Minutes of the meeting of the Confidentiality Advisory Group

19 September 2019 at HRA Manchester, Barlow House

Present:

Name	Present	Notes
Dr Tony Calland (Chair)	Yes	Chair
Ms Clare Sanderson (AVC)	Yes	Alternate Vice Chair
Dr Malcolm Booth	Yes	CAG Member
Mr David Evans	Yes	CAG Member
Dr Lorna Fraser	Yes	CAG Member
Mr Myer Glickman	Yes	CAG Member
Mr Anthony Kane	Yes	CAG Lay Member
Dr Rachel Knowles	Yes	CAG Member
Dr Simon Kolstoe	Yes	CAG Member
Mr Andrew Melville	Yes	CAG Member
Mr Marc Taylor	Yes	CAG Member

Also in attendance:

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

1. Introduction, apologies and declarations of interest

There were no external attendees present at the meeting. No apologies for absence were received for the meeting.

The CAG noted that Professor Jennifer Kurinczuk, CAG Member, was a named co-applicant for agenda item 4.b. 19/CAG/0142, which was noted for transparency purposes.

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 **19 September 2019** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **19 September 2019** meeting applications.

3. NEW APPLICATIONS – Research

a. 19/CAG/0166 – HPS2-THRIVE Trial Legacy Study

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertake long-term follow-up of patients who were previously recruited to the HPS2-THRIVE Trial to see if differing levels of LDL-cholesterol amongst the participants affected their longer-term risk up to 40 years post-trial of dementia, major diseases such as heart attack, stroke or kidney disease or death.

Dementia is a leading cause of death in the UK and affects many people. Dementia is a condition that develops over a long period before symptoms lead to diagnosis. Cardiovascular risk factors, such as LDL-cholesterol (an essential component of blood, which at increased levels can build up on the walls of arteries increasing the risk of heart disease), are associated with the risks of developing dementia. It is as yet unknown whether increased levels of LDL cholesterol in older people are associated with increased risk of dementia, say 15-20 years later or longer. By using established patient cohorts from existing long-term follow-up studies, such as the HPS2-THRIVE trial, the applicants would be able to examine long-term outcome data in the older population now.

The HPS2-THRIVE trial recruited 8,035 patients between 2007 and 2010 to a randomised controlled trial looking at the impact of cholesterol on risk of heart attack and stroke. Existing study records will be linked with routinely collected health data held by NHS Digital and NHS Wales Informatics Service to form a legacy study database. This database will be utilised together with existing stored blood and urine samples of HPS2-THRIVE participants to study the effect of LDL-cholesterol lowering on reducing the risk of developing dementia and other diseases such as the long-term risk of death, other important diseases and healthcare use in the UK.

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

Confidential patient information requested

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

Cohort	All patients from England and Wales who were recruited to the HPS2-THRIVE trial.
Data sources	1. Existing HPS2-THRIVE Trial data

	2. HES, NHS Digital, 3. Mental Health Minimum Dataset, NHS Digital 4. ONS Mortality Information, NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Date of death 5. Postcode (district level) 6. Sex 7. Study ID
Identifiers required for analysis purposes	1. Study ID
Additional information	• The study involves a historic patient cohort in Scotland and Northern Ireland which are out of scope for the CAG remit. Separate applications have been made to the appropriate bodies in these nations in relation to the application. • The study also involves the use of historic patient samples on the basis of consent which is out of scope for the CAG application.

Confidentiality Advisory Group advice

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

Public interest

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

Members were assured that the application was within the public interest as it would enable assessment of the impact of cholesterol levels on the risk of developing dementia in later life. The study proposed reuse of an established historic cohort of patients who were recruited to a fully consented trial studying the impact of cholesterol on the risks of heart attack and stroke. The reuse of this data would enable the proposed study assessment to be undertaken now, without the requirement to prospectively follow a patient group.

The CAG was assured by the application that there was significant justification to undertake the follow-up study focusing on dementia in this cohort. The Group was assured that this defined a significant public interest which supported the reuse of this historical dataset.

Practicable alternatives

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

- Feasibility of consent

The applicants sought guidance from the Data Access Request Service (DARS) and the Independent Group Advising on the Release of Data (IGARD) at NHS Digital around the existing consent which was in place for the historic trial. The feedback provided confirmation that an assessment of the existing information and consent materials had been undertaken. It had been agreed that the historic consent was not considered valid, in relation to the common law duty of confidence, to extend to the wider research purposes set out in this revised application.

The CAG considered the guidance which was provided by NHS Digital and accepted the decision provided in relation to the historic consent. Members commented that whilst the historic consent did not provide a legal basis for the proposed data processing described in this new application, it was agreed that this was very much in the spirit of the original consent.

Consideration had been given to the feasibility of reconsenting patients for the new application activities. The applicant had explained that due to the historic nature of the cohort and risks associated with their health conditions, it was likely that some of the patients may now be deceased. It was also noted that, due to the size of the sample, operation of a consenting model would burdensome and potentially unreliable and may introduce bias into the sample. The Group was assured by the rationale provided and agreed that a consented model was not feasible in this instance.

- Use of anonymised/pseudonymised data

The Group was assured that confidential patient information was necessary to facilitate the described linkage with wider datasets, 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 provided a privacy notice which would be displayed on the University's website to promote the study. Members agreed that this document appropriately addressed the patient notification requirements in relation to the common law duty of confidence as well the transparency requirements under current data protection legislation.

The Group agreed that the patient's right to object could be made clearer within the text, by including a specific heading. This revision would be requested.

Patient and Public Involvement and Engagement

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

The applicant provided an overview of patient and public involvement and engagement activities which had been undertaken in relation to an overarching series of trials. Specific feedback was provided around the number of patients which had been involved, the questions posed, and the views expressed. This activity had specifically sought views around the necessity to reconsent patients for the revised study. From the information provided, those involved were supportive of not seeking

further consent. The CAG agreed that the activity undertaken was appropriate and proportionate to the proposed activity.

