Minutes of the meeting of the Confidentiality Advisory Group

21 November 2019 at HRA Manchester, Barlow House

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr Patrick Coyle	Yes	CAG Vice-Chair
Professor Barry Evans	Yes	CAG Member
Dr Lorna Fraser	Yes	CAG Member
Dr Katie Harron	Yes	CAG Member
Prof Jenny Kurinczuk	Yes	CAG Member
Dr Harvey Marcovitch	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Mrs Diana Robbins	Yes	CAG Member
Mr Marc Taylor	Yes	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Natasha Dunkley (by telephone)	Head of Confidentiality Advice Service
Ms Kathryn Murray	Senior Confidentiality Advisor

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **17 October 2019** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **17 October 2019** meeting applications.

3. **New Applications** – Research

a. 19/CAG/0223 – TwinsUK: Phenotypic enrichment of the TwinsUK cohort through data linkage to electronic health records and other databases

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to undertake record-based follow-up of patients recruited to the Twins UK trial. The Twins UK study was established in 1992 and is the largest longitudinal cohort of community dwelling adult twins in the UK, comprising over 14,000 volunteer twins

in predominantly midlife. All patients are included within the main study on the basis of informed consent.

Participants have provided self-reported questionnaires, physical/cognitive measures and biological samples through clinical visits approximately every four years, for researchers to investigate how environmental factors and genetics interact to impact health over the life course. The longitudinal biobanking of samples over the last 25 years has enabled research on early detection of disease. TwinsUK participants have, from enrolment, given their informed consent for these data to be used for health research.

This application has been submitted to seek section 251 support to enable the Twins UK cohort to be linked with primary and secondary care records, cancer registration and mortality data held in a variety of data sources. Wider linkage with educational records held by Department for Education is also requested. The application has been informed by the ALSPAC (Avon Longitudinal Study of Parents and Children) programme which operates with support under the Regulations via reference ECC 1-05(b)/2012.

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	All participants within the Twins UK trial. This encompasses 14,400 patients.
Data sources	1. Hospital Episodes Dataset, NHS Digital 2. Mental Health Minimum dataset (MHMDS), NHS Digital

	3. Office for National Statistics (ONS) Mortality Data, NHS Digital 4. Cancer registration, NHS Digital 5. Patient Demographics Service, NHS Digital 6. Patient Episodes Dataset Wales (PEDW), NHS Wales Informatics Service 7. GP Practice records, various providers 8. Educational data, Department for Education
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. GP Registration 5. Date of birth 6. Date of death 7. Postcode (unit level)
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode (unit level) 4. Sex 5. Ethnicity
Additional information	

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 that the TwinsUK dataset was an incredibly valuable dataset which would be enriched via the proposed data linkage exercise. It was noted that there was potential for significant public interest to be achieved from the study of clinical outcomes within twins, which would be improved from the proposed activity.

Whilst the Group recognised this overarching public interest in the data linkage exercise, it agreed that assurance was required of the purpose and value of each of the cited data sources to ensure that there was a clear public interest in each specified activity. The applicant would be asked to provide an overview of the potential research questions, specific to twins, which it was hoped would be addressed from the linkage with each proposed data source. This additional assurance was required to ensure there was a clear medical purpose and perceived public interest to be achieved from each of the proposed data linkages.

Scope

The applicants had cited within the application that support was sought for the disclosure of confidential patient information items to the various named healthcare data providers, in order to facilitate linkage with the named health datasets. It was explained that the linkage to educational data and wider environmental information did not form part of the application for support, on the basis that these were not healthcare datasets and were of out the CAG's remit.

Members noted that whilst support could not be extended to the disclosures from educational and environmental datasets, there would still need to be a legal basis in place to facilitate the disclosure and processing of confidential patient information required to undertake the linkage processes. As the participants within the TwinsUK study had not provided consent for the use of their data for these purposes, the

applicant would be required to clarify what legal basis was being relied upon, in relation to the common law duty of confidentiality, to legitimise these activities.

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 patient cohort is included in the overarching TwinsUK research programme on the basis of consent. The study was established in 1992 and since this time has had active engagement with participants, collecting questionnaires and self-reported clinical outcomes as well as biological samples every four years. Whilst there is active engagement from the patient cohort, the applicant cited the ALSPAC model to support the justification that attempting to seek consent from the full patient cohort for the record linkage project may have a negative impact on the potential value of this element of the research project.

The ALSPAC study has been working towards seeking consent from one cohort of its patient group – in seven years of postal and face to face follow-up, consent has been confirmed from 43% of its 13.327 patients in this cohort. The ALSPAC study has also reported that those patients who actively engaged in consent differentiated in social and health status. The applicants for this proposal stated that in operating the data linkage element of the research programme on a consented basis there was potential for the cohort to be biased to a certain patient demographic which will impact the validity of the results.

The applicants will send direct contact information to all enrolled participants about the data linkage exercise and provide a means for dissent to be raised. This direct communication would also be supplemented by a programme of scheduled contact with participants across the duration of the linkage study – it is estimated that 750 pairs of twins will be seen each year and directly asked for their view on consent for the data linkage exercise. Any newly recruited patients would be asked to provide consent to the data linkage activities as part of standard consent for participation.

Members acknowledged that there were similarities between the proposed activity and the existing ALSPAC programme. However, it was noted that the TwinsUK study cohort consisted of consented patients, which in itself could be considered a bias sample, as it included only those patients which were willing to consent. By contrast, the ALSPAC study included a whole birth cohort. On this basis, the Group commented that the bias argument did not carry the same weighting for the TwinsUK study.

The CAG was persuaded that, on the basis of the size of the TwinsUK cohort, operating an informed consent model for the data linkage project was not feasible. Members acknowledged that whilst there was potential that the patient cohort included within the TwinsUK study may not be representative of the twins population, having initially operated on a consented model, they accepted that this was a significant and valuable cohort and were assured that this activity should proceed on an unconsented basis.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to facilitate the linkage process between the TwinsUK cohort and the specified data sources, which the CAG accepted could not be achieved in another manner.

Justification of identifiers

The Group noted discrepancies in relation to the items of confidential patient information which were required for the proposed activity between the application form and supporting documentation. As an example, hospital number was specified within the application form, but had not been included in the data flow diagram. It was also noted that the application suggested that section 251 support was not required to extend to the use of patient postcode, which was generally considered to be an item of confidential patient information, which required a legal basis for processing.

Members agreed that confirmation would be sought from the applicant around all items of confidential patient information which would be utilised within the proposal and to provide a justification for each item. This would ensure any recommendation of support extended to all required data items.

Data flows

The application described a complex and comprehensive programme of data linkage. Whilst a detailed overview had been provided around the data sources which would be linked within the scope of the application activity, Members were unclear about the specific data flows which would support this, what items of confidential patient information were necessary for each linkage and what information would be included in the resulting dataset following linkage.

