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17 June 2021

Karen Hallt
NHS England and NHS Improvement
7E56, Quarry House
Quarry Hill
Leeds
LS2 7UE

Address
Dear Ms Hallt,

Application title: **National Cancer Patient experience survey 2021 (NCPES)**
CAG reference: **21/CAG/0084**

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 precedent set CAG meeting held on 28 May 2021. 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. It is noted that for this application the survey controller is not the CQC, it is NHS England and Improvement, however the members were content to review via the precedent set process.

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:

The application, to allow the disclosure of confidential patient information from participating NHS Trusts to Picker Institute Europe and its sub-contractor Greens Ltd., to enable the patient survey to be distributed 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 from Picker Institute Europe on behalf of NHS England and NHS Improvement set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2021. This will enable comparisons between Trusts, for commissioners, providers and patients (all of whom can access the published results), allow for monitoring of improvements in services, drive further improvements, and provide NHS England with an up to date overview of cancer patient experience across England.

The Cancer Patient Experience Survey (CPES) 2021 fieldwork period will begin at the end of October 2021 and is due to close in January 2022. Survey findings will be published in March 2022.

The 2021 survey will replicate the methodology used in previous iterations of the survey. Picker Institute Europe works with Greens Limited to mail initial questionnaires and then reminders (as required) to eligible participants following the above checks using name and address. The survey will be conducted by post, with two reminders (to non-responders only) as is the case with other national patient surveys. A standard questionnaire, covering letter and up to two reminder letters will be used. Patients will also be sent a link to complete the survey online should they prefer to do so.

Although the methodology is the same as previous surveys, the questionnaire is slightly altered, to allow for the pandemic, and to allow further inclusivity. Information on gender identity alongside sex will be collected, however this is self reported in the questionnaire rather than disclosed to Picker from Trusts. ICD 11 code will also be collected alongside ICD 10 code.

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	approximately 125,000 patients All adult patients (aged 16 and over), with a **confirmed diagnosis of cancer**, who have been admitted to hospital as inpatients for **cancer related treatment**, or who were seen as day case patients for **cancer related treatment**, and have

	been discharged between 1st April 2021 and 30th June 2021 will be included in the survey
Data sources	1. Acute and specialist NHS Trusts in England that provide adult cancer services.
Identifiers required to be disclosed to Picker	Identifiers disclosed by the Trusts: 1. Trust Code 2. Anonymised reference number for each record (applied by Trust) 3. Name 4. NHS number 5. Full address 6. Sex 7. Ethnic group 8. Date of birth 9. ICD10 code 10. ICD11 code 11. Admission and discharge dates 12. Speciality code 13. Referring CCG 14. Admission type 15. Site treated at
Identifiers required for analysis purposes	16. Postcode – (modified for analysis) 17. Anonymised reference number for each record (applied by Trust) 18. ICD10 code 19. ICD11 code 20. Speciality code 21. Ethnic group 22. Age 23. Self reported sex (from questionnaire response) 24. Self reported gender (from questionnaire response)

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.

Members agreed that this activity has a clear medical purpose and is in the public interest.

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 has put forward a number of justifications regarding not using consent, including the burden on clinicians that consenting this amount of patients would cause, and the potential for bias to be introduced into the patient sample. These justifications are in keeping with rationale previously accepted for survey activities, and the Sub-Committee accepted that consent was not a practicable alternative.

- Use of anonymised/pseudonymised data

Confidential patient information is required to validate the patient sample and circulate questionnaires, and the members agreed that this could not be undertaken without using identifiable information. It was noted by the members that confidential patient information may also required for Picker to undertake "deceased checks", and queried whether this would involve further disclosure of identifiers. It appears this is conducted through the DBS (demographics batch service), and is secure, however it was not clear if support is required for the disclosure of identifiable information from Picker to NHS Digital.

‘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 object 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.

The applicants advised that the Trusts were sent dissent posters, and leaflets to advertise the 2021 survey during the sampling frame of April, May and June. The design of the poster and leaflet was made suitable for display on digital screens, and Trusts have been able to request them in alternative languages to English. This could additionally have been displayed on websites, but no specific website wording was provided. This material provided space to add details of a nominated person within each local trust that patients could contact, should they wish to opt out of the survey, which is in line with previously supported applications.

