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11 November 2022

Laura Thomas
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Dear Ms Thomas,

Application title: **2022 NHS Adult Inpatient Main Stage Survey – Mixed Methods**
CAG reference: **22/CAG/0152**

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 21 October 2022. The application was considered via the precedent set process under category 11: Applications to administer patient surveys made by organisations on behalf of Care Quality Commission (CQC).

Secretary of State for Health and Social Care decision

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

The application, to allow the disclosure of confidential patient information from NHS Trusts to one of three approved contractors for the purpose of sending out questionnaires for the 2022 Adult Inpatient Survey, and for disclosure of postcode to IPSOS MORI for analysis purposes, 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 non-research application submitted by Ipsos MORI on behalf of the Care Quality Commission, sets out the purpose of conducting the 2022 NHS Adult Inpatient Survey. The Adult Inpatient Survey started in 2002 and falls within the NHS Patient Survey Programme (NPSP). The NPSP was initiated in 2002 by the then Department of Health, and is now overseen by the Care Quality Commission (CQC), the independent regulator of health and social care in England. The 2022 Adult Inpatient survey will be the twentieth carried out to date, and the third mainstage to be completed using a mixed method approach.

All eligible trusts (134) will be asked to conduct the survey, with preparations expected to begin in the autumn of 2022 and fieldwork expected to start from January 2023. Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (IPSOS MORI) and one of three approved contractors (Patient Perspective, Quality Health or Picker Institute Europe). The contractors will distribute questionnaires to patients using the approach detailed below:

	Mode of contact
Contact 1	Postal letter inviting the patient to take part online (and a paper questionnaire included for those over 80 years old)
Contact 1.1	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 2	In week 2, a reminder letter will be sent to non-responders
Contact 2.2	Three days later an SMS reminder will be sent, including a direct link to the online survey
Contact 3	Final, postal reminder sent, along with a paper questionnaire

Ahead of each reminder mailing, it will be necessary to remove all respondents who have completed the survey already, and to conduct a DBS or local check on the full sample. If anyone has requested to be opted out of further reminders, they should also be removed at these timepoints.

A recommendation for class 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Inpatients aged 16 years old or over who were discharged from acute and specialist NHS hospitals in November (and earlier for smaller trusts), having had at least one overnight stay in hospital.

	A list of reasons for exclusion, such as deceased patients and those under 16 years of age at the time of sampling, was included in the application.
Data sources	1. Electronic patient records with acute and specialist trusts in England (134).
Identifiers required for contact purposes	1. Name 2. Address fields including postcode 3. Mobile phone number 4. Patient unique identifier
Identifiers required for analysis purposes	1. Unique identifier (a three digit Trust code and 4 digital serial number related to sampled patient) 2. Postcode 3. Trust code 4. Year of birth 5. Gender 6. Ethnic category 7. Date of admission 8. Date of discharge 9. Length of Stay 10. Treatment Function Code 11. ICD-10 Chapter Code 12. Treatment Centre Admission 13. Admission method 14. NHS Site code-Admitted 15. NHS Site code-Discharged 16. 'Decided to admit' date
Additional information	Trusts may also choose to collect additional sample variables outside of those detailed in the Survey Handbook. This can be valuable to trusts in enabling them to make greater use of their survey locally to target quality improvements. Sample and mailing data will be submitted by trusts to approved contractors in a single file. The file which contains both mailing and sample information will be split into separate files by the contractor before submitting only the sample information to the Coordination Centre for checking and approval. Please note that the Survey Coordination Centre does **not** receive any names or full addresses

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 Members agreed the public interest in this activity is clear.

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

There are three central arguments as to why consent is not practicable, and which have been accepted across the National Survey Programme:

  - Trusts will not benefit from the expertise of a specialist survey contractor,
  - Potential to introduce bias into the survey findings,
  - Potential burden on clinical staff through the requirement to take consent.

The Members agreed with the justification provided.

- Use of anonymised/pseudonymised data

Confidential patient information is required to facilitate the invitation process which could not be otherwise achieved. For analysis, postcode is deleted after mapping to LSOA and local authority, as per previous surveys. The CAG agreed that It is not practicable to undertake these activities without confidential patient information.

'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.

As per previous surveys, posters will be displayed in participating Trusts throughout the sampling period to inform patients that they may be approached to participate in the survey and provide a means for prior dissent to be raised. These have been produced in English and translated into 11 other languages to improve accessibility. Although the provision of posters is the primary method of informing the study population of the survey, Trusts will also be informed that they can undertake their own additional promotional activities, where considered appropriate, for example through press releases and local social media.

The poster provides information about how a patient can opt out of the survey. Trusts are also asked to remove any records where existing dissent has been recorded. Contractors and those trusts that administer the survey themselves, will provide a freephone telephone

line, email address and postal address on survey materials and posters (which must be displayed in trusts throughout the sampling period) for people to call for advice, assistance or to opt-out of future mailings.

Applicants have considered the feasibility of including an opt-out mechanism within the SMS reminders but have ruled it out for reasons detailed in the application form. CAG accepted the reasons for not using an SMS opt out mechanism for previous surveys, and the same reasoning applies to this application. There is a helpline number included in the SMS which applicants can call to opt-out if required.

The surveys have exemption from the national data opt out – see here.

