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13 June 2016

Chris Graham
Picker Institute Europe
Director of Research and Policy, Picker Institute Europe and Chief Investigator of National Patient Survey Programme
Picker Institute Europe
Buxton Court
3 West Way
Oxford
OX2 0JB

Dear Mr Graham

Application title:	**2016 Accident and Emergency Survey**
CAG reference:	**16/CAG/0077**
IRAS project ID:	**N/A**
REC reference:	**N/A**

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 for Health (SoS) on whether an application should be approved, and if so, any relevant conditions. This application was considered at the sub-committee CAG meeting held on 17 May 2016.

Health Research Authority approval decision

The Secretary of State for Health, 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 the Picker Institute Europe set out the purpose of carrying out the 2016 Accident and Emergency Survey sponsored by the Care Quality Commission. This was specifically to enable the transfer of identifiable data from acute trusts, to an approved survey contractor for the purpose of mailing out questionnaires for the 2016 accident and emergency survey. It was expect from past experience that the vast majority trusts involved will opt to use an approved survey contractor, either: Picker Institute Europe, Quality Health, Patient Perspective, CAPITA Surveys & Research or the new approved contractor, Membership Engagement Services Ltd. (MES).

The 2016 A&E survey will be the sixth carried out to date. It was expected that 147 trusts will be eligible for the survey (dependent on the outcome of the development work and chosen sampling strategy). Trusts will be asked to conduct the survey with preparations expected to begin in July 2016 and fieldwork expected to start from November 2016. All trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey. An overview of the survey methodology was provided with this application.

A recommendation for class 4 and 6 support was requested to cover access to confidential patient information in order to carry out the survey.

Confidential patient information requested

There are two files to be provided to contractors;

Mailing file used to address questionnaires to the appropriate person for this access was requested to;

- standardised unique identifier code, to be constructed as survey identifier, trust code followed by a whole number (consecutive across the sample of patients from each trust), e.g. AE16XXXnnnn where XXX is the trusts 3 digit trust code and nnnn is the 4 digit serial number relating to sampled patients.
- Title (Mr, Mrs, Ms, etc.)
- First name
- Surname
- Address Fields
- Postcode

The sample data file will be used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn. For this access was requested to;

- The unique identifier code (as above)
- Date and time of attendance
- NHS Site code (hospital where treated)
- Department type
- Ethnicity
- Gender
- Year of birth
- Referring CCG- this replaces the GPPC code that we collected in the 2012 and 2014 survey

Confidentiality Advisory Group advice

Public interest

Members were in agreement that this project was in the public interest with clear benefits to patients.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of patient identifiable data without consent existed, taking into account the cost and technology available in line with Section 251 (4) of the NHS Act 2006.

- Feasibility of consent

Members were in agreement that consent was not practicable prior to the survey being sent out.

Justification of identifiers

Members were in agreement that identifiable information was needed in order to carry out the survey.

Exit strategy

Members noted that all identifiable information was to be destroyed once the survey had been completed.

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

Specific conditions of support

1. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **Confirmed 13/05/2016**

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 13 June 2017 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) [AE16 S251 Precedent Set Review CK AW]	v2.3	10 May 2016
CAG application from (signed/authorised) [AE16 S251PrecedentSet Review]	v1.0	10 May 2016
Confidentiality policy [Sampling flow chart]	v1.0	10 May 2016
[CAGSF4 CAG Precedent Set Review Form]		
[Guidance Manual]	v1.0	04 April 2014
[AE16 dissent]	v1.0	10 May 2016
[Advisory Group Terms of Reference]	v1.0	10 May 2016
[Service contract briefing]	v1.0	09 May 2016
[Sample Declaration Form Trusts using contractor]	v1.0	09 May 2016
[Model service contract]	v1.0	09 May 2016
[Email IG Toolkit]		25 February 2016
Patient Information Materials [poster FINAL]		
Patient Information Materials [First Reminder Letter FINAL]		07 May 2014
Patient Information Materials [Questionnaire FINAL AGREED]		15 April 2014
Patient Information Materials [Second reminder mailing letter FINAL]		07 May 2014
Patient Information Materials [First mailing letter FINAL]		07 May 2014

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

Diane Pryce
On behalf of the Secretary of State for Health
Email: HRA.CAG@nhs.net

Enclosures: *List of members who considered application*

Standard conditions of approval

Copy to: Karen Hallt (CQC)
Tamatha Webster (CQC)

Confidentiality Advisory Group sub-committee meeting 17 May 2016

Name	*Profession*	*Present*	*Notes*
Dr Patrick Coyle (Chair)		Yes	
Ms Sophie Brannan		Yes	
Ms Clare Sanderson		Yes	

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.