Health Research Authority

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

14 January 2022

Present:

Name	Capacity	Items
Dr Tony Calland MBE	CAG Chair	1a, 1b, 1c, 2a
Dr Malcolm Booth	CAG Member	1a, 1b
Dr Lorna Fraser	CAG Member	1a, 1b
Mr David Evans	CAG Member	1c, 2a
Dr Harvey Marcovitch	CAG Member	1c
Mr Andrew Melville	CAG Member	2a

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 22/CAG/0017– Supervised Pulmonary Hypertension Exercise REhabilitation (SPHERe): a multi-centre randomised controlled trial

Context

Purpose of application

This application from the University of Warwick set out the purpose of medical research of a multi-centre randomised controlled trial (RCT) to test if supervised pulmonary hypertension exercise rehabilitation (Sphere), a programme of online remotely supervised, home-based exercise rehabilitation, with psychosocial and motivational support, can improve walking distance and quality of life (QoL), more than best-practice usual care, in people with all forms of pulmonary hypertension (PH) (particularly groups 2 & 3). This application to CAG is only for the screening and inviting of eligible patients to consent to the trial, by a researcher who is not considered part of the direct care team, in Patient Identification Centres (PIC) where the direct care team has indicated they do not have capacity to do so. This trial has been running since 2019 using only the direct care team to screen and invite eligible patients, however participating sites have identified that the direct care team have low or no capacity to undertake this activity.

PH is a debilitating long-term condition characterised by severe exercise intolerance. Pulmonary and cardiovascular function are progressively compromised, often during minimal physical exertion. Consequently, exertional breathlessness, fatigue and dizziness are common, impacting on QoL, morbidity and mortality. For people with PH secondary to cardiac or pulmonary disease (groups 2 & 3), there are no specific treatments of proven benefit. Supervised exercise rehabilitation is a common treatment for many heart and lung conditions, however, exercise rehabilitation has not yet been adequately tested in PH groups 2 & 3, or in an out-patient setting in the UK. This RCT will examine if exercise rehabilitation for PH delivered in an NHS out-patient setting is effective or cost effective, or if there are any long-term health benefits or harms.

All patients are consented in to the trial, and the main trial therefore does not require ‘s251’ support. Potential participants will be invited to participate by clinical teams involved in their care, which does not require ‘s251’ support, or by the SPHERe Clinical Research Fellow (CRF) based at Warwick Clinical Trials Unit (WCTU) at some PIC sites, which does require ‘s251’ support. The SPHERe CRF will support PIC sites in their screening and mail out work. To do so, this person will require access to medical records to screen for eligibility, and name and address in order to send out invitation letters. In doing so, they will therefore be processing confidential patient information without consent. No confidential patient information will be disclosed to the University of Warwick without the consent of the patient to do so.

A recommendation for class 3 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	352 Adults with pulmonary hypertension (groups 1-5) from at least 10 centres will be consented and randomised. However CAG support is required for all those screened and invited. Applicants estimate that approximately 1000 patients will be screened per PIC site by the Warwick CRF. Applicants further estimate that approximately 25-35% of those screened will be eligible to invite. 32 participants have been recruited to the trial to date, and 's251' support does not extend to these individuals.
Data sources	**Participating Patient Identification Centres (PIC);** Hospital medical records, (both paper notes and electronic medical records) including clinic letters, discharge records, operation notes and scan reports e.g. echocardiogram reports. Screening may also include local secondary care disease registers.
Identifiers required for screening/identification purposes, and for inviting patients to consent	1. Access to full medical record to determine diagnosis of PH 2. Date of Birth (to check eligibility) 3. Patients full name (to send invitation letter) 4. Patients address including full postcode (to send invitation letter)
Identifiers required for analysis purposes	N/A all data for analysis is collected with consent
Additional information	In all instances, an appropriately qualified clinician will be asked to confirm diagnosis prior to any patient contact.

	Confidential patient information will not be disclosed from the NHS Trust to the University of Warwick until the patient has consented into the trial.

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.

