Health Research Authority

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

15 January 2021

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice-Chair	1a, 1b, 1c, 1d
Dr Martin Andrew	CAG Member	1b, 1d
Ms Sophie Brannan	CAG Member	1a, 1d
Dr Lorna Fraser	CAG Member	1a, 1c
Mr Marc Taylor	CAG Member	1b, 1c

Also in attendance:

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

1. New Precedent Set Review Applications – Research

a. 21/CAG/0002 - Ventilation Strategies in COVID-19; CPAP, High-flow, and standard care (RECOVERY – Supportive care)

Context

Purpose of application

This application from the University of Warwick sets out the purpose of medical research that seeks to determine whether Continuous Positive Airway Pressure (CPAP) or High Flow Nasal Oxygen (HFNO) is clinically effective compared to standard care in relation to intubation and mortality in patients with confirmed or suspected COVID-19.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) emerged at the end of 2019 as a new coronavirus, resulting in a current global pandemic of respiratory illness, (Covid-19). This illness can cause serious breathing difficulties and it is important to provide ventilatory (lung or respiratory system) methods to support the patient to breathe. Deciding which form of ventilatory support for patients with Covid-19 is the most effective is critical to ensure the best therapy is given to patients and to protect vital UK critical care resources and NHS organisations. The trial will also have the potential to provide information on the global ventilation practice for patients with COVID-19. Three different approaches to providing ventilatory support to patients with suspected or confirmed Covid-19.

Patients will be randomised to one of three treatments – CPAP, HFNO or standard care. Following randomisation patients will be followed up through weekly reviews up until day 30, or hospital discharge, whichever is later. The study will also undertake follow up data linkage with NHS Digital (mortality and HES data). NWIS (Patient Episodes Database for Wales) and ICNARC.

A recommendation for class 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	Eligible patients in the RECOVERY – Supportive care study for whom there is no consent or consultee advice in place.
Data sources	1. Participating Trusts 2. University of Warwick 3. NHS Digital (HES and Mortality Data) 4. NWIS (Patient Episodes Database for Wales) 5. ICNARC
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	1. Date of Birth 2. Date of Death 3. Gender 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 to transition the study to support under Regulation 5.

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 there was a public interest in the study.

Scope of support

Much of the study acts under a consented model and is therefore outside the scope of this support. Any review of medical records prior to consent is outside the scope of support as the legal basis for access is direct care. Any disclosure of confidential patient information under consultee advice meets the common law duty of confidentiality. However, there are a small proportion of patients that either died or were discharged prior to gaining any form of consent or consultee advice. As such there is no legal basis for the sharing of confidential patient information from Trusts to University of Warwick, and for the onward linkage with NHS Digital, NWIS and ICNARC. It is this reason why the applicants are currently relying on the COPI notice, and for which support is requested under Regulation 5 once the COPI notice expires.

Data flow

The CAG reviewed data flow diagram v4.1, and requested a clearer data flow diagram during the course of the review, as there appeared to be some uncertainty as to whether applicants will disclose confidential patient information to each data source individually or all via NHS Digital. It was suggested that applicants could provide the CAG with two alternative data flow diagrams for the linkage and then confirm which they plan to use before the linkage is undertaken. The applicant provided data flow diagram v5.0 for CAG review, which provided two alternate flows as suggested. It is a condition of support that the applicant confirm which data flow will be used, before the linkage is undertaken and provide CAG with a finalised data flow diagram at that timepoint.

The CAG also noted that the data flow appeared to show that identifiable data was also being returned to University of Warwick from the named data processors. In most cases this flow of data is usually pseudonymised with a study identifier, which is best practice, although it is noted that date of death is required for analysis, which can be an identifier and may be returned from some of these data sources. It is a condition of support that the applicant confirm with CAG if there is a flow of identifiable data back from each data processor, (taking date of death into account), and alter the return arrows on the data flow diagram to indicate if identifiers are returned to University of Warwick, or if these data flows can be performed using pseudonymised data.

