Health Research Authority

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

June 2019

Present:

Name	Capacity	Items
Dr Patrick Coyle	CAG Vice-Chair	1.a, 1.b
Dr Malcolm Booth	CAG Member	1.b
Dr Lorna Fraser	CAG Member	1.a
Mr Anthony Kane	CAG Member	1.a
Dr Harvey Marcovitch	CAG Member	1.b
Dr Tony Calland MBE	CAG Chair	1.c, 1.d
Professor Jennifer Kurinczuk	CAG Member	1.d
Ms Diana Robbins	CAG Lay Member	1.d
Mr Marc Taylor	CAG Member	1.c
Ms Gillian Wells	CAG Lay Member	1.c

Also in attendance:

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

1. NEW PRECEDENT SET REVIEW APPLICATIONS – RESEARCH

a) 19/CAG/0088 - Realist Evaluation of Pressure Ulcer Risk Assessment Instruments in Clinical Practice: Theory Testing

Context

<u>Purpose of application</u>

This application from the University of Leeds set out the purpose of medical research which aims to develop understanding of how risk assessment tools to assess pressure ulcers (PU) are used in clinical care.

Two tools will be assessed. The standard form is the Pressure Ulcer Risk Assessment (PU-RAI) forms, which help nurses to identify patients 'at risk' to prompt preventative measures (e.g. nursing care, mattresses). The Pressure Ulcer Risk Primary or Secondary Evaluation Tool (PURPOSE-T) was robustly developed/evaluated and has since been implemented in several NHS acute hospitals. A realist evaluation will be undertaken to understand how different contexts influence particular nursing team responses and give rise to different outcomes when using PURPOSE-T and standard forms. The realist evaluation incorporates four phases; ward based theory testing, wider interviews with staff from other hospitals, a focus group held with the Pressure Ulcer Service User Network (PURSUN), and a guideline development stakeholder focus group.

The application to the CAG focuses on one element of the first project phase which will be undertaken prior to patients being approached for consent. The researcher will observe staff handover and ward meetings where patient details will be discussed, including medical details and care planned and delivered. The applicant will utilise these observations to identify and discuss patients who maybe potentially suitable to be approached for consent for the wider elements of the study.

A recommendation for class 3, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients within the following treatment wards during the time of staff observations at each of the two participating Trusts. Eight wards will be included in the research observations, including two high-risk elderly medical wards (one admission, one medical) and two varied-risk adult surgical wards (one surgical admission, one general surgical).
Data sources	1. Observations of staff handovers and meetings held within Leeds Teaching Hospitals NHS Foundation Trust and Bradford Teaching Hospitals NHS

	Foundation Trust
Identifiers required for linkage purposes	Not applicable – no confidential patient information will be accessed or recorded
Identifiers required for analysis purposes	Not applicable – no confidential patient information will be retained
Additional information	Confidential patient information will be disclosed during the observations of staff handover and ward meetings. Nothing will be recorded at this stage and is not required for the purposes of analysis.

Confidentiality Advisory Group advice

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

Public interest

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

Scope of support required

It was recognised that within the application form at Q56, Class 3 support which extended to the identification of patients to be approached for their consent, had been selected as necessary to cover the application activities. However, the application itself only described the requirement for support to cover the incidental disclosures of confidential patient information during the staff handover and ward meeting observations.

Members queried whether the applicant was also seeking support to cover the approach to potential participants for the patient observation element of the study. The Group agreed that clarity would be required from the researcher in this area. It was further commented that, to obviate the need for support for this activity, this consent approach could be made by the direct care team. The

applicant would need to justify why this was not feasible, if seeking support for this element of the application activity.

