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

SEPTEMBER 2019

Present:

Name	Capacity	Items
Dr Martin Andrew	CAG Member	1.c, 1.e.
Ms Sophie Brannan	CAG Lay Member	1.d, 1.e.
Dr Malcolm Booth	CAG Member	1.a.
Dr Patrick Coyle	CAG Vice Chair	1.a, 1.b
Dr Liliane Field	CAG Member	1.a.
Professor Jennifer Kurinczuk	CAG Member	1.b.
Dr Murat Soncul	CAG Alternate Vice-Chair	1.c, 1.d, 1.e.
Mr Marc Taylor	CAG Member	1.d.
Ms Gillian Wells	CAG Lay Member	1.b.

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor
Miss Kathryn Murray	Senior Confidentiality Advisor

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a. 19/CAG/0149 - Mammographic Predictors of Cancer Recurrence after Breast Conservation and Adjuvant Endocrine Therapy

Context

Purpose of application

This application from the University of Dundee set out the purpose of medical research which aims to prove whether a reduction in breast density is a physiological sign that endocrine treatment provided to women with breast cancer is effective in keeping the cancer away.

The study will involve wider analysis of mammograms taken from women who are recruited to the Mammo50 research project. The patient cohort includes women who are all over 53 years old and have had a lump removed. 2000 are on endocrine therapy and did not have chemotherapy. Mammograms were taken at baseline, one year and three years post-diagnosis. The mammograms will be transferred to a central imaging centre to enable radiologists to assess if the breast tissue has become more or less dense. The study will also include mammograms from 500 similar women who did not have endocrine therapy as a control group. The progress of these women would then be followed to see if a change in density of the breast tissue is related to the effectiveness of the endocrine therapy.

A recommendation for class 1 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	2000 female patients who were recruited into the Mammo50 trial and underwent endocrine treatment for breast cancer. 500 female patients with breast cancer who did not undergo endocrine treatment will also be included as a control cohort.
Data sources	1. Mammo50 trial database held at the Warwick Clinical Trials Unit 2. Mammogram records held within the PACS systems at individual Mammo50 trial sites in England (93 sites) and Wales (1 site)
Identifiers required for linkage purposes	1. Patient ID 2. Name 3. NHS Number 4. Hospital ID 5. Date of birth
Identifiers required for analysis purposes	Not applicable – no data items are required for the purposes of the study analysis.
Additional information	The applicant has made associated applications to the Public Benefit and Patient Privacy Panel (Scotland) and the Privacy Advisory Committee (Northern Ireland) in respect of patients within these nations.

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.

Members agreed that the proposed activity was within the public interest as it would lead to greater understanding about the impact of treatments on breast cancer.

Scope

It was recognised that the project would collect data from sites across the UK. The applicant had provided assurance that separate applications had been made to the appropriate bodies in respect of data generated in Scotland and Northern Ireland. The Group sought clarification around the anticipated number of patients within the overall cohort which would be included from sites in England and Wales to confirm the scope of support which was required under this application.

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 had advised that it was not feasible to reconsent patients for the wider use of the scans in this proposed study due to time limitations. Members commented that whilst the overall patient cohort for the study was of a reasonable size, it was noted that these 2500 patients were being recruited from 94 differing sites.

The Group queried whether it would be feasible for each individual site to seek appropriate consent for the wider use of the scans from patients within their care. The CAG agreed that the applicant would be asked to consider this point. If this was not deemed a feasible option; a strong justification would be required to support the decision.

- Use of anonymised/pseudonymised data

It was recognised that the applicant did not require confidential patient information for the purposes of the analysis which was to be undertaken; however, justification had been provided to explain why it was not feasible for the sites to carry out the anonymisation process prior to disclosure of the mammogram scans to the central research site.

It was firstly explained that the undertaking of the pseudonymisation process at a central site would ensure a consistent and robust process was applied. This would also prevent an unnecessary burden for site staff at each of the Trusts providing data which would not be directly involved in the proposed study.