Exit strategy

Members were unclear when support under the Regulations would cease to be required for the proposed activity as it was suggested that data would be retained for five years following the end of the study . It was unclear whether section 251 support was required to extend for this duration or would cease at the end of the study. Clarification would be sought from the applicant.

Follow-up of patient across wider UK nations

The historic trial had included patients from across the UK. The applicant had confirmed that applications had been submitted to the relevant bodies in Scotland and Northern Ireland to legitimise data processing.

When preparing the application, the applicant was unaware that NHS Digital was only able to undertake follow-up of English patients. As such, the necessity for disclosures to the NHS Wales Informatics Service had been omitted from the application. The applicant was in the process of progressing this linkage. The CAG agreed, to prevent any delays in commencing the follow-up of English patients, the Welsh sub-cohort of patients would not be considered within the scope of this activity. The applicant would be asked to submit an amendment to the study when the linkage process had been established with NHS Wales Informatics Service.

Wider use of stored tissue samples

The Group noted that the study also proposed the wider use of retained tissue samples, which would be shared with an American partner for analysis. The remit of the CAG extends only to the use of data without consent and does not extend to tissue samples. However, Members sought assurance from the applicant that the Material Transfer Agreement which would be established for the transfer of tissue would clearly set the legal basis under which these would be shared. This was to ensure that there was clarity that these samples were not being disclosed with section 251 support.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Revise the privacy notice to include a specific heading around the patient's right to object to ensure this is made clear.

2. Clarify the exit strategy from section 251 support and when this is expected to be enacted.

3. Provide assurance that the Material Transfer Agreement sets out the basis under which tissue samples are shared with the American partner.

4. An amendment request should be submitted to bring the Welsh patients within the scope of support once the data flows and linkage process with NHS Wales Informatics Service has been established.

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. Support currently only extends to patients in England. Applications have been made to the appropriate bodies in Scotland and Northern Ireland for patients in these nations.

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: University of Oxford - Medical Sciences Division – Nuffield Department of Primary Care Health Sciences (EE133863-MSD-NDPCHS) – DSPT review pending. NHS Digital has a confirmed 'Standards Met' grade on DSPT 2018/19.**

b. 19/CAG/0167 - SEARCH Trial Legacy Study

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertake long-term follow-up of patients who were previously recruited to the SEARCH Trial to see if differing levels of LDL-cholesterol lowering amongst the participants affected their longer-term risk up to 40 years post-trial of dementia, major diseases such as heart attack, stroke or kidney disease or death.

Dementia is a leading cause of death in the UK and affects many people. Dementia is a condition that develops over a long period before symptoms lead to diagnosis. Cardiovascular risk factors, such as LDL-cholesterol (an essential component of blood, which at increased levels can build up on the walls of arteries increasing the risk of heart disease), are associated with the risks of developing dementia. It is as yet unknown whether increased levels of LDL cholesterol in older people are associated with increased risk of dementia, say 15-20 years later or longer. By using established patient cohorts from existing long-term follow-up studies, such as the SEARCH trial, the applicants would be able to examine long-term outcome data in the older population now.

The SEARCH trial recruited 12, 064 patients between 1998 and 2008 to a randomised controlled trial looking at the impact of cholesterol-lowering drugs versus placebo in patients who had suffered myocardial infarction. Existing study records will be linked with routinely collected health data held by NHS Digital and NHS Wales Informatics Service to form a legacy study database. This database will be utilised together with existing stored blood and urine samples of SEARCH participants to study the effect of LDL-cholesterol lowering on reducing the risk of developing dementia and other diseases such as the long-term risk of death, other important diseases and healthcare use in the UK.

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

Confidential patient information requested

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

Cohort	All patients from England and Wales who were recruited to the main SEARCH trial.
Data sources	1. Existing SEARCH Trial data 2. HES, NHS Digital, 3. Mental Health Minimum Dataset, NHS Digital 4. ONS Mortality Information, NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Date of death 5. Postcode (district level) 6. Sex 7. Study ID
Identifiers required for analysis purposes	1. Study ID
Additional information	• The study involves a historic patient cohort in Scotland and Northern Ireland which are out of scope for the CAG remit. Separate applications have been made to the appropriate bodies in these nations in relation to the application. • The study also involves the use of historic patient samples on the basis of consent which is out of scope for the CAG application.

Confidentiality Advisory Group advice

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

Public interest

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

Members were assured that the application was within the public interest as it would enable assessment of the impact of cholesterol levels on the risk of developing dementia in later life. The study proposed reuse of an established historic cohort of patients who were recruited to a fully consented trial studying the impact of cholesterol-lowering medications in patients who had suffered a myocardial infarction. The reuse of this data would enable the proposed study assessment to be undertaken now, without the requirement to prospectively follow a patient group.

The CAG was assured by the application that there was significant justification to undertake the follow-up study focusing on dementia in this cohort. The Group was assured that this defined a significant public interest which supported the reuse of this historical dataset.

Practicable alternatives

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

- Feasibility of consent

The applicants sought guidance from the Data Access Request Service (DARS) and the Independent Group Advising on the Release of Data (IGARD) at NHS Digital around the existing consent which was in place for the historic trials. The feedback provided confirmation that an assessment of the existing information and consent materials had been undertaken. It had been agreed that the historic consent was not considered valid, in relation to the common law duty of confidence, to extend to the wider research purposes set out in this revised application.

The CAG considered the guidance which was provided by NHS Digital and accepted the decision provided in relation to the historic consent. Members commented that

whilst the historic consent did not provide a legal basis for the proposed data processing described in this new application, it was agreed that this was very much in the spirit of the original consent.

