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

07 July 2023 via correspondence

Present:

Name	Role	Items
Professor William Bernal	CAG Alternate Vice Chair	2a, 2b, 2c
Mr David Evans	CAG Member	2a, 2c
Dr Rachel Knowles	CAG Member	2b, 2c
Dr Pauline Lyseight-Jones	CAG Member	2a, 2b
Mr Andrew Melville	CAG Member	2a, 2b, 2c

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr Will Lyse	HRA Approvals Administrator

1. Expressions of interest

There were no conflicts of interest declared.

2.New Precedent Set Review Applications

a. 23/CAG/0086 - Transforming Ovarian Cancer diagnostic pathways (TranSforming Ovarian caNcer diAgnosTic pAthways - SONATA)

Context

Purpose of application

This application from the University of Birmingham set out the purpose of medical research that seeks to determine the accuracy of the ROMA algorithm in diagnosing ovarian cancer.

Approximately 7,500 women in the UK are diagnosed with Ovarian cancer (OC) each year. 5-year survival is around 45%, lower than comparable European countries. Improved diagnostics are critical to improving outcomes. Standard of care tests in the NHS for primary care are sequential CA125 and ultrasound. Standard care of test in the NHS for secondary care is an algorithm that combines CA125 and an ultrasound score called the Risk of Malignancy Index algorithm (RMI). The same tests are used at both primary care and secondary care, often with ultrasound repeated in secondary care. The risk of ovarian malignancy algorithm **(**ROMA), a newer algorithm, incorporates cancer antigen 125 (CA125), human epididymal protein 4 (HE4), ultrasound findings and menopausal status. A pilot study conducted in primary care demonstrated that ROMA had a better diagnostic performance compared to RMI. The applicants now seek to undertake a larger scale evaluation, testing the ROMA algorithm incorporating CA125, HE4 and ultrasound results against CA125 testing alone.

Confidential patient information for patients who underwent CA125 testing for ovarian cancer at the request of their GP will be disclosed from Black Country Pathology Services and South Tyne and Wear Pathology Service to Sandwell and West Birmingham Hospitals NHS Trust. Confidential patient information from Gateshead Health NHS Foundation Trust, The Royal Wolverhampton NHS Trust will be disclosed to Sandwell and West Birmingham NHS Trust, for linkage to the pathology services data. Confidential patient information for patients treated at Sandwell and West Birmingham NHS Trust will also be linked to the pathology services data. Any data not needed for analysis will be deleted. NHS numbers will be

replaced with a study identifier and dates of birth amended to age group and time to cancer/non-cancer diagnosis. The anonymised data set will be encrypted for secure transfer for analysis at the University of Birmingham.

A recommendation for class 1, 4 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	Female patients who presented to primary with symptoms of ovarian cancer and underwent a CA125 test after the study start date, which is currently planned for 31 August 2023. The applicants estimate that 41000 patients will be included.
Data sources	1. Confidential patient information from patient records held at: a. Black Country Pathology Services b. South of Tyne and Wear Pathology Service c. Gateshead Health NHS Foundation Trust d. The Royal Wolverhampton NHS Trust e. Sandwell and West Birmingham NHS Trust
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Ethnicity
Additional information	Dates of birth will be amended to age group and time to cancer/non-cancer diagnosis before the dataset is transferred to the University of Birmingham for analysis.

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 Sub-Committee agreed that the 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.

- **Minimising flows of identifiable information**

The applicant noted the use of paper documentation, that would be kept in a locked file until its disposal. The CAG requested further details on how the data would be kept securely.

- **Feasibility of consent**

The applicants advised that consent was not feasible due to the number of GP practices that would need to be recruited and trained. A pilot study, 19/CAG/0108, with a similar design was cited as supporting evidence that consent was not feasible.

The Sub-Committee was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link datasets from different sources.

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 applicants advised that a Privacy Notice would be included on the website for each organisation participating in the project. The draft text was provided in the applicant’s response to queries raised by the Confidentiality Advice Team. The text advised patients that the National Data Opt-Out would not be applied.

The CAG advised the applicant to explore additional methods of advertisement. For example, promoting the study on the Target Ovarian Cancer website, or the websites of other charities and organisations.

The CAG requested that revisions were made to the Privacy Notice, to explain the purpose of the study and the use of confidential patient information. The role of the CAG also needed to be explained. Members suggested that the following wording, or similar, was used, “The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that our application should be supported, and the Secretary of State for Health/Decision Maker within the Health Research Authority approved this.”

The applicants had stated that the National Data Opt-Out would not be applied. The Sub-Committee noted that application of the National Data Opt-Out was mandatory for all applications processing confidential patient information under s251 support, unless an application to CAG seeking a specific exemption had been made. Members agreed that advised that the National Data Opt-Out needed to be applied to this study.

