Health Research Authority

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

October 2019

Present:

Name	Capacity	Items
Mr David Evans	CAG member	1.a
Mr Andrew Melville	CAG member	1.a
Ms Clare Sanderson	CAG alternative vice-chair	1.a, 1.b, 1.c
Dr Katie Harron	CAG member	1.b, 1.c
Dr Simon Kolstoe	CAG member	1.b
Dr David Evans	CAG member	1.c
Dr Tony Calland MBE	CAG Chair	1.d, 1.f, 1.g
Dr Lorna Fraser	CAG member	1.d, 1.g
Mr Anthony Kane	CAG member	1.d
Dr Rachel L Knowles	CAG member	1.e,1.f
Dr Harvey Marcovitch	CAG member	1.f, 1.g

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	Confidentiality Advisor

1. New precedent set review applications – research

a. 19/CAG/0172 - A Population Based Study of Genetic Predisposition and Gene-Environment Interactions in Endometrial 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 germline genetic variation in susceptibility to breast, endometrial and ovarian cancer. This application covers the endometrial arm of the SEARCH study.

The SEARCH study has been running since 1996. Support under Section 251 has not previously been required as patients were recruited via a local cancer registry, the Eastern Cancer Registration and Information Centre, which has now been amalgamated to the National Cancer Registration and Analysis Service (NCRAS). In line with advice received from Public Health England, the applicants are seeking support to revise the recruitment process, so that patients are identified by NCRAS.

NCRAS will identify suitable patients and then disclose the patient list to NHS Digital, who will remove patients who are deceased, have moved away from the UK or who have registered a dissent. The revised list will then be disclosed to the NHS Digital Personal Demographics Service (PDS), who will attach patients' addresses and the name and address of patients' GP. This list will then be sent to the SEARCH study co-ordinator to facilitate the invitation process.

The SEARCH study co-ordinator will contact the GPs of eligible patients, asking them to invite patients to take in the study. The GP will be 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 wish to take part. Patients participation

in the project will then proceed on a consented basis. Patients will not be approached if the GP 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	4,000 SEARCH Study participants with endometrial cancer and 3,500 controls who have already taken part in the study and completed a consent form. Patients are aged 18 – 70 years of age.
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. Postcode 6. GP name and address
Identifiers required for analysis purposes	No identifiers will be 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 was satisfied that there was a clear public interest in the project. Members noted that a similar application from the SEARCH team had been considered at a recent precedent set meeting under reference 19/CAG/0171.

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 will make contact with the GPs of suitable patients and the GPs will be asked to send the study information to the patients. If the patients contacted by the study team express interest, then their participation will proceed on a consented basis. The Sub-Committee accepted that it was not feasible to seek consent in any other way, which prevented an initial breach of patient confidence.

- Use of anonymised/pseudonymised data

Confidential patient information is required to identify suitable patients in NCRAS and link their data to data held by NHS Digital to verify that they were still contactable. Confidential patient information will then be disclosed from the study team to the GPs of patients, so that the GPs could send on information about the study. This could not 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 will be updated to explain the revised mechanism of recruiting patients. This will include information on how to opt-out or withdraw from the study, or dissent from being contacted. A notice explaining how to opt-out of NCRAS will also be included.

The list of patients provided by NCRAS will also be sent to NHS Digital to be checked for any Type 2 or National Opt-Outs applied. Patients will then be contacted by their GP, at the study team’s request, with information about the study. Patients will be invited to contact the study team to express dissent and non-response will also be treated as dissent.

NCRAS do not have a mechanism for project specific dissent, but patients are able to opt-out of the use of their data for purposes other than direct care. NCRAS have advised that the patient records would be checked for documented opt-outs prior to sharing the data with the SEARCH team.

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 the SEARCH programme had been in progress for over 20 years, and that patients had been involved in different stages of the study. Feedback had been provided on the study documents, including the consent form and study questionnaires. Results of the study had been disseminated through the study webpages and patient newsletters.

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 also provided information on research that PHE and NCRAS and undertaken in this area.

