Minutes of the meeting of the Confidentiality Advisory Group

18 June 2020 at Meeting via Teleconference

Present:

Name	Present	Notes
Dr Tony Calland MBE	Yes	CAG Chair
Dr Patrick Coyle	Yes	CAG Vice-Chair
Dr Murat Soncul	Yes	CAG Alternative Vice-Chair
Dr Rachel Knowles	Yes	CAG member
Mr Andrew Melville	Yes	CAG member
Dr Martin Andrew	Yes	CAG member
Dr Simon Kolstoe	Yes	CAG member
Dr Liliane Field	Yes	CAG member

Also in attendance:

Name	Position (or reason for attending)
Ms Caroline Watchurst	Confidentiality Advisor

Dr Paul Mills	Senior Confidentiality Advisor/Service Manager
Ms Natasha Dunkley	Head of Confidentiality Advice Service

1. Introduction, apologies and declarations of interest

2. Support decisions

Secretary of State for Health & Social Care Decisions

At the time of preparing this agenda, the Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care has not reviewed the advice provided by the CAG in relation to the **04 June 2020** meeting application.

Health Research Authority (HRA) Decisions

At the time of preparing this agenda, the Health Research Authority has not reviewed the advice provided by the CAG in relation to the **04 June 2020** meeting applications.

3. Consideration Items

a. 20/CAG/0079 - Long-term safety of cabergoline in hyperprolactinaemia (Resubmission of 20/CAG/0006)

Context

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research which aims to determine whether there is a link between cabergoline at low doses and the development of fibrotic heart disease.

The drug cabergoline is used in low doses for the treatment of benign pituitary tumours called 'prolactinoma'. There is evidence that the drug may cause heart valve disease so anyone taking cabergoline has heart scans every 6-12 months. This project seeks to determine if there is a link at low doses. To do this the project team seeks to use the Discovery data service to identify all eligible patients taking cabergoline (cases) and 5

matched controls for each case. The bulk of this data will be pseudonymised. Only when a case took cabergoline and subsequently developed a cardiac problem will the NHS number of that patient be collected in order to determine if that patient had an echocardiogram at Bart's Health NHS Trust. If so, the scans will be re-reviewed by a consultant cardiologist.

Section 251 support is requested for use of the NHS number to access patient records and collect echocardiograms. Whilst the applicant is employed by Bart's Health NHS Trust and works in the same department, he may not necessarily have been providing direct care to the patients. Section 251 support is also requested for a consultant cardiologist from Queen Elizabeth Hospital Birmingham to come to Bart's Health NHS Trust to re-review scans. Whilst every effort will be made to minimise access to identifiable data, the consultant will likely see names, dates of birth and NHS/hospital numbers as this information is embedded on to the images.

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	From previous work on anonymised data, the team estimate 24 patients that have taken cabergoline and developed heart problems.
Data sources	1. Discovery Data Service (data service of all hospital and GP records in North East London) 2. Bart's Health NHS Trust
Identifiers required for linkage purposes	1. NHS Number
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. NHS/Hospital number (The above are embedded onto the images that will be re-reviewed)

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.

Whist the group acknowledged that, with a small group of patients, there would be no statistical significance, they recognised the importance of estimating the true incidence of this complication with respect to the current wider research and for informing further research into the area.

Scope of support

Members queried the role of the Discovery Data Service, and whether they had a legal basis to process confidential information in order to provide NHS number of relevant patients to Bart's Health NHS Trust, and pseudonymised data to Queen Mary University of London. It was noted that the role of the data discovery service was to manage clinical data, and that provision of pseudonymised data to Queen Mary University of London is outside the scope of this support request.

The group were content with this description.

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 noted by members that the research team did not want to use consent as 24 was the minimum number to give scientific validity, and this uncertainty was the reason for the previous deferral. The applicant provided further justification in that the whole study includes 1.5 million people, of whom around 600 are taking cabergoline. Of these around 20 have had a cardiac problem diagnosed after starting. The applicants specifically need to look at these patients to see whether their echocardiograms show evidence of damage which is directly attributable to cabergoline or whether it is due to other factors. It is believed that any effect caused by cabergoline is small and the research team need to look at the heart scans from as many of these 20 patients as possible to try and determine the true incidence of this problem in large populations. Further, it is not possible to replace these patients from another geographical area as the research team do not have the wider data from other locations.

Members considered this argument and agreed that the reasons for not seeking consent were valid.

- **Use of anonymised/pseudonymised data**

It was noted that NHS number was required to identify patients at Bart's Health NHS Trust, and that the echocardiograms were embedded with patient name, date of birth and hospital/NHS number. The applicants explained that the use of an external cardiologist was

necessary to provide a standardised, expert review of the images, which not be achieved by using the clinical care team(s) of patients.

Members were content with this reasoning

'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 provided a poster that would be displayed within patient areas at Bart's Health NHS Trust. It was also noted that the content would be displayed on the study website. Members commented that the poster was well designed and were satisfied with the content.

The poster provided a clear mechanism to allow patients to dissent from the use of their confidential patient information. The group agreed that the dissent mechanism was appropriate.

