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16 November 2018

Ms Jenny King
Chief Research Officer and Chief Investigator of NHS Patient Survey Programme
Picker Institute Europe
Buxton Court
3 West Way
Oxford
OX2 0JB

Dear Ms King

Application title: **2019 Community Mental Health Survey**
CAG reference: **18/CAG/0183**

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 and Social Care on whether an application should be approved, and if so, any relevant conditions. This application was considered at the precedent set CAG meeting held on 02 November 2018. The application was considered via the Precedent Set process under criteria 11 – Applications made by the Picker Institute Europe to administer surveys on behalf of CQC.

Secretary of State for Health and Social Care decision

The Secretary of State for Health and Social Care, 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 and specific conditions of approval.

Please note that the legal basis to allow access to the specified confidential patient information without consent is now in effect.

Context

Purpose of application

This non-research application from Picker, CQC and NHS England set out the purpose of administering the 2019 Community Mental Health Survey, to gauge patient experience and views of the service they received. A recommendation of support was requested to enable the transfer of patient identifiable data from mental health providers, to an approved survey contractor for the purpose of mailing out questionnaires. The vast majority of trusts involved were expected to opt to use an approved survey contractor, either: Picker Institute Europe, Quality Health and Patient Perspective.

All 56 eligible mental health provider Trusts will be asked to conduct the survey, drawing a sample of service users according to set criteria, and following standardised materials and procedures for all stages of the survey. The aim was to ensure organisations carry out patient surveys in a consistent and systematic way, using a standardised methodology and survey instrument, to build up a national picture of people's experience.

The end product from this survey will be a set of aggregate statistical data that does not contain patient identifiable information. This statistical dataset is used for a wide variety of purposes to support ongoing improvement in overall patient experience by NHS Trusts and CCGs and by CQC, to inform its regulatory functions.

NHS Patient Survey Programme

This survey is part of the NHS Patient Survey Programme, and as such follows the same methodology as other surveys within the programme. The methodology is approved in principle by the CAG, and applications are usually considered via the Precedent Set pathway.

New approaches are often piloted within the NHS Patient Survey Programme. For the current application (Community Mental Health Survey 2019), the following interventions would be added as part of a pilot:

- Dissent posters being available in the ten most commonly spoken languages in England. Trusts can display these optional posters alongside the mandatory English poster to maximise reach for their service user population.
- The inclusion of relevant Trust email and postal address information, if available, on dissent posters alongside a contact telephone number for service users to contact should they wish not to participate
- An earlier first reminder letter, sent 5 working days after the first mailing has been sent rather than 2 – 3 weeks which was standard practice previously.
- No longer including a CQC flyer within mailing packs to respondents.
- Piloting email augmentation in the survey by including a link to an online questionnaire in the initial postal letter. This would be followed up by a reminder email, which included a link to the online questionnaire. The primary aim of this pilot was to increase response rates overall and from lesser heard groups. A secondary aim of the pilot will be to determine whether a potential move towards a mixed mode (paper and digital) methodology for this survey and the NPSP is possible in future years. The eligibility criteria for the intervention will be different from the main stage survey as email contact is necessary. Therefore service users must have an email address listed to be eligible for sampling. For clarity, please note that the Survey Coordination Centre do **not** receive any names, postal addresses or email addresses.

A recommendation for class 3, 5 and 6 support was requested to cover activities as described in the application.

Confidential patient information requested

Data from mental health providers in relation to people aged 18 and over who had been in contact with NHS mental health services in the three month period, 1 September to 30 November 2018, and who were receiving specialist care or treatment for a mental health condition, including those who receive care under the Care Programme Approach (CPA).

The **mailing file** is used to address questionnaires to the appropriate person, and is sent to the **Approved Contractor**. It contains:

- Trust code
- A standardised unique identifier code,
- Title (Mr, Mrs, Ms, etc.)
- First name
- Surname
- Address Fields
- Postcode

The **sample data file** is 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 and is sent to the **Coordination Centre**. This file contains:

- Trust code
- The unique identifier code (as above)
- Year of birth
- Gender
- Ethnic category
- Day of last contact
- Month of last contact
- Year of last contact
- CPA status
- CCG code
- Mental Health Care Cluster Codes

Pilot study

As part of the pilot work, between 5-10 Trusts participating in the pilot work will also be asked to include the following:

- Email address for intervention and control pilot sample only.

Confidentiality Advisory Group advice

Public interest

The CAG was assured that the application defined an appropriate medical purpose, which was the management of health and social care services. Members were assured of the ongoing public interest in the NHS Patient Survey Programme as a service evaluation tool, gaining knowledge on patient experience.

