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Tamatha Webster
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Dear Ms Webster

Application title: **2020 Children and Young People's Patient Experience Survey**
CAG reference: **20/CACG/0145**

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 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 precedent set CAG meeting held on 06 November 2020. The application was considered via the precedent set process under category 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 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 NHS Trusts to approved contractors to facilitate the distribution of the 2020 Children and Young People's Patient Experience Survey, is

conditionally supported, subject to compliance with the standard and specific 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 application submitted by Picker Institute Europe and commissioned by the Care Quality Commission, set out the non-research purpose of facilitation of the 2020 Children and Young People's Patient Experience Survey. The survey, which will be fifth carried out to date, forms part of the NHS National Patient Surveys Programme and was last run in 2018 (CAG reference 18/CAG/0150).

The applicants are seeking support for the transfer of patient identifiable data from acute trusts, to an approved survey contractor for the purpose of mailing out questionnaires for the 2020 Children and Young People's Survey. The applicants expect that the vast majority of the trusts involved will opt to use an approved survey contractor, either: Picker, Quality Health or Patient Perspective. In 2018, 125 of 129 trusts chose to use a contactor.

The methodology for the 2020 survey is largely unchanged from the 2018 survey. In 2018, the applicants received support to send three separate, age-dependent, self-completion questionnaires to patient's home addresses. One questionnaire is for the parents/carers of children aged 0-7 year's old, one for children and young people aged 8-11 years old and their parents/carers, and one for young people aged 12-15 years old and their parents/ carers. The sampling methodology is also unchanged from the 2018 survey. The sample for the survey is a disproportionate stratification model with a total sample size per participating NHS Trust in England of 1250 patients. The total sample size is comprised of a target sample size for each age group: 450 patients within the 0-7 year-old category, 400 patients within the 8-11 year-old category and 400 patients within the 12-15 year-old category. All eligible trusts will be asked to conduct the survey with preparations expected to begin in October 2020 and fieldwork expected to start from February 2021. All trusts will draw a sample of patients according to set criteria and will follow standardised materials and procedures for all stages of the survey. An overview of the survey methodology, the Survey Handbook and Sampling Instructions were provided with the application.

The applicants seek to collect additional sample variables as part of the data submitted by NHS trusts to the Survey Coordination Centre for Existing Methods (SCCEM). These variables are:

- Full postcode information for each patient in the sample from a trust – to enable the SCCEM to map case level postcodes to the Lower Layer Super Output Areas (LSOA) deprivation indices in order to examine links between deprivation and patients' experience of hospital care.
- A flag to indicate whether there is a mobile phone number recorded for the patient's parent or carer – to assist in the planned transition from a purely paper-based approach to a mixed mode design where respondents will have the option of providing their feedback through a paper questionnaire or online.

- Covid-19 diagnosis – to aid in assessing the impact that Covid-19 has had on services.
- Treated as a suspected or confirmed covid-19 case - to aid in assessing the impact that Covid-19 has had on services.

A recommendation for class 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	Children and young people aged between 14 days and 15 years who were admitted as inpatients, day-cases and emergencies to an acute hospital between 01 November and 31 December 2020. Trusts will be required to draw a disproportionate stratified sample of patients who were admitted and discharged during this time period. The maximum sample size for the survey is 1250 patients. If a trust is unable to draw a minimum sample size of 400 patients they must contact the SCCEM directly and will be instructed to also sample back to 01 October 2020.
Data sources	1. Each participating NHS trust in England providing hospital services (inpatient and day case) to children and young people
Identifiers required for linkage purposes	1. The **mailing file** is used to address questionnaires to the appropriate person. It contains: ▪ A 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. CYP20XXXNNNN where XXX is the trusts 3 digit trust code and NNNN is the 4 digit serial number relating to sampled patients. ▪ Child/ young person's first name ▪ Child/ young person's surname ▪ Address Fields ▪ Full Postcode
Identifiers required for analysis purposes	1. The **sample 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. This file contains: ▪ Trustcode