The Members agreed that this could be a valuable piece of research into the potential rehabilitation of people with pulmonary hypertension using a home-based protocol, and that the activity was therefore 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**

At many PIC sites it is not practicable for a member of the patients clinical care team to carry out screening or mail out activities because of resource limitations due to the COVID-19 Pandemic. Many sites are prioritising other trials or staff members are being re-deployed to cover hospital pressures due to Covid-19. The applicants explained that this is significantly impacting on trial recruitment and therefore trial progress. It is not possible for the WCTU SPHERe clinical research fellow to obtain the patients consent prior to the medical notes being screened to check potential suitability or for contact details to be used to send out patient invitations, as these activities take place prior to the first point of contact with the patient. The Members accepted the justification provided that consent is not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to identify potentially eligible participants and invite the patient to take part in the trial. It is not possible to do this if only using pseudonymous or anonymous information. The Members accepted this reasoning.

'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 applicant has provided an invitation letter and patient information leaflet, and these documents will be viewed after the breach has occurred. The invitation letter states that 's251' is the legal basis under common law for the Warwick CRF to view confidential patient information whilst screening and sending invitation letters. Patients can decline the study on receipt of these invitation materials.

Information about this specific breach has been included as part of a poster, which will be put up in clinical areas in participating PIC sites and on social media platforms, that includes an opportunity to opt out. This is in line with other similar applications.

The National data opt out will also be applied locally prior to the Warwick CRF viewing confidential patient information.

The Members were content with the notification and dissent materials provided. However it was commented that it was unclear if someone receives an invitation letter but does not respond to it, will further invites be sent? If so, then how many? The Members would be content with 1 additional letter being 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 applicants have a patient and public involvement (PPI) representative on the Trial Management Group. This PPI representative has been consulted regarding a member of the SPHERe team supporting screening and mail out activities at PIC sites. The PPI representative was supportive of this as long as the SPHERe team member is suitably qualified and was reassured that this would be the case.

The CAG commented that there does appear to be PPI support for the use of confidential patient information without consent – however, only one person has been consulted. The applicant is required to undertake further patient and public involvement with some additional patient representatives, and provide a report back.

Exit Strategy

The exit strategy for the individual patients screened is consent. Where consent is not obtained the anonymisation/deletion of identifiable data is the appropriate exit strategy, and this has been confirmed by the applicant. The Sub-Committee were content with this exit strategy.

The length of time support is required for the Warwick CRF to screen and invite patients is expected to be on a continuous basis until April 2024.

Capacity to consent

The Sub-Committee queried how the applicants plan to assess those who may not have capacity to give consent – as those with PH and Down's syndrome were mentioned in the application. The CAG queried whether the CRF will have enough information about whether

the patient has capacity to consent, or if the CRF will be able to discuss this with the clinical care team? The Members were eager to ensure this patient group were not excluded unfairly due to this new recruitment strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Please confirm if someone receives an invitation letter but does not respond to it, will further invites be sent? If so, then how many? Please provide a response to CAG within three months from the date of this letter.

2. Please undertake further patient and public involvement with some additional patient representatives, in order to explore the acceptability of this use of confidential patient information without consent, and provide feedback to the CAG within three months from the date of this letter.

3. Please confirm whether the CRF will have enough information about whether the patient has capacity to consent, or if the CRF will be able to discuss this with the clinical care team in order to ensure every person who has capacity to consent is offered the opportunity to take part. Please provide a response to CAG within three months from the date of this letter.

4. Favourable opinion from a Research Ethics Committee. **Confirmed: Amendment 4 10 January 2022**

5. 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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

b. 22/CAG/0018– Rehabilitation Exercise and psycholoGical support After covid-19 InfectioN' (REGAIN): a multi-centre randomised controlled trial

Context

Purpose of application

This application from The University of Warwick set out the purpose of medical research of a multi-centre randomised controlled trial (RCT) to test the clinical and cost-effectiveness of an intensive, on-line, supervised, group, home-based rehabilitation programme that supports long-term physical and mental health recovery (REGAIN) vs. best-practice usual care for people

discharged from hospital after COVID-19 infection. This application to CAG is only for screening, and inviting eligible patients to consent to the trial, sent by a researcher who is not considered part of the direct care team, in Patient Identification Centres (PIC) where the direct care team has indicated they do not have capacity to do so. This trial has been running since the end of 2020, using only the direct care team to screen and invite eligible patients, however participating sites have identified that the direct care team have low or no capacity to undertake this activity.