A dataflow diagram had been provided within the application; however, this single document provided an overview of all proposed disclosures and linkages. Members agreed that the document was too complex and did not provide sufficient clarity on each linkage.

The applicant was reminded that where section 251 support is recommended, this is proscriptive and only extended to the organisations, purposes, data items and flows described within the application. As such, a clear and specific overview was required of the organisations which would be processing with support and the data items which each would receive.

The Group agreed that the applicant would be asked to provide individual flow diagrams for each proposed linkage, to ensure that the data flows required to facilitate linkage with each proposed data source were clearly understood. These documents should follow the flow of data between the applicant and wider organisations, specifying the items of confidential patient information being processed at each stage, which data flows required a recommendation of section 251 support and the entities which were undertaking the processing. Any acronyms which were cited within the dataflow diagrams should also be explained.

Data sources

The CAG requested a detailed overview of the dataset which would be compiled from each proposed data linkage, to understand the scope and value of the resulting dataset. Members requested an overview of the information which would be provided from linkage with the Department for Education. It was noted that National Pupil

Database only held data from 1996 onwards. On the understanding that the majority of the patient cohort was now in midlife, it was unclear how many would be present within these records and what value would be achieved from this linkage. The patient information leaflet also made reference to collating information on courses and training participants were undertaking and it was unclear how this information would be collated.

It was further commented that the Department for Education had access to wider social care data, including information around children who received free school meals and those who had been cared for outside the home. Whilst the applicant had not made reference to linkage with this wider data within the application, the CAG agreed this was pertinent to raise as its remit did extend to access to social care data.

The Group also noted that the patient information leaflet described linkage with eye and hearing tests and also dental records, which had not been referenced elsewhere in the application. Clarification was sought around the source of this information.

Data storage and retention

The Group queried whether, following all proposed linkages, the resulting linked data would all be compiled into one research database, or whether the individually linked datasets would be retained separately in silos. It was agreed that clarity was required around this point, as due to the breadth of data linkage being proposed, there was potential for the resulting linked data, though held separately from the direct patient identifiers, to be identifiable due to the richness of the dataset.

Data access arrangements

The applicant confirmed that only King's College London (KCL) approved researchers would be able to apply to access the linked dataset which would be created as a result of the application activity. Members were assured by this access limitation at this initial stage of the project due to richness of the dataset which would result from the linkage.

Whilst the application process for approved KCL researchers was explained, Members remained unclear around how requests for multiple datasets would be

scrutinised. For example, where an applicant wants access to both mental health data and educational attainment, would there be wider assessment of the scientific need of both datasets to answer the proposed research question and would wider security constraints be applied to the dataset which would be made available. The applicant would be asked to provide further information around these processes.

'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.

Direct communications would be sent to all participants in the TwinsUK study to inform them of the proposed data linkage activities and to provide a means of dissent. The applicant had provided copies of the covering letter, information sheet and decision form which formed this communication.

Having reviewed patient information materials, Members agreed that there were a number of required revisions to ensure the information which was provided to the cohort was consistent with the scope of support being requested and provided sufficient detail about the scope of these activities.

Whilst the information leaflet provided a high-level overview of the linkage with health, educational and environmental information, no details were provided around the items of confidential patient information which would be used to facilitate this linkage or the organisations which were involved. The CAG agreed that on the basis of the information presented, it was unclear that the patient cohort would fully understand the breadth of data which would be available from the data linkage exercise, which must be made clearer.

Reference had been made within the documents to the information being made available to researchers outside of KCL, which contradicted the scope of support being requested in the application. This would need to be revised to ensure that it was clear to patients that only KCL researchers would have access to linked information.

References which were made to the CAG within the information leaflet were incorrect and would need to be revised. This would involve removing ‘National’ from the beginning of each reference. Whilst it is noted that the document included a link to the CAG area of the HRA website where interested parties could find out further information, the document itself should provide a clearer overview of the CAG and its function and to explain why it has reviewed the application. It was agreed that this should also be made clearer in the covering letter which supports the information sheet.

It should also be explained that the function of the CAG is to provide independent advice only on the use of confidential patient information without consent. The decision to approve any research-based section 251 support application is taken by the Health Research Authority in its capacity as nominated decision-maker.

It was also commented that the first case study which was introduced into the document required further introduction as its purpose, as currently presented, was unclear.

Members also commented that the patient’s right to object should be made clearer at the beginning of the lengthy information sheet, as this was currently being introduced on page 11 of 15.

The Group acknowledged that a number of comments had been made around the patient-facing information materials. However, it was noted that this would be the first introduction to the patient cohort about activities which would be taking place without their consent, in a hitherto consented study. As such, it was important that the information provided to the patient cohort was clear and understandable. The revised and finalised information materials would be required for review prior to any final recommendation of support coming into effect. It was also noted that in the current drafts, a number of diagrams and images were omitted from the documents. These

should be included in the final draft submitted to ensure the CAG had considered the materials as they would be received by the patient cohort.

Members also recommended that the applicants consider revising the information materials which have been designed for the newly consenting patients, to ensure that these provided clear information about the scope of the data linkage activity which they were signing up to. This would be important when relying on this consent as the legal basis, in relation to the common law duty of confidence, to facilitate the data linkage process in future. The controllers undertaking linkage would undertake an assessment of the consent materials to ensure these appropriately described the linkage it was being asked to facilitate. The applicant may benefit from liaising with the relevant controllers in advance of the rollout of these revised informed consent materials to ensure these were considered 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 research programme has a Volunteer Advisory Panel (VAP) which is made up of 12 participants from the TwinsUK cohort who meet twice per year to discuss and advise the programme. There are also a further 17 members who provide feedback and advice via email only (eVAP). The applicant provided an overview of the specific activities which have been carried out in relation to the use of patient data without consent to facilitate the data linkage with these two forums. An overview of the feedback from both the physical meeting was provided together with comments from the virtual group. An overarching letter of support from the user group for the proposed data linkage was also included in the application.

A key element of the user feedback was guidance that the linked information should not be made available to commercial entities. The applicants had taken this feedback onboard and assurance was provided within the application and patient-facing documents of this restriction.

The CAG acknowledged that user involvement was integral to the overarching research programme and agreed that the specific activity which had been undertaken in relation to the data linkage project was appropriate and proportionate to the described activity.

Research Ethics Committee (REC) Favourable Opinion

Queries had been raised in advance of the CAG review by the Confidentiality Advice Team as to the status of the REC favourable opinion for this application. In response, the applicant had explained that there was an existing ethics application for the TwinsUK Biobank. It was also explained that the patient-facing information materials had been considered by this REC, together with the data linkage proposals.

Members received the information but remained unclear as to whether the REC had specifically considered the application to utilise the confidential patient information held within the TwinsUK dataset on an unconsented basis to facilitate the data linkage described in the application. The IRAS reference number cited for the TwinsUK Biobank differed to that which had been assigned to the application submitted to the CAG, which suggested that a separate application had been made to the REC.