	▪ The unique identifier code (as above) ▪ Year of birth ▪ Gender ▪ 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 ▪ Patients full postcode ▪ Parents or carers mobile phone indicator ▪ Covid-19 diagnosis (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified. Note: some trusts may have upgraded to using ICD-11 codes. If that is the case, those trusts would create this variable from using ICD-11 RA01.0 COVID-19, virus identified and RA01.1 COVID-19, virus not identified) ▪ Treated as a suspected or confirmed covid-19 case The two sets of information listed above will be submitted by trusts to approved contractors as one file. Approved contractors will split the data out and only the sample data will be provided to the SCCEM to enable centralised checks on the appropriateness of samples drawn. Some trusts may experience delays in clinical coding needed for the COVID-19 specific sample variables. Consequently, if a trust is not able to provide the COVD-19 specific variables as part of their sample file submission, the applicants will request that these trusts submit the COVD-19 related variables as part of a separate attribution file to be sent directly to the SCCEM during fieldwork. This file would contain: ▪ NHS Trust code ▪ Patient Record Number (PRN)- the unique identifier code for each sampled patient ▪ Covid-19 diagnosis (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified. Note: some trusts may have upgraded to using ICD-11 codes. If that is the case, those trusts would create this variable from using ICD-11 RA01.0 COVID-19, virus identified and RA01.1 COVID-19, virus not identified) ▪ Treated as a suspected or confirmed covid-19 case The file would be transferred to the SCCEM directly using the file transfer secure site. It would be matched into the final survey response file to aid analysis

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

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

The CAG noted that additional questions had been included to collect information on confirmed COVID-19 or probable COVID-19 diagnosis, and impact on patients' experience of care. The CAG raised no issues in relation to these additional questions.

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. The CAG agreed that the application had a medical purpose and was in the public interest.

- Feasibility of consent

The applicants cited three central arguments support why consent is not feasible for the survey process, which have been accepted in relation to other applications submitted for the NHS National Patient Survey Programme. These are; that it would remove the benefits of the Trusts being able to employ a specialist contractor to facilitate the survey process as it would require them to arrange their own mailing to patients, it would introduce a systematic bias in response rates by changing the nature of the survey from an opt-out system to an opt-in system, and that the introduction of a prior consent process for the survey would put an unrealistic burden on busy staff. The CAG noted this information and raised no queries.

- Use of anonymised/pseudonymised data

Processing of confidential patient information is required to enable the surveys to be sent to the correct patients. The CAG noted this information and raised no queries.

'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.

Trusts will be required to display Dissent posters in prominent locations at their site locations to inform possible service users about the potential for them to be sent a questionnaire. On these posters, there is a requirement for contact details at a trust to be provided (email address, telephone number and postal address) so patients can indicate dissent. The trust is required to keep a record of this so these patients can be removed from the eligible population of patients admitted to and discharged from hospital during November and December 2020. The dissent posters are to be displayed for the full sample period (November and December 2020) and have been made available in English and 11 other languages (most commonly spoken in England). Trusts will be informed in early October 2020 to display these posters and will be made publicly available on the NHS Surveys website.

Although the provision of posters is the primary method of informing the study population of the survey, trusts will also be advised and encouraged to undertake their own supplementary activities to inform patients of the upcoming survey, where considered appropriate, for example through press releases and local social media. The survey handbook will be updated with suggestions on how trusts can do this.

Posters will be used to promote the survey and will supply a telephone, email and postal contact to enable patients to raise an objection to their involvement in the survey process. Trusts will be required to keep a record of objections and dissent. However, the method in which they do this is at the discretion of the trust. The applicants anticipate that the majority of trusts will use a flag on the electronic records systems and have a data field specifically about whether the service user is happy for their contact details to be used for any other purpose than clinical care. Other trusts will keep a separate record which is cross referenced against the eligible population before the final sample file is drawn. This method is a long-standing approach adopted for the Children and Young People's Patient Experience Survey and has been successfully managed by trusts in previous surveys.

The CAG noted that the questionnaire and other patient facing materials were still in development. Members asked that the final versions were provided for review prior to being sent to participants.

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.

