Health Research Authority

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10 September 2019

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

Dear Ms King

Application title: **National Cancer Patient Experience Survey 2019**
CAG reference: **19/CAG/0137**

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 CAG meeting held on 18 July 2019.

Secretary of State for Health and Social Care decision

The Secretary of State for Health and Social Care, having considered the recommendation 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 Picker Institute Europe, to enable the patient survey

to be distributed, is fully supported subject to compliance with the standard and specific conditions of support.

This letter should be read in conjunction with the outcome letter dated 13 August 2019.

Context

Purpose of application

This application from NHS England set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2019. This would enable comparisons between Trusts, for commissioners, providers and patients (all of whom could access the published results), would 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 purpose of collecting and analysing data via this survey is to:

- Secure continuous improvement by building on the results of previous surveys, enabling local providers and Cancer Alliances to assess their performance improvement with other providers,
- Enable commissioners to assess local improvements in cancer patient experience,
- Provide NHS England and NHS Improvement with an up to date overview of cancer patient experience across England,
- Provide NHS England and NHS Improvement with data on each participating Trust and the areas on which quality improvement needs to be focused,
- Enable patients to make informed choices about where to go for cancer treatment via publishing the provider level analysis on publicly available websites.

The Cancer Patient Experience Survey (CPES) 2019 fieldwork period will begin at the end of September 2019 and there is an aspiration to close fieldwork in January 2020, rather than at the end of March as in previous years, to enable more timely reporting of outputs.

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 adult patients (aged 16 and over), with a primary 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 were discharged between 1st April 2019 and 30th June 2019 would be included in the survey. This is estimated to cover 125,000

	cancer patients.
Data sources	1. Electronic patient records at participating Trusts in England
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Full address 4. Sex 5. Ethnic group 6. Date of birth 7. ICD10 code 8. Admission and discharge dates 9. Speciality code 10. Referring CCG 11. Admission type 12. Site treated at.
Identifiers required for analysis purposes	1. Sex 2. Age 3. Ethnic group 4. ICD10 code 5. Admission and discharge dates 6. Speciality code
Additional information	

Confidentiality Advisory Group advice

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

1. **Provide further details on how any opt-outs recorded at Trust level would be applied, and whether Picker Institute Europe would be provided with any details on patients who opted-out and a justification for this latter approach if this approach was to be used.**

The applicants advised that the Trusts were sent dissent posters, leaflets and wording to be used on their websites to advertise the 2019 survey during the sampling frame of 01 April to 30 June. These materials included contact details for the patient to contact the Trust if they wished to opt-out of the survey. Trusts were required to maintain a record of patients who dissented and remove them from the patient list prior to submission to Picker, to ensure that Picker were not provided with the details of these patients.

During the fieldwork stage, patients were able to opt-out of inclusion by contacting the Picker Freephone, by returning a blank questionnaire or by contacting the Trust. In these three options, Picker would be informed of the patients details to ensure that they

were correctly identified and removed from the list of patients. The Sub-Committee reviewed this information and raised no further queries regarding the opt-out process.

2. **Provide details on whether the issue of access to confidential patient information prior to consent being sought was discussed during the public and patient involvement and engagement activities carried out and provide any relevant feedback.**

Patients that volunteered for cognitive interviews were given an overview of the survey methods i.e. that the questionnaire is sent to all cancer patients treated within a specific time frame. These patients were provided with the survey materials, which made it clear that their personal details had been provided by the NHS Trust that treated them. None of the volunteers had expressed concern with consent or the use of patient information for the purpose of carrying out this survey.

The applicants advised that NHS England had not received any such concerns from engagement with stakeholders or patients in recent years, including meetings with the Cancer Patient Experience Advisory Group (CPEAG).

The applicants advised that out of the 123,512 patients included in the 2018 survey, there were 10 calls from patients who were exercising a formal right to erasure request under GDPR. All 10 requests were actioned as soon as practically possible and within one calendar month. 1 patient raised a complaint about their data being shared with Quality Health, as they were registered under the National Data Opt-Out programme. This was raised with and responded to directly by the NHS Trusts concerned.

The Sub-Committee noted the information provided and raised no additional queries.

3. **Provide further details on the survey advisory group to be set up for the 2019 survey, including whether the issue of access to confidential patient information prior to consent being taken will be discussed with this group.**

The meeting of the CPEAG on the 4th June was the last to meet prior to the 2019 survey's fieldwork. No concerns regarding access to confidential patient information without prior consent were raised.

A new advisory group was in the process of being set up. This will include representatives from Trust staff, patients, cancer charities, Cancer Alliances and Clinical Commissioning Groups. The first meeting of this group was scheduled for 23 September 2019, which is after the mailing for the 2019 iteration of the survey are due to start. The applicants will ensure that discussion of access to confidential patient information without consent is added to the agenda of this meeting, which will aid the applicants in preparing for the 2020 survey. The Sub-Committee noted the information provided and raised no further queries.

