



## Health Research Authority

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07 February 2022

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Dear Ms Thomas,

**Application title:** 2022 NHS Maternity Survey - Mixed Methods  
**CAG reference:** 22/CAG/0016

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 14 January 2022. The application was considered via the precedent set process under category 11. Applications to administer surveys on behalf of 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 Maternity Survey, and for disclosure of postcode to IPSOS MORI for analysis

purposes, is fully supported, subject to compliance with the standard 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 Maternity Survey.

The Maternity Survey started in 2007 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 Maternity Survey will be the ninth carried out to date, and the second using a mixed method approach.

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:

<b>Contact</b>	<b>Type</b>	<b>Content of contact</b>	<b>Days from first mailing</b>
1	Postal	Invitation letter inviting the patient to take part online, Multi-language sheet	1
1.1	SMS	SMS reminder (if phone number available), including a link to the survey	4
2	Postal	Reminder letter, Multilanguage sheet	15
2.1	SMS	SMS reminder (if phone number available), including a link to the survey	18
3	Postal	Reminder letter, Paper questionnaire, Freepost return envelope, Multi-language sheet	29
4	Postal	Reminder letter, Multilanguage sheet	43
4.1	SMS	SMS reminder (if phone number available)	46

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.

Whilst the survey remains similar to previous years, and as in 2021, the applicants have added in COVID status to the data requested for analysis so they can distinguish between these 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

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.

<b>Cohort</b>	<p><b>ALL</b> maternity service users <b>aged 16 and over</b> at the time of delivery who had a live birth in <b>February 2022</b>. (and earlier for smaller trusts),</p> <p>Except for those meeting any exclusion criteria as listed in the application.</p>
<b>Data sources</b>	<ol style="list-style-type: none"> <li>1. Electronic patient records within all eligible Trusts in England (120-130 trusts)</li> </ol>
<b>Identifiers required for contact purposes</b>	<ol style="list-style-type: none"> <li>1. Title</li> <li>2. Initials or first name</li> <li>3. Surname</li> <li>4. Address Fields including postcode</li> <li>5. Mobile phone number</li> <li>6. Patient unique identifier</li> </ol>
<b>Identifiers required for analysis purposes</b>	<ol style="list-style-type: none"> <li>1. Patient unique identifier</li> <li>2. Postcode</li> <li>3. Mother's year of birth</li> <li>4. Mother's gender</li> <li>5. Time of delivery</li> <li>6. Number of babies born at delivery</li> <li>7. Day of delivery</li> <li>8. Month of delivery</li> <li>9. Year of delivery</li> <li>10. Maternity Care Setting (Actual Place of Birth)</li> <li>11. Actual delivery place</li> <li>12. Mother's ethnic group</li> <li>13. Trust code</li> <li>14. NHS Site code (of birth)</li> <li>15. Mobile phone indicator</li> <li>16. Whether or not mother received antenatal and/or postnatal care from the trust</li> <li>17. Treated as a suspected or confirmed covid-19 case</li> </ol>
<b>Additional information</b>	<p>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.</p> <p>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</p>

	<p>files by the contractor before submitting only the sample information to the Coordination Centre for checking and approval.</p> <p>Please note that the Survey Coordination Centre does <b>not</b> receive any names or full addresses</p>
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### **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 noted that this application is a re-run of previous Maternity Surveys, the ninth such survey and the second using 'mixed methods'. The Members were assured that this activity remained 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 provides three central arguments as to why consent is not practicable, and which have been previously 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 were content with the justification provided, and agreed that consent was not a practicable alternative.

- 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 Sub-Committee were content that the use of pseudonymised data was not a practicable alternative for undertaking the activity.

### '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.

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 9 other languages to improve accessibility. Trusts are asked to consider the impact of Covid-19 on the visibility of posters, and to think carefully about where to place them appropriately. 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.

16-17 year olds additionally have a specific notification leaflet, and will be informed directly by hospital staff about the survey. This is a recommendation from CAG regarding 16-17 year olds in a previous survey. The content of these documents is the same as for the fully supported 20/CAG/0139 survey.

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 for the 2022 Maternity Survey. 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.

The content and methodology for notification and opt out was accepted by the Sub-Committee, who noted that no changes have been made since previously supported surveys.

