Minutes of the meeting of the Sub Committee of the Confidentiality Advisory Group

13 January 2023 via correspondence

Present:

Name	Role	Items
Dr Patrick Coyle	CAG Vice-Chair	2a, 2b, 2c, 2d
Dr Malcolm Booth	CAG Member	2b, 2d
Dr Sandra Duggan	CAG Member	2a, 2c
Mr. Anthony Kane	CAG Member	2b, 2d
Mr Andrew Melville	CAG Member	2a, 2c

Also in attendance:

Name	Position (or reason for attending)
Mr Michael Pate	HRA Confidentiality Advisor
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Caroline Watchurst	HRA Confidentiality Advisor

1. Expressions of interest

There were no conflicts of interest declared.

2.New Precedent Set Review Applications

a. 23/CAG/0002- Haematological inflammatory markers and survival in mesothelioma

Context

Purpose of application

This application from University Hospitals of Leicester NHS Trust set out the purpose of medical research that seeks to contribute to the body of evidence on the role on inflammation in MPM prognosis, specifically within a UK population, where very few studies have been conducted in this regard.

Malignant pleural mesothelioma (MPM) is an uncommon cancer which is related to previous asbestos exposure. The disease has a poor survival, with studies quoting a median overall survival (OS) time of 9–17 months regardless of the tumour stage at diagnosis. The British Thoracic Society mesothelioma guideline quotes a high neutrophil-lymphocyte ratio (NLR) as an independent predictor of poor survival in MPM. However, there is limited evidence on other prognostic inflammatory markers such as the platelet-lymphocyte ratio (PLR), lymphocyte-monocyte ratio (LMR) and systemic immune inflammation index (SII) in the literature. These markers have been well-studied in other cancer sites, such as lung cancer, and have been associated with similar poor survival.

Confidential patient information from the mesothelioma MDT database at the University Hospitals of Leicester NHS Trust will be disclosed to the Chief Investigator, who is not considered direct care team, and therefore requires ‘s251’ support. The Chief Investigator will use the hospital number to obtain data from medical records of all patients with a pleural mesothelioma diagnosis from 2014-2021 (expected to number 250 to 300 patients). Date of death will be used to calculate overall survival time from diagnosis in days. It will be deleted from the database once this has been calculated, and analysis will be undertaken on an effectively anonymous dataset.

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 University Hospitals of Leicester NHS Trust patients aged 18 years and above, with a pleural mesothelioma diagnosis from 2014-2021 (expected to number around 250-300 patients)
Data sources	University Hospitals of Leicester NHS Trust 1. Mesothelioma MDT database (local cancer register) 2. Patient medical records
Identifiers required for linkage purposes	1. Hospital number 2. Entire medical record will be viewed in the process of extracting a dataset for analysis
Identifiers required for analysis purposes	1. Date of death will be used to calculate overall survival time from diagnosis in days. It will be deleted from the database once this has been calculated.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006 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 applicant reasoned that contacting patients for their consent in retrospect will be impossible as most patients will have passed away, due to the poor prognosis of the disease. Moreover, calling patients to organise consent will include further

infringement of privacy, as patients may not wish to disclose their contact information to people not directly involved in their clinical care. The Sub Committee were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The hospital number of those patients aged 18 years and above, with a pleural mesothelioma diagnosis from 2014-2021, is required for the Chief Investigator to link to their medical records, in order to analyse treatment decision, stage and blood results. The Chief Investigator is currently part of the direct care team for mesothelioma patients but has been working in the team from January 2020-1 and November 2021-present. The study aims to look at long term survival in patients going back to 2014, when the Chief Investigator was not employed in the Trust. There are few members of the mesothelioma team who have been consistently working in this capacity in the last 8 years.

The study forms part of a dissertation which has a time sensitive deadline and none of the team would be able to undertake extensive data collection on top of their intensive job within the next 2 months - which is expected to take at least 40-60 hours of dedicated work. This is especially unfeasible to arrange with the current critical strain on NHS personnel due to winter pressures.

The Sub-Committee were content that using anonymous information was not a practicable alternative.

'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.

A patient notification strategy has not been devised as the tight timeframe of the study will not make it possible to reach a significant part of the patient cohort on time, e.g. dissemination of cards/leaflets in clinic or outreach by the mesothelioma nursing team.

The Sub Committee noted that in terms of patient's notification, it is assumed that surviving patients were regular attenders at cancer treatment units, so a poster could easily have been put up in the clinic for patient's information.

The Trust is in line with the National Data Opt-Out policy and has an SOP in place for such situations.