The applicants planned 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. Discussion of the specific issue of access to confidential patient information without consent is on the agenda for further patient and public involvement held. The applicant advised that SEARCH staff were undertaking training in patient and public involvement.

The Sub-Committee noted the information given and asked that a report on the further patient and public involvement and engagement carried out was provided at the next annual review. Members also asked that different ways of notifying patients that the project was being undertaken and providing a project specific opt-out were explored during patient and public involvement.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, 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. Further patient and public involvement is to be carried out with feedback to be provided at the time of first annual review. This activity should explore different methods of notifying patients that the study is being undertaken and ways of facilitating study specific dissent.

2. Favourable opinion from REC. **(Confirmed 21 February 2019).**

3. 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. **(Confirmed: University of Cambridge (by NHS Digital email 08 July 2019), Public Health England (by NHS Digital email 02 September 2019) and NHS Digital (by NHS Digital email 10 June 2019).**

b. 19/CAG/0183 - Are children with a history of Cleft Palate and/or Lip from a non-English language speaking homes more susceptible to atypical speech sound errors at 3 and 5 years old?

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research that seeks to determine whether children with a history of Cleft Palate and/or Lip from a non-English language speaking homes more susceptible to atypical speech sound errors at 3 and 5 years old.

In primary schools the number of children believed to be exposed to a language other than English is 21.2%. A proportion of these children will also have been born with Cleft Palate or Lip and will make use of NHS cleft services. Previous research conducted had suggested that typically developing bilingual children may develop different rates of speech sound or phonological development compared to monolingual children, and that more advanced speech sound development was seen in bilingual groups. No research has previously been conducted into clinical speech outcomes for children born with cleft or lip palates, comparing the outcomes for children exposed to England at home and those exposed to non-English languages.

The applicant is seeking support to search records at Birmingham Children's Hospital to identify patients who meet the inclusion criteria and to extract qualitative and quantitative data from speech assessment outcomes at 3 and 5 years. The extracted data will be stored in an anonymised format against a study ID number assigned to patients, and no confidential patient information will be extracted or retained.

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	200 children aged between 3 and 6 years of age with a history of cleft and/or lip palate born between 01 January 2011 and 31 December 2012 and treated and Birmingham Children's Hospital.
Data sources	1. Electronic and paper records held at Birmingham Children's Hospital
Identifiers required for linkage purposes	1. Name
Identifiers required for analysis purposes	No identifiers will be 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 investigating the differences in speech development for children born with cleft palate and/or lip from homes where English is the first language versus homes where English is not the first language.

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

Patients had already given consent for their data to be used for audit purposes, but not for use in research. The Sub-Committee noted that the applicant had cited the time constraints of their master's degree as a reason to justify not seeking consent from patients. Members noted that this reason alone would not usually be sufficient to justify proceeding on an unconsented basis. However, it was acknowledged that there were wider concerns around the cost implications of producing patient information materials in the various languages required or sourcing interpreters. The Sub-Committee accepted the wider justification given in this particular set of circumstances and clarified that it was not establishing a precedent in relation to the time constraints on a project.

- Use of anonymised/pseudonymised data

The applicant required access to confidential patient information in the medical records of relevant patients in order to extract anonymised information. This could not be undertaken in 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 Sub-Committee noted that the applicant did not plan to carry out patient notification. Data was only to be collected within one hospital and members determined that it would be reasonable for a poster to be displayed in relevant waiting areas, providing information about the study and advising how patients and their parents can dissent to their data being used in the study. This document would be requested for review.

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.

No patient and public involvement had been carried out by the applicant. The Sub-Committee noted that the applicant was an NHS employee and would be able to make contact with relevant patient groups. Members asked that the applicant discussed the study with their patients and sought views on the use of confidential patient information without consent, and provided feedback to the CAG.

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. A poster, containing information on the study and how patients or their parents can dissent from their confidential patient information being used, is to be created and displayed in relevant waiting areas at the participating hospital. The poster needs to be submitted for review.