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 explained that it would not be feasible to seek consent from all patients within the ward, prior to undertaking the observation of staff activities. It was explained that as it would be unclear which patients would be discussed within these staff interactions, the burden of seeking consent from all patients, including some who will not be discussed was disproportionate to the proposed activity. It is also commented that this appeared to place an unnecessary burden on patients, when confidential patient information will not be directly accessed or recorded during the observations. It is further noted that operating a consenting mechanism would heighten awareness of the ongoing project which may lead to changes in normal clinical practice.

Members were assured by the rationale provided in this area and were content to provide a recommendation of support to the activity on this basis.

- Use of anonymised/pseudonymised data

The CAG recognised that support was being sought to legitimise the incidental disclosure of items of confidential patient information during the researcher's observation of staff meetings and handover activities. The focus of this activity was the staff interaction and no confidential patient information would be recorded or retained. No issues were raised in this area.

'Patient Notification' and mechanism for managing dissent

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

A poster document had been provided which would be displayed in wards to inform patients about the research observations which were being undertaken. The document included detail around the patient's right to object. It was recognised that the ward staff were blinded to the purposes of the research observation to prevent any change to the care delivered. As such, the document did not provide specific detail about the focus of the study.

Members acknowledged that the document included a picture of the researcher, to enable this person to be immediately identifiable to patients and staff, which was helpful. However, it was commented that the document did not make clear that staff meetings and handovers would also be observed. The Group agreed that the document should be revised to provide clear information around the complete scope of the project and provide a means to object to this element.

Patient and Public Involvement and Engagement

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

A specific Pressure Ulcer Research Service User Network was established to support research in this area. The Group considered and were supportive of the application and will also consider the findings and how these can be implemented into future guidance. Members were satisfied that the activity undertaken in this area as appropriate and proportionate to achieve the study aims. No queries were raised in this area.

Confidentiality Advisory Group advice conclusion

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

In order to complete the processing of this application, please respond back to all of the request for further information, within one month,

Request for further information

1. Confirm whether is the request for support under the Regulations was intended to cover the approach for patient consent for the direct patient observations.

2. If so, provide a stronger justification to support why this approach for consent cannot be made by the direct care team.

3. The poster document should be revised to provide detail around the potential for incidental disclosures of confidential patient information during the staff observations. This should provide details of how a patient can object to this element of the study.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. (**Confirmed 15 April 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: Leeds Teaching Hospitals NHS Trust and Bradford Teaching Hospitals NHS Foundation Trust – NHS Digital reviews pending)**

b. 19/CAG/0108 - Utility of biomarkers for ovarian cancer risk assessment in primary care: a pilot study

Context

<u>Purpose of application</u>

This application from the University of Manchester set out the purpose of medical research which aims to assess the efficacy of a blood test, known as CA125, versus testing for presence of a biomarker known as HE4, in the identification and diagnosis of ovarian cancer.

The study was designed in two phases. The first phase involved comparing the performance of the HE4 and CA125 tests in the samples of 1200 symptomatic women who presented to their GP. CA125 samples underwent additional

testing for HE4 at Central Manchester University Hospitals NHS Foundation Trust. As this additional testing was undertaken on the surplus routine sample material and research was led by members of the usual gynaecological clinical care team, consent was not taken from patients for this phase of the study.

In order to complete this phase of the study, the applicant intends to follow-up the patient cohort via the National Cancer Registration and Analysis Service at Public Health England, in order to determine which patients have subsequently been diagnosed with cancer. The application has been submitted to the CAG to seek support under the Regulations to legitimise the disclosure of NHS Numbers to Public Health England in order to facilitate linkage with the NCRAS database and collate the required follow-up data. The second phase of the study is out of scope for the application to the CAG as, whilst based on the initial phase of the study, this will involve a separate patient cohort which will be approached for consent to participate in the study by a member of the clinical care team at Manchester Central University Hospitals NHS Foundation Trust.