The Group recognised that data would be provided from 94 sites for the purposes of this study. As such, the number of scans which would be provided by each site did not seem to present a considerable burden. The Group reiterated, as with the feasibility of consent, that a stronger justification was required from the applicant to explain why it was not feasible for individual sites to anonymise the scans prior to disclosure.

It was noted that the applicant had also raised concerns that there may be issues around the consistency and effectiveness of the anonymisation process if carried out by multiple sites. It was agreed that this point would need to be explained further if this was being relied upon to justify the necessity for support under the Regulations to be recommended for the study.

Exit strategy

Support under the Regulations was requested on a time limited basis to enable the patient cohort to be established and the relevant scans to be identified. Members raised no concerns with the proposed exit strategy, should the study proceed via the proposed methodology.

‘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 explained that patient-facing documents would be drafted to be displayed on the original MAMMO50 trial website. The Group agreed that sight of this documentation was necessary prior to any final recommendation of support coming into effect. It was also suggested that this information should be made more widely available in clinics at the Trust sites which participated in the original study.

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 explained that one patient had been approached for views around the study and the proposed use of confidential patient information without consent. From the feedback provided, it was explained that the patient was supportive of the study but did raise a concern on the basis that patients can be quite sensitive around consenting issues.

Members received the feedback and agreed that whilst the information was helpful, further activity was required in this area to seek the views of a wider patient group around the proposed study. In particular, due to the concerns raised by the patient representative around consenting issues, it was important that a wider group provided views on the use of confidential patient information without consent for the purposes of the study. It was suggested that a breast cancer patient support group could be

approached about the proposal. Feedback would be required prior to any final recommendation of support coming into effect for the application activity.

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.

Request for further information

Practicable Alternatives

The CAG is unable to provide a recommendation of support to an activity where there is a potential practicable alternative to processing confidential patient information without consent.

The applicant was asked to provide further stronger justification to support why the following two options were not deemed to be feasible methods for the study:

1. Individual Trusts seeking consent from patients within their site for use of the data within the study.

2. Anonymisation process being undertaken by individual Trusts prior to disclosure of scans to the central site.

If it is determined that either of the above methods can be employed, confirmation should be provided that a practicable alternative had been established and the study withdrawn from review. If the above options are not considered feasible, justification should be provided in a covering letter, together with response to the below request for further information.

Request for further information

Confirm how many patients were estimated to be included in the study from sites in England and Wales.

Provide copies of the patient-facing materials which will promote the study and the patient's right to object to the use of their data for consideration. Provide confirmation that this information will be displayed on the MAMMO50 website and within clinics at participating sites.

Further patient and public involvement and engagement activity should be undertaken to test the acceptability of using confidential patient information without consent for the study purposes. Feedback around the activity undertaken, the details of those present and an overview of the views expressed should be provided. If the responses given were negative, the CAG would take this into account when considering whether support can be recommended.

Specific conditions of support

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. Support extends to data generated in England and Wales only. The applicant has made separate applications to the appropriate bodies in respect of data generated in Scotland and Northern Ireland.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 12 August 2019**

3. 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. **Pending – Royal Surrey NHS Foundation Trust**

b. 19/CAG/0153 - A Retrospective cohort study on the ability of acupuncture to improve chemotherapy-induced peripheral neuropathy symptoms and the quality of life

Context

Purpose of application

This application from the Northern College of Acupuncture set out the purpose of medical research which aims understand the impact of a standardised acupuncture protocol in improving symptoms of chemotherapy-induced peripheral neuropathy (CIPN) and quality of life in patients with cancer.

Support under the Regulations is sought to legitimise access to patient medical records to enable eligible patients to be identified and approached for consent. Two patient groups will be identified for inclusion – the first will include cancer patients who developed chemotherapy-induced peripheral neuropathy and received treatment with acupuncture. The second cohort will include patients which also developed chemotherapy-induced peripheral neuropathy but did not receive acupuncture. Patients will be invited to participate the study which will involve the completion of three questionnaires.