Patient and Public Involvement and Engagement

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

The applicant sought support from the Pituitary Foundation, providing further evidence with this application of the details provided to the Pituitary Foundation as well as further supporting information received from them.

Members were satisfied, with the additional information, that sufficient Patient and Public Involvement and Engagement had been undertaken.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Favourable opinion from a Research Ethics Committee (**Confirmed – 12 June 2020**).
2. Continual achievement of 'Standards Met' in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT

submission as standards met' for the duration of support, and at time of each annual review. **Bart's Health NHS Trust and NHS Tower Hamlets Clinical Commissioning Group (checked on DSPT tracker 16 June 2020) have been confirmed as 'Standards Met' by NHS Digital.**

b. 20/CAG/0070 - The Prognostic Performance of the Enhanced Liver Fibrosis Test in UK Patients with Chronic Liver Disease Assessed 20 Years After Recruitment to the EUROGOLF study (EVenti). (Resubmission of 20/CAG/0040)

Context

Purpose of application

This application from the Royal Free London NHS Trust set out the purpose of medical research which aims to determine the value of using the enhanced liver fibrosis test (ELF) as part of an evaluation of liver disease risk in middle life.

An original cohort of 921 participants (497 in the UK) were consented into the EUROGOLF study between 1998 and 2000, which identified and validated the ELF test. In 2008/09 the investigators interrogated the 497 records in the UK which established it was at least equal, if not superior to, a liver biopsy in predicting liver related and all cause mortality at 7 years. It has now been 20 years since participants were enrolled and many patients have likely reached clinical endpoint. The applicants wish to use confidential patient information related to these 497 patients held by the Royal Free London NHS Foundation Trust to link to HES, cancer registry and mortality data from NHS Digital. The resulting data will be used to understand the value of the ELF test as part of an evaluation of liver disease in middle life.

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	All 497 patients recruited into the original EUROGOLF study
Data sources	1. NHS Digital
Identifiers required for linkage purposes	1. Name 2. Date of Birth 3. Gender
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode

Confidentiality Advisory Group advice

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

Public interest

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

Whilst the group recognises that this is the second deferral of the application, they wish to place on record that they believe that this study does have a significant public interest and encourage a further application once the issue around the legal basis of the original dataset is resolved.

Legal Basis

As understood by the group, participants originally gave consent between 1998-2000 Members initially questioned whether the consent originally obtained enabled the information to still be retained 20 years past the original consent time period. The reason for this question is that when advising whether 'section 251 support' should be provided, it is important for the lawful basis for the pre-existing data sources, under the common law of confidentiality, to be established. This is to ensure that support is not 'layered' onto less clear lawful bases that need to be addressed.

The applicant confirmed that the participant information sheet and consent form used is no longer available to view, therefore members were unable to give a view on whether the original consent obtained covered ongoing retention and further uses. The applicant also confirmed that a follow-up study using identifiable information without consent from this cohort was undertaken in 2008/09 under an ethical favourable opinion, but there is no record of applying for 'section 251 support' at that time. Members were therefore unclear on the lawful basis for that processing under the common law duty of confidentiality, noting that ethics committees do not have jurisdiction to provide a legal gateway to avoid a breach of the common law duty of confidentiality.

A view proposed by the research department at University Hospital Southampton NHS Foundation Trust (the data controller for the research) that, in line with ICH-GCP, it was standard practice to retain the original source data for ethically approved studies for a minimum of 15 years. Further, that the second ethical approval received in 2008/09 'reset' the clock for storage of this data.

Whilst the applicant accepted that the original consent would not have provided a legal basis under the common law duty of confidentiality for storing identifiable information for 20 years, they proposed the view that the legal basis under the common law duty of confidentiality was met because the research has an overriding public interest.

The group discussed this issue at length and concluded that, on the basis of the evidence provided, that they were not certain that the current holding of identifiable information from these participants has a legal basis under the common law duty of confidentiality. The group needs certainty that the confidential patient information is being held lawfully, before advising that support should be given for the activities proposed in this application. Without this certainty, and as clarity of lawful basis is a fundamental element to considering applications, members agreed that the application should be deferred to enable the applicant to seek the appropriate advice and provide a comprehensive response to explicitly address these points.

Members note that the original information was generated from University Hospital Southampton NHS Foundation Trust, but that the applicant had moved to the Royal Free London NHS Trust, from which this application is being made. The group suggested that the applicant seeks legal advice from the Royal Free London NHS Trust about the lawful basis, under the common law duty of confidentiality, for the current holding of this data, in collaboration with the Trust Caldicott Guardian and Data Protection Officer. Any lessons learnt and actions arising from this discussion that would support a resubmitted application should be provided as part of a future submission. Members asked that the advice should focus specifically on meeting the common law duty of confidentiality in this context, and confirm that current holding of the information is compliant with data protection legislation, with the appropriate amount of granular detail.

If it is concluded that there is no lawful basis under the common law duty of confidentiality for the currently held data, or if there is appropriate evidence that robustly demonstrates continued holding does not breach the common law duty, the group would welcome a further application for support from the applicant. The application should clearly request for support to (a) provide a legal basis under the common law duty of confidentiality to continue to hold the confidential patient information at the Royal Free London NHS Trust and (b) allow linkage with data from NHS Digital. This would provide a secure legal basis under the common law duty of confidentiality to continue to hold the confidential patient information, noting that this support would not apply retrospectively, and allow linkage with NHS Digital data.

