Health Research Authority
Confidentiality Advisory Group
On behalf of the Secretary of State for Health

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24/02/2016

Dr Marisa Mason
NCEPOD
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74-76 St John Street
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Dear Dr Mason

Application title: **Child Health Clinical Outcome Review Programme**
CAG reference: **15/CAG/0210**

Thank you for your non-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 Secretary of State (SofS) for Health on whether an application should be approved, and if so, any relevant conditions. This application was considered by a sub-committee meeting via correspondence following cancellation of the CAG meeting scheduled on 10th December 2015.

Secretary of State decision

The Secretary of State for Health, having considered the recommendation from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is approved, subject to compliance with the standard and specific conditions of approval.

This letter should be read in conjunction with the outcome letter dated 7 January 2015.

Context

Purpose of the application

The aim of the Child Health Clinical Outcome Review Programme is to review the organisation of care and clinical practice to identify potentially remediable factors in the care provided for children and young people. The programme will look at the quality of the delivery of care.

The programme comprises two studies; one focusing on adolescent and young peoples' mental health and one on chronic neurodisability. A report of the findings will be published and widely disseminated. The commentary and recommendations made in the report will be based on peer review of the data submitted.

Support under the Regulations is requested to be able to extract and collect identifiable data on a large sample of cases from which the applicant will take random samples for in-depth case note review, and to be able to request data from different care providers such as secondary care and GPs, to build a picture of the quality of care being provided.

Confidential patient information requested

Access was requested to patient case notes in order to extract patient identifiable information.

Information to be extracted is;
NHS number, hospital number, date of birth, gender, date of admission, source of admission, name of admitting clinician/operating clinician, date of discharge/death, date of procedure, type of procedure (OPCS code), diagnosis (ICD10 code), name and postcode.

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 Secretary of State, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Clarification about the difference in approach between the data collection taking place in Northern Ireland and that in England and Wales, including justification for using identifiable information in England and Wales. **Justification for the approach in England and Wales provided 01/02/2016**
2. Clarification on the scope of support requested;
    a. When will the data collection be taking place? **Response 01/02/2016. Collection to start March 2016 support is restricted to collection covering a 6 week period and not 6 months as outlined in the response letter, an amendment will be required if this is for a 6 month period.**
    b. Collection of case notes – is this from the site where patients were treated and any others expected to provide care in the pathway or are details of the whole random sample to be sent to all organisations delivering care? **Response 01/02/2016. Case notes will be available to treating sites only and not across sites.**
    c. Previous notes – please provide justification for this and clarify how it will affect the current care which is under investigation. **Response 01/02/2016. Updated application received to cover this request.**

Support is restricted to case notes covering a 3 year period and not 5 years as had originally been outlined in the protocol.

   d. Pilot study – is support required for this? **Response 01/02/2016, support is not required for the pilot**

3. Attachment B_ STUDY TYPES UNDERTAKEN BY NCEPOD – please advise which are relevant to this application? **Response 01/02/2016. Updated document provided**
4. Confirmation that the organisations involved will be reminded of their responsibilities, as Data Controller, under the DPA Fair processing to notify patients about the use of their personal information. **Confirmed 01/02/2016**

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 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 no later than 16/02/2016 and preferably 4 weeks before this date. If at any stage you no longer require support under the Regulations as you will cease processing confidential patient information without consent you should inform the Confidentiality Advice Team of this in writing as soon as possible.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised)	2	16 November 2015
Other [Attachment B_NCEPOD method and data collection 2015]		
Other [Attachment i - Child Health CORP Data Flow]		
Other [Attachment ii - Child Health HRA Decision Tool]		26 November 2015
Other [Attachment iii - Information for service users]		
Other [Attachment iv - Introduction to the Child Health Review]		
Research protocol or project proposal [Attachment Ci_Cerebral Palsy Study Protocol]		01 August 2015

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item or submitted written comments are listed below.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use

the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

Yours sincerely

Diane Pryce
Senior Confidentiality Advisor
Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*
Standard conditions of approval

Copy to:

Confidentiality Advisory Group sub-committee meeting 10 December 2015

Mark Taylor	**Chair**
Patrick Coyle	
Clare Sanderson	
Hannah Chambers	

Standard conditions of approval

The approval provided by the Secretary of State for Health 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.