2. Views on the study and the use of confidential patient information without consent are to be sought from relevant patients. Feedback on this activity is to be provided to the CAG.

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 25 September 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. (**DSPT for Birmingham Women and Children's Hospital NHS Foundation Trust is pending).**

c. 19/CAG/0185 - Understanding Multidisciplinary approaches and Parental Input in perinatal mortality Review

Context

Purpose of application

This application from the University of Leicester set out the purpose of medical research that seeks to explore how the implementation of the Perinatal Mortality Review Tool (PMRT) has influenced the multi-disciplinary approach to perinatal mortality review and engagement with bereaved parents.

The PRMT was introduced in 2018 as a web-based tool for maternity and neonatal units in England, Scotland and Wales to review all stillbirths, neonatal deaths and death of babies within the post-neonatal period who had received neonatal care. The PRMT was commissioned by the Healthcare Quality Improvement Partnership (HQIP) and led by MBRRACE-UK, in order to address inconsistencies in the incidence and quality of review carried out within and between hospitals when a baby died. In this

study the applicants intend to explore how the introduction of the PMRT had affected whether the expertise of different healthcare professionals and the views of bereaved parents were included in the review. The aim is to inform professional guidelines around improved multi-disciplinary review and how to better support bereaved parents.

This is a multi-centre study using qualitative and ethnographic methodologies. Direct observations of perinatal mortality review meetings will be undertaken, as well as interviews with healthcare professionals and bereaved patients. The project is comprised of three stages.

Stage One – the researcher will observe a minimum of two perinatal mortality review meetings at each participating site in order to observe how the reviews are carried out by the healthcare professionals. This involves the incidental disclosure of confidential patient information to the researcher while observing. No confidential patient information will be recorded during these observations.

In Stages Two and Three the researcher will conduct face-to-face interviews with healthcare professionals involved in perinatal mortality review and with parents whose babies were stillborn or who died. Support under Section 251 is not required for these stages.

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	It is anticipated that between 5 to 12 eligible cases will be discussed per perinatal mortality review meeting. The timeframe for inclusion in the study is not yet known, as it is dependent on when the observation period in each participating trust takes place.

Data sources	1. Maternal and neonatal medical details discussed during the perinatal mortality review meetings
Identifiers required for linkage purposes	No identifiers will be collected for linkage purposes
Identifiers required for analysis purposes	No identifiers will be 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 that the application had a clear public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

The applicant advised that consent was impracticable as it was not always known in advance which cases would be discussed at each perinatal mortality review meeting. They also sought to avoid causing unnecessary distress to the parents by approaching them for consent.

The research methodology required the observation of naturally occurring phenomena. If parents refused consent and the researcher needed to exit the meeting during discussion of those patients, the natural flow of meeting may be disturbed, potentially impacting on the usefulness of the information gathered during the observations. Members accepted that seeking consent was impracticable and that parents may be distressed if approached for consent.

- Use of anonymised/pseudonymised data

The applicant explained that the study was conducted using ethnographic research methodology. Attempts to anonymise or pseudonymise confidential patient information during the perinatal review meetings would potentially impede the discussions carried out and affect the quality of the data collected. The Sub-Committee noted that it was impracticable to anonymise or pseudonymise the discussions and that the applicant would not collect any items of confidential patient 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.

Prior to undertaking the observations, a letter will be sent to all parents whose baby may be subject to perinatal mortality review during the subsequent six months. The letter explains the research project and how parents can object to the researcher being present during a meeting when their child's death was discussed. The Sub-Committee noted the process and supporting documentation and was satisfied that the described mechanism was appropriate.

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 local Sands (Stillbirth and Neo-natal Death charity) Group co-ordinator and the Chair of the local Maternity Voices Partnership both sat on the Thesis Committee for this research project. The applicant also met with volunteers who run the local Sands support group and the Senior Research and Prevention Advisor at Sands in order to discuss the proposed methodology and the study documents. The study documents were revised following this consultation.

