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30 June 2016

Dear Mr Umesh

Study title: **United Kingdom Immune Thrombocytopenia Registry**
CAG reference: **CAG 5-03 (PR2)/2013)**

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 15 July 2017.

Context

Purpose of application

This application from Barts Health NHS Trust set out the purpose of studying the natural history of immune thrombocytopenia (ITP), a rare disease characterised by platelet drop and bleeding, estimating prevalence and incidence of comorbid illnesses in the ITP cohort, and describing current treatment pattern and measuring treatment effectiveness. A database was already in place collecting demographic, clinical and treatment data using a fully consent based model.

A recommendation for class support was requested to cover access to Hospital Episode Statistics (HES) and mortality data from the Health and Social Care Information Centre as the consent form did not make reference to this. The additional HES data would be used in order to validate data already collected by the study and enhance the overall data capture.

Confidentiality Advice Team advice

Security arrangements

A satisfactory Information Governance Toolkit score of 76% v13 was noted.

Study Progress

The applicant reported that the conditions of approval continue to be met. The CAT followed-up on progress the advice and conclusion set out in the annual review from 2015; the applicant was advised to ensure that patients were informed about the linkage to HES data within any materials sent to patients from the registry.

The applicant set out several measures they have introduced, which are;

- a notice is published on the registry website for anyone, including participants and centres, to access readily
- the letter from CAG is also part of the study documents sent and accessible by all centres
- reminders are sent to all centres so that participants are given the opportunity to object to the being part of the HES linkage

Steps taken to anonymise the information or obtain consent from individuals

Two sets of data are received from the HSCIC. One set of data is on existing enrolees on whom the applicant have obtained consent to have identifiers and did not require any new ones from the HSCIC. These identifiers are kept so that the applicant can run the registry. When the data are analysed all identifiers are removed.

The other set of data that received from the HSCIC was already pseudonymised in that it had only part date of birth and part post code. No other identifiers were provided.

Projected end date

This is a rare disease registry with REC approval until 0U05/2017, it is intended to run studies until this date it is then planned to extend this under a future amendment because there are more aspects on immune Thrombocytopenia that require investigating and the registry will enable this to happen.

Project Changes

It was noted there had been no changes to the data controller, purpose, scope, data flows, data sources or identifiable data items of the project.

User feedback and involvement

It was noted that no user involvement has taken place this year.

Patient feedback and objections

The applicant has reported that no complaints have been received on the linkage. Whenever participants are consented they have the choice to opt out of the data linkage and therefore no linked data have been obtained on them during the last refresh which was received in January 2015. There has been no objection from any enrolees about the data linkage service. lf there are any the applicant has stated they will ensure that the enrolees' data are not used in any studies which required the data from HSCIC. All data is processed as per enrolees' consent.

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

Diane Pryce
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.