Members confirmed they would be supportive of a resubmission of the application to allow linkage to NHS Digital data, once the issue of the legal basis of holding the data has been satisfactorily resolved.

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**

In line with the previous application where CAG had confirmed that consent would not be a practicable alternative, CAG was assured that, on the basis of the time since original consent and that many patients may have reached a clinical endpoint, it would not be feasible for the research to be carried out on the basis of consent.

- **Use of anonymised/pseudonymised data**

Members noted that the use of identifiable information is required for linkage by NHS Digital. Once the data linkage had been made there would be no further requirement for identifiable information in this study and the data would be pseudonymised.

The group queried whether the confidential patient information would be kept for future follow-up research. If so, this should be made clear on any future potential application the CAG.

'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 group reviewed the patient notification materials provided with this application. The general view of the members was that the patient notification materials appeared highly detailed with significant amounts of information contained. Information on how a patient could object to the processing was not included, noting it is a standard condition of support that patient objection be respected.

Members agreed that, for any future application, the applicant should consider these points to potentially simplify the information to make them easier to view by patients. Members advised these should also clearly describe how a participant can opt out of this data collection, providing both a contact email and telephone number to do so. It was suggested by members to have the notification materials reviewed by a patient group.

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 noted that, at the previous application review, members commended the applicant on the Patient and Public Involvement and Engagement that has been undertaken. Particular compliments were given on the richness of the responses obtained from a small pool of applicants, due to the care taken to explain the research.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Further information required

To support a future application, the below points should be taken into consideration. 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. Prior to a further application for support, the applicants are advised to seek absolute clarity on the legal basis under the common law duty of confidentiality for the current holding of the confidential patient information collected in the EUROGOLF study. This should be in collaboration with the Trust Caldicott Guardian and Data Protection Officer and consider seeking legal advice from the Royal Free London NHS Trust.

2. Where it is considered that there is no legal basis under the common law duty of confidentiality for the current holding of the confidential patient information, a further application for support; to provide a legal basis to hold the information (this will not provide retrospective support), and to link the data with NHS Digital.

3. Regarding the above two points, the Confidentiality Advice Team will be happy to provide pre-application assessment advice to further guide the applicant prior to a new submission. Please contact Paul Mills (paul.mills@hra.nhs.uk, 020 7972 2470) when ready to discuss this outcome.

4. With regards the patient notification materials:

    a. Revise the notification materials to make them lay friendly, and easily readable.

    b. Add a separate section to clearly detail how participants can opt out of this study, providing a contact email and telephone number.

    c. Request review of the proposed materials by a patient group.

4. New applications - Research

a. 20/CAG/0064 - Health, education and social outcomes of children with visual impairment and blindness (VI/SVIBL) (Escalated from Precedent Set Review)

Context

Purpose of application

This application from the University College London set out the purpose of medical research that seeks to investigate the health, educational and social outcomes of children who are newly diagnosed with full spectrum visual impairment.

Severe visual impairment and blindness in childhood (SVIBL) is uncommon but has a significant impact on all aspects of life. Children diagnosed with SVIBL are likely to have worse health outcomes and therefore experience poorer health compared to children without a visual disability. The applicants aim to explore outcomes for children diagnosed with SVIBL and visual impairment within England.

Socio-demographic and clinical data collected in two previous national surveillance studies, BCVIS and BCVIS 2, will be linked to administrative hospital and school records by NHS Digital in order to obtain long-term follow up data for the cohorts involved in the two studies. BCVIS 2 had support under s251, under CAG reference 14/CAG/1028, to collect the confidential patient information required via the British Ophthalmological Surveillance Unit and the British Paediatric Surveillance Unit. BCVIS was started in 1998, prior to the creation of s251. The longitudinal linked data collected during these studies will be used to develop understanding of the health and educational trajectories of children with visual disability, from

the point of diagnosis throughout their childhood. The applicants aim to identify factors associated with few hospital admissions and better school attendance and educational attainment. Two representative cross-sectional samples of the general child population will also be sought from NHS Digital as control groups for the BCVIS and BCVIS 2 cohorts. The control groups will be selected to mimic the cross-sectional design of the BCVIS studies and reflect the distribution across age groups.

The applicants also seek support to disclose items of confidential patient information, including patients' date of birth, full postcode, sex and ethnicity, and the study ID for participants in the British Childhood Visual Impairment and Blindness Study (BCVIS) to be sent via a secure transfer system to the ONS Secure Research Service. The ONS Secure Research Service will carry out the data linkage to the National Pupil Database (NPD) and return a pseudonymised extract from the NPD, alongside the study ID, to the research team at University College London.