The issue of access to confidential patient information without consent was also discussed with the local Sands group, who gave opinions on whether it was appropriate to have a researcher present during review meetings. A written statement of the group's support for this and a letter of support from the Senior Researcher and Prevention Advisor at Sands was submitted with the application.

The Sub-Committee noted the ongoing patient and public involvement carried out and the contribution that Sands had made to the development of the study information.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further actions are required to address the standard conditions of support.

Specific conditions of support

The following sets out the specific conditions of support.

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

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 - An NHS Digital DSPT submission for Kettering General Hospital NHS Foundation Trust is required.**

d. 19/CAG/0188 - A Population Based Study of Genetic Predisposition and Gene-Environment Interactions in Prostate Cancer In East Anglia, Trent and West Midlands

Context

Purpose of application

This application from the University of Cambridge set out the purpose of medical research that seeks to obtain epidemiological information and biological material on a population-based series of prostate cancer cases, for the purpose of Identifying novel cancer susceptibility genes

The SEARCH study began in 1996. Participants were identified by the local cancer registry, the Eastern Cancer Registration and Information Centre (ECRIC). Participants were asked to provide a blood sample, from which the research team extracted DNA for genetic analyses, to complete a comprehensive questionnaire on their lifestyle and family history of cancer and gave consent for the research team to access their medical records and to retrieve pathology material. The applicants ceased recruiting new participants to the prostate arm of SEARCH in March 2013, due to funding. The anonymised data already collected is still used for research. The applicants are now seeking support to link this data to National Cancer Registration and Analysis Service (NCRAS) data held by Public Health England in order to update the data. NCRAS also provided regular updates on vital status from routine death notification data.

The original consent form for the application contained a clause giving consent for this access. Due to recent developments, and in accordance with guidance from the Medical Research Council and the HRA on the preparation of participant information, the participant information sheets and consent forms for arms of SEARCH where new participants are still being recruited had been updated to fully explain the access to patient records and data linkages required, including specifying that patient's electronic patient records would be accessed. The applicants had determined that it would be impracticable to recontact and consent the existing participants in the SEARCH prostate study, and were therefore seeking support under Section 251 to continue to receive confidential patient information from the Public Health England (PHE) Cancer Registry.

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	4,700 patients diagnosed with prostate cancer, who had already consented to take part in SEARCH prostate.
Data sources	1. National Cancer Registration and Analysis Service, held by NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Cancer Registration identifier
Identifiers required for analysis purposes	No identifiers will be 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 CAG was reassured that there was sufficient public interest in the research to justify the level of intrusion required.

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 advised that patients had consented to take part in SEARCH prostate study, but the consent form used at the time of recruitment had not specified that the research team would access confidential patient information contained in digital and electronic records. Almost 38,000 patients had been included in SEARCH as a whole since 1996, and the applicant had explained that they did not have up to date contact details for all patients and a significant number of patients may have died. The applicants did not have the resources to trace and reconsent the number of patients involved.

The Group noted that participants had previously given consent but there were now aspects of the project which were considered to be outside the strict interpretation of the original consent and an alternative legal basis was required to legitimise the described processing. Members accepted the rationale given for not reconsenting the cohort.

- Use of anonymised/pseudonymised data

Confidential patient information is required to link data held in the SEARCH prostate database with NCRAS data held by PHE. The Group accepted that this could not be undertaken in 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.

All patients included in this application had already provided written informed consent, agreeing to take part in the study. The SEARCH website had been updated to explain that electronic patient records would also now be accessed and how this was done. Contact details for the study team were also included, should patients wish to withdraw their consent.

Further recruitment to SEARCH prostate was not planned. The applicant advised that, should recruitment restart, then the patient information materials would be updated to reflect that electronic patient records would be accessed and to contain further information on how patients could 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 original study had been reviewed by patients from the Cambridge Breast Cancer Unit, who had also reviewed the original consent form. Regular feedback was provided from patients by telephone and email, and also when returning their questionnaires, as the questionnaires contained space for free text comments.