Consideration had been given to the feasibility of reconsenting patients for the new application activities. The applicant had explained that due to the historic nature of the cohort and risks associated with their health conditions, it was likely that some of the patients may now be deceased. It was also noted that, due to the size of the sample, operation of a consenting model would be burdensome and potentially unreliable and may introduce bias into the sample. The Group was assured by the rationale provided and agreed that a consented model was not feasible in this instance.

- Use of anonymised/pseudonymised data

The Group was assured that confidential patient information was necessary to facilitate the described linkage with wider datasets, 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 provided a privacy notice which would be displayed on the University's website to promote the study. Members agreed that this document appropriately addressed the patient notification requirements in relation to the common law duty of confidence as well the transparency requirements under current data protection legislation.

The Group agreed that the patient's right to object could be made clearer within the text, by including a specific heading. This revision would be requested.

Patient and Public Involvement and Engagement

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

The applicant provided an overview of patient and public involvement and engagement activities which had been undertaken in relation to an overarching series of trials. Specific feedback was provided around the number of patients which had been involved, the questions posed, and the views expressed. This activity had specifically sought views around the necessity to reconsent patients for the revised study. From the information provided, those involved were supportive of not seeking further consent. The CAG agreed that the activity undertaken was appropriate and proportionate to the proposed activity.

Exit strategy

Members were unclear when support under the Regulations would cease to be required for the proposed activity as it was suggested that data would be retained for five years following the end of the study . It was unclear whether section 251 support was required to extend for this duration or would cease at the end of the study. Clarification would be sought from the applicant.

Follow-up of patient across wider UK nations

The historic trial had included patients from across the UK. The applicant had confirmed that applications had been submitted to the relevant bodies in Scotland and Northern Ireland to legitimise data processing.

When preparing the application, the applicant was unaware that NHS Digital was only able to undertake follow-up of English patients. As such, the necessity for disclosures to the NHS Wales Informatics Service had been omitted from the application. The applicant was in the process of progressing this linkage. The CAG agreed, to prevent any delays in commencing the follow-up of English patients, the Welsh sub-cohort of patients would not be considered within the scope of this activity. The applicant would be asked to submit an amendment to the study when the linkage process had been established with NHS Wales Informatics Service.

Wider use of stored tissue samples

The Group noted that the study also proposed the wider use of retained tissue samples, which would be shared with an American partner for analysis. The remit of the CAG extends only to the use of data without consent and does not extend to tissue samples. However, Members sought assurance from the applicant that the Material Transfer Agreement which would be established for the transfer of tissue would clearly set the legal basis under which these would be shared. This was to ensure that there was clarity that these samples were not being disclosed with section 251 support.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Revise the privacy notice to include a specific heading around the patient's right to object to ensure this is made clear.
2. Clarify the exit strategy from section 251 support and when this is expected to be enacted.
3. Provide assurance that the Material Transfer Agreement sets out the basis under which tissue samples are shared with the American partner.
4. An amendment request should be submitted to bring the Welsh patients within the scope of support once the data flows and linkage process with NHS Wales Informatics Service has been established.

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. Support currently only extends to patients in England. Applications have been made to the appropriate bodies in Scotland and Northern Ireland for patients in these nations.
2. Favourable opinion from a Research Ethics Committee. **Pending**

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: University of Oxford - Medical Sciences Division – Nuffield Department of Primary Care Health Sciences (EE133863-MSD-NDPCHS) – DSPT review pending. NHS Digital has a confirmed 'Standards Met' grade on DSPT 2018/19.**

c. 19/CAG/0162 - Prehospital early warning scores for sepsis

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research which aims to test the efficacy of early warning scores in the identification of sepsis. It is noted that an accurate early warning score could help clinicians ensure that patients with sepsis are identified and treated quickly. Conversely, an inaccurate early warning might cause sepsis to be missed or patients with other conditions to be falsely diagnosed.

Workstream one is a retrospective cohort study using routing data sources to estimate the accuracy of prehospital early warning scores (index test) for predicting potential to benefit from time-critical treatment for sepsis (reference standard) in adults with possible sepsis who are attended by emergency ambulance. This will involve retrospectively identifying the patient cohort from ambulance records and linking with wider follow-up data from and local hospital Trusts.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the

application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	All adults with possible sepsis transported by emergency ambulance to four acute hospitals over the course of the year 01/04/2018 to 31/03/2019. It is estimated that this will include 46,000 patients.
Data sources	1. Yorkshire Ambulance Service NHS Trust electronic patient records 2. West Midlands Ambulance Service University NHS Foundation Trust electronic patient records, 3. Sheffield Teaching Hospitals NHS Foundation Trust electronic patient records 4. Barnsley Hospital NHS Foundation Trust electronic patient records 5. Emergency Care Data Set, NHS Digital 6. Hospital Episodes Statistics (HES), NHS Digital 7. ONS mortality data, NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital Number 4. Date of birth 5. Hospital site attended
Identifiers required for analysis purposes	1. Hospital site attended 2. Sex 3. Ethnicity 4. Age at event

	5. Time of day of event
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 acknowledged that sepsis was a topical issue and were assured that there was a clear public interest in assessing the efficacy of early warning scores in its identification.

Scope of support

The applicant had clarified in the response to queries which were raised by the Confidentiality Advice Team that neither the research paramedics or nurses which would be processing confidential patient information within the scope of this project were considered to be part of the direct clinical care team. The CAG received this assurance and agreed that it would not consider these roles to have a legitimate basis to access confidential patient information for the purposes of the study. The Group was content to extend the scope of section 251 support to the processing activities which would be undertaken by these roles.