In order to ensure that individual patients have not opted out of their data being accessed, the researcher will ask the Cancer Centre Data Manager to send the list of patients eligible for the study to the Research and Innovation team who can then cross-check the patients' details with the NHS Spine system and remove any people who have asked for their data to be excluded.

The Sub-Committee were content with this explanation

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 researcher confirmed that she has unfortunately been unable to complete formal patient involvement activity due to the tight timeframe involved with the completion of this study project. Recruitment of patient focus groups with the current NHS winter pressures will take additional time and manpower which is currently not available.

On 11 January, the researcher said that she was currently in discussions with the local mesothelioma research team and they will identify patients whom she can contact for a discussion. No other details were provided.

The Sub Committee noted that, given the number of cancer patient groups who could be approached and consulted relatively easily e.g., by zoom or email, the applicant should gather public views (from 5 or more cancer survivors and/or members of cancer support groups), particularly on accessing patient data without consent.

Exit strategy

The exit strategy will be anonymisation, by deletion of hospital number and date of death. However, the Sub-Committee were not clear from the response to the Confidentiality Advice Team (CAT) queries whether the Chief Investigator actually receives the Date of Death and deletes it once the survival time is calculated, or whether survival time is calculated by the cancer centre data manager. If the Chief Investigator receives the date of death, then this will require 's251' support, however if this is calculated and removed by the cancer centre data manager, who is considered direct care team, no 's251' support will be required, and the exit strategy from support will be the deletion of hospital number by the Chief investigator only. The applicant is to clarify this.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please undertake further patient and public involvement with 5 or more cancer survivors and/or members of cancer support groups. This can be by video conference or email, and should focus specifically around the use of confidential patient information without consent and feedback from this provided to the CAG.

2. Please provide a poster to display in relevant areas in the clinic so information about the study would be displayed, and that patients can choose to opt out if they wish to.

3. Please confirm whether the Chief Investigator actually receives the Date of Death and deletes it once the survival time is calculated, or whether survival time is calculated by the cancer centre data manager.

4. Please ensure contact details are included on the poster, in order for patients to be able to opt-out if they wish. The CAG usually expect that email, telephone and postal details are included.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 10 January 2023**

2. 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 review for **University Hospitals of Leicester NHS Trust** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (24 January 2023)

b. 23/CAG/0010 - The SHIPS Study: Sharing Information at the Primary / Secondary care interface – improving patient care by ensuring that GPs get the information they need when someone is discharged from hospital

Context

Purpose of application

This application from University of Bristol – Bristol Medical School set out the purpose of medical research that seeks to explore the communication of poor prognosis between secondary care and primary care when a patient is discharged from hospital. The aim is to understand what information should be shared with General Practitioners (GPs) after a hospital stay, and how it might best be shared. GPs find it challenging to identify patients with advanced illness, who might have limited life expectancy, and would welcome clear communication from hospital specialists concerning these patients. Communication of this information to GPs enables better continuity and coordination of care. Advance care planning discussions can then enable patients’ wishes to be identified and respected, including preferences for place of care and death, and future admission avoidance.

On average, people dying in Britain spend three weeks of their last year of life in hospital as a result of one or more emergency admissions. The SHIPS study is relevant, and needed now, as emergency admissions in the last year of life are predicted to translate to a need for 8000 extra hospital beds by 2038. Strategies that improve Summary of application for CAG continuity of care lower hospital admissions, potentially improving the quality of end of life care, while reducing its cost. To ensure the delivery of well-coordinated and continuous care by GPs, applicants need to establish how primary and secondary care can communicate effectively and efficiently.

Part 1 of The SHIPS study is already underway regarding a literature review to inform part 2. Part 2 includes a number of different methodologies at 2 participating Trusts, including consented interviews and reviewing anonymised discharge

information. These elements do not require ‘s251’ support. However the applicant is also undertaking ethnographic observations, of multidisciplinary team meetings, board round meetings, observed daily at each site, informal interactions between HCPs on hospital wards, and observations of clinicians preparing discharge communications about patients on the ward. Support under Regulation 5 is required for this aspect of the study as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded, but the researcher may record age, gender and ethnicity, which would be effectively anonymous to the researcher.

The researcher will spend approximately 48 days in total on six wards (three wards per study site), conducting interviews and 80-100 hours of observations. The study sites are Great Western Hospitals NHS Foundation Trust and North Bristol NHS Trust. The wards will be purposively sampled focusing on respiratory, oncology and care of the elderly wards, as these wards are most likely to be caring for patients in the last year of life. Other wards, including surgery and cardiology may also be selected, to include wards who are known to be effectively identifying and communicating limited life expectancy at discharge, and wards who may have development needs in this area.