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	1074 patients whose data was collected during the BCVIS and BCVIS 2 studies. Control group for BCVIS cohort – all children 0-16 years of age with any outpatient hospital attendance between 01 January 2003 and 21 December 2003. The applicants anticipate that approximately 544,000 visits will have been made to ophthalmology departments. Control group for BCVIS 2 cohort – all children 0 – 18 years of age with any outpatient hospital attendance between 01

	January 2003 and 31 December 2003. The applicants anticipate that approximately 814,448 visits will have been made to ophthalmology departments.
Data sources	1. Data collected for the BCVIS study, held at University College London Great Ormond Street Institute of Child Health. 2. Data collected for the BCVIS 2 study, held at University College London Great Ormond Street Institute of Child Health. 3. HES data held by NHS Digital 4. The National Pupil Database, held by the Department for Education
Identifiers required for linkage purposes	1. NHS Number 2. Hospital ID number 3. Date of birth 4. Postcode – unit level 5. Sex
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – district level 4. Name of hospital where treatment took place 5. Gender 6. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Legal Basis

Whilst it was noted that support was requested in the original application for 'section 251' support for BCVIS 2, members were less clear on the legal basis for the applicants to retain the data for the BCVIS participants. The first study preceded section 60 and

members thought this was likely to have been kept in good faith but, regardless, the group need clarity on the common law duty of confidentiality legal basis for holding of the identifiable data for BCVIS participants for so long.

Practicable alternatives

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

- **Feasibility of consent**

The applicants advised that this was not practicable to seek consent from patients in BCVIS, due to the historic nature of this dataset, as some patients may have died or not be contactable. The applicants also hoped to avoid bias, noting that the most socio-economically vulnerable families were less likely to take part and were also more likely to have adverse outcomes.

Members agreed that it was impracticable to seek consent due to the reasons described by the applicant.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required in order to link data collected for the BCVIS and BCVIS 2 studies to data held by NHS Digital. This cannot be undertaken in any other way.

It was noted that the applicants wish to retain the identifiers until 2033. Members who voiced concerns about the length of time proposed. Members wished for further justification as to why these should be retained until 2033.

'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.

Privacy notices containing information on how patients can dissent will be linked to the information page about the study on the UCL GOS Institute of Child Health website. The privacy notice will also be shared on the websites of key national vision charities, including VISIONUK and the RNIB. The Great Ormond Street Hospital Young Persons Advisory Group (YPAG) will advise on the content of a 'child-friendly' privacy notice, which will also be available on the study website and above channels.

Those involved in the original BCVIS studies will be referred to the NHS Digital website, as per the information in the privacy notice. The National Data Opt-Out will also be applied by NHS Digital.

Members felt that the patient notification materials were appropriate, but they wished to emphasise that these should be in an appropriate format for the cohort. The group encouraged the applicants to take up the offer of VISION UK to support development of materials, as outlined in their letter of support.

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 have consulted the GenerationR Alliance Young People's Advisory Group for Moorfields Hospital. This Group is comprised of 25 children and young people with vision or eye disorders. Feedback from this group was supportive and was used to inform the development of public and patient facing study literature. The discussion with the Young People's Advisory Group included consideration of the language used to explain use of 'unconsented data' and creating a dissemination strategy.

Members commended the applicants on their Patient and Public Involvement and Engagement activities and noted that the appropriate questions were put to the user groups.

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 a clear explanation of the legal basis, under the common law duty of confidentiality, for which identifiable information of the BCVIS participants has been kept.

2. Consider providing the patient notification materials in an appropriate format for this cohort.
    a. Provide any updated materials as a result of this consideration.

3. Provide further justification for retaining the identifiers until 2033.

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

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 8 June 2020**

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. **The NHS Digital DSPT review was confirmed as 'Standards Met' for University College London Great Ormond Street Institute of Child Health (DSPT Tracker checked 22 May 2020), NHS Digital (confirmed by email 10 June 2019) and Department for Education (confirmed by email 26 June 2020).**

b. 20/CAG/0071 - Birmingham and Lambeth Liver Evaluation Testing Strategies - 10 Year Follow Up

Context

Purpose of application

The application from University Hospitals Birmingham NHS Foundation Trust sets out the purpose of medical research to determine the extent to which a 'fatty liver' leads to serious liver disease later in life.

Non-alcoholic fatty liver disease (NAFLD) is the most common liver condition in high-income countries, affecting 25% to 30% adults. There is no doubt that NAFLD can progress to more severe diseases; first to a condition called 'steatosis' and then to established cirrhosis. While the possibility of such progression is not in doubt, the risk of progression is unclear and disputed. It is important to provide scientific evidence regarding the magnitude of the risk of progression since the recommendation has been made that all people with NAFLD should be investigated by means of serial blood tests and scans of the liver. Such a policy would have massive implications in terms of costs and harms resulting from serial investigation of a fruitless 'treadmill' of investigations for about one third of the entire adult population. The BALLETS study provides a population of patients typical of those that might be identified in the course of routine primary care practice. To our knowledge, our proposed study would be much the largest cohort study of people with NAFLD.

The BALLETS study consented participants in 2005-2008 to participate and have been characterised into one of four groups. The group represents a ideal opportunity to determine the risk of progression. Whilst applicants consented to future follow up, the researchers at the time did not know what form that follow up would take, and the original consent is not deemed sufficient for the proposed study. This study wishes to link the original study data (held by University of Birmingham and passed to University Hospitals Birmingham NHS Foundation Trust) with ONS and HES data from NHS Digital to create a pseudonymised dataset for analysis.