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 study is primarily consented (or undertaken with consultee advice), and this is the primary route. However, there are instances where a patient has died, or discharged prior to consent for which no consent/consultee advice is in place. It is not feasible for applicants to consent in these cases, and the CAG were content with the justification provided.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to link to central datasets held by NHS Digital, ICNARC and NWIS. The CAG were content this could not be done in any less disclosive manner.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

This research follows a consented/consultee advice model where at all possible. For those that die prior to this being in place, the next of kin will be able to access the RECOVERY RS website.

For those that are discharged prior to consent/consultee advice the research team will initially attempt to make contact by phone (not post) up to three times for consent. Where contact is not made then the RECOVERY RS website will be available.

Currently the website does not detail the linkage to other sources without consent.

Those who object when contacted by phone will not be included in the study linkages. Currently there is no study specific opt out provision (as primarily relying on a consented model) but NHS Digital will apply the National Data Opt Out, once the COPI notice expires.

The CAG members have provided a condition of support for applicants to update the trial website with patient notification materials for those where no consent/consultee advice is in place, and consider adding the same notification materials to participating site websites.

Patient and Public Involvement

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 applicant has undertaken significant PPI in the circumstances. Given this is a primarily consented study the PPI was focussed on this aspect, as well as the emergency provisions that have been put in place. However, the applicant stated that they were in touch with an independent member of the Clinical Research Ambassador Group, University Hospitals Birmingham NHS Foundation Trust where planned uses of data without consent were discussed and agreed as being necessary, and acceptable.

The CAG were content with the patient and public involvement undertaken.

Exit Strategy

Follow up with NHS Digital, NWIS and ICNARC is currently expected to last until March 2022. The applicants have confirmed that patient identifiable data will be deleted from systems as soon as it is no longer required (i.e. once communication with patients/legal representatives and data linkage work is complete and final report accepted for publication).

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. Support only extends to England and Wales

2. Support cannot be relied upon for those who decline consent/consultee advice.

3. Applicants are to update the trial website with patient notification materials for those where no consent/consultee advice is in place within 6 months, and consider adding the same notification materials to participating site websites.

4. Applicant to confirm which data flow will be used, before the linkage is undertaken, and provide CAG with a finalised data flow diagram at that timepoint. This should be provided before the COPI notice expires.

5. Applicant to confirm if there is a flow of identifiable data back from each data processor, (taking date of death into account), and alter the return arrows on the data flow diagram to indicate if identifiers are returned to University of Warwick or if these data flows can be performed using pseudonymised data. This is to be confirmed before the linkage is undertaken, and CAG should be provided with a finalised data flow diagram at that timepoint. This should be provided before the COPI notice expires.

6. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

7. The National Data Opt Out will apply to processing of Confidential Patient Information under Regulation 5.

8. Favourable opinion from REC **Received 02 April 2020**

9. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review. **The applicant must ensure that NHS Digital confirmation of 'standards met' for University of Warwick, NHS Digital, and ICNARC are in place once support under Regulation 5 is active, as well as a CPiP for NHS Wales Informatics Service (NWIS).**

b. 21/CAG/0010 - Peritoneal Mesothelioma Retrospective Sample Collection

Context

Purpose of application

This application from the Royal Papworth Hospital NHS Trust (MesobanK database) set out the purpose of medical research which aims to prepare tissue microarrays (TMAs) of retrospective peritoneal mesothelioma samples, which will be initially be used to determine if expression of the transcription factor CHOP predicts survival in peritoneal mesothelioma. The remainder of the TMAs will remain in the MesobanK database to be used in subsequent mesothelioma research. The tissue specimens were taken for diagnostic purposes and retained for many years in case of legal claims due to the occupational nature of asbestos-related diseases. Consent for the use of these samples in research may not be in place, however, as the vast majority of the tissue samples will belong to subjects who are deceased it will not be possible to obtain their consent, and applicants feel that contacting relatives to seek their consent would cause unnecessary distress. Applicants have previously used this approach during assembly of similar mesothelioma TMAs, and this is fully compliant with the Human Tissue Act 2006.