The survey is exempt from the National data opt out, but local Trust contacts will be provided to manage any patient dissent regarding an invitation. The covering letter also provides details on how to opt out at the point of receipt.

The Members were content that the patient information provided is clear and appropriate, and the opt out options are in line with previously supported surveys.

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 survey is overseen by an advisory group which consists of patients, professionals, voluntary sector representatives, academics and patient survey experts. For 2021, the questionnaire has been redeveloped to bring it up to date with service provision. The Cancer Patient Experience Advisory Group (CPEAG) were involved in the development process advising on the themes the questionnaire should cover and how specific questions should be worded. In addition to this, the questionnaire has gone through cognitive testing with 30 patients and 8 members of staff to ensure that questions are being understood as intended.

As a response to queries regarding the acceptability of the use of confidential patient information without consent for the purposes of the survey, the applicant provided further supportive information; During the cognitive testing phase with 30 patients, patients were also asked about how they would feel about receiving a survey in the post without providing previous consent. All patients were happy with their data being shared as long as this organisation was approved by the NHS and as long as it was clear that they had the option of not completing the survey and opting-out if they wanted to.

The Sub-Committee were content with the patient and public involvement undertaken.

Exit strategy

The exit strategy is the deletion of confidential patient information by Picker and Greens Ltd. For those patients who do not confirm that their data can be retained, confidential patient information will be destroyed 12 months after publication, by 31 March 2023. Those patients who consent to the inclusion and retention of their data will be out of scope of support once this has been confirmed in their survey response.

The CAG Sub-Committee were content with this exit strategy.

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

1. Please confirm if support is required for confidential patient information to be disclosed from Picker to NHS Digital in order to undertake ‘deceased checks’, within one month from the date of this letter.

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:**

The NHS Digital **19/20** DSPT reviews for **Picker Institute Europe and Greens Ltd** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 15 June 2021)

As the above conditions have been accepted or 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 **17 June 2022** 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) [P-101565_Section 251 application form CPES_19.05.2021_v2.0_Final]	2.0	19 May 2021
Covering letter on headed paper [CPES21_First covering letter_V1.3_CEG MB_13.05.2021_protect]	1.3	13 May 2021
Other [19CAG0137 Fully Supported Outcome v1 revised 14102019]		14 October 2019
Other [19CAG0137 s251 non-research provisional outcome v4]		13 August 2019
Other [CPES21 - Data Flow Diagram_v1.3_18.05.2021]	1.3	18 May 2021
Other [CPES21 - GDPR information - final]		
Other [CPES21_Questionnaire_JK JAM MB_060421_V3.0]	3.0	06 April 2021
Other [CPES21_Sampling Instructions_V1 0_MB_26.04.2021_protect]	1.0	26 April 2021
Other [CPES21_Second covering letter_V1.3_CEG MB_13.05.2021_protect]	1.3	13 May 2021
Other [CPES21_Survey Handbook_V1.0_MB_26.04.2021_protect]	1.0	26 April 2021
Other [CPES21_Third covering letter_V1.3_CEG MB_19.05.2021_protect]	1.3	19 May 2021
Other [NHSEI CPES recommendation letter]		
Patient Information Materials [REVISED_CPES information A3 poster 18032021]		18 March 2021
Patient Information Materials [REVISED_CPES information A5 flyer 18032021]		18 March 2021
Patient Information Materials [CPES21_First covering letter_V1.4_CEG MB_27.05.2021_protect]	1.4	27 May 2021
Patient Information Materials [CPES21_Second covering letter_V1.4_CEG MB_27.05.2021_protect]	1.4	27 May 2021
Patient Information Materials [CPES21_Third covering letter_V1.4_CEG MB_27.05.2021_protect]	1.4	27 May 2021

Membership of the Committee

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

No conflicts of interest were declared.

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

Caroline Watchurst
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 precedent-set meeting attendance
28 May 2021

Members present:

Name	
Dr William Bernal	CAG alternative vice-chair
Dr Katie Harron	CAG member
Mr Marc Taylor	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Caroline Watchurst	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 relevant 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.