Health Research Authority

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09 November 2018

Ms Jenny King
Chief Research Officer
Picker Institute Europe
Buxton Court
3 West Way
Oxford
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Dear Ms King

Application title: **2018 Children and Young People's Patient Experience Survey**
CAG reference: **18/CAG/0150**

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 and Social Care on whether an application should be approved, and if so, any relevant conditions. This application was considered at the CAG meeting held on 20 September 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 the CQC.

Secretary of State for Health and Social Care approval 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 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.

This letter should be read in conjunction with the outcome letter dated 08 October 2018.

Context

Purpose of application

This application submitted by Picker Institute Europe and commissioned by the Care Quality Commission, set out the non-research purpose of facilitation of the 2018 Children and Young People's Patient Experience Survey. The survey, which will be third carried out to date, forms part of the NHS National Patient Surveys Programme and was last ran in 2016 when it was called Children and Young People's Inpatient and Day Case Survey (15/CAG/0209).

Trusts will be asked to conduct the survey with preparations expected to begin in January 2019 and fieldwork expected to start from February 2019. All Trusts will draw a sample of patients according to set criteria, and follow standardised materials and procedures for all stages of the survey. There are some proposed changes to the methodology for the 2018 Children and Young People's Patient Experience Survey. These changes are in line with applications within the wider NHS National Patient Surveys Programme, which had recently been considered by the CAG in relation to other submissions. The changes are as follows:

1. The inclusion of relevant Trust email and postal address information, if available, on dissent posters alongside a contact telephone number for patients to contact should they wish not to participate
2. 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 patient population.
3. An earlier first reminder letter, sent five working days after the first mailing has been sent.

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

Confidential patient information requested

Cohort

Patients aged between 14 days and 15 years who were admitted as inpatients, day cases, and emergencies to an acute hospital between 01 November 2018 and 31 December 2018. Trusts will be required to draw a minimum sample of 400 patients, up to a maximum of 1,250. If this is not possible across the sample period, Trusts will be instructed to sample back to 01 October 2018 to achieve the required 400 patients.

The following two datasets will be shared by the participating Trusts in order to achieve the purposes sets out:

Mailing File – is used to facilitate the circulation of the survey and ensure this is addressed to the appropriate patient:

- Standardised survey identifier,
- Child's first name and surname,
- Address Fields,
- Postcode.

The sample file is being 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. This will contain:

- Trust code,
- Standardised survey identifier (as above),
- Year of birth,
- Sex,
- Ethnicity,
- Date of admission,
- Date of discharge,
- Length of stay,
- Main speciality on discharge,
- Treatment function code,
- CCG code,
- Treatment centre admission,
- Admission method,
- NHS Site code of admission,
- NHS Site code of discharge.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Confirm the sampling timeframe of patient eligibility for inclusion in the survey.**

The applicant confirmed that all eligible admitted patients, discharged from the Trust between 1st November 2018 and 31st December 2018, who were aged between 15 days and 15 years (inclusive) at the time of their discharge.

The maximum sample size for this survey is 1,250 and the minimum total sample size is 400. If a Trust is not able to draw a sample of at least 400 eligible patients within the established inclusion timeframe, they will be given the option to include eligible patients discharged between within October 2018.

The Sub-Committee received the response and no issues were raised in this area.

2. **Provide confirmation that confidential patient information submitted in relation to patients in a larger sample size than 400 would be destroyed and confirm the timeframe for undertaking this destruction.**

The applicant confirmed that the maximum sample size for this survey is 1,250, with the aim being that all Trusts will be able to achieve as close to this target as possible using the agreed stratified sampling method. The 1,250 sample size is unchanged from the 2016 Children's Survey (CAG reference: 15/CAG/0209), consisting of: 450 patients aged 14 days to 7 years, 400 patients aged 8-11 and 400 patients aged 12-15. These target sub-sample sizes have been carefully designed to boost representation from the 8-11 and 12-15 age groups, as they account for a small proportion of admitted patients (compared to those aged 14 days to 7 years). The reason for setting the subsample size for those aged 14 days to 7 years slightly higher is to account for the lower response rate achieved for this group previously. By setting the sample sizes in this way, the applicants should be able to provide Trusts with results broken down by the 0-7, 8-11 and 12-15 age groups separately, allowing more targeted improvement initiatives to be implemented (compared to Trusts only having results combined for all patients aged 0-15)

It was explained that the rationale for setting a minimum sample size of 400 patients per Trust, was also driven by the value of reporting. If a Trust were to submit a sample below this limit, there are concerns they would receive too few responses to allow statistically

robust analysis to be conducted, reducing the confidence Trusts and CQC have in their results.

This means no patients in a sample greater than 400 but less than or equal to 1,250 would need to be destroyed. However, if a Trust were to exceed the 1,250 maximum sample size, the applicant confirmed that they would consider this a breach of Section 251 approval and immediately destroy the information, requesting approved contractors and Trusts to do this also, where appropriate. Any incidences of this would also be reported to the Confidentiality Advisory Group.

