Health Research Authority

Skipton House
80 London Road
London
SE1 6LH

Tel: 020 797 22557
Email: cag@hra.nhs.uk

22 September 2020

Laura Thomas
Ipsos MORI
3 Thomas More Square
London
E1W 1YW

Dear Ms Thomas,

Application title:	**2020 NHS Adult Inpatient Main Stage Survey – Mixed Methods**
CAG reference:	**20/CAG/0085**

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 20 August 2020.

This outcome should be read in conjunction with the provisional support letter dated 07 September 2020.

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:

1. The application to allow the disclosure of confidential patient information from acute and specialist trusts one of three approved contractors for the purpose of sending out questionnaires for the 2020 Adult Inpatient Survey, and for disclosure of information 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 2020 NHS Adult Inpatient Survey.

   The Adult Inpatient Survey is the most established survey 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 2020 Adult Inpatient survey will be the eighteenth carried out to date, and the first mainstage to be completed using a mixed method approach, following a pilot of the approach during 2019.

   Following a pilot in the 2019 survey, the survey will use a mixed methods approach for conducting the surveys. 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, as successfully piloted:

	Mode of contact
Contact 1	Postal letter inviting the patient to take part online
Contact 1.1	SMS reminder timed to arrive with the initial letter including a link to the survey
Contact 2	Postal reminder inviting the patient to take part online
Contact 2.2	SMS reminder timed to arrive with the second letter including a link to the survey
Contact 3	Postal reminder along with a paper questionnaire

   Whilst the survey remains similar to previous years, COVID status has been added to the data requested for analysis so the applicants can distinguish between these patients for reporting purposes.

   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

   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. Exclusions: • deceased patients • children or young persons aged under 16 years at the time of sampling • obstetrics/maternity service users, including spontaneous miscarriages • patients admitted for planned termination of pregnancy • psychiatry patients • day cases • private patients (non-NHS) • any patients who are known to be current inpatients patients • patients without a UK postal address or patients whose address was unusable because it was incomplete • any patient known to have requested their details are not used for any purpose other than their clinical care, including those responding to posters displayed on hospital wards referring to the survey (the survey instructions request that all responses to posters are logged and used for this purpose).
Data sources	1. Electronic patient records within acute and specialist Trusts in England
Identifiers required for linkage purposes	1. Title 2. Initials or first name 3. Surname 4. Address Fields including postcode 5. Mobile phone number 6. Patient unique identifier
Identifiers required for analysis purposes	1. Trust code 2. Patient unique identifier 3. Postcode 4. Year of Birth 5. Gender 6. Ethnic Category 7. Mobile phone indicator 8. Day of the month of admission 9. Month of admission 10. Year of admission 11. Day of the month of discharge 12. Month of discharge 13. Year of discharge 14. Length of stay 15. Treatment Function Code 16. ICD-10 or ICD-11 (Chapter Code) 17. Covid-19 diagnosis (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not

	identified) 18. Treated as a suspected or confirmed covid-19 case 19. CCG code 20. Treatment Centre Admission 21. Admission Method 22. Hospital Site Code on Admission 23. Hospital Site Code on Discharge

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.

Provide detail on how use of confidential patient information without consent for the purposes of the survey has been explored as part of planned patient engagement activities, providing an overview of the feedback.

The applicant provided information on this aspect. Patient views were sought on their information being used for research purposes without consent. The majority of patients were comfortable with this approach and cited it as being similar to customer experience surveys they are sent from their banks and dentists. A key consideration was reassurance about who was conducting the survey and there being a need for transparency. The letters were reviewed in detail for the pilots and the text updated to ensure that it was explicit to patient who was conducting the survey on their trust behalf and who to contact with any queries or how to opt out

The CAG was content with this explanation.

Consider using other notification methods of the survey to raise further publicity among patients

The applicants noted the original document sent to the CAG for consideration on publicising the study was corrupted and provided the full document for review. It was also explained that other methods, such as social media, can be used by participating Trusts for notifying patients. Further, as a result of patient feedback, instructions to Trusts have been amended to ensure that notification will be placed in a position that patients are most likely to see. We have attached an updated document for publicising the survey. Trusts are being asked to consider whether any COVID-19 arrangements in may impact patients' opportunities to see the poster and ensure the posters are widely visible.

The group were content with this explanation and raised no issues.

Provide detail on the flow on information related to COVID-19 status, including:

a. Whether the mailing contractors receive this information.
b. If mailing contractors will receive this information, provide a justification why these organisations receive the COVID-19 status.

The applicants provided a specific data flow diagram for the flow of COVID-19 status information. It was confirmed that mailing contractors will not be receiving COVID-19 status, and they only receive the minimum contact details to send out the postal or SMS mailings.

COVID-19 status linked to patient contact details will be limited to approved contractors only. Patient contact details, along with the sample information including COVID-19 status, will be securely transferred by trusts to the approved contractor they have commissioned to conduct the survey on their behalf. The approved contractors will send the pseudonymised sample information (with the exception of postcode which has been discussed previously) to the Coordination Centre. At the end of the survey approved contractors will send the survey dataset to the Coordination Centre, where it will be combined with the pseudonymised sample information (including COVID-19 status) for analysis purposes.

Members were content with this explanation.

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. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The NHS Digital DSPT submission for Ipsos MORI, Patient Perspective, Quality Health and Picker Institute Europe were confirmed as 'Standards Met' by NHS Digital by check of DSPT tracker (03 August 2020)**

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 **22 September 2020** 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 project 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 form		21 July 2020
Sampling handbook	4	
Survey handbook	4	
Survey flowchart	1	

Sampling flowchart	1	
Postcode flowchart	1	
Dissent Poster	1	
SMS content	2	
Dissent Management	4	
Publicising the Survey	1	
T1 mailing letter	4	
T2 mailing letter	3	
T3 mailing letter	3	
Questionnaire		
Multilanguage sheet	1	
AIP Cognitive interview report	1	
Cognitive and stakeholder interviews report	1	
Maternity Pilot cognitive interviews report	1	
Documents provided in response to the provisional outcome		
Response to Provisional Outcome		
Publicising the Survey	2	
COVID-19 Status Data Flow Diagram		

Membership of the Committee

The members of the Confidentiality Advisory Group who were present at the consideration of this item 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/

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

Paul Mills
Confidentiality Advice Service Manager

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 meeting attendance
21 September 2020

Members present:

Name	
Dr Patrick Coyle	CAG vice-chair
Dr Liliane Field	CAG member
Ms Diana Robbins	CAG member
Ms Clare Sanderson	CAG alternative vice-chair

Also in attendance:

Name	*Position (or reason for attending)*
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Health Research Authority

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.