It is a requirement under the Health Service (Control of Patient Information) Regulations 2002 that those processing confidential patient information without consent can do so once approved by the Health Research Authority, following advice from the CAG, and providing a favourable ethical opinion is in place.

The Group required assurance that a favourable ethical opinion was in place for the data linkage activities which were described within the CAG application which had been considered. A copy of the REC outcome letter, which referenced the same IRAS ID as that detailed in the CAG application, was required to ensure the opinion could be correlated to this application.

Security assurance

It is the policy position of the Department of Health and Social Care (DHSC) in England that all applications seeking ‘section 251 support’ to process confidential patient

information without consent must evidence satisfactory security assurances through completion and satisfactory review by NHS Digital of the Data Security and Protection Toolkit. This is required for all entities in England which would be processing confidential patient information with support under the Regulations.

This assurance was in place for NHS Digital; however, clarification of the wider entities which would be undertaking data linkage activities within the scope of support was required in order ascertain the further assurances required.

Security assurance for organisations in Wales was provided via satisfactory review of a 'Caldicott Principles into Practice' report. This assurance was in place for NHS Wales Informatics Service.

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

The below list details a summary of the requirements – please refer back the CAG consideration provided above for the detail and rationale behind each request.

1. Clarify the purpose of the proposed linkage with each named data source. This should include an overview of the types of research questions, which are specific to the twin cohort, which could only be addressed by the proposed linked data.

2. Confirm what legal basis, in relation to the common law duty of confidentiality, is being relied upon for the disclosure and processing of the confidential patient information held in the TwinsUK dataset to facilitate linkage with the Department for Education records and wider environmental data as it is noted that patients have not provided informed consent for these purposes.

3. Confirm all items of confidential patient information which would be utilised in the described data linkage activities and provide a justification for the requirement of each item.

4. Individual data flow diagrams should be provided to explain the data linkage process which each named data source. These should address the following points:

    a. Data items being processed at each stage of the data linkage process,

    b. Name the organisations handling data at each stage,

    c. Identify which data flows require section 251 support,

    d. Ensure any acronyms used are explained.

5. Provide a detailed overview of the information which would be returned from each described data linkage, to understand the scope of the information which would be included in the resulting dataset.

6. Provide further information to explain the value of linkage with the Department for Education dataset, acknowledging that due to the average age of the TwinsUK cohort, a significant proportion are unlikely to be included in these records.

7. Clarify whether the datasets returned following linkage would be stored in one overarching database, or in individual silos to ensure security of the information held.

8. Provide further information around the assessment process which would be undertaken where an applicant is seeking access to more than one source of data, i.e. mental health data and educational information, to provide assurance that data will only be disclosed where relevant to the proposed research question.

9. Revise the patient-facing information materials to address the following points:

a. Provide a clear and detailed overview of what the data linkage activity entails, which organisations will be involved in linkage and the information which would be provided for use in the dataset,

b. Correct the information around which researchers would be able to access the database to make clear that this would be KCL approved researchers only,

c. A clearer explanation of the CAG and the section 251 support provided for the application activity should be provided correcting in accurate references to the CAG and its remit,

d. Provide a clearer introduction to the first case study which is presented so readers understand why this is being introduced and its relevance to the proposed data linkage,

e. The right to dissent to the use of data within this project should be introduced at an earlier point in the document,

f. Ensure all diagrams/images which would be present in the final document are included for review.

Recommendation

The applicant is recommended to review the updated information and consent materials for newly recruited participants to the overarching TwinsUK study, to ensure that this provided a clear overview of the data linkage activities and what individuals were consenting to. It may be beneficial to liaise with the controllers which will be facilitating this linkage to ensure they are satisfied that the consent would be considered to provide a legal basis, in relation to the common law duty of confidence, to support this activity.

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

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 – see above queries.**

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 confirmation of all entities processing with support – see above queries.**

b. 19/CAG/0213 – Investigating the impact of the Health in Pregnancy Grant on birth outcomes in England and Wales, 2009-2011

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to undertake record-based follow-up of patients recruited to the Twins UK trial. The Twins UK study was established in 1992 and is the largest longitudinal cohort of community dwelling adult twins in the UK, comprising over 14,000 volunteer twins in predominantly midlife. All patients are included within the main study on the basis of informed consent.

Participants have provided self-reported questionnaires, physical/cognitive measures and biological samples through clinical visits approximately every four years, for researchers to investigate how environmental factors and genetics interact to impact health over the life course. The longitudinal biobanking of samples over the last 25 years has enabled research on early detection of disease. TwinsUK participants have, from enrolment, given their informed consent for these data to be used for health research.

This application has been submitted to seek section 251 support to enable the Twins UK cohort to be linked with primary and secondary care records, cancer registration and mortality data held in a variety of data sources. Wider linkage with educational records held by Department for Education is also requested. The application has been informed by the ALSPAC (Avon Longitudinal Study of Parents and Children) programme which operates with support under the Regulations via reference ECC 1-05(b)/2012.

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

This application from The London School of Economics and Political Science set out the purpose of medical research which aims to evaluate the effect of the Health in Pregnancy Grant (HPG), which was introduced by the Labour government in April 2009, as a tax-free lump sum of £190 payable in the third trimester to all pregnant women in the UK. The aim of the grant was to promote healthy birth outcomes by subsidising better nutrition and reducing stress during pregnancy. However, the HPG was abolished in 2011 on grounds that it was poorly designed for nutritional impact, and that there was no evidence to suggest its impact on birth outcomes.

This research will evaluate the success of the HPG in improving birth outcomes in England. This is the first study into the impact of the HPG in England – previous research concerned Scotland only (Leyland et al., 2017). The applicants have undertaken preliminary analysis using ONS Birth Registrations microdata, which suggested that the HPG did have a significant positive impact on average birthweights. Within the scope of this application, this analysis will be extended, using maternity-related Hospital Episode Statistics (HES). This will enable the applicants to identify eligibility for the HPG with more accuracy, as eligibility was determined by the baby's due date, for which gestation at birth as well as birth date data is required. The HES data will also enable prematurity as an additional birth outcome to be assessed and to investigate potential variation in the impact of the policy across ethnic groups and area deprivation. NHS Digital will disclose confidential patient information to the applicant at The London School of Economics and Political Science for the purposes of analysis.

A recommendation for class 1, 2, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

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

Cohort	All live, single-child, births in England from 06/04/2006 to 16/04/2014 inclusive. It is estimated that 6,300,000 records will be included.
Data sources	1. HES Maternity episodes dataset, NHS Digital
Identifiers required for linkage purposes	No linkage to be undertaken – NHS Digital will disclose a complete dataset.
Identifiers required for analysis purposes	1. Date of birth – child 2. Lower super output area 3. Sex 4. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Members recognised the importance of researching the impact of policy initiatives on the health outcomes of the patient cohort. It was recognised that gestational age and birth weight were generally accepted as valid measures of the health and wellbeing of an infant at birth and appeared to be an appropriate basis for the analysis. However, as there was no way to confirm what mothers in receipt of the grant had spent this additional money on, it would be difficult to correlate birth outcomes to the grant alone. As such, the Group was unclear whether the findings of the project would provide reliable evidence about the benefits or disadvantages of the grant.

