be possible to obtain anonymised data from Public Health England given that PHE held the retrospective BINOCAR data. It was noted that although PHE held the retrospective BINOCAR data this had not been uploaded into the new National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) as the system was not yet fully operational. Discussions between PHE and the applicant had suggested that PHE were currently focusing on establishing the prospective data collection. It was noted that waiting until these facilities were operational would not be possible given the funding for the current research projects.

Members recognised that the alternative via PHE would currently not be practicable, although once the PHE uploads/downloads and mechanisms were in place, this final state could be the appropriate exit strategy.

It was noted that the large and retrospective nature of the dataset meant that it would not be possible to seek consent.

Exit strategy

The application specified that identifiers would be deleted once linakges had been established. Members agreed that support should be recommended for a period of 2 years and that progress towards this should be reported at annual review stage.

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. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed**
2. Confirmation of suitable security arrangements for CARIS will need to be provided following the establishment of a MoU between NHS England and NHS Wales Informatics Service and confirmation of process for review of CPIP.
3. Confirmation of a favourable Research Ethics Committee opinion for the linkages should be provided prior to receiving data from the HSCIC.

Reviewed documents

Document	*Version*	*Date*
BINOCAR extension request letter		21 July 2015
BINOCAR extension request letter		6 May 2015
Data items collected		July 2015
Data flow diagram		July 2015
BINOCAR research protocol	1	July 2015
BINOCAR HES inpatient data request		
BINOCAR justification for the data items requested		
BINOCAR ONS DEATCH EXTRACT Record layout 2010		
Kurinczuk BINOCAR application		August 2015

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

Claire Edgeworth
Deputy Confidentiality Advice Manager
On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

Enclosures: Appendix 1 – list of registers and data controllers
Standard conditions of approval

Appendix 1 - Registers and associated organisations

East Midlands and South Yorkshire Congenital Anomalies Register – University of Leicester

Congenital Anomaly Register and Information Service – Public Health Wales

Wessex Antenatally Detected Anomalies Register – University Hospital Southampton NHS Foundation Trust

Congenital Anomaly Register for Oxfordshire, Berkshire and Buckinghamshire – University of Oxford

Northern Congenital Abnormality Survey– Newcastle University

South West Congenital Anomaly Register – University Hospitals Bristol NHS Foundation Trust

National Down Syndrome Cytogenetic Register – Queen Mary University London

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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.