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 participants that consented to participate in the original BALLETS study. (1290 participants)
Data sources	1. University of Birmingham – Trial Data 2. NHS Digital – ONS and HES datasets
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of Birth 4. Hospital Number
Identifiers required for analysis purposes	1. Date of Birth 2. Date of Death 3. Gender

Confidentiality Advisory Group advice

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

Public interest

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

Members agreed that the application had a public interest in contributing to the evidence base of the risk progression of Non-alcoholic fatty liver disease to serious liver disease in later life.

Scope

Members were unclear on the flows of data, and in which organisation the linkages will happen (and so the scope of support requested. The group agree that the applicants should clearly detail the data flows of confidential patient information the identifiable data items used as well as where the linkages will happen.

The group also requested clarity on the size of the cohort for which confidential patient information will be used without consent. There were uncertainties whether the inclusion/exclusion meant that less than the 1290 original participants would be included in this study.

Practicable alternatives

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

- **Minimising flows of identifiable information**

The group were uncertain as how the applicants will move away from using confidential patient information ('exit strategy') and for how long applicants anticipate requiring support.

Members also requested further information on whether this linkage will be a one-off activity, and whether it is anticipated that the linkage will be repeated in the future.

- **Feasibility of consent**

Members agreed with the applicant's argument that consent is impracticable because of the time that has passed, that participants may have moved or died, and the cost/effort involved will be disproportionate to the activity to be undertaken.

- **Use of anonymised/pseudonymised data**

The group noted that these activities could not be undertaken using anonymised/pseudonymised data alone.

Justification of identifiers

As detailed above, the group were unclear on the identifiers used in this application to link with NHS Digital data, and request clarity on this aspect.

'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.

It was noted that the applicants had not provided any patient notification material, and that NHS Digital will apply the national data opt out.

Members request that the patient notification materials are provided for consideration, as well as the applicants provide a local opt out mechanism (which should be detailed in the patient notification).

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.

Whilst the Patient and Public Involvement and Engagement involvement was small, members agreed that this was undertaken in depth. No concerns were raised on this element.

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. Describe exactly the flows of data between organisations in this study, including detail on:
    a. What identifiable data items will be transferred between which organisation.
    b. Where the linkage between datasets will be undertaken.

2. Provide clarity on how the research will move away from using confidential patient information.

3. Please clarify for how long is support is anticipated.

4. Provide confirmation on the size of cohort for which support is requested.

5. Clarify whether this is a one-off linkage, or whether it is anticipated that further linkages are planned in the future.

6. Detail a local mechanism for the patient cohort to opt out of this study

7. Provide the patient notification materials to be used in this study, which should detail the local opt out mechanism.

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

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 26 March 2020**

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. **The NHS Digital DSPT review for University Hospitals Birmingham NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 10 June 2020).**

   The NHS Digital DSPT review for University of Birmingham was confirmed as 'standards not met (NHS DSPT tracker checked 10 June 2020). The applicants are advised to follow the procedure outlined to gain security assurances.

c. 20/CAG/0073 - Assessing the cancer risks due to occupational exposure to styrene

Context

Purpose of application

This is an application from the Institute of Occupational Medicine (IOM) which sets out the medical purposes to determine whether workers in the British glass reinforced plastic manufacturing industry are at an increased cancer incidence or mortality risk from their occupational exposure to styrene. Whilst this is a UK study, the resultant pseudonymised dataset will be transferred to Denmark to feed into a wider international study.

Styrene is a high-production high-volume chemical with about 18 thousand tonnes produced annually in the manufacture of plastic and synthetic rubber products worldwide. The general population is exposed to very low levels of styrene while occupationally exposed workers may encounter much higher levels of exposure. High exposures to styrene occur in the reinforced plastics industry, and co-exposures to other known and suspected carcinogens are limited, making this industry ideal for studying the carcinogenicity of styrene. The Health and Safety Executive (HSE) styrene cohort has previously been included in an international pooled cohort study coordinated by the International Agency for Research on Cancer (IARC) but has never separately been analysed. This study will use the HSE styrene cohort data and link this with cancer and mortality data held by NHS Digital to determine whether these workers are at an increased risk of cancer incidence.

The HSE will transfer the study dataset (including name, date of birth, gender and address) to IOM. IOM will then request cancer and mortality data from NHS Digital, using their name, NHS number and date of birth, which will be transferred back to IOM. The data from NHS Digital will be linked to the HSE dataset to produce the final pseudonymised dataset.

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

Confidential patient information requested

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

Cohort	Workers at a glass reinforced plastics manufacturer, aged 18 and over (1807 workers)
Data sources	1. Health & Safety Executive 2. NHS Digital (cancer registration data and mortality data)
Identifiers required for linkage purposes	1. Name 2. Date of Birth 3. Gender 4. Address
Identifiers required for analysis purposes	1. Date of birth (month and year) 2. Date of Death (month and year) 3. Gender

Additional information	The data used in analyses will consist of month and year of birth, details of work carried out in the industry (for the assessment of exposure to styrene) the timing of this work and any mortality or cancer registration data

Confidentiality Advisory Group advice

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

Public interest

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

The group agreed that there was a strong public interest in this research that will strengthen the evidence base into the link between styrene exposure and cancer.