A contact email for the project will be included on the Privacy Notice. Patients were asked to provide their NHS number when dissenting to use of their data.

The Sub-Committee agreed that it was unreasonable for those wishing to opt-out to have to provide their NHS number. Members advised that patients should be asked to provide their NHS number if they knew it, but that other identifiers could be used to identify patients.

The application stated that it was “unlikely” that the research team would be able to “reliably identify dissenting patients.” The CAG asked for further clarification as to why this was the case.

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 worked with Target Ovarian Cancer, a national patient charity committed to improving diagnostic pathways and outcomes for women with ovarian cancer. Target Ovarian Cancer has reviewed the project plan, discussed it with their patient advocates, have fed back and are very supportive of this work. They will also advise and be involved in the dissemination of the findings.

The Sub-Committee asked for further detail on the demographics of the patient and public involvement group, along with any feedback or study modifications that have been made as a result.

Exit strategy

An anonymised dataset will be disclosed to the University of Birmingham for analysis.

The applicants estimate that the data linkage process will be completed within 6 months of the analysis of the last sample, which is expected to be in June 2025.

Ideally the confidential patient information would be deleted one year after publication to allow for any post publication queries which require checking of the data linkage. The applicants noted that they would welcome advice from the CAG.

The CAG was content with the proposed 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 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 to all of the requests for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Provide details on how documentation in hard copy would be kept securely.

2. Additional ways of promoting the study, such as advertising on the Target Ovarian Cancer website, or the websites of other charities and organisations need to be explored.

3. The Privacy Notice needs to be revised as follows:

    a. The purpose of the study needs to be explained.
    b. The use of confidential patient information, as proposed in the application, needs to be explained.
    c. Information about the CAG and its role needs to be provided.
    d. Patients should be asked to provide their NHS number, if known, but advised that other identifiers can also be used to identify and remove their data.

4. Ensure the National Data Opt-Out is applied.

5. Clarify why it is “unlikely” that the research team would be able to “reliably identify dissenting patients.”

6. Provide detail on the demographic of the patient and public involvement group, along with any feedback and any changes made to the study as a result.

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: 17 July 2023**
2. Due to the number of participating sites where confidential patient information will be accessed, individual DSPT submissions are not required for the purpose of the application. Support is recommended on the basis that the applicant ensures the required security standards are in place at each site prior to any processing of confidential patient information with support under the Regulations.

b. 23/CAG/0088 - Community based continuity of midwifery care models for women living in areas of ethnic diversity and social disadvantage

Context

Purpose of application

This application from King's College London set out the purpose of medical research to evaluate the impact of the LEAP caseload midwifery team on care of women living in areas of ethnic diversity and social disadvantage.

Recent enquiries into maternal and perinatal death in the UK have consistently found that women and babies from the poorest backgrounds and those from Black, Asian, and Minority Ethnic (BAME) groups are at the greatest risk of severe morbidity and mortality. The proportion of preterm births also varies by ethnicity, with infants of BAME parents more likely to be born preterm. Socioeconomic circumstances could also be contributing to the differences in birth outcomes across ethnic groups, with women who live with social complexity also experiencing poorer quality maternity care. The NHS Long-Term Plan aims to reduce stillbirth, maternal and neonatal mortality, and serious neonatal brain injury by 50% by 2025. It includes a commitment to implementing a targeted model of continuity of midwifery care for 75% of women from BAME communities and a similar percentage of women from the most deprived groups to help improve outcomes for the most vulnerable mothers and babies.

Women eligible to take part in the survey will be given information in the postnatal period by the midwife prior to discharge from midwifery care. At each site, a monthly report will be run by the PI or a supporting IT midwife. This report includes the relevant information of postnatal women who gave birth (alive baby) less than 3-6 months ago and live in the LEAP postcodes. Support is needed as potential participants will be identified by the IT team/midwife, who will provide the list of potential participants to a member of the clinical research team who will

subsequently send the invitation for the survey. Participation will then proceed on a consented basis.

A recommendation for class 3, 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	Women aged 16 – 50 years of age, who live in LEAP postcodes and underwent a live birth.
Data sources	1. Maternity health records at: a. Guy's and St Thomas' NHS Foundation Trust b. King's College Hospital NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Date of birth 5. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level 3. Occupation 4. Ethnicity

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 agreed that the application was in the public interest.

Scope

The CAG noted that the answer given to Q14 on the CAG application form was focused on the data collection undertaken for the consented interview study, rather than the larger scale survey that is the subject of the application to CAG. Members asked that a formal letter of response from the Chief Investigator was provided, which set out of the aims of survey component of the study. Further details on the mechanism used to contact patients, such as whether telephone or email contact would be made, also needed to be provided.