The applicant noted that participants had given consent for the research team to obtain confidential patient information from patient records, but that this consent did not specifically mention access to electronic patient records. They had received feedback that many patients expected that electronic patient records would be accessed in order to obtain information. The applicants were planning to undertake focus groups with study participants that would include discussion of access to confidential patient information without consent.

The Sub-Committee noted the information given and asked that a report on the further patient and public involvement and engagement carried out was provided at the first annual review. Members also asked that different ways of notifying patients that the project was being undertaken and providing a project specific opt-out were explored during patient and public involvement.

Exit strategy

The applicant explained that recruitment to SEARCH prostate began in 2007 and will run as long as grants continue to be awarded and REC approval is still in place.

Confidential patient information will be held securely and accessible only to the immediate SEARCH recruitment team. All data used in research would be anonymised. Confidential patient information will be deleted at an agreed scientific end point.

The Group agreed that the timeframe given on when confidential patient information would be deleted was not specific enough and asked that a review date, such as three years from the date that support under Section 251 was confirmed, was provided. The Group noted that a justification for any further retention needs to be provided as part of the annual reviews submitted to the CAG.

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. A specific date for the review of the retention of confidential patient information needs to be provided.

Specific conditions of support

The following sets out the specific conditions of support.

1. Further patient and public involvement is to be carried out with feedback to be provided at the time of first annual review. This activity should explore different methods of notifying patients that the study is being undertaken and ways of facilitating study specific dissent.

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

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. **(Confirmed: Public Health England (by NHS Digital email 02 September 2019) and University of**

Cambridge (School of Clinical Medicine) (by NHS Digital email 16 July 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).

e. 19/CAG/0189 - Bart's Gynae Tissue Bank

Context

Purpose of application

This application from the Bart's Cancer Institute at the Queen Mary University of London, sets out the purpose of medical research that seeks to continue the Bart's Gynae Tissue Bank, which was established to provide tissue samples to be used in specific research programmes aimed at improving the treatment of patients with gynaecological cancer.

The applicants will collect gynaecological cancer samples, including ascites, blood and urine for research purposes. In addition to this, they will collect blood, urine and tissue from patients with surgical pathology (benign or malignant), as well as blood and urine from healthy volunteer donors. Tissue samples will be collected via a diagnostic or therapeutic procedure and will include tissue derived from the primary site and from metastatic spread. Fresh tissue will be harvested at the time of biopsy or surgery.

Patients at sites other than Bart's Health NHS Trust will be identified by a suitably trained member of the direct care team at their appointment when the ascitic drain, biopsy or surgical procedure is discussed or when the patient's case is reviewed at a gynaecology-oncology or other multidisciplinary team meeting (MDT). Members of the healthcare team will discuss blood, urine and tissue collection with patients during routine clinical consultations.

At Bart's Health NHS Trust sites, patient records held on electronic and paper records will be screened to identify suitable patients. In this application, support is sought for members of the Research Tissue Bank team, as well as the direct care team to screen and approach suitable patients. Once a member of the Research Tissue Bank team has identified a suitable patient, they will ask a member of the direct care team if it is appropriate to approach the patient. If so, the patient will then be approached for consent and their inclusion in the tissue bank will proceed on a consented basis.

A recommendation for class 1, 3, 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	Patients diagnosed with gynaecological cancer and treated within Bart's Health NHS Trust. The applicants anticipated that 35 patients per month would be deemed eligible for inclusion in the tissue bank.
Data sources	1. Electronic and paper records held within Bart's Health NHS Trust.
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID number 4. Date of birth 5. Date of death 6. Ethnicity
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Date of death 4. Gender 5. Ethnicity
Additional information	The analysis dataset will be retained on the basis of patient consent.