It was explained that two further hospital sites were still to be recruited to the study. These sites would be serviced by the West Midlands Ambulance Service University NHS Foundation Trust. Members agreed that these supplementary sites could be added to the scope of support via submission of an amendment when they had been confirmed, to prevent delaying the overall proposal.

Practicable alternatives

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

- Minimising flows of identifiable information

The data flows within the study had been limited to prevent the applicants within the University of Sheffield having access to confidential patient information.

- Feasibility of consent

The study involved a large retrospective patient cohort from whom it would be difficult to seek consent. It was further noted that, due to the poor prognosis of sepsis patients, it was likely that a significant proportion of the cohort would be deceased. The CAG was assured by the rationale presented and was content to provide a recommendation of support to enable the study to proceed on an unconsented basis.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate linkage with wider data sources 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 confirmed that information would be displayed at participating sites to inform patients of the study. The format of this information would depend on the facilitates available at site but was likely to be a poster or display on an electronic noticeboard. Members agreed sight of this document was necessary prior to any

final recommendation of support coming into effect. It was further agreed that this information should also be displayed by the participating ambulance Trusts and on the websites of all organisations involved.

It was explained that any known objections would respected within the study dataset and would be applied both at a Trust level and by NHS Digital. The applicant had also confirmed that the patient notification materials will promote a project-specific objection mechanism which would be operated by the research nurses working within the Trusts. Members were assured by the described mechanism but agreed that the patient-facing materials would need to be assessed to see how this was presented.

The Group further queried whether the applicant had explored the possibility of displaying information about the study via the Sepsis Trust's website. It was suggested that patients who had survived sepsis may have links with this charity, which would provide useful mechanism for wider publicity about the trial.

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 four patients were involved in the study planning and oversight for the application via involvement in the study team and Project Management Group. It was further explained that the applicant was in the process of establishing a project-specific patient and public involvement group. Three patients had already been identified and it was planned to recruit a further two members. Further feedback on the establishment of this group would be requested.

It was confirmed that no specific activity had been undertaken to test the acceptability of using confidential patient information without consent as described in the application. Members agreed that feedback was required in this area prior to the study commencing to ensure patients were supportive of the activity. The applicant advised that there were established links with the Sheffield Emergency Care Forum user group. It was suggested that this group be approached to seek views around the use of patient data within the study, whilst the applicant progressed the project-specific user group.

Exit strategy

Members recognised that only pseudonymised data would be shared with the applicant at the University of Sheffield, following linkages, for the purposes of analysis. However, at Q31-3 of the application form it was stated: *Once the study has been completed and all data linkage and transfers completed any indirect identifiers will be removed from the dataset held within the University of Sheffield CTRU, as far as possible.* The Group was unclear what information within the dataset would be classified as an indirect identifier and agreed that clarification around this point would be sought from the applicant.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Provide a copy of the patient-facing information which will be displayed within participating Trusts. Confirm that this information would also be displayed by the ambulance Trusts and on associated websites.
2. Explore the feasibility of promoting the study more widely via the Sepsis Trust. Provide feedback on whether this is possible, and if not, provide justification to explain why.
3. Specific patient and public involvement and engagement activity needs to be undertaken in order to test the acceptability of using confidential patient information without consent for the application purposes. Provide an overview of the activity undertaken, those present and the views which were expressed.
4. Provide an update on the progression of the study-specific patient group.
5. Clarify what information will be contained within the database at the University of Sheffield and how this could be considered an indirect identifier. Also clarify in what circumstance it would not be possible to delete this information.

6. Support will be extended to those sites which have confirmed participation at this stage. Supplementary hospital sites should be added within the scope of support via submission of an amendment once recruited.

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 06 September 2019**
2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Due to the number of sites involved in processing data with section 251 support, individual DSPT submissions are not required for the purpose of the application. Each site is expected to have achieved a 'standards met' in relation to their organisational DSPTs.**

4. Resubmission - Research

a. 19/CAG/0144 (Previously ECC 5-07(a)/2009) Infections in Oxfordshire: a Research Database (IORD) version 3.0

Context

Purpose of application

This application from the Oxford University Hospitals NHS Foundation Trust set out the medical purpose of medical research via the ongoing maintenance of the Infections in Oxfordshire Research Database (IORD), which collects information on the treatment of infection in Oxfordshire. This application has operated within support under the Regulations since October 2009 under the CAG reference ECC 5-07(a)/2009.

The primary aim of the database is to use routinely recorded electronic data on hospital administration records, electronic medical records, pathology tests, radiology and other imaging data to prospectively investigate predictors of and instances of infection and infection-associated syndromes within Oxfordshire from 1998. This will also include investigating trends, the severity of presentation and any adverse outcomes following the infection. This also includes investigation of incidence of and outcomes following infection in populations particularly at risk of infections, including, for example, those with cancer or chronic kidney disease.

The database links together a wide range of standard healthcare records from Oxford University Hospitals Foundation NHS Trust for inclusion in the database. These include patient administration records, pathology records, clinical assessments, electronic prescribing, data interactions with primary care, Oxford maternity database and infection control databases which are linked within the Oxford University Hospitals Clinical Systems Data Warehouse. Once linked, a dataset is disclosed to the Infections in Oxfordshire Research Database, which is held within a separate NHS server. Limited items of confidential patient information are included within the dataset disclosed to the research database for the purposes of informing analysis datasets.

A recommendation for class 1, 2 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 admitted/attended Oxford University Hospitals NHS Foundation Trust as an inpatient, outpatient, at A&E or who provided a specimen to be processed within the pathology laboratories from 01 January 1997 onwards. It is estimated that approximately 4 million patients are included in the database.
Data sources	1. Oxford University Hospitals Clinical Systems Data Warehouse (OUH CSDW)
Identifiers required for linkage purposes	No identifiers are needed for validation or linkage. Linkage is carried out by Oxford University Hospitals Clinical Systems Data Warehouse (OUH CSDW)
Identifiers required for analysis purposes	1. IORD identifier 2. Date of birth 3. Date of death 4. Gender 5. Ethnicity

	6. Electoral ward 7. Postcode district 8. GP practice code 9. Strategic health authority
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 established database provided an incredibly rich resource for research purposes and were satisfied that its ongoing retention and data collection had a clear public interest.