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	1. 168 cancer patients who developed chemotherapy-induced peripheral neuropathy and were treated with

	acupuncture by South Tees Hospitals NHS Foundation Trust. 2. 168 cancer patients who developed chemotherapy-induced peripheral neuropathy and did not receive acupuncture treatment at Barnsley Hospital NHS Foundation Trust and Sheffield Teaching Hospitals NHS Foundation Trust.
Data sources	1. Hospital notes and electronic patient records at the Trinity Holistic Centre (South Tees Hospitals NHS Foundation Trust), 2. Hospital notes and electronic patient records at Barnsley Hospital NHS Foundation Trust 3. Hospital notes and electronic patient records at Sheffield Teaching Hospitals NHS Foundation Trust.
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Full address and postcode
Identifiers required for analysis purposes	Any identifiers retained for analysis will be on the basis of patient consent and is out of scope for the CAG application.

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.

Members were assured that the proposal was within the public interest through gaining a wider understanding of the impact of complementary medicine on the quality of life for cancer patients.

Scope

The Group recognised that the applicant aimed to recruit 168 patients into each cohort; however, it was unclear how many patient records would need to be screened to identify the eligible cohort to be invited to participate. It was agreed that clarification would be sought from the applicant on this point, to ensure the scope of support required under the Regulations was clearly specified.

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 CAG recognised that support under the Regulations was being sought to enable a patient cohort to be identified and approached for their consent to participate. There was an established precedent to support application activities of this type on the basis that section 251 support would legitimise access to data to enable a consenting mechanism to be operated.

- Recruitment by the direct clinical care team

The applicant had confirmed it was not feasible for members of the direct clinical care team to undertake the record screening and facilitate the invitation process on behalf of the project as this would be too time consuming and burdensome for the service It was recognised that the student researcher undertaking the proposal was also employed as a Consultant Physician within the NHS and was bound by appropriate confidentiality clauses. Members recognised that there was precedent for offering support under the Regulations for proposals of this type, to reduce the burden on clinical teams and accepted the applicant's assurance.

- Use of anonymised/pseudonymised data

Confidential patient information was required to identify the eligible patient cohort and to facilitate the recruitment mechanism which could not be otherwise achieved.

Exit strategy

Members noted that the study timeline which had been provided within the supporting documentation was now out of date. A revised document was requested to enable a clear overview of the key milestones for the study to be understood. The applicant would also be asked to confirm when confidential patient information in relation to the wider patient cohort which did not provide consent to participate would be destroyed, to clarify the timeframe for enacting the exit strategy from support under the Regulations.

'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 had provided a copy of a generic privacy notice for the South Tees Hospitals NHS Foundation Trust within the application documents. Members noted that this document did not appear to address the use of confidential patient information without consent for research purposes.

It was agreed that further information was required from the applicant in this area to understand how the proposed research would be promoted across the various research sites and patients informed of their right to object. Copies of any documentation used to facilitate this mechanism would be requested for review. The applicant would also be asked to provide assurance that patient records would be checked for evidence of historic dissent.

Members considered the patient-facing materials which would be sent as part of the invitation process. It was noted that patient information sheet included an incorrect

reference to the CAG providing permission for the use of data which would need to be corrected.

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 Group noted that, from information provided within the application, there did not appear to be any user involvement in the study to date. Members agreed that the applicant would be required to undertake proportionate activity in this area to test the acceptability of using confidential patient information without consent for the application purposes.

Data Protection Compliance

Further information was required from the applicant to evidence how the proposed data processing was compliant with the principles of the General Data Protection Regulation and Data Protection Act 2018. Confirmation was specifically required around the legal basis, in relation to the current data protection legislation, which was being relied upon for processing of data within the study.

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.

Request for further information

1. Confirm how many patient records would need to be accessed in order to identify the patient cohort which would be invited to participate in the study.

2. A mechanism to inform patients about the proposed study and their right to dissent to their information being used for these purposes needed to be established across all sites. Provide copies of any documentation to support this.

3. Explain how the dissenting mechanism would be operated. Also provide assurance that patient records would be checked for evidence of historic dissent.