At least 80,000 people in the UK have been discharged from hospital by the NHS after treatment for COVID-19, a substantial proportion of which will have ongoing health problems. There are few, if any, rehabilitation or structured support programmes for COVID-19 survivors who continue to have physical and mental health problems several months after hospital discharge. The potential benefit is unproven, therefore research is needed to tackle the multiple long-term physical and mental health consequences of COVID-19. This application aims to test the REGAIN intervention, including researching the appropriate time point for delivery, looking at cost-effectiveness and how to deliver at scale whilst adhering to continued general population infection control measures.

All patients are consented into the trial, and the main trial therefore does not require 's251' support. The REGAIN research staff will support PIC sites in their screening and mail out work, which does require 's251' support. To do so, REGAIN staff will require access to confidential patient information including medical record and date of birth to check eligibility, and name and address in order to send out invitation letters. In doing so, they will therefore be processing confidential patient information without consent. No confidential patient information will be disclosed to the University of Warwick without the consent of the patient to do so.

A recommendation for class 3 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	535 Adults recruited ≥ 3 months after any UK hospital discharge related to COVID-19 infection, will be consented and randomised. Applicants have already consented 190 patients. CAG support is required for all those screened and invited. Applicants estimate that to recruit the remaining 345 participants approximately 15,000 patients will be invited.

Data sources	**Participating Patient Identification Centres (PIC);** Hospital medical records, (both paper notes and electronic medical records) including discharge records
Identifiers required for screening/identification purposes, and for inviting patients to consent	1. Access to full medical record to determine eligibility 2. Date of Birth (to check eligibility) 3. Patients full name (to send invitation letter) 4. Patients address including full postcode (to send invitation letter)
Identifiers required for analysis purposes	N/A all data for analysis is collected with consent
Additional information	Confidential patient information will not be disclosed from the NHS Trust to the University of Warwick until the patient has consented into the trial.

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.

The CAG were assured that this application 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**

At many PIC sites it is not practicable for a member of the patients clinical care team to carry out screening or mail out activities because of resource limitations due to the COVID-19 Pandemic. Many sites are prioritising other trials or staff members are being re-deployed to cover hospital pressures due to Covid-19. The applicants explained that this is significantly impacting on trial recruitment and therefore trial progress. It is not possible for the REGAIN research staff to obtain the patients consent prior to the medical notes being screened to check potential suitability or for contact details to be used to send out patient invitations, as these

activities take place prior to the first point of contact with the patient. The Members accepted the justification provided that consent is not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to identify potentially eligible participants and invite the patient to take part in the trial. It is not possible to do this if only using pseudonymous or anonymous information. The Members accepted this reasoning.

'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 applicant has provided an invitation letter and patient flyer, and these documents will be viewed after the breach has occurred. The invitation letter states that 's251' is the legal basis under common law for the REGAIN team to view confidential patient information whilst screening and sending invitation letters. Patients can decline the study on receipt of these invitation materials.

Information about this specific breach will be included as part of a poster, which will be put up in clinical areas in participating PIC sites and on study websites, that includes an opportunity to opt out. This is in line with other similar applications, however CAG have not received the final version of the poster.

The National data opt out will also be applied locally prior to the REGAIN team viewing confidential patient information.

The Members were content with the notification and dissent materials provided. However it was commented that it was unclear if someone receives an invitation letter but does not respond to it, will further invites be sent? If so, then how many? The Members would be content with 1 additional letter being sent.

The CAG also noted that the mortality post covid-19 discharge is well know, and therefore would like to be assured of how the REGAIN team would ensure invitation letters were not sent to those who were deceased.

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 applicants have a patient and public involvement (PPI) representative on the Trial steering committee. This PPI representative has been consulted regarding members of the REGAIN

team supporting screening and mail out activities at PIC sites. The PPI representative was supportive of this, and suggested clarifications to the invitation letter. Applicants will identify two further COVID-19 survivors to join the Trial Management Group and Steering Committee.