The Sub-Committee received the clarification and raised no issues in this area.

3. **Clarify in what format free text information provided in the questionnaire would be shared with Trusts, the CQC and researchers. If information will be disclosed in an identifiable format, clarify what the lawful basis would be for this onward disclosure in relation to current data protection legislation.**

The applicant confirmed that all free-text comments are required to be submitted, in excel spreadsheet format, to the Survey Coordination Centre. Free-text comments would be analysed to check for safeguarding concerns that CQC needs to be aware of. In order to enable CQC to make the most effective use of the comments for regulatory activities these comments are not anonymised before being shared with the Survey Coordination Centre.

It was confirmed that the legal basis for the onward disclosure of information is consent. A disclaimer is present on each questionnaire to make it clear to participants that by writing any free-text comments they are providing consent for that information to be shared in full with the hospital, CQC and researchers in the Survey Coordination Centre. As participants are aware of how their comments will be used they have control over what they feel comfortable disclosing, are able to make a choice about opting in to volunteering this optional information (no question on the survey is mandatory) and have a free choice to opt out by not providing any comments.

All comments would be anonymised by CQC, approved contractors and Trusts prior to publication if there is a possibility the individual could be identified from their comments in isolation or by being combined with other response data. Additionally, prior to sharing comments as part of final data, where comments name a member of staff member, Trusts can exercise discretion and redact this information.

The Sub-Committee received this response and raised no issues with the clarification provided. It was noted that parents/carers would also be completing parts of the questionnaire and would be able to review their child's response. Members commented whether there had been any consideration of the potential impact this may have on the child's freedom to respond. It was agreed that no formal action was required from this point; however, it would be noted for information purposes for the applicant's consideration.

4. **Clarify why contractors would retain confidential patient information for a period of up to 12 months, acknowledging that survey reminders would be circulated within five days of the initial correspondence. If this extended retention is not required, confirm a shorter duration.**

It was clarified that confidential patient data, including free-text comments, is retained by approved contractors for both safeguarding and to support data quality assurance. Free-text comments are analysed to check for any safeguarding concerns that CQC may need to be made aware of. In the case of serious safeguarding issues, CQC may request patient information from the contractor. Information is held for a period of up to 10

months, the duration of the survey from sampling to publication, to ensure data remains available should issues arise following safeguarding analysis. It should be noted that all information held by contractors is held in compliance with GDPR guidelines.

Additionally, it was confirmed that confidential patient data and survey data is kept to ensure that investigations can be carried out where any data quality issues arise. The time from sampling to publication is typically ten months on a national survey and so data is kept for this period to ensure it is available for the reasons identified.

The Sub-Committee received the response and no issues were raised in this area.

5. **Clarify whether the five recommendations which came out of the stakeholder consultations were incorporated into the questionnaire.**

The applicant provided a detailed over of the five recommendations from the stakeholder consultations, how these were assessed and acted on for consideration.

The Sub-Committee received the response and raised no issues in this area.

6. **Provide copies of the survey questionnaire documentation for information purposes.**

Copies of the questionnaires, information flyers and dissenting posters were provided for information.

Documentation was received by the Sub-Committee and no issues were raised in this area.

7. **Confirm the final contractor which will facilitate the survey distribution, together with the NHS IG Toolkit organisation code to enable security assurances to be checked.**

The applicant confirmed that there would no longer be a fourth contractor involved in the survey.

The Sub-Committee received the clarification and no issues were raised.

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 Care, 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 NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Picker Institute Europe, Quality Health and Patient Perspective all have a published satisfactory 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 **09 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) [CYP18_Section 251 Application]	1	09 August 2018
Covering letter on headed paper [CYP18 Section 251 response to provisional approval]	3	30 October 2018
Other [18CAG0150 CAT Advice Form_Response]		10 September 2018
Other [CYP16 Sampling Errors Report]	1	10 April 2017
Other [CYP18_Survey handbook]	1	
Other [CYP18_Instruction manual]	1	
Other [CYP18_Dissent Poster]	1	
Other [CYP18_supplementary GDPR information]	1	
Other [Questionnaire 0-7]	1	19 October 2018
Other [Questionnaire 12-15]	1	19 October 2018
Other [Questionnaire 8-11]	1	19 October 2018
Patient Information Materials [CYP16_CQC flyer]	1	
Patient Information Materials [CYP18_Multilanguage_sheet]	1	
Patient Information Materials [CYP18_Voluntary Poster]	1	11 October 2018
Patient Information Materials [Info sheet children]	1	19 October 2018
Patient Information Materials [Info sheet young people]	1	19 October 2018
Patient Information Materials [Dissent Posters (Alternative Languages)]	1	11 October 2018
Research protocol or project proposal [CYP18_Sampling flowchart]	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*

Confidentiality Advisory Group Sub-Committee Meeting in Correspondence

Group Members:

Name	*Present*	*Notes*
Dr. Liliane Field	Yes	
Ms Clare Sanderson	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.