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03 June 2015

Dear Mr Williamson

Application title: **2015 Inpatients Survey**
CAG reference: **CAG 10-02(b)/2015**

Thank you for your service evaluation 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 at the CAG meeting held on 15 January 2015.

Secretary of State approval decision

The Secretary of State, 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 and specific conditions of approval.

Context

Purpose of application

This application from Care Quality Commission set out the purpose of the 2015 Inpatient Survey. The inpatient survey would include all 154 eligible trusts who would be asked to conduct the survey with preparations expected to begin in August 2015. Approximately 1,250 patients would be included at each trust. A pilot would be undertaken to determine the effect of inclusion of a CQC flyer and 4 Trusts would submit details on an additional 625 patients each as part of the pilot.

A recommendation for class 5 and 6 support was requested to cover access to information from relevant trusts to allow surveys to be administered.

Confidential patient information requested

Access was requested to name, address and postcode.

Confidentiality Advisory Group advice conclusion

At the meeting held on 15 January 2015, agreed that the minimum criteria under the Regulations appeared to have been met, however, further information would be required and therefore advised recommending support to the Secretary of State, subject to satisfactory responses to the request for clarification and compliance with the specific and standard conditions of support as set out below.

Further information was received in response to the request for further information and specified conditions of support below on 23 March 2015 and the responses are outlined below in bold.

Request for further information

1. Please confirm why it is necessary to share the respondent level data with NHS England and Department of Health. **A response outlining the requirement to share respondent level data with NHS England and Department of Health was provided.**

Specific conditions of support

1. Information in surveys and patient letters should be provided which informs patient about the right to object to future and current surveys and that their information will be shared with other organisations such as NHS England and Department of Health. **It was confirmed that the following text would be included within the covering letter "The data will also be shared with the Health and Social Care Information Centre, or other organisations, working on behalf of Department of Health or NHS England for the purpose of generating these indicators."**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **IGTK confirmed for Picker, Capita Business Services Ltd, Quality Health and Patient Perspective.**

The responses were forwarded to members who noted that the information provided to patients in relation to condition 1 meant that the potential organisations that could access the information were broad and undefined. The applicant was asked whether it would be possible to define these further and it was confirmed that as the contracting out of additional analyses was beyond CQC's control, 'other organisations' were included to avoid listing all possible organisations that may be contracted in the future and that data sharing agreements would be in place with those organisations. Members noted the difficulties faced and that there were opportunities for patients to obtain further information via CQC's website which could be used to inform patients.

It was advised that as the data sharing only applied to those patients who returned questionnaires, the CQC should ensure that the consent in place was sufficient and that information provided in relation to organisations and purposes for sharing

was clear as possible. Data should only be shared for the purposes detailed within the application form and specified to patients.

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 28 May 2016 and preferably 4 weeks before this date.

Reviewed documents

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Survey flyer	Final	05/03/2014
20140724 IP14 First Mailing Letter	2	29/07/2014
20140724 IP14 First Reminder Letter	1	24/07/2014
20140724 IP14 Second Reminder Letter	2	29/07/2014
20141208 IP15 dissent	1	08/12/2014
20141208 IP15 Sampling flow chart	1	08/12/2014
20141209 IP15 section 251 application	5	09/12/2014
IP14 First Mailing Letter	1	29/07/2014
IP14 Questionnaire v2	2	04/09/2014
Response letter – Karen Hallt		23/03/2015
Email from Karen Hallt		10/04/2015

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/

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/

Yours sincerely

Claire Edgeworth
Deputy Confidentiality Advice Manager
On behalf of the Secretary of State for Health

Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*

Confidentiality Advisory Group meeting 15/10/2015

Group members

Name	Capacity
Dr Patrick Coyle	
Dr Tony Calland	
Dr Kambiz Boomla	
Dr Robert Carr	
Ms Hannah Chambers	Lay
Professor Barry Evans	
Professor Julia Hippisley-Cox	
Mr Anthony Kane	Lay
Professor Jennifer Kurinczuk	
Ms Clare Sanderson	
Dr Murat Soncul	
Mr C Marc Taylor	
Ms Gillian Wells	
Dr Miranda Wolpert	

In attendance

Name	Capacity
Ms Natasha Dunkley	Confidentiality Advice Manager, HRA
Ms Claire Edgeworth	Deputy Confidentiality Advice Manager, HRA
Mrs Nana Baffoe	Confidentiality Advisory Group Assistant, HRA
Ms Alex Bell	HSCIC Observer

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.