Health Research Authority

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20 November 2020

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Dear Mr Peter Williamson

Application title: **Under 16 Cancer Patient Experience Survey 2020-2023**
CAG reference: **20/CAG/0111**

Thank you for submitting a **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 CAG meeting held on 17 September 2020.

This outcome should be read in conjunction with the provisional support letter dated 16 October 2020.

Health Research Authority decision

The Health Research Authority, 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 NHS Principal Treatment Centres (PTCs), delivering children's cancer care and treatment in England, to Picker Europe Ltd, is fully 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 from NHS England and NHS Improvement and Picker Institute Europe (Picker) set out the purpose of a patient survey to collect patient experience data for patients aged under 16 years of age with a diagnosis of cancer.

The National Cancer Patient Experience Survey (CPES), commissioned and managed by NHS England and NHS Improvement, is one of the ways that patient experience data for cancer patients in England is captured. The results of these surveys are used to help commissioners, providers and national policy makers to identify priority areas of improvement for services. However, as recognised in the Achieving World Class Cancer Outcomes: A Strategy for England 2015-2020, January 2015, NHS Independent Cancer Taskforce, the CPES is not appropriate for use with children with cancer. This Strategy recommended that NHS England and NHS Improvement "should develop a methodology to collect data on patient experience for under 16s". This commitment to improvement was recently restated in the NHS Long Term Plan, January 2019, NHS England. This application supports NHS England and NHS Improvement to fulfil the Cancer Strategy recommendation and Long-Term Plan objectives. NHS England and NHS Improvement has commissioned Picker Europe Ltd.to develop and carry out the Under 16 Cancer Patient Experience Survey over the period 2020-2023.

The applicants are seeking support to collect and use confidential patient information for patients under 16 years of age diagnosed with cancer and other tumours in order to conduct the Under 16 Cancer Patient Experience Survey between 2020 and 2023. Confidential patient information will be disclosed from NHS Principal Treatment Centres (PTCs), delivering children's cancer care and treatment in England, to Picker Europe Ltd. Picker will also liaise with PTCs so that patient questionnaires are sent to recipients on the letter-headed paper for the appropriate trust. The survey materials will be addressed to parents of children who have received care. The first wave of data collection is due to take place in the autumn of 2020 and repeated on an annual basis thereafter. Support is sought for the first three years of the survey.

Once Picker receives the patient information from the PTCs, most of the checking and mailing processes are automated (in-house) with access limited to approved individuals in accordance with their Information Security Management System.

Other details are needed to verify survey responses, check eligibility to take part or to provide data that patients could not be expected to supply. These details (e.g. age and coding of cancer diagnosis ICD10 codes) will be used to check the accuracy of the sample data, and to compare different groups' experiences of acute cancer care at the reporting stage, where numbers allow.

As hospitals do not routinely collect email and/or mobile phone numbers for patients, for the first 1-2 survey waves, the applicants intend to approach patients by post using a paper-based survey, with the option for respondents to complete the survey online, should they prefer. However, in response to advances in digital communications, for future waves the applicants intend to explore a mixed-method approach in instances where email and/or mobile phone numbers are available, e.g. an initial approach by email, or survey reminders sent by SMS. Support is therefore requested for email and/or telephone number to be collected to further explore the digital potential for the survey. The patient name and address will be needed to send out postal surveys to recipients, and the email address and mobile phone number of the parent(s)/carer(s) (where available) will be needed to explore whether a mixed-mode approach could be used in future waves of data collection.

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	All children aged under 16 at the time of their care, with a confirmed primary diagnosis of cancer or a non-malignant brain, other central nervous system or intracranial tumour, who are aware of their diagnosis and have received NHS care and/or treatment for their cancer or tumour within a recent twelve-month period. This will include: • Admitted patients who did not stay overnight (e.g. emergency admissions and planned day cases) • Admitted patients who did stay overnight • An ICD-10 code of C00 – C97, D32 - D33, D35.2 - D35.4, D42 - D43, D44.3 - D44.5, D48, D76.1. The applicants estimate that this will include between 1,000 and 10,000 patients per year.
Data sources	1. NHS Principal Treatment Centres (PTCs)
Identifiers required for linkage purposes	1. Patient name 2. Address 3. Sex 4. Ethnic group 5. Date of birth 6. ICD10 code 7. Discharge date 8. Specialty code 9. NHS number 10. Site code 11. Trust code 12. Patient classification 13. Parent email address and mobile phone number will be

	collected, where available.
Identifiers required for analysis purposes	No identifiers are required for analysis purposes

Confidentiality Advisory Group advice

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.