Scope of support

Members noted that the application described linkage between the Trust records and GP practice and out of hours service provider records. It was unclear from the information provided whether this linkage was undertaken as standard as part of direct clinical care, or whether this was specifically undertaken for the purposes of the project. The applicant would be asked to provide clarity around this point to ensure the scope of support under the Regulations was clearly defined.

Practicable alternatives

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

- Feasibility of consent

The applicant had explained that to date, over four million patient records had been included in the database. The Group was assured that seeking consent for the use of confidential patient information within the database was not feasible due to the volume of health interactions which were recorded.

- Use of anonymised/pseudonymised data

The CAG was concerned that the research database had been described within the application as an anonymised dataset as it was clear that there were data items included which were considered to fall within the definition of confidential patient information, for example date of birth and death.

Members agreed that it would beneficial for the applicant to reassess the terminology used to describe the data retained within the research database. It was suggested that the it may be helpful to use the public language which was developed by the Medical Research Council (MRC) to describe the identifiability of data when dealing with patients and the public.

The Group further commented that, due to the richness of the information held within the database, it was unlikely that this would ever be truly anonymous.

Justification of identifiers

The applicant had explained that date of birth was only required where the focus of the research was on neonates. On the basis of this information, the Group was unclear of the justification for collecting and retaining this data item in relation to all other patients. The applicant would be asked to provide further justification to support this requirement. If the justification provided was not considered strong enough to support this, the CAG would consider whether there would be a requirement for this data item to removed and replaced in a less identifiable format.

It was suggested that this could be undertaken for all entries within the database. Should a specific application involving neonates be made in future, the applicant for that proposal could submit a project-specific request for section 251 support to enable access to complete date of birth.

The CAG was also unclear why date of death needed to be retained in the database in complete format. It was suggested that this could be translated to either age at death or time to death, to reduce the identifiability of the research database. The applicant would be required to provide a stronger justification to support the requirement for this data item to be retained in its complete format.

Sensitive data items

The Group commented that some infections were considered more sensitive to patients than others, noting sexually transmitted infections as example. The application form did not appear to identify whether any sensitive data was held within the database which may require more stringent security measures to be put in place. The applicant would be asked to consider this point and make assessment of whether

there was any sensitive information within the database and provide feedback in this area.

‘Patient Notification’ and mechanism for managing dissent

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

The applicant had provided copies of posters which were displayed in the Trust and within GP practices to inform patients about the database. The Group raised significant concerns around these documents as they described the database as anonymous and did not explain the items of confidential patient information which would be processed. It was also noted that the documents did not explain a patient’s right to dissent to the use of their data within the database.

Members also reviewed the generic Trust level privacy notices and the project specific website. It was agreed that the project website also did not clearly describe the database or the patient’s right to dissent to the inclusion of their data.

It was agreed that revised patient notification materials were required which appropriately described the database and made clear the patient’s right of objection. It was suggested that the revised documents should be drafted with patient and public engagement to ensure these are fit for purpose and accurately describe the status of the information which is retained.

Patient and Public Involvement and Engagement

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

The applicant explained that the research database team included service user and public involvement. A separate patient panel which supported the database had also been created which aimed to have three active members. Further information was provided around wider consultation which had taken place in the Trust and within a research consortium at the University.

Members commented that, due to the scope and richness of the database, further activity was required in this area. This should test the acceptability of using confidential patient information without consent for the database purposes. It should also seek

feedback from patients around any areas they deemed particularly sensitive which may require stronger controls. It would also be helpful to seek the views of patients around the types of organisation which require access to the database. Due to longitudinal nature of the proposal, the CAG agreed that the applicants should develop an ongoing programme of activity in this area to ensure patient views were accounted for on an ongoing basis. Feedback would be requested around the planned activity prior to any final recommendation of support coming into effect under the revised application reference.

Governance and access arrangements

Internal and external applicants were able to apply to use the database for research purposes. It was explained that applications were reviewed by a panel who determined whether the request could be approved. It was noted that there were two individuals who were classified as patient representatives within this panel; however, the separate patient panel did not appear to play any role in decision-making. The Group agreed that, due to the richness of the data which would be made available, a wider lay perspective in the approval process would be beneficial. This point would be followed up with the applicant.

It was noted that researchers applying to use the database may want to use the data for wider purposes than the study of infections. Members agreed that further information would be requested around the review and approval process, to understand what assessment was undertaken of the purpose behind an applicant's research proposal.

The application also stated that data would be released to organisations outside the UK. The Group raised concerns around what data would be released in these circumstances, specifically due to the inaccurate classification of the database as anonymous. It was agreed that further information was required in this area to provide assurance that identifiable data, or datasets at a higher risk of being identified, were not being disclosed.

It was further noted that commercial entities were also able to apply to use the database. The CAG agreed that the applicant would be asked to provide a copy of its policy on use of the database by commercial entities for consideration, to see what safeguards were put in place around these disclosures.

The CAG noted from the information provided in response to queries raised by the Confidentiality Advice Team that members of the research database team would be appointed either by NHS contract or honorary contract. Members agreed that assurance would be requested from the applicant that those operating under honorary contracts were bound by the same confidentiality requirements as permanent staff.

Confidentiality Advisory Group advice conclusion

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

Request for further information

1. Clarify whether linkage with GP and out of hours records is undertaken as part of standard care, or if it forms part of the scope of support which is requested under the Regulations.