A recommendation for class 1, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	1227 women who were included in phase one of the trial, following presentation at their GP practice symptomatic of ovarian cancer and were referred to the Manchester Central University Hospitals NHS Foundation Trust to undergo CA125 testing between 03/04/18 and 18/04/19.
Data sources	1. Electronic patient records held at Manchester Central University Hospitals NHS Foundation Trust, 2. National Cancer Registration and Analysis Service database held by Public Health England.
Identifiers required for linkage purposes	1. NHS Number.

Identifiers required for analysis purposes	The applicant advised that no items of confidential patient information would be required for analysis.
Additional information	The study involves a second phase which will be operated on a consented basis and is out of scope of 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 study was within the public interest due to the potential for improvements in the diagnosis of ovarian cancer.

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 provided a number of arguments to support the application proceeding on an unconsented basis. It was explained that as the testing of patient samples carried out in the initial phase of the study had been undertaken without specific consent, to approach patients at this stage for consent for follow-up via the cancer registration service may lead to undue distress. It was further explained that as the patient cohort was referred from across 30 GP practices, it would be difficult to operate a consenting model.

The Group was assured by the applicant's justification for proceeding on an unconsented basis with support under the Regulations. No issues were raised in this area.

- Use of anonymised/pseudonymised data

It was acknowledged that confidential patient information was required to facilitate linkage with the NCRAS database which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

Members recognised that the proposed linkage process would be undertaken using patient's NHS number alone, which was the minimum to facilitate this linkage. No queries were raised in this area.

'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 detailed rationale to support why it would not be feasible to send information to patients included in the study on an individual level. Members were in agreement that this did not appear to be a feasible model.

Information about the study would be placed on the Cancer Research UK (CRUK) Clinical Trials website and the UK Clinical Trials database. Members agreed that the text displayed on the CRUK website should include information around the patient's right to object to the use of their data within the study. It was noted that the UK Clinical Trials database website appeared to be designed for a clinical audience, rather than patients.

Whilst Members agreed that the CRUK website was an appropriate place to display information about the study, it was unclear whether patients within the cohort would have reason to review this website. The Group agreed that further action was required to promote the study locally and to inform patients of their right to object to the use of their data within the study.

It was recognised that the Manchester Central University Hospitals NHS Foundation Trust website had a specific area focussed on research which could be utilised to promote the study. It was also noted from this area of the website that the Trust circulated a newsletter about ongoing research studies to interested patients. Members queried whether it would be possible to include an item within the newsletter around this specific phase of the study. These

communication methods would also allow promotion of a patient objection mechanism. The applicant would be asked to explore these wider communication options and confirm a local strategy for promoting the study together with a dissenting mechanism for patients.

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 advised that five patients were involved in a patient group which was organised by NIHR Manchester Biomedical Research Centre. These were women aged between 45 and 70 with a diagnosis of ovarian cancer. Notes from the meeting were provided for information purposes.

The feedback provided from this meeting evidenced support for the project and its proceeding on an unconsented basis. The attending representatives did state that as they had a diagnosis of ovarian cancer, their views may differ from those patients who were not affected. Members acknowledged the summary provided from the engagement activity, which was overall in support of the project. No further issues were raised in this area.

Confidentiality Advisory Group advice conclusion

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

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Revise the text to be displayed on the Cancer Research UK website to include information around how a patient can raise an objection to the use of their data in the study. This should include relevant contact details. Provide a copy of the revised text for consideration.

2. The study should also be promoted via the Manchester Central University Hospitals NHS Foundation Trust website. Provide an overview of how this additional communication would be undertaken,

together with copies of any text for consideration. The information should also include details of how a patient can object to the use of their data within the study.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

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

1. 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 – NHS Digital's review of Public Health England DSPT is outstanding**).

c) 19/CAG/0089 - Evaluation of diagnostic accuracy of punch biopsies

Context

Purpose of application

This application from the Norfolk and Norwich University Hospital NHS Trust set out the purpose of medical research which aims to evaluate whether the size and position of a punch biopsy taken from a lesion effects the accuracy of the of the subsequent histological diagnosis.