The overall methodological approach for the survey is broadly similar to that which has been used since the national NHS Patient Survey Programme (NPSP) was established by the Department of Health and Social Care in 2002. The applicants note that methodology is based on best research practice and evidence accrued during the course of the programme to date and learnings adopted from previous iterations of the survey being implemented. It involves a postal paper self-completion questionnaire being mailed directly to a patient's home address.

The first Children and Young People's Patient Experience Survey, run as part of the NPSP, occurred in 2004 on behalf of the Healthcare Commission. Since then the national survey has been run another three times: in 2014, 2016 and 2018 on behalf of CQC. The 2020 Children and Young People's Patient Experience Survey will be the fifth time it has been carried out and over time patients have been involved in the following ways in developing, reviewing and refining the survey questionnaire. The applicants

provided details on the patient and public involvement conducted in preparation for the 2004, 2014, 2016 and 2018 surveys.

In preparation for the 2020 survey, the applicants had begun questionnaire development work in August 2020, to determine the changes needed to the questionnaire content. The finalised questionnaire is anticipated to be ready in November 2020. The applicant provided details on the preparation work that had been undertaken.

The CAG noted that the patient and public involvement had been hindered by the coronavirus pandemic. Extensive patient and public involvement had been carried out when developing the 2018 survey, which remained relevant. Members accepted that additional patient and public involvement need not be carried out for the 2020 survey but agreed that further patient and public would need to be undertaken prior to any further applications for future Children and Young People surveys.

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 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

The following sets out the specific conditions of support.

1. Provide the final versions of the questionnaires and patient-facing documents for review before they are sent to patients.

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed: Patient Perspective, Picker Institute Europe and Quality Health (by check of the NHS Digital DSPT tracker on 19 November 2020) have confirmed 'Standards Met' grade on DSPT 2018/19).**

Application maintenance

Annual review

Please note that this legal support is subject to submission of an annual review report, for the duration of support, to show that the minimal amount of patient information is being processed and support is still necessary, 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.

The next annual review should be provided no later than **04 December 2021** and preferably 4 weeks before this date. Reminders are not issued so please ensure this is provided annually to avoid jeopardising the status of the support. 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.

Please ensure you review the HRA website to ensure you are completing the most up to date 'section 251' annual review form as these may change.

For an annual review to be valid, there must also be evidence that the relevant DSPT submission(s) for organisations processing confidential patient information without consent are in place and have been reviewed by NHS Digital. Please plan to contact NHS Digital in advance of the CAG annual review submission date to check they have reviewed the relevant DSPTs and have confirmed these are satisfactory.

Register of Approved Applications

All supported applications to process confidential patient information without consent 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. It contains applicant contact details, a summary of the research and other pertinent points.

This Register is used by controllers to check whether support is in place.

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. Changes to processors will require evidence of satisfactory DSPT submission. The amendment form can be found in the Confidentiality Advisory Group pages on the Health Research Authority website.

Support for any submitted amendment would not come into effect until a positive 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 and signed CAG application form and supporting documentation 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, and that the legal support in place is related to the correct legal entity.

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 timings.

Further information and relevant forms to amend the support is available on the HRA website.

Reviewed documents

The documents reviewed at the meeting are as follows.

Document	*Version*	*Date*
CAG application from (signed/authorised) [p101572_CYP20 Section 251 form non research applications V1_20201016]	1.0	
Other [CYP18 Sampling Instructions_V1.0_PROTECT]	1.0	
Other [CYP18_ Survey handbook_V1.0_PROTECT]	1.0	
Other [CYP20_Data flow diagram - post codes_V1_PROTECT]	1.0	
Other [CYP20_GDPR Model service contract_V1.0_PROTECT]	1.0	
Other [P101572_CYP20 Sampling flowchart V1_20201016]	1.0	
Other [16.CAG.0041]		
Patient Information Materials [CYP20_Dissent poster_v1.0_PROTECT]	1.0	

Membership of the Committee

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

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

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

Email: cag@hra.nhs.uk

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

Confidentiality Advisory Group meeting attendance
06 November 2020

Members present:

Name	
Dr Malcolm Booth	CAG member
Dr Anthony Calland	CAG Chair
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor

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.