Health Research Authority

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02 November 2018

Professor Julia Sanders
Professor of Clinical Nursing and Midwifery
Cardiff University
School of Healthcare Sciences, College of
Biomedical and Life Sciences, Cardiff University,
Room 1.7, Ty Dewi Sant, Heath Park, Cardiff
CF14 4XN

Dear Professor Sanders

Application title:	**The POOL study: Establishing the safety of waterbirth for mothers and babies: A cohort study with nested qualitative component.**
CAG reference:	**18/CAG/0153**
IRAS project ID:	**238743**
REC reference:	**18/WA/0291**

Thank you for your 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. This application was considered at the CAG meeting held on 20 September 2018.

Health Research Authority 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 conditionally approved, subject to compliance with the standard and specific conditions of approval outlined below.

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

This letter should be read in conjunction with the outcome dated 02 October 2018.

Context

Purpose of application

This application from Cardiff University set out the purpose of medical research which aims to evaluate whether the use of birthing pools during labour and water births leads to an increased risk in poor maternal and infant outcomes. Data will be collected on all births in around 30 maternity units between January 2015 and November 2020 to find out how many women used birthing pools during labour, the number of water births and whether the women or infants come to any extra harm as a result of water birth. Routinely collected data will be used. For infants needing specialist care, data will be retrieved from the National Neonatal Research Database (NNRD). The NNRD operates with support under the Regulations via application reference ECC 8-05(f)/2010. There is a supplementary qualitative element to the study which involves online discussion boards and site case study observations which does not require consideration by the CAG.

A recommendation for class 1, 4 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Cohort

All women giving birth at a participating NHS site in England or Wales between January 2015 and November 2020. It is anticipated that this will include 600,000 maternity records.

The following items of confidential patient information will be released by EuroKing to the National Neonatal Research Database, based at the Chelsea and Westminster Hospital NHS Foundation Trust, for the purposes of sample validation and linkage:

- Study-specific Linking Field,
- Surname,
- Infant's NHS Number,
- Infant Date of Birth,
- Postcode,
- Maternity Unit of Birth,
- Ethnicity – for analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicants written response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Clarify the retention period for confidential patient information by EuroKing Maternity Software Solutions and Chelsea and Westminster NHS Foundation Trust.**

It was confirmed that Chelsea and Westminster NHS Foundation Trust via the NNRD currently holds identifiable data for the purpose of linkage in perpetuity, as per the conditions of support under the Regulations (ECC 8-05(f)/2010). NNRD will destroy all confidential patient information provided for linkage after linkage or before the date of study completion 3 August 2021.

Euroking Maternity Software Solutions would remotely access each of the NHS site's servers, run the data extract script and download the extract onto the EuroKing secure server. The extracts will then be immediately transferred to both NNRD and Cardiff University and on confirmation of successful receipt of data transfer by Cardiff University and NNRD, the data extract held on EuroKing server will be deleted. A copy of the extract will be retained on the site server as a database reports to ensure an audit trail of data extracted is retained for the duration of the study.

The Sub-Committee received the response and raised no issues in this area.

2. **An alternative mechanism for raising an objection to the use of confidential patient information within the study should be offered as part of the patient notification strategy – provide confirmation of this alternative means and revise the supporting documentation accordingly.**

The applicant confirmed that a further mechanism in which women can opt-out from the POOL study by phoning or emailing the maternity unit and requesting their record be flagged as opted-out had now been included. This would ensure any women uncomfortable requesting this directly with their midwife has a mechanism to opt out. The applicant confirmed that this has been discussed with the lay representatives on the study, who were happy with this additional method to opt-out. It was also confirmed that where the National Opt Out scheme had been put in place at study sites these opt-outs would also be upheld for this study. A revised copy of the information leaflet was provided for information purposes.

The Sub-Committee was content with the additional objection mechanism. The revised information leaflet was considered. Members agreed that the word retrospectively should be removed from the dissenting paragraph. As this revision was minor, this requirement would be added as a condition of support to be enacted prior to the study commencing; however, it could be reported back at the time of first annual review that this actioned.

3. **Confirm that women who have a water birth will be proactively provided with a copy of the study information leaflet.**

The applicant confirmed leaflets would be readily available for distribution in the birthing unit to women having a water birth. Midwives would be advised, as part of training, to provide a leaflet to each woman who uses a pool.

The Sub-Committee received the response and no queries were raised.

<u>Recommendation</u>:

The following point is added as a recommendation only and will not be considered as part of the final recommendation of support.

1. It would be beneficial if wider patient and public involvement and engagement activity was undertaken as the study progressed, in order to assist with a means of disseminating research findings as example.

The applicant confirmed that a PPI stakeholder event was planned at the end of the project, no formal decisions had been made as yet but this is scheduled for the dissemination phases of the project. The planning of the PPI event would be carried out between analysis of data and publication of results. This event is planned with the specific aim of PPI representatives being able to inform the interpretation of study results and assist in drafting in recommendations for practice. In addition, lay and PPI representation

is in place on the study's monthly management group meetings and annual study steering committee meetings. These representatives have already and will continue to inform strategies for study publicity and dissemination.

The Sub-Committee received the supplementary information and raised no queries.

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 (Final)

1. Revise the patient leaflet to remove the word 'retrospectively' from the dissenting paragraph. This should be actioned prior to the study start; however, confirmation should be provided at the time of first annual review that this was undertaken.
2. Favourable opinion from a Research Ethics Committee (**Confirmed – 09 October 2018**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Chelsea and Westminster NHS Foundation Trust and EuroKing Maternity Software Solutions (Healthcare Software Solutions YGMAJ) have confirmed satisfactory reviewed grade on Version 14.1, 2017/18**).

As the above conditions have been accepted 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 **02 November 2019** and preferably 4 weeks before this date.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [CAG_Form]		30 August 2018
Covering letter on headed paper [CAG Response Letter]		22 October 2018
Data Protection Registration [ICO Registration number]		
Other [CAT Advice Form Response]		06 September 2018
Other [Opt out strategy]	1	06 June 2018
Other [IGT V14.1 assessment - CHELSEA AND WESTMINSTER HOSPITAL NHS FOUNDATION TRUST]		16 October 2018
Other [NIGB_CAG[2]]		03 March 2015
Patient Information Materials [POOL Leaflet - Medical Records]	1.1	09 October 2018
REC favourable opinion letter and all correspondence [18_WA_0291 Acknowledgement of response]		09 October 2018

REC favourable opinion letter and all correspondence [REC Conditions Met]		09 October 2018
Research protocol or project proposal [Data Flow]		
Research protocol or project proposal [POOL Protocol]	1	18 July 2018
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [POOLStudy Sponsor Letter]		06 September 2018

Membership of the Committee

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

There were *no* further declarations of interest in relation to this item.

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/

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at: http://www.hra.nhs.uk/hra-training/

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.

With the Group's best wishes for the success of this project.

Yours sincerely

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Health Research Authority

Email: HRA.CAG@nhs.net

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

Copy to: corinne.scott@wales.nhs.uk
hra.approval@nhs.net

Confidentiality Advisory Group Sub-Committee meeting in Correspondence

Group Members:

Name	*Present*	*Notes*
Dr. Liliane Field	Yes	
Ms Clare Sanderson	No	Alternate Vice-Chair
Ms Gillian Wells	Yes	Lay Member

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

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.