A recommendation for class 1,5 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	Individual observation of secondary care clinicians: 30-40 clinicians, each clinician observed up to 1-3 times Out of scope for ‘s251’: Secondary care clinician interviews: 24-28 interviews GP interviews: 18-22 interviews Interviews with patients and carers: 24-28 interviews Anonymised discharge documentation: 30-40 items The researchers undertaking observations of MDT meetings may be exposed to confidential patient information relating to patients discussed at the MDT meetings. It is these patients who are the cohort for ‘s251’ support.

Data sources	1. Clinical meetings recorded via written field notes, at the following Trusts; • Great Western Hospitals NHS Foundation Trust • North Bristol NHS Trust
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	1. Age 2. Gender 3. Ethnicity This is effectively anonymous to the researcher

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006 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 researcher conducting the observations of clinical meetings will not know in advance which patients under the care of the organisation may be discussed by staff in meetings. Therefore, seeking consent in advance of observations taking place is not possible. The applicant reasons that due to the logistics of high patient turnover and the inherent unpredictability of the observations, it will not be possible to obtain informed consent for this access from every patient on each ward, and it is also impractical for the researcher to be present only for discussion of patients who have given informed consent. The Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The applicants do not require access to confidential patient information in order to undertake the research, however, the researchers may be exposed to confidential patient information when observing MDT meetings. No items of confidential patient

information will be recorded. Patient data is not the focus of the research activity and no patient data will be recorded or used for research purposes in the study. The researcher is only recording anonymous information. The Sub-Committee was content that using anonymous information was not a practicable alternative.

'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 notifying patients of the observations will be displayed on all wards where the observations are taking place. Ward information sheets will also be made available to all patients residing on those wards. Both confirm that no confidential patient information will be recorded and the ward information sheet provides information for patients on how they can opt out. The poster will contain a picture, which CAG have previously identified as a positive in these types of applications. There is an opt out option on information sheet, however this is not clear on poster. It has previously been accepted by CAG that it is not possible to apply the NDO to incidental disclosures.

The Sub-Committee noted that the ward information sheet should include a brief reference to 's251' support, and why it is required in this instance. The Members also requested that the poster should also include a very brief reference to the breach of confidentiality and 's251' support, and should also include details of how to opt out.

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.

This study has been developed with the Bristol Palliative and End of Life Care PPI Advisory Panel, who have reviewed all patient-facing materials. This research question and study design have been shaped by patients and current or bereaved carers. Members of the panel will continue to be involved during the study to provide oversight and co-produce a patient-facing publication of study findings.

In 2019 two patient and public involvement (PPI) workshops were held and attended by 18 members of the public, representing culturally diverse populations in Bristol. Attendees were either past or current carers for loved ones at the end of life.

Following these workshops, attendees were invited to become part of the Bristol Palliative and End of Life Care PPI Advisory Panel. Eight members of this panel have now formed a PPI group for the SHIPS study. The SHIPS PPI group has met on four occasions. At a meeting on 09 June 2022, the group supported the use of confidential patient information without consent. The group were in agreement that it is not possible to obtain individual patient consent from every patient on each ward in order that the researcher can be present at meetings, where she will have access to their confidential information. They were reassured that the researcher is a qualified GP. The group also understands that no confidential patient information will be collected in fieldnotes or documents.

The Sub-Committee were content with the Patient and Public Involvement undertaken.

Exit strategy

No items of confidential patient information will be recorded. Therefore the exit strategy will be the time point that the applicant stops the observations. Observations of MDT meetings are estimated to be completed by 31st July 2024. 's251' support required until this point. The Sub-Committee are content with the exit strategy provided.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide an updated ward information sheet to include a brief explanation regarding 'Section 251' support and why it is required.

2. Please provide an updated poster to include a brief explanation regarding 'Section 251' support and why it is required, and also include information on how to opt out.

Once received, the information will be reviewed by the Confidentiality Advice Team (CAT) in the first instance and a recommendation and decision issued as soon as

possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed 20 December 2022**

2. 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 **Great Western Hospitals NHS Foundation Trust** & **North Bristol NHS Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (24 January 2023)

c. 23/CAG/0014- 2023 NHS Maternity Survey – mixed methods

Context

Purpose of application

This non-research application submitted by Ipsos UK on behalf of the Care Quality Commission, sets out the purpose of conducting the 2023 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 2023 Maternity Survey will be the tenth carried out to date, and the third 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 UK) 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:

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 removed the collection of COVID-19 status from the data requested for analysis, updated some of the questions, and plan on boosting the numbers of maternity service users from ethnic minority backgrounds, by sampling over an additional two-month period (January and March). Fieldwork length has also been shortened to 13 weeks.