The Group acknowledged that a similar analysis had been undertaken in relation to Scottish patients; however, it had been unable to ascertain from the published information what methodology this study had followed to clarify if confidential patient information had been used. It was also unclear whether any analysis between the findings of the Scottish study and this proposed research was planned, to understand how outcomes differed between the two nations.

It was further commented that, from the information provided, it was unclear how the findings of the proposed study would be utilised to inform policy change. The proposal as described involved processing confidential patient information for an extremely large patient cohort. The CAG was not assured that a strong enough argument for the potential public interest which would be achieved from the proposed study had been evidenced to justify the described breach of patient confidence. On this basis, the Group agreed that the recommendation for the application would be deferred, pending further assurance from the applicant.

Scope

The application had specified that the study would focus on eligible births in England and Wales. In advance of the CAG meeting, the Confidentiality Advice Team had queried the scope of support requested, as it is was recognised that NHS Digital was the only data source specified in the application, it would only be able to disclose information in relation to English born babies, as the HES-Maternity dataset extended

to England only. The applicant had confirmed that the scope of the study would be limited to babies born in England only.

The Group agreed that, should a revised application be submitted by the applicant for consideration by the CAG, the application form and supporting documentation would require revision to reflect the reduced scope of the proposed research.

Practicable alternatives

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

- **Feasibility of consent**

The CAG was assured that, on the basis of the numbers included in the patient cohort, it was not feasible for the research to be carried out on the basis of consent.

- **Use of anonymised/pseudonymised data**

The application had been submitted to seek section 251 support to legitimise the disclosure of infant date of birth only. The applicant stated that this was necessary to enable eligibility for the HPG to be calculated with more accuracy, as this was based on the child's due date, for which gestational age at birth and date of birth were required to make an accurate calculation.

Members were unclear whether this rationale alone provided sufficient justification for the breadth of the disclosure proposed for the application activity. Firstly, it was commented that full date of birth would only be required for those babies which were born around the boundaries of the grant being introduced and abolished, as the remainder of the cohort, which would be utilised as a comparator against the eligible births, was clearly outside of scope. By only requesting full date of birth for those babies born around the start and end boundaries of the lifetime of the grant, the scope of support required under the Regulations would be significantly reduced.

The Group queried whether month and year of birth would be sufficient for the proposed analysis. Requesting date of birth in a less identifiable format would negate the requirement for section 251 support to be in place to legitimise the disclosure.

The CAG agreed that reducing date of birth to month and year format would remove the requirement for section 251 support to be in place for the application activity. The applicant would be required to consider this proposed change in methodology to determine whether this presented a practicable alternative to seeking section 251 support for the proposal.

If the applicant determined that this was not a feasible alternative, the applicant would be required to provide a much stronger justification for the necessity of date of birth in any revised application submission. Consideration would also need to be given to the reduction in the scope of support being requested, through limiting the disclosure of full date of birth to those babies born around the boundaries of the grant's availability. The revised application should specify the exact timeframes for which full date of birth of the infant would be necessary.

'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 confirmed that information would be made publicly available about the study on the Centre for Analysis of Social Exclusion (CASE) website at London School of Economics. A draft of the document was provided for review. Members agreed that the proposed text would require revision to make this accessible to lay audience. A revised document should be provided with any revised application submission.

The Group acknowledged that the only means for patients to object to the use of their data within this study would be through the registration of a national opt-out via NHS Digital. It was agreed that this option for dissent should be promoted via the website and would need to be included in any revised text. This should explain that the opt-out would need to be registered in respect of the child, not the mother.

Members commented that it was unlikely that many patients would review the London School of Economics website for information about health research. As such, the applicants would need to consider other ways to promote the study more widely. It was suggested that online forums, such as MumsNet, may be appropriate mechanisms to reach the wide and generic cohort of birth mothers. Should a revised application for section 251 support be made for the activity, the applicant would be required to describe wider patient notification plans.

Patient and Public Involvement and Engagement

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

The applicants had attended a Maternity Voices Partnership meeting in September 2019 to discuss the proposal with approximately 20 new mothers. An overview of this activity was provided together with confirmation of support for the project.

It was also explained that the applicants were seeking to arrange focus groups to further explore patient and public opinion and involve users in the dissemination of the research findings. Further information around the planned recruitment strategies for representatives for the focus group was provided, which included promotion at primary schools, as this was the average age of the children who were born during the grant timeline.

Members recognised the difficulties in undertaking targeted user involvement when involving a national patient cohort over such an extended timeframe. It was recognised that the applicants had taken steps to seek views from a relevant patient cohort. Further information should be provided in any revised submission about the progress which had been made in establishing the focus groups.

Exit strategy

The Group agreed that further information was required from the applicant around the proposed duration of support and exit strategy, should a required submission be made to the CAG, as it was suggested that six-months appeared to be quite a significant duration for the limited processing which was required.

Data protection compliance

The applicant would be asked to review the cited legal basis which was being relied upon for the processing of special category data under GDPR. The application specified that Article 9(2)(g) – substantial public interest was the basis; however, it was queried whether this would be more accurately covered by Article 9(2)(j) Archiving, research and statistics. Clarification would be required as part of any revised submission.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided.

Practicable Alternatives

1. Consideration should be given to whether the proposed analysis could be undertaken on a dataset which included month and year of birth only. This would prevent the requirement for section 251 support to be established for the application activity as there would be no disclosure of confidential patient information.

2. If this is not deemed a feasible alternative, a stronger justification for the requirement for complete date of birth would needed to be presented in the revised application submission.

Further information required

If the above practicable alternative is not deemed to be feasible, further information is required to address the below points. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Provide a stronger public interest argument to support the application, explaining how the findings of the study would be utilised to inform changes in public policy or provide patient benefits.

2. Confirm whether there is any intention to undertake wider comparison with the findings of the Scottish-led study.

3. The CAG application form and wider supporting documentation should be revised to reflect the reduced scope of English births only.

4. Consider whether the requirement for complete date of birth can be limited to only those babies born around the threshold of the implementation and abolition of the grant. If so, provide the start/end dates of the specific timeframes full date of birth would be required. If not, the justification provided to support the requirement for full date of birth should clearly set out why this is necessary for the full cohort.

5. The patient notification text requires revision to make this accessible to a lay audience. The document should also include information about an individual's right to dissent and provide a link to the national data opt-out.

6. Consideration should be given to wider patient notification mechanisms which would promote the study and the right to dissent in a wider public arena. Details of wider planned notifications should be included within the revised submission.