Peritoneal Mesothelioma is a form of cancer that affects the membrane that surrounds the abdominal cavity - the peritoneum, often following exposure to asbestos. It is widely accepted that progress in the treatment of mesothelioma requires a better understanding of its biology. As with many rare cancers, the fundamental mechanisms regulating mesothelioma cell growth and death are poorly understood. Peritoneal mesothelioma has previously not been collected by MesobanK, there is therefore an unmet need for peritoneal mesothelioma tissue samples.

Pathologists at collaborating pathology departments will identify suitable retrospective diagnostic specimens of patients with proven peritoneal mesothelioma stored in the form of paraffin blocks. The study aims to identify as many eligible samples as possible, and support is requested for samples of up to 100 individuals. The local pathologist will assign a unique code to the blocks, and these will then be submitted pseudonymously to the Pathologist at Royal Papworth Hospital in Cambridge where they will be checked for quality and suitability for inclusion in the TMA. Upon being accepted for use in the TMA, the pseudonymised block will be linked to a unique MesobanK identifier, fully catalogued and sent to Cancer Research UK Cambridge Research Institute (CRUK). TMAs will be constructed at the CRUK from these tissue samples, and the paraffin blocks from which the TMA samples are taken, will then be returned to their provider using the unique code assigned by original pathology unit. MesobanK will then store and control access to the remaining TMA sections.

In addition, a minimal clinical dataset will be collected for each patient whose tissue is used in the TMA, including the original pathology report, which will be sent from collaborating pathology departments. A member of staff from the direct care team at the pathology department will enter identifiers for each eligible patient onto the MesobanK database, linked to the unique code assigned by the pathology department, which is also linked to the MesobanK ID. MesobanK staff will then transfer the minimum identifiers required to PHE, for the purposes of linkage with The Cancer Registration and Analysis Service (NCRAS). Linked data will be transferred back to MesobanK, including the MesobanK ID, and date of death and other clinical details as listed in the application. National data opt out will be respected. Data transfer to and from PHE will be by PHE Secure File Transfer Service. The data will be collated and stored on the MesobanK electronic data capture/tissue tracking database. All identifiers will be modified and removed from the database, with the exception of NHS number which will be retained indefinitely. MesobanK will store and manage the release of the TMA blocks, along with linked clinical data, to other researchers, who will not receive any confidential patient information.

A recommendation for class 1, 4 & 6 support was requested to cover 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	Up to 100 adult patients with a pathological diagnosis of Peritoneal Mesothelioma. (Aged 18-100) Some of the FFPE blocks may have been in the archives prior to 2006 and some post-2006, however no sample that has been stored for over 20 years will be used due to likely degradation of material.
Data sources	1. Collaborating Pathology departments that hold diagnostic specimens of peritoneal mesothelioma: a. Basingstoke and North Hampshire Hospital (Hampshire Hospitals NHS Foundation Trust) b. The Royal Marsden NHS Foundation Trust

	c. Other pathology labs (Royal Liverpool University Hospital in set up, but names of other Trusts not yet confirmed) 2. The Cancer Registration and Analysis Service (NCRAS), held at Public health England (PHE)
Identifiers required for linkage purposes	• Date of birth • NHS number • Date of diagnosis • MesobanK identifier
Identifiers required for analysis purposes	1. Date of death (modified to MM/YYY) 2. Date of birth (modified to MM/YYY) 3. Age 4. Age at diagnosis (calculated from DoB and date of diagnosis) 5. MesobanK identifier 6. Gender 7. Ethnicity NHS number is only identifier retained in the research database indefinitely, it is stored alongside the MesobanK ID, which is separated from the clinical data, and not required for analysis.
Additional information	The applicants expect only one data request from PHE, however depending on the samples included a second data request could be required, and this will be confirmed with PHE once the samples have been sourced.