2. Reassess the terminology used to describe the database. It is suggested that the MRC's guidance is used as a basis for this assessment.

3. Provide a stronger justification to support the requirement for date of birth and death to be retained in the database in true format.

4. Assess the database content for sensitive items and whether there is a requirement for more stringent security protocol to be in place for data items which fall into this category.

5. Patient notification materials and website text should be revised to provide a clearer overview of the database content and provide a clear mechanism for patient objection. It is recommended that these materials are devised with patient input.

6. Further patient and public involvement and engagement activity needs to be undertaken to test the acceptability of using confidential patient information without consent for the purposes. Submit a plan for this activity and explain how it this will be incorporated, on an ongoing basis, into the management and oversight of the database.

7. Further patient and public involvement should be incorporated into the database oversight committee, with particular reference to the decision-making process. Provide an overview of how this would achieved.

8. Provide further information around the application and approval process for researchers wishing to access the database. Specific information should be provided around how applications seeking to use the database for research which does not focus on infections are considered.

9. Clarify what disclosures are made outside the UK, providing assurance that no confidential patient information is included in these disclosures.

10. Provide a copy of the policy for use of the database by commercial entities for consideration.

11. Clarify that members of the research database team which operate under an honorary contract are bound by the same contractual confidentiality requirements as permanent staff.

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: Oxford University Hospitals NHS Foundation Trust requires confirmation.**

b. 19/CAG/0142 (Resubmission PIAG 2-08(e)/2002) - Linked de-identified research database for congenital anomaly outcomes (BINOCAR)

Context

Purpose of application

This application from St George's University of London set out the purpose of medical research through the creation of a research database into the outcome of children affected by congenital abnormalities registered in the UK prior to 01 April 2015. The application has existing support under application reference PIAG 2-08(e)/2002; however, a refreshed application became necessary due to a change in controller for the proposal.

The application support to enable the BINOCAR regional registers to transfer specified legacy data to St George's University of London to enable linkage with health, mortality and educational data with a view to creating a congenital anomaly outcomes research database to facilitate research into the outcomes of children affected by congenital anomalies. Support is also requested to enable the disclosure of complete BINOCAR legacy datasets relating to the Northern Congenital Abnormality Survey (NoCAS) and the South West Congenital Anomaly Register (SwCAR) from Public Health England. Ongoing linkages are proposed with administrative health datasets, mortality data and educational outcomes. The applicant is seeking support for the ongoing processing and retention of confidential patient information for the complete BINOCAR legacy dataset until June 2021. The database will only contain legacy information registered prior to 01 April 2015; no newly registered congenital anomalies will be included.

A recommendation for class 1, 2, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	Patients registered in the following regional congenital anomaly registers will be transferred into the database: 1. Congenital Anomaly Register for Oxfordshire, Berkshire and Buckinghamshire (CAROBB) - births from 1991 to 31 March 2015; 2. East Midlands and South Yorkshire Congenital Anomaly Register (EMSYCAR) - births from 1997 to 31 March 2015; 3. South West Congenital Anomaly Register (SWCAR) – births from 2002 to 31 March 2015; 4. Northern Congenital Abnormality Survey (NorCAS) – births from 1985 to 31 March 2015; 5. Wessex Antenatally Detected Anomalies Register (WANDA) – births from 1994 to 31 March 2015.
Data sources	1. Hospital Episodes Statistics (HES), NHS Digital 2. ONS mortality data, NHS Digital 3. GP Prescriptions data (CPRD) – QUERY linkage by NHS Digital? 4. National Pupil Database, Department for Education
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID 4. Date of birth 5. Date of death

	6. Postcode (Unit level) 7. Ethnicity
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.

The Group recognised that the local registries held valuable legacy data which would be utilised for important research purposes. Members were sympathetic to the delays which had been experienced by the applicant when trying to establish a centralised base for retention of this historic data. It was noted that this application had been submitted to enable the pending research projects to progress whilst the applicant worked together with Public Health England to confirm a longer-term plan for the data retention.

The CAG was assured that the proposed activity was within the public interest as it would enable progression of important research into congenital anomalies.

Scope of support

The applicant provided a revised data flow chart in response to queries raised by the Confidentiality Advice Team in advance of the CAG meeting. This document made reference to the inclusion of a control cohort which was not cited at any other point in the application documentation. Whilst Members recognised the scientific merit of including a control cohort within the study database, to enable comparison with the patient cohort, the application provided no detail around this group, how it would be identified and whether there was any requirement to extend the scope of support under the Regulations to its creation. It was further commented that as the control cohort was not referenced within the application form or study protocol, it did not appear that the ethical opinion which was in place for the study extended to this group.

The CAG agreed that whilst supportive in principle for this application, it could not recommend support where such a fundamental issue remained outstanding in relation to the scope of the proposed activity. It was agreed that the recommendation would be deferred pending further clarification from the applicant around the control cohort. If this group was to be included within the study, a revised application form and protocol would be required to provide clear information around this group.

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 Group recognised that the application concerned the onward processing of confidential patient information which had been historically collected with support under the Regulations. Members were assured that, as the original information had been collated on an unconsented basis, it was not feasible to seek consent at this stage for the wider activities described in this application. It was also noted that, due to the poor prognosis for patients within the cohort, it was likely that a significant proportion would now be deceased. The CAG was content for the application activity as described to proceed on an unconsented basis.

It was recognised that this determination did not extend to the control cohort if this was to be included within the scope of the application activity. If confidential patient information would be processed without consent in relation to this additional cohort, the applicant would be required to provide specific rationale to support this as part of the revised application submission.

- Use of anonymised/pseudonymised data

Confidential patient information was required for the purposes of linkage which Members recognised could not be otherwise achieved.