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 advised that pre-screening was necessary to ensure that only women who met the eligibility criteria were recruited. If the pre-screening was not done, every woman attending would have to be approached, which may mean women who had experienced pregnancy loss were approached.

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

- **Use of anonymised/pseudonymised data**

The research team require access to confidential patient information to send the survey to eligible patients.

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.

A poster was provided. This will be displayed at Guy’s and St Thomas’ NHS Foundation Trust and King's College Hospital NHS Foundation Trust.

The poster included an email address for patients to register if they did not want to be contacted.

The CAG asked that the poster was revised to include an additional route for dissent, such as a telephone number or postal address.

It is stated within the application and opt-out notification that women will be sent an email invitation regarding the study; however, the IRAS application references a telephone call. The CAG requested clarity on the correct method of contact. Members also asked that the patient notification materials were revised to consistently explain how contact would be made.

At each site, a monthly report will be run by the Principal Investigator or a supporting IT midwife. This report includes the relevant information of postnatal women who gave birth (to a live baby) less than 3-6 months ago and live in the LEAP postcodes. Women who have opted out of being contacted locally and nationally will be removed automatically as part of the search criteria.

The CAG queried whether the storage of data to those women who have opted out of the study would be retained. The Sub-Committee requested that the applicant clarify the correct process and for assurance the process was explained consistently within all the patient notification materials.

Members noted a passage within both ‘Notification_LEAP_GSTT_v1’ and Opt Out Notification_LEAP’, which referred to approval by the CAG. Members asked that this was revised and suggested that the following wording, or similar, was used, “The application was reviewed by the Confidentiality Advisory Group (CAG). CAG is an independent group of lay people and professionals which provides expert advice on the use of confidential patient information without consent. CAG recommended that

our application should be supported, and the Secretary of State for Health/Decision Maker within the Health Research Authority approved this."

The CAG agreed that the current patient notification documents were not suitable for the intended audience and asked that the documents were revised. Members suggested that patient and public involvement included a review of the documents by those of a similar age to the cohort.

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.

Several online events with local services users and organisations/charities representatives have been conducted over the last six months.

A patient and public involvement and engagement group is also being set up as part of the NIHR ARC Patient and Public Involvement and Engagement Strategy Group, to provide guidance on how to work with BAME and disadvantaged communities. The patient and public involvement and engagement group has already been introduced to the project. Feedback and reflections on their lived experiences, cultural values and individual needs have been taken into consideration when designing some of the objectives, strategy, and outcomes that are important.

Future patient and public involvement and engagement group meetings have been planned twice a year for the group to aid in interpreting findings and help present findings to relevant lay and academic audiences to ensure the patient voice is heard.

The Sub-Committee asked that the applicants continue to involve new participants in the patient and public involvement group so that they bring in fresh views along with views from more experienced participants. This will help naturally introduce new ideas, whilst moving on and thanking those who have already contributed their time and effort to the group.

As a result of one of the patient and public involvement and engagement group meetings a commentary paper entitled "Addressing health inequalities among women living in areas of social disadvantage and ethnic diversity" was produced, which is under review at BMC Public Health.

To help improve engagement from those from ethnically diverse backgrounds, the Sub-Committee asked that patient and public involvement materials were made available in languages other than English, as well as a simplified versions in English.

Patient and public involvement materials were referred to on Page 15 of the Protocol but did not appear to have been included in the submission. The CAG asked that these materials were provided for review.

Exit strategy

Consent is the exit strategy. Potential participants will be identified by members of the research team and will be contacted by email/phone to invite them to complete a postnatal survey. If participants do not wish to participate, they will not be contacted again. For those interested in completing the survey, only 1 reminder will be possible.

The duration of support required would be for 12 months (up to 30th June 2024) to enable recruitment of the required sample size.

The Sub-Committee was content with the proposed 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 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. Provide a formal letter of response from the Chief Investigator, providing an overview of the research and study aims, as well as details of the

mechanisms used for contacting potential participants, i.e., telephone, email, or both.

2. The patient notification materials need to be revised as follows:

    a. The materials need to be re-written for the intended audience and reviewed by the patient and public group.

    b. Additional methods of dissent within the poster, such as telephone, postal address, or both, need to be described in the poster.

    c. The methods used to contact patients, e.g. whether the first contact will be by telephone or email, need to be described.
    d. A clear description of the CAG role needs to be included.

3. Clarify whether the storage of data to those who have opted out of the study would be retained and ensure this clarified and kept consistent throughout the patient notification materials.

4. New participants should be involved in the patient and public involvement group.

5. The patient and public involvement materials need to be made available in languages other than English. A simplified English language version also needs to be created.