Confidentiality Advisory Group advice

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

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The Group agreed that the level of intrusion involved was proportionate to the public interest of the application. Members recognised that there was an established precedent for activities of this type via the Orchid Tissue Bank, which also operated with section 251 support at Bart's Health NHS Trust.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- Feasibility of consent

At most sites, suitable patients would be identified and approached for consent by members of the direct care team. At Bart's Health NHS Trust, members of the research tissue bank team would identify and approach suitable patients. Bart's Health NHS Trust was the main site and recruited a larger number of patients than the other sites involved. The direct care team currently undertook the identification and consent process, but did not have the resources to continue to consistently undertake this. Support under Section 251 was therefore requested. A letter from the team of Consultant Gynaecological Oncologists at Bart's Health NHS Trust was provided with the application to support this. The Group accepted the rationale given for members of the research team identifying and approaching patients.

- Use of anonymised/pseudonymised data

Members of the research tissue bank team require access to confidential patient information in order to identify and approach patients suitable for inclusion in the tissue bank. The Group accepted that this could not be undertaken in any other way.

Access to confidential patient information

The Group recognised that a different identification and recruitment process would be undertaken at Bart's Health NHS Trust than in the other participating Trusts. Members queried how many research staff would access the notes and requested assurance that the number of staff would be restricted to the minimum number required to undertake the activity.

The Group noted from the information provided within the application that the research staff were working under honorary research contracts at Bart's Cancer Institute and queried who the usual employers of these staff were.

'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 would be approached for consent and given an information sheet and consent form. Patients were able to express dissent at this point.

Bart's Health NHS Trust planned to include information about research in clinic invitation letters, which would provide patients with an opportunity to opt-out, but these had not been created at the time the application was made. The Group noted that the clinic invitation letter would be used as the main method for notification and objection and asked that the text of these letters was provided.

It was explained within the application, that the Bart's site was also currently planning for the implementation of the National Opt-Out, which would be operated from March 2020.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

This application had previously been reviewed by the Experimental Cancer Medicine Centre Steering Group when the original research tissue bank application was submitted to REC. Peer review by a Consultant Genitourinary Pathologist and Principal Investigator of The Orchid Tissue Bank had also been undertaken.

A tissue bank management committee had been created to provide guidance and oversight to the tissue bank. This committee included a patient representative, who attended the quarterly committee meetings where applications to the tissue bank were reviewed and governance of the tissue bank was discussed.

Patients attending gynaecological-oncology outpatients and pre-assessment clinics within Bart's Health NHS Trust were consulted, by way of a survey, to request their views on accessing confidential patient information prior to consent. The surveys were performed between August and September 2019, and were given to women aged between 32 and 78 and from a diverse ethnic background, reflecting the demographics of patients attending Bart's Health NHS Trust. There was general acceptance (100% of 10 patients) that processing of identifiable patient data without consent was acceptable. The survey used was included with the application. The Group reviewed the provided information and were satisfied by the details given.

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. Further information is needed regarding the research staff who will undertake the screening and recruitment process at Bart's Health;

    a. Provide clarification regarding how many research staff will access confidential patient information at Bart's Health NHS Trust in order to identify and recruit suitable patients.

    b. Provide assurance that the number of staff will be restricted to the minimum number required to undertake the activity.

c. Confirm the substantive employers of the research staff who will be undertaking the screening exercise.

2. Provide the text to be used in the clinic invitation letters.

Specific conditions of support

The following sets out the specific conditions of support.

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

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.

   a. **Confirmed: Bart's Cancer Centre has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 04 August 2019.**

   b. **Confirmed: Bart's Health NHS Trust - NHS Digital have confirmed qualified assurance against the organisation's 2018/19 DSPT submission on the basis that the Trust has not met the 95% standard relating to staff security awareness training.**

      As a result, the following specific condition of support has been added: all staff involved in processing data under this section 251 support must have successfully completed local security awareness training before processing any data.

f. 19/CAG/0190 - A prospective surveillance study of conservatively managed children with end-stage kidney disease in the United Kingdom and Republic of Ireland.

Context

Purpose of application

This application from the Renal Association set out the purpose of medical research that seeks to identify incidences of new cases of children who progress to end stage kidney disease (ESKD) for whom a decision is made not to start long-term renal replacement therapy and instead manage their kidney disease conservatively.