The CAG commented that there does appear to be PPI support for the use of confidential patient information without consent – however, only one person has been consulted, although noting that two further individuals are being approached. The applicant is required to undertake further patient and public involvement with some additional patient representatives, and provide a report back.

Exit Strategy

The exit strategy for the individual patients screened is consent. Where consent is not obtained the anonymisation/deletion of identifiable data is the appropriate exit strategy, and this has been confirmed by the applicant. The Sub-Committee were content with this exit strategy.

The length of time support is required for the REGAIN team to screen and invite patients is expected to be on a continuous basis until December 2022.

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 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 provide the REC favourable Opinion required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide a Favourable opinion from a Research Ethics Committee regarding the screening element of the study, as per standard condition of support.

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. If the outstanding actions listed in the specific conditions of support are met, 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. Please provide the study poster when it is available

2. Please confirm if someone receives an invitation letter but does not respond to it, will further invites be sent? If so, then how many? Please provide a response to CAG within three months from the date final support is provided.

3. Please explain if the REGAIN team have a process for confirming mortality status prior to sending invitation letters. Please provide a response to CAG within three months from the date final support is provided.

4. Please undertake further patient and public involvement with some additional patient representatives, in order to explore the acceptability of this use of confidential patient information without consent, and provide feedback to the CAG within three months from the date final support is provided.

5. Favourable opinion from a Research Ethics Committee. **Pending. Amendment 5 confirmed 21 October 2021 (for sending letters only), however pending for screening.**

6. 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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

c. 22/CAG/0021– The South London Stroke Register: Improving the lives of stroke survivors with data. (SLSR)

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to develop the South London Stroke Register (SLSR) to estimate the incidence of stroke and its outcomes in South London (Lambeth and Southwark) to address key questions in stroke epidemiology, particularly around the health of newly classified mild stroke patients and long term stroke survivors.

The SLSR is a consented observational study which has been recruiting patients since 1995, and at present there are over 7,000 people on the register. Data from the SLSR have underpinned improvements in acute stroke care and rehabilitation in the UK, which have led to reduced stroke death and disability, better long-term health outcomes, and cost savings for the NHS. Stroke is the fourth leading cause of death in the UK and the single largest cause of complex disability in adults. Definitions of stroke are changing, and therefore updated data is required to describe survivors' needs and outcomes adequately. The updated SLSR will address the challenges posed by the changing nature of stroke leading to future improvements in stroke care and patient outcomes. Since 1995, the SLSR team have been screening and

consenting patients at the Trusts, however due to evolution in Trust policy, the clinical researchers are no longer considered direct care team, and ‘s251’ support is now requested.

As a consented register, ‘s251’ support is not required for the majority of study processes. However ‘s251’ support is sought for members of the SLSR research team from King's College London, who are not considered direct care team, to screen medical records at participating Trusts in order to identify eligible participants for the purposes of seeking consent. The applicants reason that this would be too onerous for the direct care team to undertake. If a patient does not consent within 6 months, their confidential patient information is deleted. No identifiable data items will leave the Trusts without the consent of a patient or their consultee. ‘s251’ support is also required for members of the SLSR research team from King's College London, to view confidential patient information regarding eligible patients who are deceased, in order to collect a pseudonymous dataset for analysis. No identifiable data will be disclosed outside of the Trusts. The applicants reason that it is important that data can be collected about people who have died from stroke. These people are more likely to have experienced severe stroke, adverse health or socioeconomic circumstances, or in some cases possibly poor quality care.