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, and it was commented that the disease has a poor prognosis with very little treatments currently available.

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 reason that consent is not practicable or appropriate for a number of reasons. Peritoneal mesothelioma is an ultra-rare cancer, which makes it impractical to recruit sufficient numbers of patients prospectively to perform prognostic research. Additionally, median survival is 6 months without treatment, and it is difficult to gain consent for the use of stored tumour samples as the majority of patients die relatively soon after diagnosis.

As Peritoneal Mesothelioma is very rare, with such a poor prognosis, the patient cases would have been referred from various external medical centres and so it would be extremely difficult for the collaborating centre to trace every patient/family to obtain consent. This would involve additional identifying information in order to contact the family, would cause undue distress, and most patients will have passed away.

The CAG agreed with the strong rationale given for not seeking consent.

- **Use of anonymised/pseudonymised data**

The NHS number is the only identifier retained in the research database indefinitely, it is stored alongside the MesobanK ID, which is separated from the clinical data, and not required for analysis. The full date of death would be deleted, after modifying to month and year of death, and would be provided to researchers applying to MesobanK if requested.

The CAG were concerned over the retention of the date of death in month/year format, because mesothelioma is an occupational disease, and there will always have been a coroner's inquest. Details of the individual and diagnosis will frequently be in the media, and as the disease is so rare, these patients could be identifiable by an internet search. This seems particularly important if the data is available to other researchers. It was suggested that applicants could delete date of death completely once they have calculated the interval from biopsy to death. The CAG have provided a condition of support, for applicants to consider whether it is necessary to retain month and year of death given that the rarity of the condition will increase identifiability, and provide either a justification for the retention, or confirmation that it will be further modified or deleted. The CAG are happy for this response to be given at annual review.

The CAG were also unsure of the reasons for retaining the NHS number in the MesobanK database after the linkage has been performed. It was commented that if it is required to be retained, it should be restricted to the Chief Investigator only. The CAG have provided a condition of support, for the applicants to consider whether it is necessary to retain NHS number in the database, and provide either a justification for the retention, and confirmation that this will be restricted to Chief Investigator only, or confirmation that this will be deleted after the linkage has been performed. The CAG are happy for this response to be given at annual review.

Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

The applicant provided a project specific statement which will be displayed on Royal Papworth Hospital NHS Foundation Trust Research & development website. This includes contact details, provided as a project specific dissent mechanism. The applicant has suggested that this could also be put on the websites of the bodies who are supportive of this project. The CAG were content with the provision of these materials.

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 undertaken some Patient and Public Involvement via the June Hancock Mesothelioma Fund, mainly involving family and friends of deceased patients, and have reported that the people asked were strongly supportive of the design of the protocol and the aims of the project. The applicants state that the discussions included the use of tissue without consent but no specific evidence has been provided regarding the use of confidential patient information without consent. The CAG members commented that there is little detail, however it seems proportionate in the circumstances.

The CAG were content to recommend support on the condition that the applicant provides a report on further patient and public involvement undertaken, surrounding the use of confidential patient information without consent, at the time of the first annual review.

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 provide a report on further patient and public involvement, surrounding the use of confidential patient information without consent, at annual review

2. Please consider whether it is necessary to retain month and year of death, and provide either a justification for the retention, or confirmation that it will be further modified or deleted, at annual review.

3. Please consider whether it is necessary to retain NHS number, and provide either a justification for the retention, and confirmation that this will be restricted to Chief Investigator only, or confirmation that this will be deleted after the linkage has been performed, at annual review

4. Favourable opinion from REC
   Favourable Opinion Received 17th September 2020

5. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met' for the duration of support, and at time of each annual review.