4. **Confirm the retention duration for confidential patient information, both for patients who had agreed to the retention of their data and those who had not.**

The applicant confirmed that confidential patient information, name, date of birth, address and NHS number, will be securely deleted on 31st August 2021 for all patients

that opt-out of receiving future surveys. All patient materials stating the deletion date have been updated and now consistently provide this date.

Confidential patient information for patients that opted into receiving future surveys will be securely stored and reviewed after 20 years. This retention period allows patients to be followed up in the future regarding their health and health care. This information is potentially useful in understanding the long-term effects of cancer and cancer treatment. At 20 years, the applicants will assess the need and usefulness of this data and decide accordingly to either securely delete the data or store the data for an agreed additional number of years. A revised covering page for the questionnaire had been provided, highlighting this change. The Sub-Committee noted the information provided and raised no further queries.

5. **Clarify the number of reminders to complete the survey that patients would receive.**

The applicant clarified that patients would be sent a maximum of two reminders, in addition to the initial contact. The first mailing packet sent included the questionnaire and covering letter. Non-responders were then sent a reminder letter three weeks later. Finally, another questionnaire and covering letter was sent after another three weeks to those that have yet to respond. A total of three contacts were made with patients. The Sub-Committee noted the information provided and raised no further queries.

6. **The patient information materials need to be revised as follows;**

    a. **Patients need to be informed of the items of confidential patient information may be shared onwards and which organisations the information may be shared with.**

    b. **Confirm that the helpline number is up to date.**

    c. **References to Quality Health need to be removed.**

A revised questionnaire and covering letters were provided. This had been amended to remove references to Quality Health and to specify that no confidential patient information would be shared onwards with research organisations. The organisations involved were not specified within the text as there are a wide range of organisations that may request to use the data. All requests would be considered on a case by case basis.

The applicant explained that Picker were currently in the process of issuing a new number for the helpline. Once this was issued, then the questionnaire and covering letters would updated accordingly. The first mailings were scheduled to take place in early October 2019, and the telephone number would be finalised in September. The Sub-Committee noted the information provided and raised no further queries.

Security Assurance

The applicant explained that confirmation remained outstanding in respect of Greens Ltd., the organisation acting as processor to facilitate distribution of the surveys. As the security assurance had been confirmed for the Picker Institute Europe, the applicant requested whether support could be recommended for the early stage of the survey cohort sampling, which involved Picker only. It was agreed that support would be

recommended for the early stage of the application, covering the disclosure of confidential patient information from NHS Trusts to Picker Europe to enable the patient cohort to be established. It was agreed that the final outcome would be reissued at the point appropriate security standards are confirmed in respect of Greens Ltd.

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

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. **The NHS Digital DSPT submission for Picker Institute Europe was confirmed as 'Standards Met' by NHS Digital on 17 July 2019.**

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

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 10 September 2020 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) [CPES19 - Cag section 251 form]		20 June 2019
Covering letter on headed paper [NCPES19_Picker response to Section 251 provisional approval]	1	16 August 2018
GP/consultant information sheets or letters [P3290_CPES19_Third covering letter_v1_20190813]	1	13 August 2019
Other [CPES19 - Questionnaire_V1 3_TG JK_20190626_protect]	1.3	26 June 2019
Other [CPES19 - Sampling Instructions_V2 1_TG JK_20190624_protect]	2.1	24 June 2019
Other [CPES19 - Survey Handbook_V2 1_20190617_protect]	2.1	17 June 2019

Other [CPES19 - GDPR information FINAL]		
Other [19CAG0137 CAT advice form_Picker]		09 July 2019
Other [P3290_CPES19_Questionnaire_V1_20190813]	1	13 August 2019
Patient Information Materials [CPES19 - First covering letter_V1 1_JK_TG_20190626]	1.1	26 June 2019
Patient Information Materials [CPES19 - First reminder letter_V1 1_JK_TG_20190626]	1.1	26 June 2019
Patient Information Materials [CPES19 - Second reminder letter_V1 1_JK_TG_20190610]	1.1	10 June 2019
Patient Information Materials [CPES19 - Patient information A3 poster]		
Patient Information Materials [CPES19 - Patient information A5 leaflet]		
Patient Information Materials [P3290_CPES19_Second covering letter_v1_20190813]	1	13 August 2019
Patient Information Materials [P3290_CPES19_First covering letter_v1_20190813]	1	13 August 2019
Research protocol or project proposal [CPES19 - Data Flow Diagram]	1.0	24 June 2019
Written recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [CPES19 - Caldicott letter 2019_2020 FINAL]		07 June 2019

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

Kathleen Cassidy
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*
Standard conditions of approval

Copy to:

Confidentiality Advisory Group Sub-Committee meeting in correspondence

Group Members:

Name	
Ms Sophie Brannan	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr Andrew Melville	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	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.