4. Patient and public involvement and engagement activity should be undertaken to test the acceptability of using confidential patient information without consent for the study purposes. Provide feedback on the format the activity took, the demographics of those involved, what was asked of attendees and an overview of the views expressed.

5. Provide an updated study timeline which has been revised in line with delayed study start.

6. Confirm when confidential patient information for those patients who do not consent to participate will be destroyed.

7. Provide further information to explain how the proposed activity is compliant with the principles of the General Data Protection Regulation and Data Protection Act 2018.

8. Confirm that the legal basis being relied upon for data processing, under current data protection legislation, is public interest (GDPR Article 6(1)(e)) and special category data is research purposes (GDPR Article 9(1)(j)).

9. Within the patient information leaflet (Part 3, bullet point 3) the reference to access to confidential patient information should be revised to state 'Permission was given by the Health Research Authority…'.

Specific conditions of support

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 26 July 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Pending: the following sites require confirmation of security assurance: Trinity Holistic Centre (South Tees Hospitals NHS Foundation Trust), Barnsley Hospital NHS Foundation Trust and Sheffield Teaching Hospitals NHS Foundation Trust.**

c. 19/CAG/0163 - Developing new care pathways for women at low risk of breast cancer

Context

Purpose of application

This application from the University of Manchester set out the purpose of medical research which sought to determine if it is safe, feasible and acceptable to reduce the frequency at which women at low risk of developing breast cancer are called from screening. The applicants also seek to design and refine information materials which highlight the benefits and harms of breast screening for women with a low risk of developing breast cancer.

In 2013, the National Institute of Care Excellence (NICE) indicated that women at high/moderate risk of breast cancer should receive the option to take chemoprevention medication, and that women at high risk should receive screening more frequently. These guidelines have not been implemented into the NHS Breast Screening Programme (NHSBSP) as women are not given information of their risk. Providing women with their breast cancer risk is currently being piloted in 5 screening sites across the North West of England by the BC-Predict study, with the primary aim of identifying women at high risk so that the NICE guidelines can be implemented. If a sizeable proportion of women at high risk opt for additional screening it is likely that compensations will need to be made elsewhere to facilitate this. Before recommending that the frequency of screening for low risk women is reduced, the applicants intend to examine the safety, feasibility and acceptability of reducing the frequency of screening by holding interviews with relevant groups.

The project is comprised of three phases.

1. In the first phase, prominent professionals with a significant role in the NHSBSP will be interview. Support under Section 251 is not required for this aspect of the study. For the second and third phases, interviews will be held with women at low risk of developing breast cancer.
2. Interviews will be held with women at low risk of developing breast cancer.
    a. One group will be women identified via BC-Predict, who will have consented to take part in other, related, research project. Support under Section 251 is not required for this group.
    b. Women approaching the screening age (46-52) will be identified from the NHS National Breast Screening Service (NBSS) database by members of the low risk study team at Manchester University NHS Foundation Trust, and invited to take part. Support under Section 251 is sought to include this group.
3. "Think aloud" interview, where women are asked to read information out loud and share their views, will be held.
    a. One group will be women identified via BC-Predict, who will have consented to take part in other, related, research project. Support under Section 251 is not required for this group.
    b. Women who are currently engaging in the NHS Breast Screening Programme will be identified via the NHS NBSS database. The low risk study team at Manchester University NHS Foundation Trust will contact this group to invite them to take part. Support under Section 251 is sought to include this group.

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	Phase 2: 15-20 women approaching screening age, living in the Greater Manchester, East Lancashire and Central Cheshire areas Phase 3:

	15-20 women active in the NHSBSP and living in the Greater Manchester area
Data sources	1. The NHS National Breast Screening Service database
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Full address and postcode
Identifiers required for analysis purposes	1. Postcode

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 were satisfied that the aims of the study were in the public interest.