   The Trusts where samples are identified will be required to have security assurances in place, alongside Public Health England (PHE) and Royal Papworth Hospital NHS Foundation Trust. However, as there are five or more organisations in total, the CAT team will not check each one individually; it is the responsibility of the applicant to ensure these are in place.

c. 21/CAG/0012 - Expression and Reception of Gratitude in Healthcare: Analytical Ethnography

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to observe and describe the various ways in which gratitude is expressed, received and displayed in a healthcare setting, in the Royal Brompton Hospital. This study is an exploratory study that will inform subsequent phases of a wider project investigating gratitude in healthcare, and how it can enhance the wellbeing of those who give and receive it.

Gratitude is an emotion essential to supporting communicative human relationships. Expressions of gratitude form a significant source of patient feedback, but few healthcare providers use the data to implement change; however, when positive patient feedback is used effectively, increased staff morale brings quantifiable benefits. Analysis of staff and patient surveys shows an association between staff experience and patient experience, from which has in turn been linked to patient safety and clinical effectiveness. A positive organisational climate and supportive peer relationships enhance staff wellbeing, and this is an antecedent for improved patient care. The King's Fund has highlighted low morale as a significant problem in the NHS, with a major contributing factor being that staff feel undervalued. The study explores gratitude as a factor that feeds into a supportive climate that has the potential to significantly enhance morale. The project overall will generate advice and guidance for healthcare institutions who wish to better recognise and facilitate gratitude for the morale and subjective well-being of their staff and patients, and therefore improve the quality of care and patient safety.

Observations will be made of exchanges of gratitude between patients and visitors with members of staff, and between staff members on six identified wards at the Royal Brompton Hospital. Observations may be followed up with informal conversations or arranged interviews. Displays of gratitude that are visible in the Hospital (e.g. noticeboards displaying thank-you cards) will also be recorded. Photographs may be taken (with permission) of objects related to gratitude, but no identifiable information will be photographed. No confidential patient information will be recorded. The study is expected to consist of approximately 30 half-day observation sessions over a period of nine months, and a total of around 450 participants are expected to be observed.

All observations and interviews with patients, staff or visitors will be undertaken where possible with informed consent, however it is possible that the researcher may be incidentally exposed to confidential patient information. Support under the regulations is required in case of accidental disclosure of confidential patient information regarding a non-consented patient during either observations or interviews with staff and consented patients. The researchers have put in a number of safeguards to protect patient confidentiality including consent where possible, observing from a distance to try to avoid overhearing where appropriate, ceasing observations when requested, and reminding all staff and patient participants to respect patient confidentiality during interviews and observations.

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	Applicants will observe approximately 450 participants, made up of patients over the age of 16, staff and visitors on specified wards. However, these will be consented observations/interviews. Support for CAG purposes is provided regarding any patient whose confidential patient information may be incidentally disclosed <u>without consent</u> whilst these observations and interviews are taking place.
Data sources	Interviews and observations carried out in the participating NHS Trust:

	The Royal Brompton and Harefield NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected for linkage 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 felt the research would serve the public interest by stimulating a reappraisal of the way the NHS receives and makes use of expressions of gratitude, which could in turn lead to an improvement in patient care.

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**

Staff, patient and visitor participants will be verbally consented for observations, alongside staff and patient interviews which will be consented on a paper consent form. Consent forms are submitted with this application, however this element is out of scope for support, as the support is merely for incidental disclosures regarding non consented patients. It is not possible to consent for

the incidental disclosure of confidential patient information as it is not possible to accurately predict what the exposure might be. The Sub-Committee were content with this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is not required for the purpose of the study, but researchers may be exposed to confidential patient information incidentally while observing and interviewing clinical staff, and consented patients. No items of confidential patient information will be collected or recorded by the researchers, without written consent. Incidental exposure during a recorded interview will result in destruction of audio-recordings of interview immediately, and the researcher will remove herself from this site of exposure. The Group accepted that it is not possible to anonymise or pseudonymise all data that could be disclosed incidentally.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Consent from staff will be sought in advance of planned observations through team meetings and a staff information leaflet. On the day of observations, permission will be confirmed through the meeting with the charge nurse. However, staff consent is not in scope for support.