6. The patient and public involvement materials referred to on Page 15 of the Protocol need to be provided.

Specific conditions of support (Provisional)

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

2. Favourable opinion from a Research Ethics Committee. **Confirmed: 10 February 2021**

3. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. **Confirmed:**

The NHS England 21/22 DSPT reviews for **King's College London**, **Guy's and St Thomas' NHS Foundation Trust** and **King's College Hospital NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS England DSPT Tracker (19/07/2023)

c. 23/CAG/0089 - Hospitalisation decision-making in Primary Care: How do, and how should clinicians approach decisions regarding hospital admission for those living with frailty or who could be near the end of their life?

Context

Purpose of application

This application from University of Bristol set out the purpose of medical research that seeks to how Primary Care clinicians approach hospitalisation decisions for frail people and those near the end of life.

This project will look at care for people living with frailty and other complex, incurable medical problems who may be near the end of their lives. It will focus on admissions to hospital and the decisions that can lead to this. A literature review has been conducted to explore what is already known about hospitalisation decisions for frail people.

Observations of staff who make decisions whether patients should be admitted to hospital will be undertaken at nursing homes, care homes, residential homes where a clinician attends to visit patients within the Bristol, North Somerset and South Gloucestershire Integrated Care System. The specific sites are Severn Side Integrated Urgent Care and Weston Care Home GP group in Weston-Super-Mare. At these sites the researcher will accompany the clinician and observe interactions with, and discussions about, frail patients who they are considering admitting to hospital. The researcher will also have informal conversations directed at understanding the decision-making process. Verbal consent will be sought from patients should their care be directly observed. Support is sought to allow for disclosures of confidential patient information that occur when the researcher is observing meetings where patients won't be present, but their information may be discussed.

A recommendation for class 5 and 6 supports 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 aged 18 years and over who are potentially towards the end of their life as per the GSF-PIG: • Those with advanced, chronic, incurable disease. • General frailty and coexisting conditions meaning they may be in the final 12 months of life. • Existing conditions leading to risk of a sudden catastrophic event that may be terminal.
Data sources	Observations of staff meetings at: • University Hospitals Bristol and Weston NHS Foundation Trust • Weston Super Mare Care Home Hub, part of Pier Health • Severnside Urgent Care Service
Identifiers required for linkage purposes	No items of confidential patient information are required for linkage purposes.
Identifiers required for analysis purposes	No items of confidential patient information are required 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. The CAG agreed that the 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**

Consent is not feasible as it is not possible for researchers or clinicians to predict which patients may be discussed.

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

- **Use of anonymised/pseudonymised data**

Confidential patient information is not required, but support is requested to allow for incidental disclosures of confidential patient information that may be made during observations of clinical meetings.

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 applicants have been asked to provide details on patient notification and dissent. The applicants were unable to provide this before the meeting but have been advised this will be requested in the CAG outcome.

The CAG requested that the patient notification materials were provided to the CAG for review. The materials need to provide information about dissent and provide contact details for patients to register dissent. Members noted that email, telephone and postal contact details should be given.

Members asked for confirmation that the notification materials will be provided to those in residential care homes.

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.

A Patient and Public Involvement group was formed in October 2022. This includes those with experience of caring for family members at the end of their life or living with frailty. Individual meetings were held with members to discuss the overall aims of the project and whether the project was worthwhile. In early 2023 the patient and public involvement and engagement members helped produce the patient facing documentation and discussed the use of clinical meetings as a site for observation.

On 4th April 2023 a patient and public involvement and meeting was held where observation at clinical meetings was discussed. The members acknowledged that the observations could be an important source of information but felt that it would not be the most important. The members accepted that seeking consent was not feasible and that this would be accepted if no information was recorded. The minutes from this meeting were provided with the application.

The Sub-Committee asked that continued patient and public involvement was undertaken. The applicants need to consider how to involve the residents and family members from the two participating homes.

The Sub-Committee requested that feedback from the patient and public involvement groups was provided at the first annual review.

Exit strategy

No items of confidential patient information will be recorded during the meeting observations.

The CAG was content with the provided exit 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.

Request for further information

1. The patient notification materials need to be provided. The materials need to explain that patients can dissent, how to dissent and contact details to register dissent need to be 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 and 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. Continue to undertake patient and public involvement. Consideration needs to be given on how the residents and family members from the two participating homes can be involved. Feedback from the patient and public involvement needs to be provided at the first annual review.

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

3. The NHS England 21/22 DSPT review for **Bristol, North Somerset and South Gloucestershire Integrated Care System** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (19/07/2023)

   Bristol, North Somerset and South Gloucestershire Integrated Care System As the above conditions have been accepted or 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
William Lyse – Approvals Administrator		26/07/2023
Signed – Confidentiality Advice Team		Date
Professor William Bernal		24/06/2023