Health Research Authority

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24 November 2020

Laura Thomas
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3 Thomas More Square
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Dear Ms Thomas,

Application title: **2021 NHS Maternity Survey – Mixed Methods**
CAG reference: **20/CAG/0139**

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 precedent set CAG meeting held on 06 November 2020. The application was considered via the precedent set process under category 11: CQC annual surveys.

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 2021 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 2021 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 2021 Maternity Survey will be the eighth carried out to date, although this will be the first time that the maternity survey will be completed using a mixed method approach, following a successful pilot of the approach during 2019/20.

Trusts will collect information of all eligible patients and, following suitability checks, will share confidential patient information with the coordination centre (IPSOS MORI) and once 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:

Contact	Type	Content of contact	Days from first mailing
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.

Please also note that whilst the survey remains similar to previous years, 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.

Cohort	**ALL** maternity service users **aged 16 and over** at the time of delivery who had a live birth between **1 February and 28 February 2021**. (and earlier for smaller trusts), Exclusions: • Mothers who were under 16 years of age at the time of delivery. • Mothers who had one or more stillbirths. • Mothers whose baby has died since delivery • Mothers who have died during, or since, delivery. • Mothers who were in hospital, or whose baby was in hospital, at the time of drawing the sample. • Where possible, mothers who had a concealed pregnancy. • Where possible, mothers whose baby was taken into care or adopted. • Mothers who delivered in a private maternity unit or wing. • Mothers who delivered in a maternity unit managed by another provider • Mothers without a UK postal address *(but do not exclude if addresses are incomplete but still useable, e.g. no postcode)*. • Mothers who have requested that their details are not used for any purpose other than their clinical care, including requests made following sight of survey pre-publicity; This does not include the National Data Opt-out Programme.
Data sources	1. Electronic patient records within all eligible Trusts in England (120-130 trusts)
Identifiers required for contact 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. Patient unique identifier 2. Postcode 3. Mother's year of birth 4. Mother's gender 5. Time of delivery 6. Number of babies born at delivery 7. Day of delivery 8. Month of delivery

	9. Year of delivery 10. Maternity Care Setting (Actual Place of Birth) 11. Actual delivery place 12. Mother's ethnic group 13. Trust code 14. NHS Site code (of birth) 15. CCG code 16. Mobile phone indicator 17. Whether or not mother received antenatal and/or postnatal care from the trust 18. Covid-19 diagnosis during labour and birth (derived from ICD-10 codes U07.1 COVID-19, virus identified and U07.2 COVID-19, virus not identified) 19. Treated as a suspected or confirmed covid-19 case

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.

Members agreed that the activity has 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.

- Feasibility of consent

The group agreed that consent is not feasible, given the potential to introduce bias, and the lack of capacity of Trust staff.

- Use of anonymised/pseudonymised data

Members were content that the use of anonymised or pseudonymised information was not practicable, given the need to distribute information to patients. The Sub-Committee also were content with the postcode being used for analysis; postcode is deleted after mapping to LSOA and local authority, as per previous surveys. Covid-19 status is the only additional sensitive information required compared to previous maternity surveys, and members were content with this flow of data, as it was comparable to the recently supported survey CAG reference 20/CAG/0085.

'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 objection 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.

The applicants provided an overview of the patient notification and awareness raising mechanisms offered to Trusts. 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 will be 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.

Members also were content that the applicants had adequately explored the use of an SMS opt out mechanism and were in agreement with the decision and reasoning not to use an SMS opt out mechanism. There is a helpline number included in the SMS which applicants can call to opt-out if required.

The members did question the amount of contacts by letter and SMS that a patient would receive, however the same methodology has been previously supported by CAG, and the applicants have performed PPI regarding the amount and type of contacts which appears to be supportive.

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, including how this 2021 survey was shaped by involvement of patients. As part of these discussions applicants checked patients' views on their information being used for these purposes without consent. The majority of patients were comfortable with this approach.