When observations commence, a poster will be placed at the bay entrance that states that observations are taking place and giving the researchers' and charge nurse's contact details for further information, and for patients to dissent.

A member of the clinical care team will seek verbal consent from patients in a bay for the researcher to approach and go through the study information with them. If all in the bay agree, staff member will introduce the researcher. The researcher will approach patients and visitors individually to explain the observation process and ask for verbal consent. A patient information leaflet will be handed out and a period of time given to consider it. After this period, verbal consent will be confirmed with those present in the bay, and if it is unanimous, observations will commence.

After observations, a thankyou card will be given to patients that thanks them for participation and invites conversation. Any conversations that do take place will be used to supplement observations. If there are stories that could serve as case studies or illustrative examples, separate written consent will be obtained.

Patients and staff will be separately consented for interviews, on a paper consent form and reminded not to mention any confidential patient information. If the patient chooses, their confidential patient information may be recorded at this point – but the researcher will record this data only with consent.

The researcher will not observe a bay if any participant withdraws or withholds consent. There are several opportunities for participants to decline, either directly with the researcher or indirectly (through communication with a member of staff). The poster displayed during observations has opt out options clearly stated. It is not possible to apply the National Data Opt Out to incidental disclosure applications.

The CAG were broadly content with the patient notification materials, however they did comment on some elements. The CAG queried if the wording in the interview topic guide could be plainer regarding the fact that there is no intention to discuss any intimate personal details and that if those details are mentioned, they will not be recorded. It was commented that the relevant statement in the interview topic guide fails to say what will and will not be recorded or retained:

> *'Please bear in mind that we have a duty of confidentiality to patients and staff, so please refrain from mentioning identifiable information during the interview.'*

It has therefore been requested that the applicant rephrase this statement in plainer English to ensure it is clear that as part of the study no confidential patient information will be recorded or retained, and that if any is recorded, this will be deleted immediately.

The CAG commented that the interview information and consent form is also vague regarding what will and will not be recorded or retained, using the example of the sentence;

> *'Please do not feel obliged to continue if you feel uncomfortable in any way*'

Which then doesn't say what will then happen to any inappropriate information that may have led to the decision to stop. Therefore, the CAG have further requested that the information sheets, consent forms, poster and other patient facing documents should state in plainer terms that no confidential information will be recorded or retained without consent.

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 applicant described various advice received from patients, members of staff and a lay advisory group. The design of the study and consent processed changed due to this feedback.

The lay advisory group was asked specifically about issues of confidentiality, and no concerns were raised.

The CAG felt the patient and public involvement was proportionate, and were content.

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 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;

1. Favourable opinion from the REC when available.

2. Please re-phrase the wording in the interview topic guide regarding this sentence; '*Please bear in mind that we have a duty of confidentiality to patients and staff, so please refrain from mentioning identifiable information during the interview.'* to ensure it is clear that as part of the study no confidential patient information will be recorded or retained, and that if any is recorded, this will be deleted immediately. Please provide the updated document to the CAG within one month from the date of this letter.

3. The information sheets, consent forms, poster and other patient facing documents should state in plainer terms that no confidential information will be recorded or retained without consent. Please provide the updated documents to the CAG within one month from the date of this letter.

Request for further information

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 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. Favourable opinion from a Research Ethics Committee
   Pending

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission

   Confirmed: The **2019/20** NHS Digital DSPT reviews for **The Royal Brompton and Harefield NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 January 2021).

d. 21/CAG/0015 - An investigation into the impact of social determinants on Bowel Cancer Screening Programme uptake: Gloucester locality

Context

Purpose of application

This application from Gloucestershire Hospitals NHS Foundation Trust set out the purpose of medical research which aims to investigate the impact of social determinants on Bowel Cancer Screening programme (BCSP) uptake in Gloucester, in order to identify recommended interventions that could be applied in Primary Care to improve the uptake of the BCSP. This study cohort will be people who have chosen not to partake in the programme, and who are registered at 3 GP practices in Gloucester, in the GL1 area. These GP practices have been chosen as they have the lowest level of uptake.

