Health Research Authority

Skipton House
80 London Road
London
SE1 6LH

Tel: 020 797 22557
Email: HRA.CAG@nhs.net

25 November 2019

Ms Jenny King
Chief Research Officer
Picker Institute Europe
Buxton Court
3 West Way
Oxford
OX2 0B

Dear Ms King

Application title:	**2020 Community Mental Health Survey**
CAG reference:	**19/CAG/0206**
IRAS project ID:	**Not applicable – non-research**
REC reference:	**Not applicable – non-research**

Thank you for submitting a **non-research** application under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support') to process confidential patient information without consent.

Supported applications allow the controller(s) of the relevant data sources, if they wish, to provide specified information to the applicant for the purposes of the relevant activity without being in breach of the common law duty of confidence. Support provides a lawful basis to allow the information to be processed by the relevant parties for the specified purposes without incurring a breach of the common law duty of confidence only. Applicants must ensure the activity remains fully compliant with all other relevant legislation.

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 and Social Care on whether application activity should be supported, and if so, any relevant conditions. This application was considered at the CAG meeting held on 07 November 2019. The application was considered via the precedent set process under category 11: Picker Institute Survey.

Secretary of State for Health and Social Care decision

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

1. The application to allow the disclosure of confidential patient information from participating mental health Trusts in England to the approved contractors Picker Institute Europe, Quality Health and Patient Perspective who would mail out surveys using addresses from the mailing file, and transfer the sample file to the coordination centre for later linkage of demographic data to survey responses, and validation of data is fully supported, subject to compliance with the standard conditions of support.

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.

The 2020 community mental health survey will be the seventeenth iteration of a mental health survey carried out. 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.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients aged 18 and over who had been in contact with NHS

	mental health services in the three-month period from 1 September to 30 November 2019, and who were receiving specialist care or treatment for a mental health condition, including those who receive care under the Care Programme Approach (CPA).
Data sources	1. Electronic patient records, Mental Health Trusts in England
Identifiers required for linkage purposes	1. Trust code 2. A standardised unique identifier code, 3. Title (Mr, Mrs, Ms, etc.) 4. First name 5. Surname 6. Address Fields 7. Postcode
Identifiers required for analysis purposes	1. Trust code 2. The unique identifier code (as above) 3. Year of birth 4. Gender 5. Ethnic category 6. Day of last contact 7. Month of last contact 8. Year of last contact 9. CPA status 10. CCG code 11. Mental Health Care Cluster Codes 12. Mobile phone indicator

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Members recognised the ongoing public interest in the national patient survey programme which facilitated patient evaluation to inform improvements in patient care.

Scope of support

Within the submission, the applicant had described how some Trusts utilised the national survey programme and external contractor to undertake wider evaluation of the services which they provided. It was explained that some Trusts chose to increase their sample sizes or increase the variables which were applied to the selected sample.

The applicants confirmed that they were not seeking support within the scope of the application for these additional processing activities; however, wanted to draw these practises to the CAG's attention. Members received the information and acknowledged that support was not being requested within the scope of the application for these activities.

The CAG thought it pertinent to remind the applicant that section 251 support was only in place for the scope of the activities as described in the application. It was suggested that the applicant remind Trusts that any disclosures which were outwith the scope of support would not have an established legal basis in relation to the common law duty of confidence unless the Trust made a separate application to CAG.

Practicable alternatives

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

- Feasibility of consent

The applicant provided three central arguments to support why it was not feasible to seek prior consent from patients for the survey invitation process. Trusts would not benefit from the expertise of the specialist survey contractor. There was also the potential for bias to be introduced into the survey through the requirement for clinicians to approach patients for consent to be invited. This requirement would also add an additional burden to clinical staff. The CAG acknowledged that there was past precedent in the justifications provided and accepted that these remained valid for the proposed survey activity.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the distribution of the patient surveys which could not be otherwise achieved.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Posters had been produced by the CQC and made available to each participating Trust, along with instructions around display during the sampling period. The poster would also be made available in the ten most commonly spoken languages. Trusts would also be advised to promote the survey in other ways including issuing press releases. A draft of this was provided for information.

Records will be checked for evidence of historic dissent which would be respected. Posters displayed in Trusts would include a telephone number, email and postal address to facilitate specific dissent.

Members were assured that the notification mechanisms described were appropriate and proportionate for the application. It was stressed that it was the Trust's responsibility to inform patients about how their data would be utilised for the survey purposes and it was suggested that the applicant remind them of this responsibility.