Patients records will be accessed on site within the pathology department at Norfolk and Norwich University Hospital NHS Trust and James Paget University Hospitals Foundation Trust by members of the research team and secretaries and administration staff within the histopathology department in order to identify a cohort which underwent punch biopsies. Theatre registers may also be accessed to identify wider patients. Confidential patient information would then be used to access histology information contained in patient records to facilitate study analysis.

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	Adult patients (aged 18 and over) who underwent skin punch biopsy at Norfolk and Norwich University Hospital NHS Trust and James Paget University Hospitals Foundation Trust between 01/04/09 to 31/03/19 who have final histology information available within the patient records. It is estimated that 1500 records will be included in the study.
Data sources	1. Health records held within Norfolk and Norwich University Hospital NHS Trust 2. Theatre registers held within Norfolk and Norwich University Hospital NHS Trust 3. Health records held within James Paget University Hospitals Foundation Trust 4. Theatre registers held within James Paget University Hospitals Foundation Trust
Identifiers required for linkage purposes	1. Name 2. Hospital ID 3. Date of Birth
Identifiers required for analysis purposes	Not applicable.
Additional information	Nothing further to add.

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.

<u>Public interest</u>

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 recognised that understanding the impact of the size and placement of a skin punch biopsy on the efficacy of the subsequent histological diagnosis could improve practice for patients in future. The Group was satisfied that this was within the public interest and raised no queries in this area.

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.

- Data extraction by the direct care team

The direct care team did not have the capacity or resources to undertake the data extraction on behalf of the researchers. The Group recognised the time commitment required to extract the required study data across the cohort of 1500 patients and raised no queries in this area.

- Feasibility of consent

The applicant advised that consent was not feasible for the proposal due to the retrospective nature of the patient cohort to be included, who may be deceased or lost to follow-up. It was further commented that operation of a consenting mechanism may introduce a bias into the patient sample.

Consideration had also been given to the feasibility of operating the study on a prospective consented basis. However, the applicant explained that it would not be possible to recruit sufficient patients within a sensible timeframe to enable meaningful analysis to take place. It was also noted that this methodology would be incredibly time-consuming for the research team who were undertaking this analysis in addition to their standard clinical commitments. Members were assured by the rationale provided and raised no queries in this area.

- Use of anonymised/pseudonymised data

Confidential patient information would be accessible to the researchers when extracting the necessary clinical information for analysis from patient records, which could not be otherwise achieved. No issues were raised in this area.

Justification of identifiers

The items of confidential patient information requested were appropriate and proportionate to achieve the study aims. No queries were raised in this area.

Exit Strategy

Support under the Regulations was being sought on a time limited basis only to enable the extraction of the necessary clinical information required for the study analysis. The applicant would be extracting anonymised information from patient records and assigning a unique study ID. Members accepted the methodology and raised no queries in this area.

'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 poster document which would be displayed in appropriate clinical areas of the Trusts to inform patients about the study. Members agreed that the poster was visually quite dense and commented that some of the language used may not be accessible to all readers. It was further noted that whilst the poster did provide contact details for any objections, it did not clearly explain the patient's right to dissent to the use of their data in the study.

The Group agreed that the poster should be revised to address these points and make the document more accessible to patients. It was recommended that the views of patients and the public should be sought during this process to inform the revised content and design. It was also commented that the onsite posters could be supported by information on the Trust websites. This would be followed up with the applicant.

The applicant had stated that there was no systematic way to check patient records for evidence of historic dissent. Members queried this point as it was known that patients had the right to object to the use of their data for purposes wider than direct care under the national opt-out mechanism and its predecessors. It was queried whether this information would be held centrally within the Trusts and could be applied to the study cohort prior to data extraction to ensure that any known patient dissent would be respected. It was agreed that further information would be requested in this area.

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.

It was advised that patients had been approached by the main applicant in clinic around the study. A limited overview had been provided about this activity and the feedback provided by patients.