7. Provide an update on the progress which has been made in establishing the parent focus groups and any feedback which has bene sought.

8. Confirm the intended duration of support under the Regulations and clarify how and when the exit from support would be implemented.

9. Consider whether the legal basis, under GDPR, for processing special category data would be more appropriately covered by Article 9(2)(j) Archiving, research and statistics.

10. Confirmation is required from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission has achieved the 'Standards Met' threshold.

Once received the information will be reviewed initially by a sub-committee of all Members present at this initial review, prior to consideration at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

c. 19/CAG/0214 – Understanding the scale and nature of avoidable harm in prison healthcare (Phases 2 & 3: Case note review and qualitative interviews)

Context

Purpose of application

This application from University of Manchester set out the purpose of medical research which aims to determine the frequency and nature of avoidable patient harm in prison healthcare.

People in prison should receive the same standard of care as people in the community. However, the demand for services and lack of adequate resources is challenging for prison healthcare providers. A large systematic review and meta-analysis examining the prevalence, severity and nature of avoidable harm found that 5% of patients experience avoidable harm and that 14% of this harm causes permanent disability or patient death. None of the studies included prisons. Whilst there are some prison-based studies on avoidable types of harm (e.g. self-harm), wider evidence on the scale, severity and nature of avoidable harm does not exist. Understanding the frequency and causes of avoidable harm in prison healthcare will inform policy to improve patient safety.

This application covers phases two and three of the overarching research programme. Phase two will use a definition of avoidable harm developed in an earlier phase of the research to screen records of 15,000 patients in a sample of prisons in England to identify and collect data on possible cases of avoidable harm. This information will be utilised to estimate the incidence of avoidable harm and quantify, classify and describe the nature of severity of these cases. This element of the study requires section 251 support to legitimise researcher access to confidential patient information within the medical records. from the 15,000 records, it is anticipated that 2,250 records will be identified for an enhanced review, following identification of harm. A control cohort of 1,500 patients not selected for enhanced review will also be selected for review by a second nurse. All prisoner records will be accessed on a 'census date', which will be determined when all relevant approvals are in place for the study. The previous 12 months recorded from this date will be accessed for information.

Phase 3 of the project involves semi-structured interviews with staff and prisoners to explore perspectives on the nature of harm incidents which will be conducted on the basis of informed consent and are out of scope for this application.

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	All prisoners present on a defined census day within 17 prisons across England. It is anticipated that this will include 15,000 patients.
Data sources	1. Electronic and paper medical records held on site at 17 participating prisons in England.

Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Prison Number 5. SystmOne Patient Identifier
Identifiers required for analysis purposes	1. Patient age 2. Sex

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 proposed activity was within the public interest as it would lead to a better understanding of the prevalence and nature of avoidable harm experienced by prisoners and inform improvements in health care management to prevent this in future.

Cohort

The Group noted that one of the inclusion criteria which was detailed for the patient cohort was to include those who had died during the study period. This criterion was queried by Members as it was understood that patients were being included on the

basis of their being an inmate on the census date of the chosen sample. Clarification was sought that this criterion extended to those patients who had died on the chosen census date, and did not extend to all patients who died at the prison within the 12 months leading up to the census date.

Practicable alternatives

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

- **Feasibility of consent**

The CAG accepted that consent was not feasible for the proposal on the basis of the size of the patient cohort to be included in the study.

- **Use of anonymised/pseudonymised data**

Whilst confidential patient information was not required for the purposes of the study analysis, this would be visible during the data collection process. Members acknowledged that, due to the scale of records to be accessed, it was not feasible for the data extraction to be undertaken by members of the clinical care team on behalf of the researchers in order to provide the anonymised dataset for analysis.

'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 confirmed that posters would be displayed on site at participating prisons to inform patients that the study was being carried out. The poster would be displayed for at least six weeks prior to the data extraction date, in order for patients to consider whether they wished to dissent to the use of their data within the study. A single point of contact would be detailed on the poster to enable objections to be raised. Members sought assurance that this named individual would be someone who was known to patients to facilitate the dissenting process.

Queries had been raised in advance of the CAG review by the Confidentiality Advice Team around any wider mechanisms which may be employed to promote the study. In response, the applicant had explained that until all sites were recruited, supplementary mechanisms could not be explored as these would need to be based on the capacity of the site to implement. A concern around the literacy levels amongst prisoners was also raised. The Group acknowledged that the applicants concerns around literacy levels amongst prisoners and queried what steps would be put in place to ensure the proposed poster would be brought to the attention of individuals who may not be able to read.

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 confirmed that a co-investigator in the study was an expert by experience (ex-offender). This individual was supportive of the study and its methodology of using confidential patient information without consent.

The applicants were also in the process of establishing a Service User Group (SUG) which will include between four and six ex-offender service users, who have previous experience of imprisonment and carers/family members who have had recent contact or an advocacy role with prison-based health services on behalf of a relative. The SUG will be led by the PPI co-applicant of the study and will be supported by the study PPI lead. The group will meet at the start of the study and then at least twice yearly to feed

into discussions and decision-making processes. This group had been established and the applicant was in the process of arranging the first meeting.

The applicant had not yet undertaken wider activity to test the acceptability of using confidential patient information without consent with prisoners/ex-offenders and was drawing on the user involvement which was carried out for their previous study, which was based in primary care, as supportive.

The CAG commented that the user involvement undertaken in the previous primary care study was not directly relevant to the proposed activity on the basis that the acceptability of using data without consent may be received differently by prisoners, which the general patient population would not represent. It was agreed that feedback from the initial SUG would be required prior to the final recommendation of support coming into effect to ensure that the proposed use of patient data was supported by a relevant patient group.

Exit strategy

The applicant had estimated that each patient record review was expected to take only five minutes to complete. Members agreed that assurance would be requested around the proposed timing, which it was agreed appeared surprisingly short, given the requirement to review 12 months of patient records.

Whilst anonymised data would be extracted for the purposes of analysis, a linkage file would be maintained on site at each individual prison, by a member of the clinical care team, for the duration of the study. This would be retained in case serious harm was identified when undertaking analysis, which would need to be escalated. The CAG agreed that the retention appeared appropriate on this basis and asked for further information around the established protocol for escalating concerns.

Confirmation of research sites

The applicant was still in the process of recruiting all sites into the study. Members agreed, on the basis that the same methodology was being implemented at all sites, there was no requirement for all sites to recruited and confirmed prior to the final

recommendation of support coming into effect. The applicant would be required to provide an update at the time of annual review of all sites which were participating in the study. If, having recruited a site into the study, there was found to be a reason to modify the agreed data access and extraction process, an amendment would be required for consideration by the CAG in this instance.