The BCSP is a national screening programme for all people aged between 60-74 years. It is non-mandatory and seeks to provide earlier cancer diagnoses, which enables better outcomes and greater chance of survival. The BCSP has an average uptake of 60%, with research indicating that gender, ethnicity and deprivation levels had an impact on uptake rates. Early diagnosis of bowel cancer will enable 92% of people to survive their disease for five years or more, in comparison with only 10% of people diagnosed at the latest stage. Despite implementation of the BCSP, late stage detection is consistently demonstrated, with approximately 25% of all bowel cancer diagnoses happening through an emergency attendance. More investigation is needed regarding non-compliance at a local level, to increase the number of patients engaging with the BCSP, and reduce the number of later stage diagnosis, to enable greater survival rates.

The researcher will request confidential patient information from 3 GP surgeries about people who are 60-74 years of age and did not partake in the BCSP. The researcher will not send any identifiers to the GP practices, but will merely send the inclusion criteria requested. The GP surgeries will send confidential patient back to the researcher, including NHS number, date of birth, gender, ethnicity and occupation to Gloucestershire Hospitals NHS Foundation Trust via secure email. The researcher will then link this dataset to A+E attendances at Gloucester Royal Hospital suffering bowel symptoms using internal hospital records, and linkage will be performed using NHS number alone. Although the researcher works at the NHS Trust, she is not a member of the direct care team, and support is required for this access. It is expected that around 400 people will be in the created dataset, which the applicant reasons would not be feasible to consent due to sample size.

Once the GP and A+E datasets are linked, identifiers will be modified for analysis, and deleted after analysis. All data will be stored securely on an NHS secure VPN, and will only be accessed by the named researcher. This study is part of an MBA at University of Gloucester; Applicant has confirmed that no identifiable data is processed there.

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	Approximately 400 People Aged 60-74 who did not partake in BCSP between a 12 month period (2019-2020)
Data sources	1. A&E attendances at Gloucester Royal Hospital - this information will be accessed through internal hospital systems 2. GP practice patient access data from 3 practices: • Bartongate GP practice • Gloucester City Health Care practice • Gloucester Health Access Centre
Identifiers required for linkage purposes	1. NHS number only
Identifiers required for analysis purposes	1. Postcode (modified to deprivation score) 2. Date of birth (modified to age) 3. Gender 4. Ethnicity 5. Occupation 6. NHS number (modified to Unique study identifier) (This data can be considered pseudonymous)

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 felt the research was in the public interest, and covered an important topic.

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**

Applicants reason that given the size of dataset, it would be prohibitive to request individual consent from each patient. The Sub-Committee were content with this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage from GP dataset to A+E attendances dataset. The clinical data disclosed to the applicant is limited in scope and proportionate to the question being asked. It is not possible to use pseudonymised or anonymised data for the purposes of linkage, however the researcher will pseudonymise identifiers as soon as possible. The members were content with the proposed use of identifiers. They did however query if the applicant was receiving postcode from the GP practice? It is not clear in the application, and as the applicant has confirmed no other identifiers are being sent from the GP aside from those listed above the CAG would like it confirmed where the postcode is sourced from. This has been added as a request for further information.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to objection and mechanism to respect that objection, where appropriate. This is known as 'patient

notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A patient notification website text including a study specific dissent mechanism has been provided. The notification will be placed on the Trust and GP websites and in GP surgeries as a printed notice. GPs will apply National Data Opt out to their datasets before sending back to applicant.