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	**Core sample: ALL** maternity service users **aged 16 and over** at the time of delivery who had a live birth between in **February 2023**. (and earlier for smaller trusts), Except for those meeting any exclusion criteria as listed in the application.

	Booster sample: Trusts that achieve a minimum sample of 300 people in February, will be asked to additionally sample all maternity service users from ethnic minority backgrounds who gave birth in January and March 2023
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. Actual delivery place 11. Mother's ethnic group 12. Trust code 13. NHS Site code (of birth) 14. Mobile phone indicator 15. Whether or not mother received antenatal and/or postnatal care from the trust 16. 'Core' versus ' Booster' sample code
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 medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006 and it is 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**

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 were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

To facilitate the distribution of the survey questionnaires.

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 was content that using anonymous information was not a practicable alternative.

'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 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 2023 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 – see here.

The Sub-Committee were content with the notification provided.

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 survey was shaped by involvement of patients. The advisory group for the development of the Maternity Survey 2023 included three maternity service users who had given birth in the past 6 months and four service user representatives.

For the 2023 Maternity Survey, twenty scoping interviews were conducted in October 2022 to understand the maternity service users' experiences of having a baby, and to sense-check whether the questionnaire is still addressing the maternity journey that service users are having. A specific focus of the interviews conducted with maternity service users was the wording around use of confidential data by Ipsos, CQC, their NHS Trust and researchers analysing the data. It's worth noting that across the 20 interviews completed, no patient spontaneously noted a concern about their personal data being used for research purposes without express consent. Patients were comfortable with the CQC survey approach and this use of confidential patient information without consent.

The Sub-Committee were content with the patient and public involvement provided.

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 was 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 **21/22** DSPT reviews for **Ipsos UK, Patient Perspective, Quality Health Limited & Picker Institute Europe** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (24 January 2023)

-

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.

d. 23/CAG/0016- How are people with motor neuron disease (MND) are supported by their clinical teams to make decisions about gastrostomy feeding tube: a multiple case study

Context

Purpose of application

This application from Sheffield Teaching Hospitals NHS Foundation Trust set out the purpose of medical research that seeks to understand how healthcare professionals (HCPs), operating within multidisciplinary team (MDT)s, support people with motor neuron disease (MND) to make decisions about gastrostomy placement. The applicant will observe real-world MND MDT practice, to inform the development of professional guidance and recommendations for practice. The research and guidance will better inform MND MDTs on the decision support they deliver to people with MND regarding placement of a gastrostomy feeding tube.

People with MND are offered a gastrostomy feeding tube (a narrow plastic tube placed directly into the stomach) when they are unable or at risk of not being able to take enough diet and fluids orally. Research has found that people with MND and HCPs find it difficult to make the decision to have a gastrostomy, due to the unpredictability of the rate of disease progression and uncertainties about the effectiveness of the intervention. There is currently no clear guidance about when HCPs should introduce the option of gastrostomy placement to people with MND or the best time to have the gastrostomy placed. There is a need to understand the process, enablers and challenges around how people with MND make decisions about gastrostomy in the context of a progressive disease and supported by a wide MDT.

The applicant is undertaking a number of different methodologies at 3 participating MND clinics, including consented interviews and focus groups, reviews of medical notes, documentation reviews, and verbally consented observed interactions between patients and HCPs. These elements do not require ‘s251’ support. However the applicant is also undertaking ethnographic observations, of 2 x 60 minute MND Clinic MDT meetings at each site, in total. There is no sample size pre-selected for HCP observations, the researcher will take opportunities to observe HCPs as they present themselves while in the field. Support under Regulation 5 is required for this aspect of the study as the applicants may be exposed to confidential patient information when undertaking the observations. Observations will be recorded via handwritten field notes. Identifiable patient information will not be recorded.

A recommendation for class 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application, which can be got from the CAT assessment form, class support requested section.