Members were unclear from the detail provided how patients had been involved in this activity, what information had been given about the study and the necessity to access confidential patient information without consent or the specific feedback given by those involved. The Group agreed that further work was required in this area to evidence that patients were supportive of the project and its design, to confirm the public interest in the activity proceeding on an unconsented basis.

It was commented that the Trusts involved in the project were likely to have established patient groups who can be approached for feedback on research proposals. Feedback would be required around the format this activity took, the demographics and number of patients involved, detail of how the study was explained and an overview of the response provided, with particular focus on the use of confidential patient information without consent. This information was required prior to any final recommendation of support coming into effect for the project.

Confidentiality Advisory Group advice conclusion

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

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. The poster document should be revised to make this more accessible to patients. It should also include clear information around the patients right to object to the use of their data in the study. It is recommended that patient views on the revised document be sought as part of wider patient and public involvement activity.

2. Supplementary patient information should be placed on the Trust websites – confirm agreement to this point and provide copies of any material for review.

3. Clarify whether the Trusts hold a central record of any known patient dissent against the use of data for purposes wider than direct care which can be applied to the study sample.

4. Further patient and public involvement and engagement activity should be carried out. Provide an overview of the format the activity took, the number and demographics of those involved, what information was provided about the study and feedback of those present, with a focus on the use of confidential patient information without consent.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 05 March 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 – reviews pending for Norfolk and Norwich University Hospital NHS Trust and James Paget University Hospitals Foundation Trust.**

b) 19/CAG/0094 - A national mixed methods study to evaluate whether out of hospital oral anticoagulation programs for children and young people with congenital heart disease are safe, high quality and effective.

Context

<u>Purpose of application</u>

This application from Great Ormond Street Hospital for Children NHS Foundation Trust set out the purpose of medical research which aims to evaluate whether out of hospital oral anti-coagulation programs for children and young people with congenital heart disease are safe, high-quality and effective.

The study will be carried out in three phases. The second phase involves a review of patient records across the 10 national children's heart disease service centres. This element of the study has been described in the application as a national audit of children receiving out of hospital oral anti-coagulation treatment programs, in order to create a baseline for the purposes of this research study. This activity is being undertaken solely for the purposes of this research application and does not have any non-research audit purposes.

A recommendation for class 1, 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	Children aged over four months, and young people in England with congenital heart disease on oral anticoagulation medication (warfarin) for more than four months and discharged home. There are estimated to be 300 eligible patients to be included in the sample.
Data sources	1. Electronic Health records held within 10 specialist children's heart disease centres in England.
Identifiers required for linkage purposes	1. Name 2. Hospital Number 3. Date of birth
Identifiers required for analysis purposes	1. Age 2. Gender 3. Ethnicity 4. County or similar geographical boundary
Additional information	The application also involves two wider phases: • Parent/patient interviews – the applicant will not have any access to confidential patient information for this element prior to consent. This element is out of scope of the CAG application. • Parent/parent questionnaire – distribution of the questionnaires will be undertaken by site-based members of the clinical team. This element is out of

	scope of 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 recognised the importance of gaining a greater understanding of the safety and efficacy of out of hospital oral anti-coagulation programs for children and young people with congenital heart disease, which are an at-risk population. Members were assured that the creation of the baseline dataset was within the public interest as this would inform the wider study.

Practicable alternatives

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

- Minimising flows of identifiable information

The applicant had confirmed that the clinical care team would identify the clinical records of patients to be included in the study. As such, the applicant would not require access to wider medical records in order to identify the cohort. The Group recognised that this limited the scope of support required under the Regulations to only those patients who were being treated with out of hospital anti-coagulant therapies. No issues were raised in this area.