Scope

Support for any given application is given for the transfer of confidential patient information without a legal basis to do so. The group were unclear on whether the data transfer of identifiable information from the HSE to the IOM was in scope of this request, because it was unclear if the information transferred from the HSE included clinical information.

Members requested further information on the data items to be transferred from the HSE, as well as clarification as to whether any of this information is clinical information.

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**

It was unclear to the group why patient identifiable information needs to be sent to the IOM and queried why this could not be sent directly to NHS Digital from the HSE, thereby minimising the disclosure.

- **Feasibility of consent**

Given that the data held by the HSE dates back to the 1980's, members agreed that it is impracticable to seek consent from the cohort.

- **Use of anonymised/pseudonymised data**

The group agreed that the use of confidential patient information is required in order to be able to link the data to that held by NHS Digital.

'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 group were provided with a patient leaflet that will be distributed to industry and the Trades Union Congress (TUC), as well being displayed on the Institute of Occupational Medicine website.

Members were content with the information within the leaflet, as well as the opt out mechanism detailed within the leaflet.

Patient and Public Involvement and Engagement

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

The group were no provided with any detail on any Patient and Public Involvement and Engagement activity that has been undertaken to support this application, and it is not clear whether any was undertaken at all.

Members request that, prior to support being provided, that the applicant undertakes some Patient and Public Involvement and Engagement with a group of users within the industry. This activity should specifically discuss the use of confidential patient information without consent.

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. Detail the data items to be transferred from the HSE, including whether or not this will include clinical information

2. Provide justification why identifiable information cannot be passed directly to NHS Digital from the HSE in order to minimise the flows of identifiable information.

3. Undertake Patient and Public Involvement and Engagement activities with a group of industry users and provide the outcomes to the CAG. This should specifically discuss the use of confidential patient information without consent.

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

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 05 May 2020.**

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. **Institute of Occupational Medicine and NHS Digital (checked on DSPT tracker 11 June 2020) have been confirmed as 'Standards Met' by NHS Digital.**

   It is unclear whether the HSE have assurances. The HSE laboratory has qualified assurance but it is unclear if this applies for this study. The applicants should clarify this and, where it does not, should seek security assurances from NHS Digital for HSE.

d. 20/CAG/0078 - Accuracy of using crown rump length measurements in dating pregnancies

Context

Purpose of application

This application from University Hospital Southampton NHS Foundation Trust sets out the purpose of medical research to whether the due date of an IVF pregnancy is better determined by measuring crown-rump length on ultrasound or using the conception dates from IVF

(known as 'dating' a pregnancy), and to if the measurements of unborn babies at 12-weeks of pregnancy which generates a due date from population data from the 1970s, are still accurate.

Calculating an accurate estimated due date (EDD) is paramount in providing optimal maternity care. For example, for making decisions at the extremes of viability, legalities for terminating the pregnancy, as well as many other aspects of antenatal care. Crown-rump length (CRL) measurements are undertaken before 14 weeks of pregnancy to determine an EDD for the baby. However, the charts used to determine the EDD from the CRL are based on data from the 1970s, which likely used less accurate technology than today. Further, IVF conceived embryos may develop at a different rate in pregnancy compared with natural conceptions. If this rate effects the size of the fetus at 12 weeks, then the calculated EDD will be inaccurate using naturally conceived pregnancy data. In IVF pregnancies, the exact date of conception is known. This is because the date of collection of the egg from a woman, the fertilisation and growth stages of the early embryo are witnessed. Using CRL to calculate an EDD is more accurate than relying on a menstrual history, but whether it is more accurate than using the IVF conception dates is not known. This study hopes to demonstrate whether IVF pregnancies have equivalent growth to spontaneous conceptions by 12-weeks, how to calculate the EDD for women who undergo IVF and hopes to claim that the currently used methods for calculating EDDs for spontaneous conceptions, is still relevant and accurate.

This study has three cohorts, of which only the first two require support. The first cohort will look at pregnancy data from all IVF pregnancies delivered in University Hospital Southampton NHS Foundation Trust between 2011-2018. The second cohort will look at the pregnancy data from all pregnancies that had a dating scan and were delivered spontaneously in University Hospital Southampton NHS Foundation Trust in the past 20 years. This data is held within a number of separate databases within University Hospital Southampton NHS Foundation Trust and a member of staff, who is not a member of the direct care team and does not have a legal basis, will access the confidential information of patients in order to link the data together to create a dataset to be used for analysis in this study.