Scope

The Sub-Committee noted that the NBSS database would be used to identify 40 suitable patients across Manchester, Lancashire and Cheshire. In order to identify the required number of patients, the research team would potentially have access to confidential patient information for millions of patients who fell into the appropriate age range.

Members queried whether the researchers' access would be limited to regional data, or if the national dataset would be accessed. Members also sought clarification on whether the database contained screening information only, or if any further data was pulled through from GP information systems. If the latter was the case, then the researchers may have access to sensitive information and the Sub-Committee requested further information about how this situation would be handled.

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

Members of the low risk study team at Manchester University NHS Foundation Trust would be accessing confidential patient information without consent in order to identify and make contact with suitable patients from the NHS National Breast Screening Service database. Patients were then contacted by the low risk study team. If patients made contact with the university to register their interest, then their involvement in the study would proceed on a consented basis.

The applicants explained that consent could not be obtained from patients prior to accessing the NBSS database as all patients in the relevant screening programmes would need to be contacted to seek consent. There were also concerns that, if all women invited for breast screening were contacted about the study, then this could have a detrimental effect on the uptake of breast screening.

The Group were not reassured that an alternative to accessing confidential patient information without consent could not be used. The applicants planned to display posters in GP surgeries and screening units to inform patients about the study and invite them to register dissent. The Sub-Committee queried why the posters, and potentially information on social media or other means of promoting the study, could not be used to invite patients to contact the research team directly to express interest in the study, without the need for screening of the NBSS database. Patient screening for eligibility could then proceed on a consented basis. The applicant was asked to provide further justification on why this method of recruitment could not be followed

and if any other methods of recruitment had been considered and deemed not to be practicable. Further justification on why the NBSS staff were unable to undertake screening for the small number of patients required also needed to be provided.

- Use of anonymised/pseudonymised data

Access to confidential patient information was required in order to identify and contact suitable patients, which cannot be undertaken any other way. The Sub-Committee were not assured that the identification of patients could not be undertaken in any other way and, as noted above, asked the applicant to provide further details on why this method had been chosen.

'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.

Patients were notified about the study when contacted by the low risk study team. Posters were also displayed in GP practices across Greater Manchester informing patients that their data may be used for this purpose and the poster included contact information to enable dissent to be raised. Patients who did not contact the research team to agree to take part in the project were not recruited into the study.

As part of the consent process for this application, participants were asked whether they consented to being contacted about future research. Processes were put in place to ensure that those who did not consent to this were not invited for future research.

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 explained that two patient and public involvement panels had been held with women in their 40s who had yet to attend screening and older women who had recently received false positives following breast screening. The feedback from these panels had actively informed this proposal.

Patient and public involvement had been undertaken throughout the creation of the study and had provided feedback on information about the study and the interview schedules. The applicants met with the PPI group regularly.

The Sub-Committee noted that it was unclear whether the patient and public involvement had been undertaken with seven women in total, or with two groups, each comprised of seven women. It was also not clear whether the issue of accessing the NBSS database had been discussed with the panel, as this aspect had been added as an amendment at a later date. Members asked that further details on the number of women involved in the patient and public involvement and whether the issue of using the NBSS database to recruit patients had been specifically discussed.

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.

Request for further information

The Sub-Committee were not satisfied that the screening and identification of suitable patients needed to be carried out by accessing confidential patient information without consent, and asked that further justification for this was provided.

1. Provide clarification as to why members of NBSS staff, with access to the database as part of their clinical role, are unable to undertake screening to identify the 40 patients required.

2. Clarify why posters and other methods of communication, such as social media, could not be used to promote the study and invite patients to contact the study team to express interest in taking part. The screening of records for suitability could then proceed on a consented basis.

If either of the options from the above list is selected as an alternative to accessing confidential patient information without consent, then support under Section 251 and its Regulations will not required for this application. If support under Section 251 is still sought, then the following issues need to be addressed;

1. Provide details on any other methods of identifying and recruiting patients that had been considered and deemed not to be practicable.

2. Clarify if the researchers' access to the NBSS database is limited to regional data or if the national dataset was accessed.

