



# Health Research Authority

Skipton House  
80 London Road  
London  
SE1 6LH

Email: HRA.CAG@nhs.net

Picker Institute Europe  
Buxton Court  
3 West Way  
Oxford  
OX2 0JB

22 December 2016

Dear Mr Chris Graham

**Application title:** 2017 Community Mental Health Survey  
**CAG reference:** 16/CAG/0157

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 (SofS) for Health on whether an application should be approved, and if so, any relevant conditions. This application was considered at the Precedent Set Sub-Committee of the CAG meeting held on 02 December 2016.

## Secretary of State decision

The Secretary of State for Health, having considered the recommendation from the Confidentiality Advisory Group as set out below, has determined the following:

1. The application is approved, subject to compliance with the standard conditions of approval.

## Context

### Purpose of application

This application from Picker Institute Europe set out the purpose of understanding patients' experiences of NHS services and to drive improvements to the services.

The application was for a recommendation of support for the transfer of patient identifiable data from mental health providers, to an approved survey contractor for the purpose of mailing out questionnaires for the 2017 community mental health survey.

Alongside this the applicant also wished to pilot four new interventions to increase response rate and make the survey more representative. These were: pre approach mailer, in a sealed envelope, redesigned covering letter, redesigned questionnaire (layout and colour) and redesigned flyer (targeted at 18 – 35 age group). Patients would be randomised to receive different combinations of these 'interventions'.

The methodology used for this survey was approved by CAG in 2015 for the 2016 Community Mental Health Survey. There had been one change to this methodology, which was approved as an amendment to the National Patient Survey Programme in August 2016. This amendment was to enable Trusts to submit one file containing both mailing and sample to the contractor, as opposed to two separate files.

Some NHS Trusts could opt to undertake the mailing of questionnaires themselves, but most would use contractors. The application concerned the use of contractors only.

A recommendation for class V1 support was requested to cover access to patient information for a survey that is aimed at auditing, monitoring and analysing patient care (under Class V support).

#### Confidential patient information requested

Access was requested to name and full address including postcode

#### **Confidentiality Advisory Group advice**

#### Public interest

Members agreed that this activity was in the public interest.

#### 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

The Sub-Committee accepted the arguments that taking consent would be impracticable for health care staff, would remove the cost and time benefits of employing a contractor to mail out surveys, and would introduce bias into the study due to variable response rates from patients.

- Use of anonymised/pseudonymised data

It was evident that the use of anonymised/pseudonymised data would not be feasible as names and addresses were required to send out the questionnaires.

#### Justification of identifiers

Members agreed that the disclosure of names and addresses from mental health providers to the approved contractor for the mail out of questionnaires was justified.

It was noted that this was in line with precedents set in previous applications. The only change to previous methodology had been approved by the CAG earlier in the year as an amendment to methodology for all National Patient Surveys. The change had been to submit both sample and mailing data in a single file from NHS Trusts to the approved contractor. The contractor, rather than the NHS Trust, would then split the file prior to submitting only the sample information to the co-ordination centre for checking – this change had occurred to reduce the risk of sample and mailing data becoming misaligned.

#### Additional points

Members noted that an additional approved contractor - Membership Engagement Services (MES) had been added to the application. The applicant had confirmed that appropriate security and Data Protection assurances had been provided.

#### Pilot of survey methodology

The CAT had raised a query with regards to whether the pilot could be considered research, as the application was a non-research application and would not result in support for any research activity. In discussion with the applicant, it was established that the results from the trial of survey approaches (described in the application as 'interventions') would not be generalizable to other surveys, as they related to the Mental Health Survey only. The approaches had been developed in conjunction with MIND to increase participation in the survey for this population only, therefore the applicant was satisfied that they were not carrying out a research activity.

Members of the CAG agreed that the aim of the pilot was to increase participation in the survey rather than to use the information for research purposes.

Although there had been involvement from MIND, members recommended that further patient and public involvement was sought, and suggested using the online patient panel to seek patient views on access to names and addresses by contractors for the purpose of the survey.

Members considered the pilot materials. It was noted that the opportunity to opt out was not mentioned in the first contact with patients, and was not prominent in the second (it was located in the FAQs for the first mailing letter, where patients would need to look for the information). Members agreed that it would be preferable to mention opt-out within the main text of the letter, for example adding the text 'if you have any questions *including what to do if you do not wish to take part...*' in the final paragraph. The Sub-Committee agreed to make this a suggestion rather than a condition of support.

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

#### **Specific conditions of support**

1. The Sub-Committee suggests using the online patient panel to seek patient views on access to names and addresses by contractors. Please note that this is a suggestion only and support is not conditional on this point.
2. The Sub-Committee suggests that the possibility of opting out of the survey is mentioned within the main text of the letter, for example adding the text 'if you have any questions *including what to do if you do not wish to take part...*' in the final paragraph. Please note that this is a suggestion only and support is not conditional on this point.

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.

### **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.

### **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 December 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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised) [CAG form]		24 November 2016
GP/consultant information sheets or letters		
Patient Information Materials [Patient Documents]	1	
Patient Information Materials [Patient Documents]	1	
Patient Information Materials [Patient Documents]	1	
Patient Information Materials [Patient Documents]	1	
Patient Information Materials [Patient Documents]	1	
Patient Information Materials [Pilot Flyer]		
Patient Information Materials [Pilot Mailing Letter]		
Patient Information Materials [Pilot Reminder]		
Patient Information Materials [Pilot Mailer]		
Patient Information Materials [Pilot Questionnaire]		
Patient Information Materials [Pilot 2nd Reminder]		

### **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/>

Yours sincerely

Rachel Heron  
Confidentiality Advisor

Email: [HRA.CAG@nhs.net](mailto:HRA.CAG@nhs.net)

*Enclosures:*

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

## Confidentiality Advisory Group sub-committee meeting 02 December 2016

### Group Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Sophie Brannan		Yes	
Dr Patrick Coyle		Yes	
Ms Clare Sanderson		Yes	

## Standard conditions of approval

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.