Justification of identifiers

The CAG was assured that the items of confidential patient information to be processed were appropriate and proportionate to achieve the study aims.

‘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 copies of updated website text which would be displayed on the BINOCAR study website and those of the local registries which were providing datasets to the study once all necessary approvals were in place for the application. Members reviewed the BINOCAR study website and it was commented that this appeared to be presented for a professional audience, rather than parents and patients. The Group agreed that that the applicant would be asked to review the website for acceptability for a lay audience. It was also advised that an additional means of contact should be provided to support the email address which was currently available.

It was further commented that consideration would need to be given, as part of the revised application, to how individuals in the control cohort would be informed about the use of their data and provided with a means of objection. This information would need to be provided as part of the revised application submission.

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 application described various links with relevant associated charities and parent groups. The main link was via the Newlife Foundation for Disabled Children which facilitates communication between interested parents and BINOCAR via the Chief Executive, who is a full member of the BINOCAR management group.

It was explained that use of data within the research database is considered by the full management group, including the representatives from parent support groups and charities. It was also confirmed that the local registries had parental involvement in their management groups and via local Trusts. Links to the associated charities and parent groups were provided via the BINOCAR website.

The CAG recognised that patient involvement and engagement activity was clearly well-established for the database and that the applicants had an ongoing schedule of activities in this area which were appropriate and proportionate to the described activity.

Members commented that consideration would need to be given to how appropriate involvement and engagement activity could be undertaken in relation to the control cohort. Feedback would be required as part of the revised application submission to

evidence how the use of confidential patient information without consent had been tested in relation to the control cohort.

Data flows

The Group considered the revised data flow chart which had been provided to support the application activity. It remained unclear how all proposed study data would be linked for analysis purposes as it did not appear that there would be any linkage between the educational and clinical data. Members agreed that the revised application should provide a detailed overview of how the data linkage would be facilitated for the study. This should be supported by a revised data flow chart which followed the flow of data through the study. This document would also need to be account for any processing of confidential patient information which would be necessary for the control cohort.

Members also requested confirmation that the proposed data linkage between the patient cohort and educational data would be undertaken by the Department for Education (DfE) directly. This query was raised again on this basis that it was current understanding that the Office for National Statistics (DfE) was acting as processor on behalf of DfE and had been undertaking data linkage with educational datasets. The applicant would be asked to provide copies of any correspondence with DfE to support this element, to ensure that the data flows were clearly understood.

Exit strategy

The applicant was seeking support until June 2021, following which the database would be de-identified. The local registries had confirmed that they would destroy confidential patient information retained locally once successful transfer of the legacy datasets had been confirmed by St George's University of London.

Members queried whether there would be onward retention of a linkage key by NHS Digital or Public Health England once the research database had been deidentified. The applicant would be asked to clarify this point.

Confidentiality Advisory Group advice conclusion

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

Further information required

The following information should be provided to allow the CAG to continue their consideration of the application:

1. Further information is required around the control cohort which was referenced within the revised data flow chart. This should clarify who these individuals are, how they will be identified and by whom and whether their inclusion would involve processing of confidential patient information without consent. The application form and study protocol would need to be updated to reflect the inclusion of this group.

2. Confirmation would be required that the favourable ethical opinion for the study extends to the control cohort. This may require the submission of a substantial amendment to the REC.

3. The revised application would need to provide specific justification for the processing of confidential patient information without consent for the control cohort, if applicable.

4. The BINOCAR study website should be reviewed for suitability for a patient and public audience to ensure the published information is appropriate for these readers. An additional contact mechanism should be provided to support the email address which was currently available.

5. Specific consideration should be given to how study information can be made available to the control cohort, including details of how these individuals can dissent to the use of their data. Copies of any revised or supplementary materials should be provided for review.

6. Wider patient and public involvement and engagement activity should be carried out in relation to the control cohort. Feedback around the activity undertaken should be provided together with the views given on the use of confidential patient information without consent, as appropriate, in relation to this group.

7. Provide further information around the data flows for the proposed activity. A revised data flow chart should be provided which follows the flow of data within the study. This should also explain any data flows in relation to the control cohort.

8. Confirm that the data linkage between the study cohort and educational data would be undertaken directly by the Department for Education. Provide copies of any correspondence which confirms this for assurance purposes.

9. Clarify whether a linkage file will be retained by any of the entities involved in the study, following the deidentification of the study database.

10. 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: assurance remains outstanding for St George’s University of London. The following**

organisations have a confirmed 'Standards Met' grade on DSPT 2018/19: NHS Digital, Department for Education and Office for National Statistics.

c. 19/CAG/0160 (Previously PIAG 3-07(g)/2002) - BRCOH - Evaluation of the NHS Breast Screening Programme

Context

Purpose of application

This application from the Queen Mary University of London set out the purpose of medical research which aims to evaluate the impact of the NHS Breast Screening Programme on breast cancer mortality in England and Wales. This is a longitudinal programme which had initially been carried out by the Cancer Screening Evaluation Unit and was transferred to the Queen Mary University of London in 2014. The study population comprised over 2 million women aged 49–64 in 1988. Individual-level breast screening histories have been linked to individual-level mortality and breast cancer incidence data from national registers. Risk of death from breast cancer has been investigated in relation to intention to screen and in first round screening attendance.

The applicants are now seeking support to flag the remainder of the cohort who have not been flagged previously in order to obtain up-to-date cancer incidence and mortality follow-up to conduct analysis on a longer-term basis. The objectives of this follow-up phase are to further assess the effectiveness of the screening programme by comparing risk of death from breast cancer in woman who were invited for screening with those who were not invited in the same period for follow-up over a 25-year period and wider objectives related to the impact of the screening programme on diagnosis of breast cancer.