3. Clarify if the NBSS database contains information about screening only or if further data was pulled through from GP information systems. If the latter, details on how access to sensitive information will be handled needs to be given.

4. Further details on the patient and public involvement carried out needs to be provided;

a. Clarify how many women took part in the patient and public involvement, e.g. seven women in total or two groups each comprised of seven women.

b. Confirm if the issue of accessing the NBSS database in order to screen for and contact suitable patients was specifically discussed during patient and public involvement events and provide details of the feedback given.

Specific conditions of support

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 26 June 2019).**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Pending for Manchester University NHS Foundation Trust).**

d. 19/CAG/0164 - Investigation of gender mortality differences in children admitted to UK Paediatric Intensive Care Units

Context

Purpose of application

This application from the University College London Great Ormond Street Institute of Child Health set out the purpose of medical research that seeks to investigate why girls admitted to Paediatric Intensive Care Units (PICU) in England and Wales have a higher mortality rate than boys.

Previous, small-scale studies had shown that infant girls may have higher mortality than infant boys in PICU. The applicants had previously carried out an analysis of all babies aged 0-12 months admitted to PICU's over an 11-year period. The rates of death between girls and boys during their admission to PICU were compared and it was found that girls had a higher death rate than boys. This differed from the general population, where infant boys had a higher death rate than infant girls. The applicants intend to examine these findings in greater detail.

Support is sought for data from PICAnet for all children aged 0-17 years of age who have been admitted to PICU to be disclosed to NHS Digital for the purposes of linkage with HES and ONS mortality data. A pseudonymised dataset, "Dataset A," will be created and sent to the study team based at the UCL GOS Institute of Child Health. NHS Digital will also provide UCL with a pseudonymised dataset of maternity data from HES. UCL will then link the pseudonymised maternity data with Dataset A using probabilistic linkage.

A recommendation for class 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	All patients aged 0 – 17 years admitted to a Paediatric Intensive Care Unit in the UK between 01 January 2010 and 31 December 2019. It is expected that around 90,000 patients would be included, once exclusions and repeat admissions had been accounted for.
Data sources	1. PICAnet national audit data for paediatric intensive care admissions 2. HES and ONS data held by NHS Digital
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Date of death 4. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – District level 4. Gender 5. Occupation 6. 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 Group noted the clear public interest in establishing the reasons behind the difference in survival rates between girl and boy infants admitted to Paediatric Intensive Care Units.

Scope

The Group noted that support was granted for the flow of PICAnet data to NHS Digital for the purposes of data linkage prior to pseudonymisation for the purposes set out in this specific application only. If any further data linkages are to be undertaken or further uses made of the data collected, then an amendment or new application will need to be submitted.

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 it was not possible to seek consent from the 140,000 patients they anticipated would be included. Disclosures of confidential patient information would also be required in order to identify and contact the relevant patients, which would be a costly process. The cohort was also historic and a number of patients may no longer be traceable. The applicants also noted the sensitive nature

of the study outcome and that the families of patients who had died may be upset by being contacted. The Group accepted the rationale for not seeking consent.

- Use of anonymised/pseudonymised data

Confidential patient information needed to be disclosed from PICAnet to NHS Digital in order to facilitate data linkage with HES and ONS mortality data, which cannot be undertaken any other way. A pseudonymised linked dataset would be disclosed to the study team at UCL, alongside a pseudonymised dataset of maternity data obtained from HES. The Group noted the information given and raised no further queries.

Exit Strategy

The research team at UCL GOS Institute of Child Health would not have access to confidential patient information. The identifiers used by NHS Digital and PICAnet to facilitate the linkage were destroyed once the linkage was completed. The applicant anticipated that the data linkage would be undertaken within six months of all relevant approvals being put in place for the study. NHS Digital will destroy confidential patient information within three months of successful linkage.

The Group noted that the CAG application form indicated that the date of death and date of birth of patients would be retained for analysis. Members queried whether it was necessary for the identifiers to be retained or whether they could be converted into year of birth and year of death.