Security assurance

It is a policy requirement from the Department of Health and Social Care, which is implemented through a standard condition of support, that all organisations physically processing confidential patient information under 'section 251 support' maintain appropriate security assurance for the duration of the application activity. Security assurance for organisational processing confidential patient information within England is provided by the Data Security and Protection Toolkit (DSPT). However, it was unclear whether prisons completed the DSPT submission, or had an agreed bespoke standard, as providers of healthcare services.

Clarification had been sought and remained pending from NHS Digital in relation to the security assurance standards which were undertaken by prison sites. Once this mechanism was confirmed, the CAG agreed that support would be recommended on the basis that the applicant would be responsible for ensuring the appropriate standard had been achieved by each site, prior to processing confidential patient information with support under the Regulations.

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. Clarify the meaning of the inclusion criterion: ‘died during the study period’.

2. Provide details of wider mechanisms which will be implemented to overcome literacy issues and ensure that the study is appropriately promoted amongst every patient who may potentially be included.

3. Provide assurance that the individual nominated at each site to handle objections would be someone who was widely known and accessible, to ensure the dissenting mechanism can be appropriately implemented.

4. Feedback should be provided from the first meeting of the Service User Group to evidence that these individuals are supportive of the use of confidential patient information without consent.

5. Provide assurance that the time allocated for each patient record review (approximately five minutes) was sufficient to undertake the necessary data extraction.

6. Provide an overview of the escalation protocol which will be followed should evidence of serious harm be uncovered during the study analysis.

7. Confirmation of the security assurance standards in place at prison sites is required prior to any final recommendation of support coming into effect.

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. Confirmation should be provided at the time of first annual review of all prison sites which are participating in the study via the agreed methodology. An amendment would be required for any site which deviates from the agreed protocol.

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. **Pending confirmation of assurance standards at prison sites.**

d. 19/CAG/0218 – Pulmonary Hypertension (PH) population characterisation and epidemiological analysis

Context

Purpose of application

This application from Sheffield Teaching Hospitals NHS Foundation Trust, IQVIA and Janssen set out the purpose of medical research which aims to gain an understanding of the profile and care pathway for patients with Pulmonary Arterial Hypertension (PAH), which is a progressive and rare disease caused by constriction of the pulmonary arteries. There are other types of Pulmonary Hypertension, including Chronic Thromboembolic Pulmonary Hypertension (CTEPH) and Sarcoidosis-Associated Pulmonary Hypertension (SAPH). Due to the complexity, late diagnosis and absence of real-world studies there is currently a lack of understanding regarding the clinical pathway leading to diagnosis and post-diagnosis. There is also the need to further explore and study patient related outcomes associates with these diseases in routine clinical practice.

The applicants propose to investigate these aims by undertaking a non-interventional retrospective database analysis of a patient cohort with pulmonary hypertension and its sub-types identified from the Pulmonary Vascular Disease Unit at Sheffield Teaching Hospitals NHS Foundation Trust. This data will be linked with wider clinical information within the HRA dataset retained by NHS Digital.

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	Patients with Pulmonary Hypertension, including Chronic Thromboembolic Pulmonary Hypertension (CTEPH) and Sarcoidosis-Associated Pulmonary Hypertension (SAPH) managed at the Sheffield Teaching Hospitals NHS Foundation Trust since 01/01/2010 to 17/09/2019. It is estimated that 5,000 patients will be included in the study.
Data sources	1. Electronic health records, Sheffield Teaching Hospitals NHS Foundation Trust 2. Hospital Episodes Statistics, NHS Digital
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth
Identifiers required for analysis purposes	Not applicable – no data items retained for analysis.

Confidentiality Advisory Group advice

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

Public interest

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

Members were assured that there was a public interest gaining a better understanding of the clinical pathways for patients with Pulmonary Arterial Hypertension (PAH). However, it was recognised that there was an established national clinical audit which focussed on PAH. The Group was unclear what additional value this proposed research study would add that was not currently being achieved by the audit. It was also queried whether the necessary information was already available within the clinical audit dataset.

The Group agreed that, whilst supportive in principle of the activity, it could not recommend support until further information was provided around the relationship between the proposed activity and the established clinical audit. This was to ensure that there was public interest in this activity proceeding which was not addressed by the existing audit. The applicant would be asked to provide further information in a revised application submission to address this point.

Cohort

Members were unclear whether the project would include only those patients who had been treated within the Sheffield Teaching Hospitals NHS Trust with Pulmonary Arterial Hypertension (PAH), as it was suggested that following linkage with NHS Digital, all patients would be included on a deidentified basis. It was agreed that clarification around this point would be sought to ensure the patient cohort was clear.

The Group was also unclear whether a control cohort was also to be included in the resulting dataset. It was noted at Q14 of the CAG application, at point four where proposed data flows were described that following linkage by NHS Digital, linked data for the patient cohort would be provided together with 'de-identified data for all other English patients.' Members were unclear whether, in relation to the above query, this comment related to all other patients in England with a diagnosis of Pulmonary Arterial Hypertension (PAH), or rest of the patient population in England. Clarification was required around this point to ensure the full scope of the project and proposed analysis was understood.

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 stated that consent was not feasible due to the size of the retrospective patient cohort which would be included in the study. It was further argued that the operation of a consented model may lead to a bias and the loss of valuable data which could be utilised in analysis to inform improvements in the patient care pathway. The CAG was assured by the rationale provided and accepted that consent was not feasible in this instance.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to facilitate the linkage between the Trust datasets and information which was held at NHS Digital, which could not be otherwise achieved.

'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 drafted patient notification materials; however, following feedback from the Research Ethics Committee, these documents were undergoing revision. Members agreed that sight of the revised documentation would be necessary as part of any revised submission as the current drafts were not appropriate for a lay audience.

The Group also raised concerns around the transparency of the documentation, as it was noted that, in the current format, clear information about the various organisations involved in the study was not provided. The revised documentation should provide a clear overview about all of the entities which are involved in the study, together with an explanation of the role each would fulfil and what access to data each would have and in what format. It was suggested that the views of the patient advocacy group could be sought to ensure the revised documents were deemed 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 applicants had engaged with Pulmonary Hypertension Association UK since the early stages of the project. The patient advocacy group within the charity were consulted about the project. The applicant provided a letter in support of the study from the charity. Members recognised that this was an appropriate organisation to engage with about the study; however, were unclear what was asked of the patient group and the feedback provided.

It was agreed that the revised application would need to be supported by further information about the user involvement activity which was undertaken. This should provide an overview of the activity undertaken, what information was given to the

group and assurance that the use of confidential patient information without consent was considered should also be provided. Members agreed that it was also pertinent to explore the involvement of the commercial entities with the patient group to seek views on the use of the resulting data by organisations of this type. Feedback of the views expressed by the patient group would need to be provided within the revised submission.

Data access arrangements

Members recognised that Sheffield Teaching Hospitals NHS Foundation Trust, IQVIA and Janssen were acting as joint controllers for the purposes of the project. However, it was unclear from the information provided which entity would have controllership of the dataset resulting from the proposed linkage. It was agreed that further information would be requested from the applicant around this point.

