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20 July 2022

Ms Nikki Gambles
7E56, Quarry House,
Quarry Hill,
Leeds
LS2 7UE

Dear Ms Nikki Gambles,

Application title: **National Cancer Patient Experience Survey 2022-2024**
CAG reference: **22/CAG/0100**

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 CAG meeting held on 14 July 2022.

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 NHS England and Picker Institute Europe set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2022-2024.

The applicants seek to work with NHS trusts to collect and use data for approximately 125,000 cancer patients to carry out the Cancer Patient Experience Surveys for 2022, 2023 and 2024. The applicants also seek to collect email and mobile telephone numbers for the first time, in order to explore the digital potential for the survey. Survey fieldwork will be conducted annually. The survey methodology, data transfer arrangements and consent issues are the same as previous iterations of the study. The questionnaire, developed with engagement from a variety of stakeholders including patients in 2021, will be used unchanged for 2022.

The results of the survey will be used to 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.

Each participating NHS trusts will extract confidential patient information required for the survey and disclose this to Picker Institute Europe. Picker Institute Europe then check that patients are still living and that the sampling guidance has been followed. Picker Institute Europe and Greens Ltd then mail the initial questionnaires and reminders, if required, to participants. Patient participation then proceeds on a consented basis.

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 have been discharged between 1st April and 30th June of the survey year will be included in the survey (for example the 2022 survey will include those discharged between 1st April 2022 and 30th June 2022)

Data sources	1. Electronic patient records at participating Trusts in England
Identifiers required for linkage purposes	1. Date of birth 2. NHS number 3. Name 4. Sex 5. Address 6. Postcode – unit level 7. Email address 8. Mobile telephone number 9. Site treated at 10. Treating NHS trust
Identifiers required for analysis purposes	1. Postcode 2. ICD 10/11 code 3. Main speciality code

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 agreed that the application had a medical purpose and was 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.

- Minimisation of identifiers

The applicants sought support to collect patients mobile telephone numbers and email addresses, however there were no plans to use these details yet to send or follow-up the surveys. Members asked whether these data items needed to be collected at this point or if the trusts could instead record whether the items of information were available.

- Feasibility of consent

The applicants presented a number of arguments as to why consent was not feasible. These arguments included; the potential duplication of contact with patients, the burden on

clinicians and patients and the possible introduction of bias in the patient sample. The CAG agreed that consent was not feasible.

- Use of anonymised/pseudonymised data

Patient names and addresses are required to enable the surveys to be sent out. Checks that patients are still alive also need to be carried out before sending the surveys. The CAG agreed that the application activity could not be conducted in any other way.

'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.

Patients consent to taking part in the survey by returning questionnaires and decline by not returning them, or by returning blank questionnaires. Confidentiality information is presented to patients in both the covering letter and questionnaire front cover. The information states that by completing the questionnaire respondents are consenting to take part in the survey and to the use of their information.

For the 2022 survey, NHS England have provided all participating trusts with fair processing information. Trusts have been made aware that the poster and leaflet can be displayed on digital screens where available. 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. The purpose of this material is to publicise the survey to patients ahead of fieldwork and provide people who are eligible for the survey with a mechanism to opt-out of the survey in advance, should they wish to do so.

The survey covering letter, first and second reminder letter, and questionnaire front cover will emphasise that participation in the survey is entirely voluntary. They will provide details about the basis upon which the information will be held and processed and provide details of how to opt out of the survey.

Information relating to individuals who have informed their trust that they would like to opt-out of the survey ahead of the sample being drawn and sent to Picker will be excluded from the sample.

The CAG noted that the survey was exempt from application of the National Data Opt-Out and asked that this exemption was explained in the patient notification materials. This needed to include an explanation that the exemption had not been granted by CAG, but via policy consideration. A link to the information around the exemption on the NHS Digital website, 7. Policy considerations for specific organisations or purposes - NHS Digital should be included on the patient notification materials.

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.