1. **Further clarification on the cohort is required:**

    a. **Provide a more precise number of anticipated patients.**

The applicants advised that a precise figure could not be provided until the first wave of sampling had concluded. There was evidence that almost 1,500 patients under the age of 15 were newly diagnosed with cancer in England between 1st January and 31st December 2017. The numbers in the sample may vary as the sample will include patients with some non-malignant tumours, all cancer patients who have been recently discharged from hospitals, not that just who have a recent diagnosis, and will include patients who are 16 years and younger. The applicants noted that they could provide a more accurate number at a later date.

    b. **Provide further clarification on when the 12-month period will be.**

The applicant noted that the exact time frame depended on when approvals were in place from NHS England and NHS Improvement to contact trusts to assemble a team to draw the sample. The applicant anticipate that this will be in place by December 2020 and that sampling would begin in January 2020. Trusts would be asked to include patients who were discharged from hospital between January 1, 2020 and December 31, 2020. Wave 2 of data collection would then include patients discharged from hospital between January 1, 2021 and December 31, 2021. Wave 3 would include patients discharged from hospital between January 1, 2022 and December 31, 2022. However, the sampling period will need to be shifted to a more recent 12-month period if there are delays in NHS England and NHS Improvement approvals to contact trusts about the survey. The applicants noted that they could confirm the start date at a later date.

    c. **The inclusion criteria need to include a criterion that patients and their parents/carers are aware that the patients have a diagnosis of cancer.**

Updated sampling instructions were provided and further details about how the sampling strategy would ensure patients were aware of their diagnosis were given in the response to point 3.

The CAG noted the above responses and raised no further queries.

2. **Advise whether the email addresses and telephone numbers of patients needs to be collected, or whether a flag could be created to indicate whether the telephone number and/or email address was available. If the telephone numbers and email addresses will be collected, then justification for this needs to be provided.**

The applicant advised that the project team had previously considered collection of a flag to indicate whether this data was available. However, this flag would only indicate if the data was available and would not provide an indication of how accurate it might be. To fully examine the feasibility of using a mixed-methodology approach in the future, the applicants explained that they would like to collect email addresses and phone numbers so that their format could be assessed for validity. This data would be used for exploratory purposes, and the applicants were receptive to having trusts submit email addresses and phone numbers separately from the core sample data, so that they are never linked to the patient record. This has been amended within the revised sampling instructions.

The CAG noted this information and raised no further queries.

3. **Advise how it will be ensured that patients, or their parents/carers, who may not be aware that their diagnosis was of cancer would not find out their diagnosis via this survey.**

Trusts will be required to liaise with a member of their clinical team, such as a lead cancer nurse, who must check that all patients have a confirmed diagnosis and that their admission was for care relating to cancer or a tumour. Trusts will have to sign a declaration form confirming that this check has been made before they can submit their patient sample. This validation check is considered to be the best way to ensure that patients and their parents/carers are aware of their diagnosis and is the approach used on the National Cancer Patient Experience Survey for those aged 16 and over.

The applicants noted that, despite these detailed manual checks by a member of the clinical cancer team, there may be some patients who were previously informed of their diagnosis but may have misunderstood this. Should this occur, potential respondents are provided with a Freephone helpline they can contact if they have any questions or concerns about the survey. The applicants anticipated that calls are likely to be rare, however the Freephone helpline provider will be briefed on the possibility of receiving such calls, and advisors trained on how to handle such calls sensitively. In such instances, parents/carers will be connected to the relevant trust as soon as possible so that confirmation of diagnosis can be provided, and clinical support given as necessary.

The applicants noted that the Under 16 Cancer Patient Experience Survey also included children who do not have a cancer diagnosis but do have a non-malignant tumour of the brain, other central nervous system or an intracranial tumour. This is explained within the covering letter of the questionnaire and the questionnaire states “These questions are about the care you received for your cancer or tumour.”