The Group also queried whether the project may have been more appropriately classified as a research database, to enable wider access to the resulting database by legitimate researchers in the field. It was further queried how results from research analysis undertaken would be made publicly available. Members agreed that further information would be required as part of any revised submission to strengthen the public interest in the activity proceeding.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that further information would be required from the applicant in order for a recommendation under the Regulations to be provided. A detailed covering letter should be provided, together with a revised CAG application form, addressing the below points.

1. Explain how the proposed activity relates to the established Pulmonary Arterial Hypertension clinical audit, clarifying the additional public interest which would be achieved.

2. Clarify the patient cohort which would be included in the resulting dataset – was this only the patients treated at the Sheffield site, or would NHS Digital provide anonymised data in relation to the national patient cohort.

3. Confirm whether a control cohort would be included in the dataset.

4. Revised patient-facing information materials should be provided. These should include a clear explanation of all entities which are involved within the project, including the various commercial entities, and detail the role of each and what access to patient data each would have.

5. Further feedback from the patient advocacy group should be provided to support the application. This should explain the format the activity took, the demographics of those involved, what information was provided around the study, including the roles of the commercial entities. An overview of the views expressed should be provided, with particular reference to the use of confidential patient information without consent and the involvement of the commercial organisations. It is recommended that the group are also asked to comment on the patient-facing information materials.

6. Confirm which of the named entities would have controllership of the resulting dataset.

7. Consider whether the study may be more appropriately classified as a research database. If so, this should be changed within the revised application form and supported by a protocol to manage access.

8. Provide further information around how the findings of any research undertaken on the resulting dataset would be made publicly available.

Once received the information will be reviewed initially by a sub-committee of all Members present at this initial review, prior to consideration at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

e. 19/CAG/0210 – Discovery and analysis of model biomarkers in urological diseases (Diamond study)

Context

Purpose of application

This application from University of Cambridge set out the purpose of medical research which aims to evaluate the utility of biomarkers to improve the screening, diagnosis, prognosis and treatment of urological cancers. The applicants wish to identify a cohort of patients which were referred to undergo an MRI scan as part of the diagnostic process for prostate cancer, in order to invite them to provide a sample to be used in the biomarker analysis. A sub-cohort of patients who were referred for an MRI, which was found to be inconclusive, and were subsequently discharged back into the community has been identified, which are not currently included in the analysis and may be causing bias in the reported results.

The application has operated since 2003 with the applicants approaching patients at the point they are attending their outpatient appointment and have been focussing on biomarkers within patients with localised or advanced disease. In recent years, the focus for prostate cancer has changed to early detection and applicants are now looking to test biomarkers in the early stage of the disease. This has led to the change in methodology which requires an application for section 251 support. The applicants are seeking support to access medical records on site at Cambridge University Hospitals NHS Trust to identify patients who have been invited for a pre-biopsy MRI scan, so these individuals can be invited to attend the early diagnostic research clinic alongside their scheduled MRI appointment. Support is sought to access the medical records and invite eligible men to participate in the study.

A recommendation for class 1, 2, 3, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	All patients being referred from their GPs to the MRI department or to Outpatient Urology clinics at

	Cambridge University Hospitals NHS Trust for a suspected urological cancer.
Data sources	1. Electronic patient records for MRI outpatient appointments
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Full address and postcode
Identifiers required for analysis purposes	Not applicable – all identifiers retained for analysis will be done so under 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.

Members were assured that the application was within the public interest as, through inviting patients to participate at this early stage in the clinical investigations, the applicant may be able to identify early biomarkers for prostate cancer.

The Group queried whether the proposed cohort size of 5,000 patients would be of sufficient size to provide sufficient clinical outputs. It was agreed that further assurance would be requested from the applicant in this area, acknowledging that the overarching public interest would only be achieved if there were sufficient statistical findings.

Cohort

Members were unclear how many patients would fall within the scope of support and the duration over which support would be required. The applicant had stated that 5,000 patients would be included; however, it was unclear whether this included the full patient cohort, or only those within the scope of support. It was also unclear how the cohort could be limited as the study was understood to be ongoing. Clarity would be sought from the applicant to ensure the scope of support was clear.

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**

Support was being sought to enable an approach for consent to be made for the project. The applicant had explained that it was not feasible to seek prior consent for the invitation process on the basis that appointments were automatically booked. The purpose of the application was to enable the research appointment to be scheduled at the same time as the clinical appointment, to reduce the burden on patients. The CAG was assured that seeking prior consent was not feasible and was content to provide a recommendation of support under the Regulations.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to facilitate the invitation process which could not be otherwise achieved.

‘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 copy of an invitation letter and patient information sheet had been provided within the application submission, which would be used to invite patients to participate in the study. Members agreed that these documents were not suitable for the patient group for which support would be recommended. It was noted that, in places, the documentation inaccurately described the recruitment process and it was suspected that these documents had been intended for the other cohort of patients, who would be approached about the study after their initial clinical scan.

The Group commented that the documents made reference to a potential cancer diagnosis. As the patient group being approached within the scope of the CAG application had only been referred for a scan to investigate a urological problem, there is a chance that their referring GP had not mentioned the possibility of cancer as a reason for the scan. As such the current content of the invitation material has the potential to cause distress and harm amongst those invited. Members agreed that revised documentation was required for the specific purposes of this patient group. This could either be a more comprehensive invitation letter, or a letter supplemented by a simplified information leaflet. This should also explain that some patients may not receive further follow-up. These revised documents would be required prior to any final recommendation of support.

The applicant had stated that, eligible patients would be approached an additional time one week following the initial invitation was sent. It was not clear from the information provided how this approach would be made. Clarification would be sought from the applicant as this would require a recommendation of support, noting that patients had not yet consented to the use of their data.

Wider information about the study was also being promoted via the Cancer Research UK website and a link to this was provided. The CAG commented that, whilst wider publicity for the study was positive, this was unlikely to be accessed by the patient cohort for which section 251 support was being sought as these individuals were unlikely to consider themselves at risk of cancer. Members recognised that this patient cohort were newly referred for investigative clinical scanning and as such, making information about the study more widely was problematic. On the basis that all patients would receive direct communications about the project and provided with a means of dissent, the Group agreed that the current notification mechanisms were suitable.

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 has previously sought involvement from the patient and public involvement group at the Trust; however, there had not been any specific activity undertaken to explore the use of confidential patient information without consent. The CAG agreed that further activity should be undertaken in this area to test the acceptability of using patient information for the newly proposed recruitment methods. This should include the views of patients both with and without a cancer diagnosis. Feedback would be required prior to any final recommendation of support coming into effect for the proposal to ensure patients are supportive of the proposed use of data.

Availability of the research team

Members noted that some Trusts operated routine clinical MRI scanning out of standard hours, at weekends for example. Assurance was sought that the availability of research appointments would mirror the timings of the standard clinical appointments.