The study database includes details of approximately 2.7 million women (n=2,669,328) born between 1923 and 1945, resident in the study area and eligible for at least one invitation by the NHSBSP between January 1988 and December 1994. The study area covered 22 Local Health Boards (LHBs) in Wales and 137 PCTs in England, and the study therefore included approximately 38% of the population of England and Wales who were eligible for invitation to NHS breast screening between these dates.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

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

Cohort	2.7 million women (n=2,669,328) born between 1923 and 1945, resident in the study area and eligible for at least one invitation by the NHSBSP between January 1988 and December 1994. The study area covered 22 Local Health Boards (LHBs) in Wales and 137 PCTs in England.
Data sources	1. Study cohort, Queen Mary University of London 2. ONS Cancer Registration and Mortality Data, NHS Digital
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. Date of death 5. Postcode
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode 4. Sex
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 the ongoing public interest in evaluating the impact of the breast screening programme. It was further noted that the additional flagging exercise which was described in this application would enable direct comparison between the outcomes of those women who were and were not invited for screening, which had a clear public interest.

Practicable alternatives

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

- Feasibility of consent

The Group was assured that it was not feasible to operate a consented model for the study due to the size of the retrospective patient included in the study, which extended to nearly three million women.

- Use of anonymised/pseudonymised data

Confidential patient information was required to facilitate the linkage with wider datasets which could not be otherwise achieved.

Justification of identifiers

The CAG noted at Q27 of the application form that patient name would be used to flag patients with NHS Digital. This data item had not been listed at Q36/37 as required for linkage purposes. Members were unclear why patient name would be necessary for flagging, based on the other data items listed, or how the applicants would have access to this item. It was agreed that clarity would be sought from the applicant on this point. If patient name was included in the study database, a rationale would be required to explain why this was necessary together with a timeframe for its destruction.

Members considered the information which was retained in the database for analysis purposes. It was queried why, once the patient cohort had been flagged with NHS Digital, there was a need for the applicant to retain confidential patient information within the study database.

The Group agreed that the applicant would be asked to reassess the necessity of the ongoing retention of the data items within the database. It was commented that date of birth and death could be translated into time to diagnosis and survival calculations. It was also unclear what level of postcode was currently retained within the database and why, after flagging had been undertaken, this could not be translated to deprivation scores. The applicant would be asked to provide a detailed overview of the data items which were necessary for analysis purposes and in what format these were required.

'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 the study privacy notice had been provided for consideration. Members noted within the section of the document entitled 'Personal data we collect about individuals' that it was explained that date of birth and death, together with wider clinical information was collected on patients within the study. The section goes on to state that names, address, postcode and NHS number were not collected, which did not appear to accurately reflect the information which was detailed in the application form, or the data items which would be processed for the purposes of the study to facilitate linkage. The Group agreed that the text would need to be reassessed to ensure this accurately reflected the data to be processed within the study and collected by the applicants. The document should also make the ongoing use of the study data clear to patients. It was suggested that patients should be involved in the revision of the document to ensure this was clear to a lay audience.

It was further noted that only the national opt-out mechanism was described within the text. Members were unclear why, on the basis that the applicant did appear to hold patient identifiers, a study-specific dissenting mechanism could not be operated. This was of particular relevance to the newly proposed flagging exercise described in this application. The applicant would be asked to consider a mechanism for operating a project-specific dissent to patients. If this was not deemed feasible, a strong justification would be required to support this decision.

Patient and Public Involvement and Engagement

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

It was explained that as this study was part of the programme of the Policy Research Unit (PRU), it was subject to the scrutiny of the PRU's patient and public involvement committee, which was comprised of nine members of the public. Due to the longitudinal nature of the study, the patient group could not be involved in its design or management.

The applicant had explained that the project had been referred back to the group to test the acceptability of using confidential patient information for its overall purposes. The CAG agreed that feedback from this activity was required, which should seek specific views on the additional flagging exercise which had been described, prior to a final recommendation of support being recommended under this refreshed application reference.

Exit strategy

The applicant had explained that the study would end in December 2022. It was unclear from the application form whether updates would continue to be received from NHS Digital after this point. It was also unclear when confidential patient information would be destroyed. The Group agreed that further clarity would be sought from the applicant around the proposed end of study and exit strategy from 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 would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. Confirm if patient name is required for the purpose of linkage. If so, clarify the source of this data, provide a justification to support its requirement and explain how and when this would be destroyed.

2. Provide further information to explain the ongoing necessity to retain confidential patient information in the study database, once the patient cohort has been flagged with NHS Digital.

3. Clarify what information is retained in the study database for the purposes of analysis and in what format. For each data item, provide a rationale to justify its requirement.

4. The privacy notice should be revised to accurately describe the items of confidential patient information which were used in the study, what was retained for analysis and in what format. The document should also provide a clear overview of the ongoing use of the study data. It is recommended that the patient group be involved in the revision of this document to provide views on its suitability for a lay audience.

5. Consider ways in which a study-specific dissenting mechanism can be operated for the study. Provide an overview of how this would implemented and ensure these details are included in the privacy notice. If it is not deemed feasible to operate a project-specific dissenting mechanism, provide a strong justification to support this decision.

6. Provide further information around the end of study arrangements, explaining when the study team would cease to receive follow-up information from NHS Digital.

7. Clarify when it is anticipated that support under the Regulations would cease to be required for the application activity, accounting for the end of study arrangements described in point six above.

Specific conditions of support (Provisional)

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

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

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: NHS Digital and Barts Cancer Centre both have confirmed 'Standards Met' grades on DSPT 2018/19 (Confirmed on DSPT tracker 10 September 2019).**

5. Minutes of the meeting held on 15 August 2019

The minutes of the meeting held on 15 August 2019 were agreed as an accurate record of events.

6. Any other business

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