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20th May 2015

Dear Mr Latinovic

Study title: **Evaluation of linked antenatal and newborn NHS Sickle Cell and Thalassaemia Screening Programme**
CAG reference: **ECC 6-06(f)/2009**

Thank you for the provision of an annual review report 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. The purpose of the annual review is to provide an update against the conditions of approval where applicable, confirm progress of the study, review the need to process confidential patient information, and ensure the minimum amount of identifiable information is being used.

Health Research Authority approval decision

The Health Research Authority, having considered the advice from the Confidentiality Advisory Group as set out below, has approved the continued processing of this application for the specified purposes for a further 12 months from the anniversary of your original final approval outcome letter, therefore until 10th April 2016.

Support under the Health Service (Control of Patient Information) Regulations 2002 will be effective for 12 months from the anniversary of the original approval, rather than 12 months from the date of the annual review. This is a change in administrative policy and means that some applicants will have an unusually short period of renewed support before there is a need to provide another annual review report. This will be a one-off occurrence to bring applications back into line with the correct annual reporting cycle.

Context

Purpose of application

This application from the NHS Sickle Cell and Thalassaemia Screening Programme set out the assessment of newborns' overall outcome and timely early entry into care of all babies identified with sickle cell disease. Information will be retained until the child is 5 years of age to allow follow up. Section 251 support was requested in order to collate patient identifiable data from newborn screening laboratories and clinical networks programme for linkage purposes.

Confidential patient information requested

Access was requested to name, NHS number, date of birth, place of birth, gender and ethnicity of child, and name, NHS number, date of birth, address and cause of death of mother.

Confidentiality Advice Team Advice

The following was confirmed by the applicant:

1. The Health and Social Care Information Centre required at least 3 identifiers to flag patients. The data was often filled out by screening staff rather than pulled out from a central IT system which increased the chance of inaccurate data.

2. It was noted that the applicant was going through a review of data collection forms /data items in order to improve the study outcomes and it was planned to submit the changes for the next annual CAG review.

3. There was still a continued need to access confidential patient information as specified within the original application.

Security arrangements

A satisfactory Information Governance Toolkit score of 72% was noted and was confirmed by the Health and Social Care Information Centre (HSCIC) on the 23rd April 2015.

Study Progress

The Confidentiality Advice Team noted that the conditions of approval continue to be met.

Steps taken to anonymise the information or obtain consent from individuals

The Confidentiality Advice Team noted that the applicant had explored methods of anonymisation or reducing the identifiable information held as an exit strategy. This included retention of mothers' and babies' NHS numbers and no other identifiers. However, it was noted that the applicant had not been able to effectively capture NHS Numbers for a number of the cohort and therefore, alternative identifiers are required for clarification of data accuracy.

The Confidentiality Advice Team commented on the work which had been carried out in relation to exit strategies and advised that the applicant should provide a report at the next annual review as to whether any of the exit strategies would be implemented. The Confidentiality Advice Team noted that it is not feasible for the applicant to only process NHS numbers as it does not provide sufficient information on the cohort, screening history or enable the collection of accurate morbidity and mortality data.

Projected end date

The Confidentiality Advice Team highlighted that the project would continue for the duration of the screening programme and noted that the applicant estimated that by April 2016, the sufficient information would had been collected to enable predictive outcomes. The applicant noted that the data would be anonymised and identifiable data would not be retained after affected babies reach five years of age. The Confidentiality Team asked for the applicant to provide an update on the evaluation of non-cancer screening programme workstream.

Project Changes

It was noted there had been no changes to the data controller, purpose, scope, data flows, data sources of the project. However, changes are due to be made regarding the future hosting of the project. The initial contract with King's College London (KCL) would have expired in 2016 and the applicant is currently reviewing possible options. The Confidentiality Advice Team noted that changes are to be made regarding the data collection templates and the data items to make ease of the data collection process and advised that an amendment request should be submitted.

Patient and Public Involvement

The Confidentiality Advice Team noted that a forum had been established which meets three times a year to assure users and healthcare professionals that data is collected and process in a secure and confidential manner. The forum also included feedback from the Sickle Cell Society and UK Thalassaemia Society. The confidentiality Advice team also noted that information is also provided on the Sickle Cell Society and UK Thalassaemia Society websites.

Patient Feedback and Objections

The applicant confirmed that there had been no complaints related to this project. The applicant regularly asked for confirmation from the Sickle Cell Society and UK Thalassaemia Society if any concerns in relation to this project had been raised.

The Confidentiality Advice Team agreed that there was still a continued need to access confidential patient information as specified within the original application.

Confidentiality Advice Team advice conclusion

As a whole, it was recommended that the approval in place for the purposes set out in the application should continue for a further 12 months from the anniversary of the original final approval outcome letter, to the date specified above.

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 4 weeks before the date indicated above.

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

Amy Ford
Senior 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.