A recommendation for class 1, 2, 3 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	Patients with a confirmed first stroke (WHO ICD-11 clinical definition) since 1st October 2021 who live in the Lambeth and North Southwark areas of South London Approximately 400 patients will be recruited prospectively per year. (2000 total over 5 years) Applicants estimate approximately 4000 records would need to be viewed per year to identify 400 potential participants annually. Therefore ‘s251’ support required for approximately 20,000 individuals records to be screened.
Data sources	1. Guy's and St Thomas' NHS Foundation Trust and 2. King's College Hospital NHS Foundation Trust

	Patient medical records (paper and electronic notes), and hospital ward lists, including stroke clinic lists, radiology reports, Electronic patient records (EPR)
Identifiers required for screening and inviting patients to consent	**Screening:** 5. Access to medical records [Screening for eligibility] 6. Postcode [Screening for eligibility] 7. NHS number [Screening for eligibility] 8. Hospital ID [Screening for eligibility] **Invitation:** 9. Name 10. Hospital number 11. Ward location [inpatients] 12. Telephone number [discharged patients]
Identifiers required for analysis purposes (relevant for deceased patients only, as the rest of the cohort is consented)	1. Date of Birth (modified to age in years at time of stroke) 2. Date of death (modified to days from stroke until death) 3. Postcode (modified to area-based socioeconomic score) 4. Ethnicity recorded as ONS broad category 5. Sex Therefore this can be considered anonymous for analysis as the register staff will not have access to CPI regarding deceased patients at KCL.
Additional information	No confidential patient information will be disclosed outside of participating trusts without consent.

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.

The Members agreed this activity 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 applicants have provided clear justification as to why consent is not a practicable alternative. It is not possible to consent participants for the screening and contacting of eligible patients prior to consent. However 's251' would not be required if the direct care team undertook this task. The applicants reason that it is important that everyone who has experienced a stroke living in the area of interest is identified and invited to participate, and that bias would be introduced into the register if direct care team only were required to refer potential participants. Possibilities include underestimating the severity of stroke, and missing participants with the most severe stroke (who potentially might have the most to gain from improved long-term stroke care). This is because the screening process for this study involves manual screening of multiple sources of records to check eligibility, which is too labour-intensive and time consuming for the direct care team to undertake.

It is also not possible to consent deceased participants into the register, however 's251' would not be required if the direct care team undertook the anonymisation of the dataset to disclose to KCL. The applicants reason that it is critical that these patients are included in the study, since they are likely to be people who have had the most severe stroke, and are likely to disproportionately comprise people who have experienced gaps in care, or other health inequalities which the study aims to address. It is again not feasible to ask the direct care team to undertake this processing due to specific training required, and the complication that deceased patients may not have reached specialist stroke services (for example, people who have died on the journey to hospital, or in the Emergency Department), and may have been under the care of a wide variety of groups of clinical staff.

The CAG accepted these justifications.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for the identification of correct patient, to contact people for consent, and to extract an anonymous dataset for analysis regarding deceased patients. The applicants reason that there is no suitable anonymised/pseudonymised dataset which could be used as an alternative to this approach: datasets such as HES are incomplete, have unreliable stroke diagnosis codes (which would underestimate stroke incidence, and lead to biased outcomes). The Sub-Committee accepted this reasoning.

'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 notification poster for the wards with photos of the researchers has been provided. This mentions that they are not direct care team, and provides an opt out option. These will be put up in the clinical areas where stroke patients will be seen – including the stroke units of participating Trusts.

The consent documents have also been provided, however these are not relevant to the ‘s251’ support, as the initial introduction by the research team will be either face to face or on the phone, where they will introduce themselves and the study verbally.

The National Data Opt Out will be applied, and these patients will not be screened by people outside of the direct care team. A study specific opt out is also available on the posters, using a number of different options. Ward staff will alert the researcher to any patients who do not wish to have their data screened; researchers will not screen these patients and will not approach further to seek consent for full participation.

The Members were content with the opt out options, and broadly content with the notification poster, however they noted that the poster does not mention that ‘s251’ is the legal basis whereby screening is undertaken. The applicant is required to include the legal basis for this processing on the posters.

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 King’s College London (KCL) Stroke Research Patients and Family Group, comprising 28 active members has been involved in this application - as this patient group has strongly advocated for better information on stroke and its outcomes.