The CAG considered that the patient notification needs to be re-worded to be more accessible to the average reader, with fewer technical terms. For example, the use of words such as 'demographic data', 'encrypted', and 'arbitrary number' is not patient friendly. It was commented that the applicant should explain a little bit about the study, list the data items being sent from the GP practices, and explain why the NHS number is required to link the GP data to the A+E dataset.

More detail is required regarding the opt out mechanism, as the notification currently refers to contacting the researcher if a patient has '*concerns about your data…*'. The notice should explicitly state '*if you want to opt-out'* and provide a telephone contact and address for opt-out in addition to the details provided currently. The Sub-Committee commented that the study specific opt out mechanism provided would only prevent the researcher linking the GP data with the A+E data, unless a patient had completed a request for the National Data Opt Out. Therefore the notification needs to ensure that this is clearly stated.

The members have requested an updated patient notification prior to recommending support, and suggested that the researcher should seek the advice of a small Patient and Public Involvement group or even a single layperson regarding the accessibility of this updated document, providing both the document and the lay feedback to the CAG.

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 applicant has considered that Patient and Public Involvement in a group of non-responders may be prohibitive. The members were not content with this response, and stated that there must be some Patient and Public Involvement even if it is limited. Although it was accepted that engaging with the cohort of non-responders would be difficult, the Sub-committee

confirmed they would be happy to accept the applicant speaking to a cohort of GP patients, or other lay people. It was also commented that this is not a rare disease, and members suggested contacting a cancer charity to help set up a virtual meeting, or online questionnaire with a few patients to discuss the use of confidential patient information without consent for the purposes of this research. The CAG have requested that some proportionate Patient and Public Involvement is undertaken to discuss the use of confidential patient information without consent, and evidence of outcomes provided to the CAG for review.

Exit strategy

The applicant will pseudonymise data for analysis within 3 days of receipt from GP practices, after linking to A+E attendances, and will modify Date of birth to age and postcode to deprivation score. The applicant will delete the entire dataset after analysis (by around April 2021). The members agreed that the deletion of identifiers would be done in a timely manner.

Physical location of data retained

In the application it is stated that all data will be stored securely on an NHS secure VPN. However members noted that in part of the application there is reference to data being held on the applicants laptop. It may be that the applicant is required to work from home during the pandemic, and as such may be planning to do analysis on the laptop. Members would like some more detail on whether any identifiable data will be stored on the applicants laptop, or whether the identifiable data stays within the hospital servers but is accessed remotely via VPN only. If there are plans for identifiable data to be stored on the laptop, it is suggested that the data should be processed at the hospital until the identifiers have been modified. This information is required before support can be recommended.

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 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;

1. Favourable opinion from the REC when available (see below condition of support).

2. Confirmation of NHS Digital review of 2019/20 DSPTs (see below condition of support)

3. Please confirm from which source postcode is sourced from? Is this sent from the GP practices? Please confirm within one month from the date of this letter.

4. Please provide an updated patient notification, with fewer technical terms, more detail about the uses of confidential patient information, clearer phrasing surrounding the opt-out mechanism and updated contact details as explained in more detail above. Please ensure this receives feedback from at least one layperson, and provide both the updated notification and the Patient and Public Involvement feedback to the CAG within one month from the date of this letter.

5. Patient and Public Involvement is to be undertaken to discuss the use of confidential patient information without consent, and evidence of outcomes provided to the CAG for review within three months from the date of this letter.

6. Please provide some further clarification on whether any identifiable data will be stored on the researchers laptop, or whether this will only be accessed remotely on hospital servers via VPN only, within one month from the date of this letter.

Request for further information

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 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. Favourable opinion from a Research Ethics Committee
   Pending

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission

Pending: The **2019/20** NHS Digital DSPT reviews for **Gloucestershire Hospitals NHS Foundation Trust** (RTE), and **NHS Gloucestershire CCG** (to cover GP practices) were not yet confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 27 January 2021).

Signed – Officers of CAG	Date
Signed – Confidentiality Advice Team	Date