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 the unconsented activity should go ahead.

A detailed overview was provided around the user involvement activities which had been undertaken in preparation for this iteration of the survey. This included review of the previous survey, interactions with key stakeholders and a specific survey advisory group.

The applicants were also undertaking in-depth interviews with service users recruited from the general public over three rounds to seek views and inform the survey design and process. Feedback was provided at the end of each round to the CQC and used to inform the next round of interviews.

Members recognised that the applicants were actively seeking patient and public views and acting upon them within the survey design. The activity in this area appeared appropriate and proportionate to the overarching survey programme.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the standard conditions of support as set out below.

Specific conditions of support (Final)

The following sets out the standard conditions of support.

1. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **Confirmed: Picker Institute Europe, Quality Health and Patient Perspective all have confirmed 'Standards Met' on DSPT 2018/19 (checked on DSPT tracker 23/10/2019)**

As the above conditions have been met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

Application maintenance

Annual review

Please note that this support is subject to submission of an annual review report to show how you have met the conditions or report plans, any public benefits that have arisen and action towards meeting them. It is also your responsibility to submit this report every 12 months for the entire duration that confidential patient information is being processed without consent.

Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support.

The annual review should be provided no later than **25 November 2020** and preferably 4 weeks before this date.

Submission of an annual review in line with this schedule remains necessary even where there has been a delay to the commencement of the supported activity, or a halt in data processing.

For an annual review to be valid, there must be evidence that the relevant DSPT submission(s) are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the annual review submission, and submit evidence in the form of direct email from NHS Digital to evidence that 'standards met' grade are in place for all relevant DSPT submissions detailed in the conditions of support above.

Register of Approved Applications

All supported applications are listed in the published Register of Approved Applications. It is a statutory requirement for the Register to be published and it is available on the CAG section of the Health Research Authority website.

Changes to the application

The application and relevant documents set out the scope of the support which is in place for the application activity and any relevant restrictions around this.

Any amendments which are made to the scope of this support, including but not limited to, purpose, data flows, data sources, items of confidential patient information and processors, require submission of a formal amendment to the application. The amendment form can be found in the 'Guidance for CAG Applicants' section of the Health Research Authority website.

Support for any submitted amendment would not come into effect until a further outcome letter has been issued.

Changes to the controller

Amendments which involve a change to the named controller for the application activity require the submission of a new CAG application form to support the application amendment. This is necessary to ensure that the application held on file appropriately reflects the organisation taking responsibility for the manner and purpose of data processing within the application.

Applicants are advised to make contact with the Confidentiality Advice Team to discuss a change in controllership for an existing application in sufficient time ahead of the transfer of project responsibility to discuss the submission process.

Reviewed documents

The documents reviewed at the meeting are as follows.

Document	*Version*	*Date*
CAG application from (signed/authorised) [19.CAG.0206_P3298_CMH20_Section 251 application_V2]	2	25 October 2019
Other [CMH20_Dissent_V1.0_PROTECT]	1	
Other [CMH19_Survey Handbook_V1.0_PROTECT]	1	18 October 2018
Other [CMH19_Sampling Instructions_V1.0_PROTECT]	1	18 October 2018
Other [Sample Declaration Form Trusts using Contractor_ V1.0_PROTECT]	1	
Other [CMH19_Questionnaire_V1.0_PROTECT]	1	
Patient Information Materials [CMH20_Dissent Poster_V1.0_PROTECT]	1	
Project proposal [CMH20_Sampling flow chart_V2.0_PROTECT]	2	
Project proposal [CMH20_Model service contract_V1.0_PROTECT]	1	

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item are listed below.

Mr David Evans, CAG Member, declared a conflict with the application. Mr Evans remained present but did not contribute to the discussion or application recommendation.

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

Included: List of members who considered application
Standard conditions of support

Confidentiality Advisory Group meeting attendance
07 November 2019

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Malcolm Booth	CAG member
Mr David Evans	No – conflict declared
Mr. Myer Glickman	CAG member
Mr Tony Kane	CAG member
Dr Simon Kolstoe	CAG member
Dr Harvey Marcovitch	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Ms Kathryn Murray (by telephone)	HRA Senior Confidentiality Advisor
Ms Catherine McCarthy	HRA Observer
Ms Rebecca Byron	External Observer
Ms. Ajike Ali-Ameh	External Observer

Health Research Authority

Standard conditions of support

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

The applicant and those processing the information under the terms of the support 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 and are acting in compliance with the application detail.

6. Activities must be compliant 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.