The CAG noted this information and raised no further queries.

4. **Clarify how many reminders the patients will be sent after the survey was initially sent.**

Patients can indicate their dissent in participating in the survey through a number of pathways. First, patients who view a dissent poster can use the contact information provided on the poster to inform their trust that they do not want to participate in the survey. Data team members drawing the sample are required to remove these patients from the sample list before it is submitted to Picker. Alternatively, once in receipt of a survey, patients can also return it blank to indicate that they do not want to participate. They would be excluded from any reminder mailings. Patients may also contact the Freephone helpline or email the study team to indicate their dissent and to be removed from any reminder mailings. The patient letter also contains contain details for NHS

England and NHS Improvement should they wish to contact the survey commissioner directly.

Patients who have not returned a completed survey or have not indicated their dissent will be sent up to two reminder mailings, sent two to three weeks apart. The first reminder mailing would consist of a short letter. The second reminder mailing would consist of a short letter and a questionnaire. These materials were included in the documents sent to CAG in the initial application.

The CAG noted this information and raised no further queries.

5. **Further details on the patient notification and dissent process are required:**

    a. **Clarify how long the poster will be displayed for.**

The applicant explained that the dissent posters had been provided to PTCs for display from July 2019. PTCs were contacted in January 2020 to ask them to continue to display the posters and they have been encouraged to continually display the posters as the sampling timeframes will be continuous for future survey waves. Copies of the poster template will be posted to the project website. These posters contain a field in which individual PTCs provide a telephone number, email, and postal address for patients to register dissent. PTCs were made aware that the text within the posters could also be displayed digitally, such as via the trust website or using digital screens within the hospital.

    b. **Confirm that all PTCs will provide a telephone number, email and postal address on the poster, for patients to use to register dissent.**

The poster templates contain a field in which individual PTCs provide a telephone number, email, and postal address for patients to register dissent. PTCs were made aware that the text within the posters could also be displayed digitally, such as via the trust website or using digital screens within the hospital.

    c. **Provide clarification as to why the names and addresses of patients who dissent will be retained to ensure patients are not re-contacted, or whether it is possible to retain patients' NHS numbers and either their date of birth or age. It also needs to be explained in the patient notification that details on those who dissented will be retained.**

The applicant advised that no information will be collected on patients who dissent from participating in the survey via the dissent poster, as trusts will be instructed to remove these patients from their sample lists. The names and addresses of patients who dissent after they have been sent a survey or who do not respond to the survey will be securely deleted at the end of the fieldwork period. This explanation has been added within the two mailing covering letters. All other information for these patients will be retained for the purposes of examining any demographic differences between responders and non-responders/dissenters. This information will be used to inform future methodology approaches (for example whether particular activities are recommended to support engagement / survey uptake from under-represented groups of patients or parents). Any requests made under GDPR will be strictly adhered to.

    d. **Additional ways of promoting the survey, including via social media, are to be considered and fed back to the CAG.**

The applicants explained that they would use social media to share information about the survey and keep people updated with progress, once the survey website is launched. Social media will be used to increase awareness of the survey amongst patients, parents and cancer staff. However, the applicants will not be able to directly ask people to complete a survey via social media without knowing their social media details. Although the survey could be promoted on social media by offering an open access survey link, the applicants would lose control over who responded, and it would not be able to ascertain whether they were eligible to take part and the PTC they are answering about. Parental consent was also needed for children to take part and it is, therefore, important that all correspondence goes to parents in the first instance. The applicants advised that they would investigate ways that survey results can be shared via social media and are currently investigating child-friendly engaging outputs that can be shared online.

The CAG noted the above responses and raised no further queries.

6. **Clarify if the specific question of sending confidential patient information to Picker and the number of contact attempts that would be made had been raised during patient and public involvement. If so, details of the feedback received need to be provided.**

During the cognitive testing phase of the project, participants were asked about their views on data sharing. All of the cognitive testing participants mentioned that they would be happy for their contact information to be passed to Picker for the purposes of being sent a questionnaire. Only two concerns were raised about contact attempts. One participant raised a concern about receiving duplicate surveys due to her child receiving care from multiple hospitals. This concern is eliminated through the de-duplication process between different PTC sample files. Another participant mentioned that bereaved parents/carers might be less inclined to answer the questionnaire. This concern should largely be addressed through DBS checks to remove deceased patients during the sampling process and before each of the survey mailings is sent.