- Feasibility of consent

The applicant had provided a number of justifications to support the study proceeding on an unconsented basis. It was firstly explained that the baseline record analysis had been designed to mirror the methodologies of the wider national audit activities carried out under the National Cardiac Audit Programme. This programme of audits operates with support under the Regulations. It was further explained that to facilitate a consenting process would put an unnecessary burden on patients, their parents and clinicians. There was also a lack of lack resource to support this activity.

The CAG was assured by the rationale to support the activity proceeding on an unconsented basis and raised no queries in this area.

- Data extraction by the direct care team

The applicant had confirmed that the local clinical teams were not able to undertake the data extraction on behalf of the study due to limited capacity in the local team. Members received this confirmation and raised no further queries in this area.

- Use of anonymised/pseudonymised data

Confidential patient information was required for the purposes of sample validation and would be accessible within the patient's records viewed by the applicant when extracting the pseudonymised clinical information required for analysis. The CAG recognised that confidential patient information would be accessed during the course of the clinical data extraction which could be otherwise achieved. No queries were raised in this area.

Justification of identifiers

The items of confidential patient information requested were agreed to be appropriate and proportionate to achieve the study aims.

Exit Strategy

Support was requested on a time limited basis to enable the data extraction from patient records to be achieved. The applicant anticipated this process would take approximately 13 months to complete, allowing for flexibility at sites and for the research team. Members were unclear whether a linkage file would be maintained at sites. It was agreed that clarification around this point was necessary.

The Group also queried how long the resulting study dataset would be retained and in what format. This point would be raised with the applicant for clarification.

'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 explained that local notification and dissent arrangements were in place at sites in relation to the overarching National Cardiac Audit Programme. Members commented that communications of this type related to the overarching

audit programme and could not be relied upon in relation to this specific research study.

The CAG agreed that a project-specific communications strategy should implemented to inform patients and their parents about this study and provide a means for dissent to be raised. Copies of any materials to support this should be provided for review, together with an overview of how project-specific objection would be managed.

The applicant had explained that clinicians would be aware of any historic dissent raised by patients or their parents and would apply this prior to releasing medical records for the purposes of the research. Members agreed that further information was required in this area to explain how the localised objection mechanism was operated and to provide assurance that this would be respected.

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 had explained that a children and young people's advisory panel had been involved with the study from an early stage. An ongoing programme of activities in this area had been described which would progress alongside the project. Members were assured that the activities described were appropriate and proportionate to the proposed activity and raised no queries in this area.

Data Protection Compliance

It is a requirement within the Regulations that any approved activity cannot be inconsistent with the General Data Protection Regulation and Data Protection Act (DPA) 2018. Limited information had been provided by the applicant to explain how the proposed activity was compliant with current data protection legislation. Further information would be requested in this area to evidence how the activity is compliant with the principles of the GDPR (Article 5(1)(a-f) and Article 5(2) accountability principle). The response would need to clarify what legal basis is being relied upon for processing data and special category data. It was recommended that guidance was sought from the data governance team around these queries.

Confidentiality Advisory Group advice conclusion

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

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Clarity whether a linkage file will be retained between the pseudonymised clinical dataset for phase two and confidential patient information. If so, please clarity who will have access to this file and at what stage this would be destroyed.

2. Confirm in what format the data extracted in phase two of the project will be retained and for what duration.

3. A project-specific communications strategy and dissenting mechanism should be established. Details should be provided around how this would be operated, together with copies of any documentation for consideration.

4. Provide further information around the dissenting mechanism which was currently operated as standard across sites and explain how this would be implemented into the study.

5. Provide further information to evidence compliance with the principles of the GDPR (Article 5(1)(a-f) and Article 5(2) accountability principle). The response would need to clarify what legal basis is being relied upon for processing data and special category data. It was recommended that guidance was sought from the data governance team around these queries.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee (**Confirmed**).

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 **(Not checked due to the number of sites involved – support is recommended on the**

basis that the applicant ensures that the security standard has been achieved at each site before processing data with support under the Regulations).