Kidney disease is a major health problem for children, their families and the NHS. Progression to ESKD means that renal replacement therapy (RRT), as either dialysis or a kidney transplant, is considered. RRT offers a level of survival but isn't a cure. Long-term treatment can also be burdensome and technically challenging, and conservative care may be a better option. Conservative care is active support of the kidney condition, without RRT, and may include palliative, end of life care. National registries collected information on children with ESKD receiving RRT, but not children with ESKD who were not receiving RRT. It was not known how many children were in the latter group within the UK, the kidney conditions they had and the reasons for opting for conservative care. The applicants aim to identify children who were progressing to ESKD who had not yet made a decision regarding long-term RRT.

British Paediatric Surveillance Unit (BPSU) methodology will be used and cases reported through their e-card reporting system. Doctors are asked to identify patients aged 16 years and under who have progressed to ESKD and for whom a decision has been made to follow conservative care. The doctors will be asked to complete a questionnaire about the child and the care they received. A follow-up questionnaire will also be completed at 12-months.

A recommendation for class 1, 2, 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	Patients aged 16 years and under, diagnosed with End Stage Kidney Disease, who are receiving conservative treatment.

	The number of patients managed conservatively would be similar or fewer to the number of patients receiving RRT, which was 99 children across the UK in 2017. The applicant anticipates that 300 children will be included.
Data sources	1. Medical records in participating Trusts across England and Wales
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Gender 2. 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 the 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 advised that kidney failure in children was rare, therefore complete case ascertainment was important. Seeking consent for this study could introduce bias and lead to the number of incidences being underestimated. Patients would also be unwell and may die outside of the hospital setting, at home or in a hospice, and it would be potentially upsetting to approach their parents or carers for consent. The Group noted that the BPSU methodology has been accepted in principle by the CAG and raised no concerns over the use of the methodology in this application.

- Use of anonymised/pseudonymised data

Confidential patient information is required for the applicant to check cases reported through BPSU for instances of duplication and to enable linkage with follow-up data. The Group accepted that this could not be undertaken in 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.

Information on how patients could opt-out or dissent from the use of their confidential patient information was included in a study information leaflet, which would be made available on the BPSU and Renal Association websites. The leaflet included contact information for the research team, advising who to contact to register dissent.

Details of patients, or their parents, who opted out of the study would be included on the project database before removal of their details. Patients were also able to contact

their treating hospital or doctor to register dissent, in which instance the applicants would not be notified of a potential case. Confidential patient information would need to be retained for patients who dissented after data collection, so that cases reported by different hospitals could be linked and a patient who dissented removed. The NHS number, date of birth and gender of these patients will be retained for the 25-month surveillance period. This retention was explained in the patient information leaflet. The Group noted the information provided and was satisfied that appropriate measures had been taken to inform patients about the 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 research project had been created following discussion with a family whose daughter had been diagnosed with kidney failure shortly after birth. The applicants had also consulted with the Renal Association patient council prior to developing and submitting a BPSU application. The research proposal was also presented to the British Association for Paediatric Nephrology (BAPN) members in 2018, who had supported the project and helped in completing the application to BPSU. Three patient representatives from Kidney Research UK and lay members of the BPSU Scientific Committee had also reviewed and supported the application.

Patient representatives from the Renal Association and Kidney Research UK will also be invited to develop plans to disseminate the results of the study and in developing infographic lay summaries for publication on the Renal Association website and other social media. Input will also be sought from parent and patient groups on social media.

The issue of access to confidential patient information without consent was discussed with patient representatives, who accepted the need for the study design but requested that confidential patient information was deleted or anonymised as soon as possible, which had been taken into consideration when designing the study. The activity in this area appears appropriate and extended further than the standard level seen within BPSU submissions. The Group noted the information provided and was satisfied by the patient and public involvement undertaken.

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.

Specific conditions of support

The following sets out the specific conditions of support.

1. Favourable opinion from REC. **Pending.**

2. 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. **Confirmed: The Renal Association has a confirmed 'Standards Met' grade on DSPT submission by 2018/19 by NHS Digital email dated 14 October 2019.**

g. 19/CAG/0191 - Glucocorticoid induced adrenal suppression in the UK and Ireland

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research that seeks to determine how many patients present to healthcare providers with adrenal suppression (AS) due to current or previous use of glucocorticoid (GC) medication.