Further to this, a response to provisional outcome for the 2020 NHS Adult Inpatient Main Stage Survey – Mixed Methods (20/CAG/0085) provided an update on PPI undertaken to date, which was accepted by the CAG in a fully supported outcome letter dated 22 September 2020.

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.
   Confirmed: The NHS Digital **2018/19** 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 (17 November 2020). The **2019/20** DSPT submissions have not yet been reviewed by NHS Digital, but the applicant has requested that these be reviewed.

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 **24 November 2021** 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 were:

Document	*Version*	*Date*
Other [20-051636-01_MAT21_Publicising the survey_V2]	2	
Other [20-051636-01_MAT21_Sampling Flowchart_V1]	1	
Other [20201002_MAT21_Attribution spreadsheet_V3_ICU]	3	
Other [20201002_MAT21_Sample declaration form - contractor_V3_ICU]	3	
Other [20201002_MAT21_Sample declaration form-in-house_V3_ICU]	3	
Other [20201005 MAT21 Sampling Instructions V3 ICU]	3	
Other [20201005 MAT21_Attribution Instructions V4_ICU]	4	
Other [20201005_MAT21_Sample construction-contractor_V4_ICU]	4	

Other [20201005_MAT21_Sample construction-in house_V4_ICU]	4	
Other [HRA letter re Service Evaluations will not be considered by HRA]		20 August 2020
Other [MAT21 Data flow diagram - postcode_V3_ICUO]	3	
Other [MAT21 Data flow diagram - sampling_V3_ICUO]	3	
Patient Information Materials [20-051636-01 MAT21 Briefing note for young mothers leaflet V2]	2	
Patient Information Materials [20-051636-01 MAT21 DissentPoster V3_ICUO]	3	
Patient Information Materials [20-051636-01 MAT21 Mailing 1 letter_V3_ICUO]	3	
Patient Information Materials [20-051636-01 MAT21 Mailing 2 letter_V3_ICUO]	3	
Patient Information Materials [20-051636-01 MAT21 Mailing 3 letter_V3_ICUO]	3	
Patient Information Materials [20-051636-01 MAT21 Mailing 4 letter_V3_ICUO]	3	
Patient Information Materials [20-051636-01 MAT21 SMS content_V1_ICUO]	1	
Patient Information Materials [20-051636-01 MAT21 Survey handbook V4_ICUO]	4	
Patient Information Materials [20-051636-01 MAT21 Young mothers leaflet V2_ICU]	2	
Patient Information Materials [20-051636-01 MAT21_Dissent information_V1_ICUO]	1	
Patient Information Materials [20-051636-01_MAT21_Draft Paper Questionnaire_V1_ICUO]	1	
Patient Information Materials [20-051636-01_MAT21_Multilanguage sheet_V1_ICUO]	1	
Write recommendation from Caldicott Guardian (or equivalent) of applicant's organisation [20200928 MAT21 Caldicott Guardian recommendation letter V2]	2	02 October 2020
Maternity Survey Pilot 2019/20 Report on cognitive testing of survey materials		05 February 2020
20CAG0085 s251 Non-research provisional outcome letter final		07 September 2020
20CAG0085 final support letter - non-research		22 September 2020
20200915 IP20 section 251 request for additional information v1	V1	16 September 2020
2020907_IP20_Data flow diagram - COVID_V1	V1	
19CAG0021 Fully Supported Outcome		15 March 2019
19CAG0181 s251 non-research conditional outcome		18 November 2019

Membership of the Committee

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

There were no declarations of interest in relation to this item.

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 Health Research Authority

Email: cag@hra.nhs.uk

Enclosures: *List of members who considered application*
Standard conditions of approval

Confidentiality Advisory Group precedent-set meeting attendance
06 November 2020

Members present:

Name	
Professor Barry Evans	CAG member
Dr Murat Soncul	CAG alternative vice-chair
Dr Malcolm Booth	CAG member

Also in attendance:

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

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.