'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 study will be publicised via institutional websites, the UCL Child Health Research website and the PICAnet website. The website information included details on how patients within England were able to opt-out of sharing of their confidential patient information by NHS Digital by requesting a national opt-out. Details on how to contact the research team so that patients can request further information or register dissent will also be included.

An information sheet, explaining how to opt-out, will also be provided on the websites. Information will also be included in the PICAnet newsletter, which is circulated to families. The information sheet and newsletter will explain how patients in England can dissent to the sharing of their data via NHS Digital by requesting a national opt-out and contact details for the research team will also be provided. The Group noted that the privacy notice was well written as was the general information on the PICAnet website.

The Group queried whether there was a mechanism for patients to opt-out of the transfer of their data from PICAnet to NHS Digital, or if registration of a national Opt-out was the only means of dissent.

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 research project had a Project Advisory Group, who had given input into the design of the project and plans for disseminating the results. Five parents were present at the initial discussion, two of which were the parents of children who had survived critical care. The issue of access to confidential patient information was discussed with the group, who were supportive. The applicant had provided further detailed information around the activity which was undertaken in this area.

The Group noted that it was unclear how much lay input there had been into the design of the study. The PICAnet website contained information about the Paediatric

Intensive Care (PIC) Families Group, which was comprised of 17 people. Three lay members were included in the group, but two of the three posts were vacant.

The Group queried whether the patient and public involvement and engagement carried out was sufficient to the size and scope of the cohort, and asked the applicant to confirm that service user views had been appropriately sought.

Due to the potential sensitivity of the research and the size of the cohort, the CAG suggested that continuing patient and public involvement and engagement was carried out, and that this included devising further ways of notifying families about the study, how the data will be handled and how the results will be disseminated.

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.

Request for further information

1. Provide further details on the patient and public involvement and engagement carried out and assurance that sufficient views have been sought from patients and the public.

2. Confirm whether it will be possible to carry out continuing patient and public involvement and engagement during the study, and that this will include devising further ways of notifying families about the study, how the data will be handled and how the results will be disseminated.

3. Clarify whether it is necessary that the date of birth and date of death of patients is retained, or whether they can be converted into year of birth and year of death prior to analysis.

4. Clarify whether patients can opt-out of the transfer of their data from PICAnet to NHS Digital.

Specific conditions of support

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. Support is given for the flow of PICANet data to NHS Digital for the purpose of linkage prior to pseudonymisation for the purposes set out in this specific application only.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 19 September 2019.**

3. 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. **It was confirmed that the relevant DSPT submission related only to NHS Digital.**

e. 19/CAG/0171 - A Population Based Study of Genetic Predisposition and Gene-Environment Interactions In Breast Cancer

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research which seeks to determine the role of inherited genetic variation in cancer risk and clinical outcomes.

The SEARCH study has been running since 1996 and was set up to investigate how normal, common genetic variation affects cancer risk. Support under Section 251 has not been required previously, however the study team are now seeking to change the recruitment process. In this application, support is being sought for the National Cancer Registration and Analysis Service (NCRAS) to identify patients suitable for the

study. NCRAS disclosed the patient list to NHS Digital, who then removed patients who were deceased, had moved away from the UK or who had registered a dissent. The revised list was then disclosed to the NHS Digital Personal Demographics Service (PDS), who attached patients' addresses and the name and address of patients' GP. This list was then sent to the SEARCH study co-ordinator to facilitate the invitation process.

The SEARCH study co-ordinator then contacted the GPs of eligible patients, asking them to invite patients to take in the study. The GPs were then provided with the study information leaflet, a letter of introduction from the study team and a reply slip for the patients to return to the SEARCH team if they wished to take part. Patients participation in the project then proceeded on a consented basis. Patients were not approached if the G.P. indicated that the patient was under the age of 18 or unfit to participate for any reason.