Data Protection Compliance

The applicant was asked to clarify the legal basis relied on for processing under Article 6 and Article 9 of the General Data Protection Regulation (GDPR).

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Provide assurance there were sufficient numbers to be included in the study to provide significant clinical findings.

2. Confirm the size of the patient cohort to be included in the study and the duration over which this cohort would be included, in order to confirm the duration of support which is required under the Regulations.

3. The patient invitation materials require revision to ensure these are appropriate for the patient cohort which would be invited to participate within the scope of section 251 support. The applicant should consider whether a more comprehensive invitation letter would be appropriate, or invitation letter and a simplified patient information sheet. Revised documentation will require review prior to any final recommendation of support coming into effect.

4. Clarify how the second invitation approach, to be made one week after the initial invitation, would be made.

5. Further user involvement activity should be undertaken to test the views of patients and the public around the use of confidential patient information without consent in the proposed revised recruitment methodology. Feedback

around the format the activity took, the demographics of those present and the views expressed is required.

6. Provide assurance that research appointments would have the same availability as the standard clinical appointments, i.e. at weekends where appropriate.

7. Confirm that the legal basis being relied upon processing data under the GDPR are Article 6(1)(E) – tasks in the public interest and Article 9(1)(J) – research purposes.

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. **Confirmed - Cambridge University Hospitals NHS Trust has a confirmed Standard Met grade on DSPT 2018/19 (NHS Digital Tracker 05 November 2019).**

4. NEW PRECEDENT SET – Research

a. 19/CAG/0207 – Survival of people with screen-detected heart failure (ECHOES-Survive)

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertaken longitudinal follow-up of patients who were recruited on a fully consented basis to the historic 'Echocardiographic Heart of England Screening (ECHOES) Study'. The ECHOES study was carried out between 1995 and 1999 in 16 General Practices around the West Midlands region. The purpose of the study was to establish the prevalence of heart failure in the general population over the age of 45 and involved assessment of detailed clinical history and examination, 12 lead ECG, and echocardiography.

All patients who participated in this trial are flagged with NHS Digital to enable follow-up via civil registration data to ascertain which members of the cohort have died and when, together with the cause of death. NHS Digital reassessed the consenting materials for the study in 2018 and determined that these were no longer valid, in relation to the common law duty of confidentiality, to support the ongoing processing of patient information and disclosure of mortality data. The applicant was advised to submit an application to the CAG to seek section 251 support to legitimise the longitudinal follow-up of the patient cohort to undertake 20-year survival analysis.

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	6,162 patients who were recruited to the ECHOES trial between 1995 and 1999 on a fully consented basis from 16 GP practices in the West Midlands.

Data sources	1. ECHOES trial dataset, University of Oxford 2. ONS mortality data, NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth
Identifiers required for analysis purposes	1. Date of birth and death – calculation of survival 2. Postcode – deprivation scoring 3. Cause of death 4. Sex 5. 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.

Members were assured that there was ongoing public interest in undertaking the proposed 20-year analysis within this established longitudinal study.

Scope of support

The CAG accepted the justification provided from NHS Digital stating that the original consent no longer endured to provide a legal basis for ongoing processing of patient information, in relation to the common law duty of confidence. On this basis, Members

queried whether the applicant was seeking section 251 support to legitimise the ongoing retention of the study dataset and any further future follow-up. It was agreed that clarification would be sought from the applicant to ensure the scope of support was clear.

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**

It was understood that the initial study had been undertaken on the basis of patient consent. NHS Digital had undertaken an assessment of the information and consent materials and determined that this could no longer be relied upon to provide a legal basis, in relation to the common law duty of confidentiality, to legitimise ongoing data processing. The CAG received the information from NHS Digital and also agreed that the consent materials did not provide a sufficient legal basis for the proposed data processing.

The applicant had explained that due to the time which had elapsed since the initial study consent was taken and the size of the patient cohort, it was not feasible to reconsent patients for the ongoing follow-up. It was also recognised that the purpose of the follow-up was to track mortality status, so it was likely that a certain proportion of the cohort would be deceased. The CAG accepted the rationale provided by the applicant and agreed that consent was not feasible in this instance.

- **Use of anonymised/pseudonymised data**

Confidential patient information was required to facilitate the linkage undertaken by NHS Digital which could not be otherwise achieved.

Exit strategy

Members were unclear whether the applicant intended to reduce the identifiability of the dataset for those patients who were found to be deceased. It was commented that once mortality status was known, there should be no further requirement for confidential patient information to be retained. The applicant would be asked to provide confirmation that steps would be taken to reduce the identifiability of the dataset when mortality status is recorded for patients.

'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 some drafted text which would be displayed on the University of Birmingham website. This provided an overview of the study and also the linkage which would be undertaken by NHS Digital. The applicant recognised within the application that some of the detail was outdated and would require revision should the project receive a recommendation of support under the Regulations. It was also confirmed that a poster would be displayed in the 16 GP Practices from which patients were initially recruited.

The CAG agreed that sight of these finalised materials would be necessary prior to any final recommendation of support coming into effect. The applicant was reminded that where offering a means of objection, a telephone number, email and postal address should be provided.

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 is supported by two patient and public members within the research group, who had been involved in the study over the longer term. The applicants explained that they had also more recently developed a project specific user involvement group which has 11 members (6 men, 5 women; 7 with heart failure, 1 carer for spouse with heart failure; 7 aged over 75 years).

The applicant provided specific feedback around written responses which were received following a request for user views on the advice form. Five written responses have been provided which were largely supportive of the ongoing patient follow-up. One responder suggested all living patients should be re-approached to seek their views on continued involvement in the study.

Members recognised that this was the ideal; however, as the purpose of this application was to seek mortality data, the breach of confidence would need to occur before any approach for consent could be made, to prevent any deceased patients from being approached. It was also noted that a wider breach of patient confidence would be needed in order to update contact information to seek consent. On balance, the CAG agreed that the user involvement appeared proportionate to the proposed activity, sought views from a relevant cohort and was largely supportive of the project proceeding on an unconsented basis. The Group commended the applicant for providing an overview of all feedback, even where this was not wholly supportive of the proposed methodology. the CAG accepted the feedback in this area and agreed no further activity was necessary.

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. Confirm whether section 251 support is also being sought to legitimise the ongoing retention of the study dataset and any further future follow-ups via NHS Digital.

2. Clarify whether the confidential patient information items retained for patients confirmed as deceased can be reduced to a less identifiable format. Confirm agreement to this and provide an overview of the data items which would remain.

3. Provide final drafts of the website text and GP practice poster for review.

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 has a confirmed 'Standards Met' grade on DSPT 2018/19. This remained pending for the University of Birmingham.**

5. Minutes of the meeting held on 17 October 2019

The minutes were received and accepted as a true and accurate recording of proceedings.

6. Any other business

No other business was raised.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date