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	People with MND who were discussed during Multidisciplinary Team Meetings (MDTs)
Data sources	1. Clinical meetings in MND clinics recorded via written field notes, at the following Trusts; England; • University Hospitals of North Midlands NHS Trust • Northern Care Alliance NHS Foundation Trust Wales: • Swansea Bay University Local Health Board
Identifiers required for linkage purposes	No items of confidential patient information will be recorded for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be recorded for analysis purposes

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006 and it is 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 researcher will be observing healthcare professional interactions with colleagues including in team meetings or informal discussions in the workplace. It will not be possible to seek informed consent from every person with MND who may be discussed in these interactions, as the discussions are often spontaneous, and the researcher will therefore not know in advance who will be discussed. Therefore, seeking consent in advance of observations taking place is not possible.

The researcher is aiming to consent for all other scenarios, and has thought in detail about how to facilitate consent for those who may have difficulty.

The Members were content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The researchers may be exposed to confidential patient information when observing MDT meetings. No items of confidential patient information will be recorded.

Patient data is not the focus of the research activity and no patient data will be recorded or used for research purposes in the study.

During observations of clinical meetings, the researcher may be incidentally exposed to identifiable patient information, however this data is not being collected and no identifiable information will be recorded by the researcher. Any recorded data (via written field notes) will use a pseudonym where necessary to record information about the patient being discussed during the meeting. The researcher will not write down any personal information about the patient.

The Sub-Committee was content that using anonymous information was not a practicable alternative.

'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.

The Principal Investigator (PI) at each site will identify and invite HCPs. This is out of scope for support.

Any patients who are consented will be approached initially by direct care team, and this is out of scope for CAG support.

There are many versions of PIS and consent forms but these have not been provided for review as they are out of scope for CAG.

The study observations of MDT meetings will be advertised to all staff and patients through posters displayed in all areas the researchers will be based. The poster will instruct all staff and service users that they can contact the researcher should they not wish to be included in the observations. The poster will contain a picture, which CAG have previously identified as a positive in these types of applications. A Study specific opt out is on the posters displayed in clinical areas. Additionally it has previously been accepted by CAG that it is not possible to apply the NDO to incidental disclosures.

The Sub-Committee were content with the notification provided.

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.

During the development of the study, the researcher collaborated with four different Patient and Public involvement (PPI) groups, with approximately 10 attendees per group;

- The Sheffield MND Research Advisory Group
- A University of Sheffield Palliative Care PPI group
- Applicants NHS departments directorate PPI group
- A University MS PPI group (a MS focused PPI group
- And two further individuals living with MND who had experience of making decisions about gastrostomy placement.

Feedback included that the proposed methods were appropriate and feasible.

The applicant has since recruited a group of 5 people with MND and caregivers, who have experience of making the decision to have a gastrostomy placed and a panel of healthcare professionals and academics with experience of decision making and MND. This group is expected to have rolling membership. The feedback from this PPI group has influenced the study design, and the panel meets periodically online.

The issue of observing HCPs discussing patient cases in MDT meetings without consent of the patients being discussed was discussed with the study PPI group. The PPI group agreed that informing patients that HCPs will be discussing their need to consider gastrostomy placement would have the potential to cause them anxiety as this may not have been a topic that had been discussed with them yet or may be a topic that was causing them anxiety. For example it could heighten their anxiety prior to or at their next clinic appointment and also have the potential to affect patient care. While the PPI group had reservations that some people may have concern about someone else being aware of their case, they also appreciated and agreed that informing them that discussions had been had about gastrostomy placement could possibly be upsetting, if this was not something they were aware was being

considered. The PPI group were also reassured that the researcher was an experienced and practicing MND healthcare professional rather than a non-clinical researcher.

Therefore, the use of confidential patient information without consent was discussed with and supported by the study patient and public involvement group.

The Sub-Committee were content with the patient and public involvement undertaken.

Exit strategy

No items of confidential patient information will be recorded. Therefore the exit strategy will be the time point that the applicant stops the observations. Observations of MDT meetings are estimated to be completed by 01 February 2024. 's251' support required until this point. The Sub-Committee 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 Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 14 December 2022**

2. 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 **University Hospitals of North Midlands NHS Trust & Northern Care Alliance NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (24 January 2023)

Swansea Bay University Local Health Board - Welsh IG team confirmed submission of the Welsh IG toolkit, via email correspondence.

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.

Minutes signed off as accurate by correspondence from		
Signed – Officers of CAG		Date
Dr Patrick Coyle, CAG Vice-Chair		*27 January 2023*
Signed – Confidentiality Advice Team		Date
Mr Dayheem Sedighi, HRA Approvals Administrator, & Ms Caroline Watchurst, HRA Confidentiality Advisor		*25 January 2023*