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	Cohort 1: All IVF pregnancies conceived at Complete Fertility, having a 12-week USS and delivered in University Hospital Southampton NHS Foundation Trust (2011-2018). (n=1000) Cohort 2: All babies of women who had a dating ultrasound scan in University Hospital Southampton NHS Foundation Trust in the past 20 years who underwent spontaneous labour and delivered in University Hospital Southampton NHS Foundation Trust. (n=100,000)
Data sources	1. Clinical systems in University Hospital Southampton NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital Number 4. Date of Birth
Identifiers required for analysis purposes	1. Gender 2. Occupation 3. Ethnicity 4. Other demographic data (including date of birth of child?)
Additional information	Cohort 1: All IVF pregnancies conceived at Complete Fertility, having a 12-week USS and delivered in University Hospital Southampton NHS Foundation Trust (2011-2018). (n=1000) Cohort 2: All babies of women who had a dating ultrasound scan in University Hospital Southampton NHS Foundation Trust in the past 20 years who underwent spontaneous labour and delivered in University Hospital Southampton NHS Foundation Trust. (n=100,000)

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 were generally satisfied that the public interest in this study has been met though there were some concerns whether this was practically achievable, as detailed below in the scope section.

Scope

The group require absolute clarity on the data items used and the data flows involved in order to provide 'section 251' support for the specific activities that require it. With this application there was uncertainty around these aspects, and members agreed that the applicant needs to provide explicit clarity on these aspects before any support can be given.

There was also uncertainty on which organisations are involved (and require support), as well as how the linkages happen. It was noted that the application makes brief references to Complete Fertility Southampton, Wessex Fertility Southampton and Portsmouth Hospitals NHS Trust. The group also require explicit clarity on the dataflows between these organisations and University Hospital Southampton NHS Foundation Trust, the data items transferred, as well as how the data is linked.

Lastly, whilst members noted the detail in the application, they requested explicit clarity in the number of patients involved, as well as the timeframe from which data will be collected.

Legal Basis

It is noted that the research would involve the transfer of confidential patient information from Complete Fertility Southampton and Wessex Fertility Southampton, both of which are IVF clinics. The identification of individuals who have received IVF is governed in part by the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology (Disclosure of Information) Act 1992.

As such, it is uncertain whether 'section 251' support is able to provide a legal basis to collect confidential patient information from the IVF clinics as the CAG understanding was that there is generally a higher standard of confidentiality applied to IVF information than that of medical confidentiality. 'Section 251 support' lifts only the common law duty of confidentiality, and cannot override any other statutory provisions. As members were unsure as to whether there may be other statutory provisions governing access to IVF data, members advised that the applicant should seek advice directly from the Human Fertilisation and Embryology Authority on access to patient information from IVF clinics without consent, and whether seeking section 251 support to lift the common law duty of confidentiality will be appropriate in this instance and would not conflict with any other restrictions governing access to IVF data. Members advised that they thought the HFEA would be best placed to either advise the applicant or direct them to appropriate sources of advice, as the legal framework governing access to IVF data is not typically within the CAG competence, and the HFEA is expert in this area due to their regulatory role.

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**

Currently, the flows of identifiable information are unclear, and the applicant is requested to provide explicit clarity on this to ensure that the flows of identifiable information are minimised.

- **Feasibility of consent**

The group agree that, due to the numbers of participants in the cohort, that consent is not practicable.

- **Use of anonymised/pseudonymised data**

Members were content that the use of confidential patient information to link these datasets is impracticable.

Justification of identifiers

The group queried how, if using data from different hospitals, using the hospital ID number will be able to link the different datasets together.

It was also unclear for how long the applicant intends to retain identifiable information, and this required clarification.

'Patient Notification' and mechanism for managing dissent

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

A poster was provided that would be displayed in the appropriate waiting areas of participating hospitals. The group were generally content with the poster but noted that it did not contain any opt out information. Members agreed that the poster should be updated with information on how to opt out of the study.

Patient and Public Involvement and Engagement

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

The applicant undertook some Patient and Public Involvement and Engagement. Whilst it appears the use of confidential patient information without consent was discussed, the detail was not specific on this. The group agreed that further clarity on this should be provided.

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 explicit detail on the identifiable data items collected, which organisations will be providing confidential patient information, the data flows and how the linkages will happen. This should include:
    a. A list of organisations that will be providing confidential patient information
    b. For each organisation, list the identifiable information that will be collected
    c. For University Hospital Southampton NHS Foundation Trust, state which databases will be used to collect information from
    d. Detail on where and how the linkage between datasets will occur

2. Detail why the use of hospital ID is required for linkage when data from several hospitals appears to be occurring.

3. Provide clarity on the size of the cohort

4. Detail the timeframes between which data will be collected

5. Provide written confirmation from the Human Fertilisation and Embryology Authority that IVF clinics are able to provide confidential patient information without consent, under ‘section 251’ support.

6. Update the poster to provide details of how patients can opt out of their data being used in this study.

7. Clarify that the use of confidential patient information without consent was discussed in the Patient and Public Involvement and Engagement activities.

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

Specific conditions of support (Provisional)

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

1. Favourable opinion from a Research Ethics Committee. **Confirmed 11 May 2020**

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. **The NHS Digital DSPT review for University Hospitals Southampton NHS Foundation Trust was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 10 June 2020).**

   Where other organisations are confirmed to be sharing confidential patient information without consent these will need to have security assurances confirmed by NHS Digital.

e. 20/CAG/0074 - YouScreen: A pragmatic implementation feasibility clinical trial of offering HPV self-sampling to cervical screening non-attenders within the NHS cervical screening programme in England

Context

Purpose of application

This application sets out the medical purpose to provide evidence that self-sampling can improve cervical screening coverage in England and can increase detection and treatment of high grade Cervical Intraepithelial Neoplasia.