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	Male and female patients aged between 18 and 70 years. It is anticipated that 40,400 patients will be recruited to the SEARCH Breast study.
Data sources	1. The National Cancer Registration and Analysis Service held by Public Health England (PHE) 2. Patient Demographics Service - NHS Digital

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. GP registration 4. Date of birth 5. Date of death 6. Postcode 7. GP name and address
Identifiers required for analysis purposes	No identifiers are retained 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 Sub-Committee noted the clear public interest in the application.

Cohort

The Sub-Committee asked that the number of patients included in the cohort was clarified. Members noted that it appeared that 25,000 female patients and 200 male patients were recruited as new participants in the breast cancer aspect of the SEARCH programme, and requested confirmation that this was correct.

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 made contact with the GPs of suitable patients and the GPs were asked to send the study information to the patients. If the patients contacted the study team to express interest, then their participation proceeded on a consented basis. The Sub-Committee accepted that prior consent for processing to enable the patient cohort to be identified was not feasible due to the size of the cohort.

- Use of anonymised/pseudonymised data

Confidential patient information was required to identify suitable patients in NCRAS and to link their data to data held by NHS Digital to verify that they were still contactable. Confidential patient information was then disclosed from the study team to the GPs of patients, so that the GPs could send on information about the study. This cannot be undertaken any other way.

'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 SEARCH website had been updated to explain the revised mechanism of recruiting patients. This included information on how to opt-out or withdraw from the study, or dissent from being contacted. This was in line with the precedent established

in linked studies within the wider SEARCH programme and was be accepted here. A notice explaining how to opt-out of NCRAS was also included.

The list of patients provided by NCRAS was sent to NHS Digital to be checked for any known opt-outs to be applied. Patients were then contacted by their GP, at the study team's request, with information about the study. Patients could contact the study team to express dissent and non-response was also treated as dissent.

NCRAS did not have a mechanism for project specific dissent, but patients were able to opt-out of the use of their data for purposes other than direct care. NCRAS had advised that the patient records would be checked for the opt-out prior to sharing the data with the SEARCH team. A notice about the NCRAS and how to opt-out was included on the SEARCH website.

The Sub-Committee noted that patients may only be made aware of NCRAS when they received information about this study, and asked that the patient leaflet was amended to also include information on how patients could opt-out of inclusion in NCRAS.

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 provided information on the feedback given by patients from the Cambridge breast cancer unit about the design of the questionnaires, information sheets and consent forms.

In 2017-18, the study team conducted a telephone survey of 100 SEARCH participants, who had previously completed a consent form indicating that their records could be accessed, but not specifying whether this referred to electronic medical records or records held by NHS Digital, ONS, PHE or other central UK NHS

organisations. All patients contacted agreed that the consent provided covered all forms of their medical records, including centrally held electronic records.

A further survey of 20 SEARCH participants was carried out in 2018. All agreed that it was reasonable for the names, addresses and contact details of eligible patients to be passed from the cancer registry to the SEARCH team, so that patients could be contacted about the research, via their GP. The applicant provided a link to research that PHE NCRAS had undertaken in this area.

The applicants plan to identify a patient group in order to undertake further patient and public involvement engagement activity. Feedback on the revised communication materials and the acceptability of the revised recruitment methodology will be sought, and the documents reviewed following the feedback. The Sub-Committee were satisfied by the information provided.

Transfer of data outside the United Kingdom

The answer to Q25 on the IRAS form referred to SEARCH contributing "samples" to a project run by the US National Cancer Institute. The Sub-Committee queried whether this referred to the transfer of patient level data samples to the US, or if this referred to the dissemination of the results of this study.

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.

Request for further information

1. Confirm the size of the cohort to be included in this application.

2. The patient leaflet needs to be amended to include information on how patients can dissent from inclusion in NCRAS, as well as this specific application.

3. Clarify whether any patient level data samples will be transferred to the US.

Specific conditions of support

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 28 January 2019).**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed: University of Cambridge (by NHS Digital 08 July 2019), Public Health England (by NHS Digital email 02 September 2019) and NHS Digital (by NHS Digital email 10 June 2019).**

Signed – Officers of CAG	Date

Signed – Confidentiality Advice Team	Date