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 Group recognised that the proposed application would operate via the standardised methodology for surveys facilitated by the Picker Institute Europe; which had been supported in principle by the CAG. The applicant explained why the surveys could not be operated on a prior consenting basis within the application – the Group was assured that this rationale remained relevant and appropriate to the current submission. Members considered the rationale and acknowledged that patients would have the choice around whether to respond to the survey request when received. It was agreed that consent was not feasible for the proposed activity and no further issues were raised in this activity.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate distribution of the survey, which could not otherwise be achieved. No issues were raised in this area.

Justification of Identifiers

The Group was satisfied that the items of confidential patient information requested were appropriate and proportionate to the facilitation of the survey.

Exit Strategy

The CAG acknowledged that the primary exit strategy was patient consent via the return of a completed survey. The mailing file may be kept until the reporting stage of the survey (a maximum of 12 months) in case of anomalies or errors discovered during sample validation. Following which, the file would be destroyed. No issues were raised in this area.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether an unconsented activity should go ahead. The applicants had confirmed that an Advisory Group was held in June 2018 to discuss questionnaire content and methodologies. The stakeholders included representatives from CQC, NHS England and the Survey Coordination Centre, plus two Patient Experience leads from mental health Trusts, two Experts by Experience, and a representative from the mental health charity MIND. Feedback from the session was provided for information purposes. The applicant explained that the information materials and questionnaire document would also be submitted for discretionary review by an NHS Research Ethics Committee. Members received the information and raised no issues in this area.

Patient Notification and Dissent

It is a general principle of the CAG, when recommending support, for reasonable measures to be taken to inform the relevant population of the activity and to provide a right and mechanism to respect objection, where appropriate. This is known as patient notification. This is separate to the local obligation to comply with the principles of the

Data Protection Act 2018. The applicants had provided copies of posters which had been produced to promote the survey and would be provided for display in participating Trusts. It was recognised that Trusts would be requested to include a contact telephone number together with postal and email addresses to facilitate patient dissent. The posters had also been made available in the ten most commonly spoken languages in the England, to make the information accessible to a wider audience. The Sub-Committee considered the documentation and raised no issues.

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

Specific conditions of support (Final)

1. Confirmation from the IGT Team at NHSD Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Picker Institute Europe, Quality Health and Patient Perspective all have a published reviewed grade on V14.1, 2017/18).**

As the above conditions have been 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 **16 November 2019** 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) [MH19_Section 251 application]	1	11 October 2018
Other [MH18_Sampling instructions]	1	06 March 2018
Other [MH18_Survey Handbook]	1	06 March 2018
Other [MH19_Dissent]	1	
Other [MH19_Supplementary GDPR information]	1	
Other [MH19_Questionnaire]	1	
Other [MH19_Questionnaire_Pilot]	1	
Patient Information Materials [MH19_Dissent Poster]	1	

Research protocol or project proposal [MH19_Sampling flow chart]	1	
Research protocol or project proposal [MH19_Pilot intervention methodology]	1	

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

Miss Kathryn Murray
Senior Confidentiality Advisor

On behalf of the Secretary of State for Health and Social Care

Email: HRA.CAG@nhs.net

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

Confidentiality Advisory Group Sub-Committee Meeting 02 November 2018

Group Members:

Name	*Present*	*Notes*
Dr Malcolm Booth	Yes	
Dr Harvey Marcovitch	Yes	
Dr Murat Soncul	Yes	Alternate Vice-Chair

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Murray	Senior Confidentiality Advisor

Standard conditions of support

Support to process confidential patient information without consent, given by the Secretary of State for Health and Social Care, is subject to the following standard conditions of support.

The applicant and those processing the information will ensure that:

1. The specified confidential patient 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, in addition to other national guidance.

4. All staff with access to confidential patient information have contractual obligations of confidentiality, enforceable through disciplinary procedures.

5. All staff with access to confidential patient information have received appropriate ongoing training to ensure they are aware of their responsibilities.

6. Activities remain consistent with the General Data Protection Regulation and Data Protection Act 2018.

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. Any significant changes (for example, people, purpose, data flows, data items, security arrangements) must be approved via formal amendment prior to changes coming into effect.

10. An annual review report is submitted to the CAG every 12 months from the date of the final support letter, for the duration of the support.

11. Any breaches of confidentiality around the supported flows of information should be reported to CAG within 10 working days of the incident, along with remedial actions taken / to be taken. This does not remove the need to follow national/legal requirements for reporting relevant security breaches.