The CAG noted this information and raised no further queries.

7. **Can the check that patients are still living be done via the Patient Demographic Service using the NHS notification of death which would be available prior to the official registration.**

The applicant explained that trusts are required to conduct Demographic Batch Service (DBS) checks prior to submitting their patient sample to Picker. Picker will also conduct its own DBS checks for the entire approved sample prior to each of the mailings. The DBS tracing service used by Picker runs on the Patient Demographic Service. In addition, trusts will be provided with the mailing dates so that they can conduct their own local checks ahead of each mailing if they wish.

The CAG noted this information and raised no further queries.

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 specific and standard conditions of support as set out below.

Specific conditions of support

1. 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 – Picker Institute Europe has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by check of the NHS Digital email dated 17 July 2019)**

As the above conditions have been accepted and 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 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 **20 November 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 were:

Document	*Version*	*Date*
CAG application from (signed/authorised) [P3313_CAG Section-251-form-non-research-applications_signed]		
Confidentiality policy [Confidentiality Policy]		
Data Protection Registration [DPO Registration Certificate 2020-2021]		
Other [U16 CPES - Data Flow Diagram]		
Other [P3313_Under 16 Cancer Survey Sampling Instructions_]		
Other [Under 16 cancer_Survey Handbook]		
Other [P3313_Sampling Feedback from Patients and Members of Public]		
Other [P3313_Sampling Feedback from Patients and Members of Public]		
Other [Picker Data Processing policy 21.08.18_Revised 13.02.2020]		
Other [IT Systems - Doc A12-14_v1.2 May 2017]	1	02 May 2020
Other [QA & ISMS v4.16 May 2020]	4	16 May 2020
Other [U16 CPES -Sponsor Recommendation]		
Patient Information Materials [P3313_U16_Questionnaire_0-7parents-V5.2-060820]		
Patient Information Materials [P3313_U16_Questionnaire_8-11Children-V5.2-060820]		
Patient Information Materials [P3313_U16_Questionnaire_12-15Children-V5.2-060820]		
Patient Information Materials [Dissent poster 2019]		
Patient Information Materials [P3313_Under16cancer_First mailing		

letter_v5.0_EB AT_310720]		
Patient Information Materials [P3313_Under16cancer_Second mailing letter_v5.0_EB AT_310720]		
P3313_Response to Section 251 Provisional Support Letter_MB AT_RH_v1.6_29.10.2020	1.6	29 October 2020
P3313_Under 16 Cancer Survey Sampling Instructions_HH EA AT EB JAM MB_V5.0_PWRH_29102020	5.0	29 October 2020
P3313_Under16cancer_First mailing letter_v5.3_EB AT MB_291020	5.3	29 October 2020
P3313_Under16cancer_Second mailing letter_v5.3_EB AT MB_291020		5.3 29 October 2020

Membership of the Committee

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

There were no declarations of interest in relation to this item.

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/

HRA Training

We are pleased to welcome researchers and R & D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Please do not hesitate to contact me if you have any queries following this letter. I would be grateful if you could quote the above reference number in all future correspondence.

With the Group's best wishes for the success of this project.

Yours sincerely

Kathleen Cassidy
Confidentiality Advisor

On behalf of the Health Research Authority

Email: cag@hra.nhs.uk

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

Confidentiality Advisory Group meeting attendance
17 September 2020

Members present:

Name	
Dr Malcolm Booth	CAG member
Ms Sophie Brannan	CAG member
Dr Liliane Field	CAG member
Dr Lorna Fraser	CAG member
Mr. Myer Glickman	CAG member
Dr Simon Kolstoe	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair
Dr Murat Soncul	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Ms Caroline Watchurst	HRA Confidentiality Advisor
Ms Natasha Dunkley	HRA Head of Confidentiality Advice Service
Dr Paul Mills	HRA Senior Confidentiality Advisor/Service Manager

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Standard conditions of support

Support to process the specified confidential patient information without consent, given by the Health Research Authority, 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.