NHS England commissioned Picker to carry out a review of the CPES in 2018. As part of this review two focus groups were carried out with patients in London and Manchester. The focus groups provided patients with the opportunity to comment on a range of aspects relating to the CPES. The findings of the review were published in August 2018 and discussed at the Cancer Patient Experience Advisory Group (CPEAG) meeting of July 2018. In light of the review's findings and reflecting a consensus among CPEAG members, the 2018 CPES survey went ahead with only minor changes / developments to maintain the comparability of the 2018 survey with those of previous years.

In 2020/21, the CPEAG supported the development of a new questionnaire for use in 2021. This questionnaire remains unchanged for 2022. During 2021/22 NHS England established a new Representation Sub-group of the advisory group which is made up of patients from a wide range of demographic groups, with the aim of helping us to understand the characteristics of those less likely to respond to the survey and to work with the survey provider to develop targeted initiatives to try to encourage participation in the survey from those under-represented groups. The Representation Sub-Group has already provided advice on how the information for patients could be improved.

The CAG agreed that it was unclear whether any patient any public involvement had been carried out since 2018. Members asked that further patient and public involvement was carried out, including discussion of the collection of patient mobile telephone numbers and email addresses.

Exit strategy

The confidential patient information used to identify patients to take part in the survey and to analyse the results will be kept where patients consent to this.

Those patients' details will be held securely and in accordance with the UK GDPR and the need for retention will be reviewed after 20 years. This includes the right for those patients to have their personal data erased. The CAG raised no queries under this heading.

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 first three conditions below need to be reported back on within 3 months of the issuing of this outcome letter:

1. Confirm whether patients mobile telephone numbers and email addresses need to be collected, or if the trusts could instead record whether or not the items of information were available.

2. The National Data Opt-Out exemption needs to be explained in the patient notification materials. This needs to include an explanation that the exemption had not been granted by CAG, but via policy consideration. A link to the information around the exemption on the NHS Digital website, 7. Policy considerations for specific organisations or purposes - NHS Digital also needs to be included on the patient notification materials.

3. Further patient and public involvement needs to be carried out, including discussion of the collection of patient mobile telephone numbers and email addresses.

4. 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 **2020/21** DSPT review for NHS England & NHS Improvement, Picker Institute Europe and Greens Ltd were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 14 July 2022).

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 **20 July 2023** 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) [CPES 22_cag-section-251-form-non-research-applications FINAL.05.07.22]		05 July 2022
Other [1. QA & ISMS Part 1 ISO27001 v4.20 NP MC]	4.20	
Other [2. QA & ISMS Part 2 ISO20252 v4.20 NP MC]	4.20	
Other [CPES recommendation letter]		
Other [CPES22 - Data Flow Diagram_JK_130422_V1 0]	1.0	13 April 2022

Other [CPES22 - GDPR information - final]		
Patient Information Materials [CPES 2022_P-10615_ information A3 poster _31.03.22]		31 March 2022
Patient Information Materials [CPES 2022_P-101615_ information A5 flyer_31.03.22]		31 March 2022

Membership of the Committee

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

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 Secretary of State for Health and Social Care

Email: cag@hra.nhs.uk

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

Copy to:

Confidentiality Advisory Group meeting attendance
14 July 2022

Members present:

Name	
Dr Tony Calland MBE	CAG Chair
Dr Martin Andrew	CAG member
Dr Patrick Coyle	CAG vice-chair
Mr David Evans	CAG member
Professor Lorna Fraser	CAG member
Dr Harvey Marcovitch	CAG member
Ms Diana Robbins	CAG member
Mr Umar Sabat	CAG member

Also in attendance:

Name	*Position (or reason for attending)*
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator
Mr Paul Mills	HRA Confidentiality Advice Service Manager
Ms Caroline Watchurst	HRA Confidentiality Advisor
Theodora Chortara	HRA Approvals Administrator (Observer)
Claudia Bywater	HRA Approvals Manager (Observer)
Sharon Northey	HRA Approvals Manager (Observer)
Zoher Kapacee	HRA Head of Data and AI Programmes (Observer)

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.