The Members noted that this mixed methodology of up to 7 contacts over a 46-day period seems a high number of contacts, and considered asking the applicant about either reducing the number of reminders, or providing some evidence about the effectiveness of six contacts over a lesser number of contacts. However, it was agreed that as this mixed methodology with this number of contacts has been tested in multiple pilot surveys, and therefore patient representatives are comfortable with the process, which appears to work in terms of satisfactory responses, the Members were content to accept this methodology, as in previous surveys. However, the applicant is advised to ensure that as part of each individual new survey application, the evidence of the acceptability of the number of contacts is clearly provided, to ensure the CAG can clearly review the justification for the

number of contacts. The Members noted this process also involves removing anyone who has completed the survey and any opt outs before further reminders are sent.

### 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 provides a detailed overview of the patient and public involvement in the development of this survey. The advisory group for the development of the Maternity Survey 2022 included two mothers who had given birth in the past 6 months and two service user representatives. As part of extensive discussions, the applicants checked patients' views on their information being used for these purposes without consent. The majority of patients were comfortable with this approach.

The Members were content with the patient and public involvement undertaken. The Sub-Committee were encouraged to note that although this is a repeat of previous surveys, the applicant does not assume that requirements remain the same. There have therefore been minor amendments to the questionnaire and it appears the advisory group is actively involved.

### Exit strategy

Identifiable information (used to send out the survey) will be destroyed within 12 months from the receipt of the sample files. Postcode will be deleted after mapping to LSOA and local authority, no later than 4 weeks from the respondent level dataset being signed off. The CAG were content with the exit strategy provided.

### **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. 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 **20/21** 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 27 January 2022)

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.

## **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 **07 February 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.

<i>Document</i>	<i>Version</i>	<i>Date</i>
CAG application from (signed/authorised) [2. CAG non-research application form V2_IUO ]	2	15 December 2021
Other [20CAG0139 non-research fully supported outcome]		24 November 2020
Other [21-061424_MAT22_Sample construction form - contractors v2_ICU]	2	
Other [21-061424_MAT22_Sample construction form - in house trusts v2_ICU]	2	
Other [21-061424_MAT22_Sample declaration form - contractor_V2_ICU]	2	
Other [21-061424_MAT22_Sample declaration form - in-house_V2_ICU]	2	
Other [21-061424-01 MAT22 Briefing note for young mothers leaflet V1 ICUO ]	1	
Other [21-061424-01 MAT22 Data flow diagram - sampling_V1_IU]	1	
Other [21-061424-01 MAT22 Questionnaire DRAFT CAG V1]	1	
Other [21-061424-01 MAT22 Sampling Instructions_V2_ICU]	2	
Other [21-061424-01 MAT22 Survey Handbook_V2_ICU]	2	
Other [21-061424-01 MAT22_Dissent information_V1_ICUO]	1	
Other [21-061424-01 MAT22_Multilanguage sheet_V1_PUBLIC]	1	
Other [21-061424-01 MAT22_ Questionnaire Change Log_V2_IU]	2	
Other [21-061424-01 MAT22_Text analytics_V1_ICUO]	1	
Other [21-061424-01_MAT22_Sampling Flowchart_V1+SH]	1	
Patient Information Materials [21-061424-01 MAT22 dissent poster V1_ICU]	1	
Patient Information Materials [21-061424-01 MAT22 Mailing 1 letter V1_PUBLIC]	1	
Patient Information Materials [21-061424-01 MAT22 Mailing 2 letter V1_PUBLIC]	1	
Patient Information Materials [21-061424-01 MAT22 Mailing 3 letter V1_PUBLIC]	1	
Patient Information Materials [21-061424-01 MAT22 Mailing 4 letter V1_PUBLIC]	1	
Patient Information Materials [21-061424-01 MAT22 SMS content V1_PUBLIC]	1	
Patient Information Materials [21-061424-01 MAT22 Young mothers leaflet V1 ICUO]	1	
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [MAT22 Caldicott Guardian recommendation letter V1]	1	07 January 2022



## **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](mailto:cag@hra.nhs.uk)

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

**Confidentiality Advisory Group precedent-set meeting attendance  
14 January 2022**

**Members present:**

<i>Name</i>	
Dr Tony Calland MBE	CAG Chair
Mr David Evans	CAG member
Mr Andrew Melville	CAG member

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Caroline Watchurst	HRA Confidentiality Advisor

### **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.