Glucocorticoids are steroid hormones produced by the adrenal glands. Natural GCs keep the body working normally and deal with the stress of trauma and infections. GCs are often used to treat diseases in children, such as eczema, asthma or arthritis, and medication can be applied to the skin, inhaled or swallowed. The absorption of large amounts of GC medication can prevent patients from producing GC naturally, which is known as adrenal suppression (AS). This can be a particular problem if a patient has an infection, as natural GC would usually be produced as part of the stress response. If additional GC is not given at this time to patients with AS, then they may become very unwell and develop adrenal crisis, which can be fatal. Health professionals may not remember that GC medication can prevent natural GC

production and that additional GC may be needed. AS may also persist if a patient has recently stopped taking GC medication. The applicants will investigate how commonly children present at hospital due to AS in order to develop ways of preventing adrenal crisis.

The study will be conducted retrospectively using British Paediatric Surveillance Unit (BPSU) methodology. Paediatricians will be contacted via BPSU and asked if they have seen a patient aged under 16 years with AS caused by GC medication. If the paediatrician reports such a case, they will be sent an in-depth questionnaire regarding the patient and their presentation to healthcare professionals. The questionnaire can be returned via REDCap software, returning the questionnaire via secure NHS.net email addresses or by post. The questionnaire data will be pseudonymised at the earliest opportunity. The applicants will also obtain HES data relating to cases of drug induced adrenocortical insufficiency, in order to gauge the size of the at-risk population. The data supplied by HES will be aggregated.

Only summary data regarding age, gender and ethnicity of identified individuals will be used in any presentations or publications.

A recommendation for class 2, 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	Patients aged 16 years and under treated or recently treated with glucocorticoid therapy who has adrenal suppression in England. It was expected 30-40 cases per year would be reported Across the 25-month reporting period.
Data sources	1. Medical records at participating Trusts in England. 2. HES data held by NHS Digital

Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – unit level
Additional information	The HES data provided by NHS Digital will be in aggregated form only.

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 the 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

Data was collected retrospectively from cases notes by the reporting clinicians, who were members of the direct care team. Most patients would have been discharged, referred on or no longer under follow-up by the reporting clinician. Some may also have died since their treatment. The applicant noted that complete case ascertainment

was required due to the rare nature of the disease and that it was important to accurately record incidences in order to estimate the prevalence. The Group noted the rationale given for not seeking consent and raised no queries.

- Use of anonymised/pseudonymised data

Confidential patient information is required in order for the reporting clinicians to send details of suitable patients to the study team, and for the study team to undertake data validation and de-duplication. The Group recognised that 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 applicant advised that a public information leaflet was available to inform patients that the study was taking place. This would be displayed on the BPSU and Newcastle University websites. The applicants would also promote the study via family support and relevant patient groups.

The patient information leaflet contained a section titled clearly 'What if I do not want to be involved'. This section states that hospitals will record if parents do not want their child's notes to be used for audit or research and that they must tell their doctor if they do not want their child's notes used. If this dissent is recorded then their child's information will not be reported to BPSU.

The Group noted the information provided and was satisfied that reasonable steps had been taken to inform the public that the research was taking place.

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 study was discussed with representatives from the Duchenne Muscular Dystrophy support group, the Pituitary Foundation and the Addison's patient organisation. Opinions were sought on the study design, including the use of confidential patient information without consent, and the groups expressed support. Letters of support from these groups were provided with the application. The Group noted the information provided and was satisfied with the patient and public involvement carried out.

Confidentiality Advisory Group advice conclusion

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

Specific conditions of support

The following sets out the specific conditions of support.

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

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: Newcastle University (by NHS Digital email 05 July 2019) and NHS Digital (by NHS Digital email 10 June 2019).**

Signed – Officers of CAG | Date

Signed – Confidentiality Advice Team	Date