Members of this group were consulted for their views on the acceptability of this use of confidential patient information without consent; Five members provided feedback, unanimously conveying strong support for pre-consent screening by fieldworkers from the South London Stroke Register. It was felt that the importance of the work of the Stroke Register and recruitment of all eligible patients justified the proposed approach. All respondents found it reasonable to hold participant contact information for a period of 6 months, for the purposes of attempting to contact and seek consent. Applicants have changed the retention period of screening data to 6 months where it is impossible to contact the patient, in response to this patient group feedback.

The Sub-Committee were content with the good quality patients and public involvement undertaken, noting that the applicants had listened to feedback and minimised the retention time for holding confidential patient information without consent, in response to the views of patients.

Exit Strategy

The screening data are stored at the recruiting sites locally, and not disclosed outside the Trusts. The screening data is retained only until contact is made with the potential participant (or up to a maximum of 6 months). The exit strategy is consent.

Where consent is not given (via the patient or consultee), or if no contact is possible within 6 months, the identifiable data will be deleted. If patient declines, no further data collected. Patient decision recorded on screening log to avoid further re-contact, and this is retained by the Trust direct care team.

For deceased patients the exit strategy is anonymisation of the data, which is undertaken prior to disclosure from the Trusts.

However, 's251' support is required in an ongoing fashion to enable continuous screening and recruitment of deceased patients - support will therefore be required for the duration of the study, and is given for 5 years in the first instance. It is noted that funding is in place until October 2026, but applicants envisage that the SLSR will continue beyond this.

The Members were content with this clear exit strategy.

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 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 provide the REC favourable Opinion required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Please provide the Favourable Opinion of the REC, as per standard condition of support.

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. If the outstanding actions listed in the specific conditions of support are met, 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. Please include on the notification poster that the screening and consent approach undertaken by people who are not direct care team, is undertaken under Regulation 5 of the Health Service (Control of Patient Information) Regulations 2002 ('section 251 support'), and provide an updated version to CAG within one month of final support provided.

2. Support provided for 5 years in the first instance to match the current funding. A duration amendment will be required at this timepoint to extend the duration of 's251' support.

3. Favourable opinion from a Research Ethics Committee. **Pending**

4. 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 **Guy's and St Thomas' NHS Foundation Trust (RJ1) and King's College Hospital NHS Foundation Trust (RJZ)** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 01 February 2022)

2. New Precedent Set Review Applications – Non-Research

a. 22/CAG/0016 - 2022 NHS Maternity Survey - Mixed Methods

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:

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.

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.

Cohort	**ALL** maternity service users **aged 16 and over** at the time of delivery who had a live birth in **February 2022**. (and earlier for smaller trusts),

	Except for those meeting any exclusion criteria as listed in the application.
Data sources	3. Electronic patient records within all eligible Trusts in England (120-130 trusts)
Identifiers required for contact purposes	13. Title 14. Initials or first name 15. Surname 16. Address Fields including postcode 17. Mobile phone number 18. Patient unique identifier
Identifiers required for analysis purposes	6. Patient unique identifier 7. Postcode 8. Mother's year of birth 9. Mother's gender 10. Time of delivery 11. Number of babies born at delivery 12. Day of delivery 13. Month of delivery 14. Year of delivery 15. Maternity Care Setting (Actual Place of Birth) 16. Actual delivery place 17. Mother's ethnic group 18. Trust code 19. NHS Site code (of birth) 20. Mobile phone indicator 21. Whether or not mother received antenatal and/or postnatal care from the trust 22. Treated as a suspected or confirmed covid-19 case
Additional information	Trusts may also choose to collect additional sample variables outside of those detailed in the Survey Handbook. This can be valuable to trusts in enabling them to make greater use of their survey locally to target quality improvements. Sample and mailing data will be submitted by trusts to approved contractors in a single file. The file which contains both mailing and sample information will be split into separate files by the contractor before submitting only the sample information to the Coordination Centre for checking and approval.

	Please note that the Survey Coordination Centre does **not** receive any names or full addresses

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of the management of health and social care services and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

The 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 are 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)

Minutes signed off as accurate by correspondence from Dr Tony Calland, MBE, CAG Chair		*14 February 2022*
Signed – Officers of CAG		Date
Caroline Watchurst		*11 February 2022*
Signed – Confidentiality Advice Team		Date