As part of a previous application, 21/CAG/0147, the CAG '*advised that the applicants work directly with the participating Trusts to promote the use of all available, innovative ways of notifying the public',* and a condition was applied; '*More work should be done with participating Trusts to encourage effective notification, and an account of this should be fed back at Annual Review.*'

The applicant's response on this issue to CAT states: '*We are encouraging trusts to share information about the survey on social media and their websites to allow more people to see that the survey is happening (and therefore opt out if needed). Unfortunately, due the nature of the survey, further notification or targeted notification of those sampled would be impractical.'*

The Members felt that although the applicant has stated that Trusts are encouraged to share information on social media and their websites, the instructions to Trusts on how to publicise the survey do not mention this aspect, although it appears this issue is addressed in webinars for Trusts. The Members mentioned that it would be helpful to know if this actually takes place at Trust level. The Members were agreed that moving beyond just posters is better practice, and again encourage the applicant to investigate developing broader notification methods, and request that the applicant advise CAG on whether this has been incorporated within the publicity instruction documentation provided to Trusts, and if not, why not.

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 application form provides a detailed overview of the patient and public involvement in the development of this survey. In addition to the usual work undertaken, the applicant has undertaken some discussions with patients specifically around the use of confidential patient information without consent, as a response to a condition applied to previous survey 21/CAG/0147; '*Patient and public involvement around the specific issue of processing of confidential patient information without consent needs to be conducted and fed-back to the CAG at the first annual review.'*

In August 2022, 15 scoping interviews were conducted with patients to obtain feedback the following areas:

- Use of patients' personal information to invite them to participate

- Contacting patients via SMS/text to participate as well as to remind participants to complete the questionnaire
- Recontacting participants via SMS/text to participate in future research.
- Patients' personal information being linked, confidentially, to their questionnaire responses
- Their experience and journey during their stay at hospital

The results found:

- Patients were happy to be contacted to take part in NHS Patient Survey Programme without having given their express permission. They found the current contact methods of either paper invites of SMS invites acceptable and did not cause any concern.
- Patients were open to the idea of being asked to participate in follow up research and their contact details being passed to CQC. They were also open to being asked about linking their survey responses to their contact details, to allow CQC to follow up on particular experiences.

Ahead of the 2022 Adult Inpatient Survey, three rounds of cognitive testing will be undertaken with patients to ensure that any revisions to the questionnaire continue to reflect their experiences and are also easy to read and understand. The questionnaire will be updated based on the feedback between each round of testing.

The members were content that the condition from 21/CAG/0147 has been addressed as part of this application, as further patient and public involvement has taken place during the last year as requested, including about the use of confidential patient information without consent, and that this was sufficient to recommend support for this application.

Exit strategy

Identifiable information (used to send out the survey) will be destroyed within 12 months from the receipt of the sample files. Post code will be deleted after mapping to LSOA and local authority, no later than 4 weeks from the respondent level dataset being signed off. The Sub-Committee were content with the proposed 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. The applicant is encouraged to develop further patient notification methods, and report back on doing so within 6 months from the date of this letter.

2. Please advise CAG if instructions '*to share information about the survey on social media and Trust websites'* has been incorporated into the publicity instruction documentation provided to Trusts, and if not, why not, within one month from the date of this letter.

3. 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 **21/22** DSPT reviews for **Ipsos MORI, Patient Perspective, Quality Health Limited, and Picker Institute Europe** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 03 November 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 **11 November 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)		30 September 2022
Confidentiality policy [Ipsos' Confidentiality policy_V1_ICUO]	1	
Corporate Level Security Policy(CLSP) [Ipsos Physical Security Policy ICUO]		01 July 2022
Corporate Level Security Policy(CLSP) [Patient Perspective System Level Security Policy 2022]	2022.01	
Corporate Level Security Policy(CLSP) [Picker - Network security policy - related sections for Section 251 IP22 ICUO]	4.17	16 August 2020
Corporate Level Security Policy(CLSP) [QH - Network security policy - related sections for Section 251 IP22 ICUO]	5	01 May 2018
Other [Multilanguage sheet_V1_INT CLIENT USE]	1	
Other [Data Flow for section n_V1_INT CLIENT USE]	1	
Other [Model Service Contract_V1_INTERNAL]	1	
Other [Questionnaire]	1	
Other [SMS Guidance and Content_V1_INT CLIENT USE]	1	
Other [Data flow diagram - postcode_V1_INT CLIENT USE]	1	
Other [Dissent information_V1_INT CLIENT USE]	1	
Other [Information Flowchart_V1_INT CLIENT USE]	1	
Other [Publicising the survey_V1_INT CLIENT USE]	1	
Other [Sample construction worksheet - contractor_V1_INTERNAL]	1	

Other [Sample construction worksheet - in house_V1_to_submit_INTERNAL]	1	
Other [Sample declaration form - contractor_V1_INTERNAL]	1	
Other [Sample declaration form - in house_V1_INTERNAL]	1	
Other [Sampling Instructions_V1_INT CLIENT]	1	
Other [Survey Handbook IP22_INT CLIENT V1]	1	
Patient Information Materials [First Mailing Letter_participants aged 80 and above V1_INT CLIENT USE]	1	
Patient Information Materials [First Mailing Letter_V1_INT CLIENT USE]	1	
Patient Information Materials [Second Mailing Letter_participants aged 80 and above V1_INT CLIENT USE]	1	
Patient Information Materials [Second Mailing Letter_V1_INT CLIENT USE]	1	
Patient Information Materials [Third Mailing Letter_V1_INT CLIENT USE]	1	
Patient Information Materials [dissent poster - English - INT CLIENT USE]		

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
21 October 2022

Members present:

Name	
Mr Tony Kane	CAG member
Mr Andrew Melville	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Ms Caroline Watchurst	HRA Confidentiality Advisor

NHS
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.