In England, there is a national cervical screening programme offered to all women aged 25-64 using a call/recall system (i.e. women are invited on a regular basis at set intervals). A challenge with introducing new tests into call/recall-based screening programmes is establishing robust pathways for accurately identifying the relevant population, recording and reporting test results and setting the correct recall intervals. It is clear that different interventions are needed to address non-participation; but little is known about which approaches might be most suitable for which women. The longstanding issues with low coverage in NE and NCL London provide an impetus to start offering self-sampling ahead of the national screening programme. The project will serve to test the new pathways for delivery, establish robust pathways for accurately identifying the relevant population, recording and reporting test results and setting the correct recall intervals, generate lessons to help ensure a smooth transition for a national or London-wide roll-out and provide the evidence-base for implementing self-sampling at scale.

This project is a trial for which consent will be obtained from women who wish to participate. However, eligible women will be identified using the national cervical screening database NHAIS (National Health Application and Infrastructure). Each month from the date the practice is included in the study, a list of women who reach the 15 month anniversary of their last test due date without being screened (by self-sample or standard cervical screening (HPV primary testing) will be extracted from NHAIS. NHAIS will send the list of eligible women to the Cervical Screening Administration Service (CSAS) who are responsible for sending invitations and reminders for the call/recall Cervical Screening Programme in England. CSAS will then send the list to a Docmail The print company will send a pre-notification letter to women (on behalf of the GP practices and the Cervical Screening Programme) informing them that they are overdue cervical screening and that a self-sampling kit will be posted to them. Within 1-2 weeks of sending the letter, Docmail will send women a self-sampling kit along with a brief invitation letter.

As well, NHAIS will provide information around last screening to King's College London (KCL) in a pseudonymised format for all eligible women (whether or not they consent). The CCGs of all eligible women will also collect the free text data on why women declined a screening test. Both NHAIS and the CCG will apply the same encryption tool in order to pseudonymise the information which will then be linked by KCL, although at no point does KCL handle any identifiable information. Further data will be extracted from NHAIS at a later time points.

A recommendation for class 1, 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	Mailout: Women aged >=25 and <=64 years old registered at one of the participating practices, who are eligible for cervical screening under the NHS Cervical Screening Programme (NHSCSP) in England and have reached the 15-month anniversary of their last test due date without being screened. (estimated 19000 women). Linkage: Women aged >=25 and <=64 years old registered at one of the participating practices, who are eligible for cervical screening under the NHS Cervical Screening Programme (NHSCSP) in England and who are overdue by at least 6 months (estimated 95000 women)
Data sources	1. NHS Digital (National Health Application and Infrastructure Services) 2. CCG records (Clarifying the actual organisation)
Identifiers required for linkage purposes	1. Full name 2. Address including postcode 3. NHS number 4. GP practice National Code (Organisational Code)
Identifiers required for analysis purposes	1. Regional level postcode 2. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

The group wishes to place on record that they believe the public interest for this research is very high, and the outcomes will have the potential to bring real benefit to the national cervical screening programme and, especially, women. Whilst this application has been deferred because of the reasons set out below, members wish to encourage the applicants to take advice and resubmit this application.

Scope of Support

Members felt the scope of support being requested by the applicants was unclear. It was understood that support was being requested to (1) use confidential patient information for mailing out invitations prior to consent, for those women being invited into the trial; (2) using confidential patient information to collect information around last screening from NHAIS on all women invited to the trial, whether or not they consented to take part and; (3) collect information from free text records held by CCGs on why women at participating practices declined a screening test.

However, this was not clear in the application, nor in the data flows. Whilst members understood the scope for point (1) above, it was harder to determine the scope of support required for points (2) and (3). As well, the group felt that the data flow chart could be revised to more clearly demonstrate these 3 aspects, clearly detailing where support is required and potentially separating these out. For example, some flows had both consent and ‘section 251’ support as the legal basis and it was unclear where the support was required.

The group were particularly unclear regarding the historical cohort referred to in the protocol, and whether identifiable information would be required to identify this cohort.

In a future application, the group felt that the data flow diagram and the accompanying description of where support is required should be made clearer.

Legal Basis

As it was understood the applicants are proposing, under support, to collect information from NHAIS for all women invited into the trial, whether or not they consent into the trial. If this scope is correct, this presents a legal issue that requires consideration by the applicant. The "Managing non-response: establishing the ICO and CAG position" published by the HRA comprehensively sets out this position.

Essentially, where consent is sought, "section 251" support to access the confidential patient information of the living, without consent cannot be given where individual does not respond to the request. Given the applicants are providing information to potential participants about both sampling and the use of data and are using implicit consent, the group considers that any non-responders should be deemed to have dissented, and support for these women could not be given.

The group advises the applicants to consider this aspect of the study carefully and how to proceed. One alternative would be to consider separating the consent aspects for sampling and data use out by deeming the return of the mailing kit as implied consent for testing of the returned sample only and separately using section 251 support for use of the data. If this route was considered, the applicants need to (a) be clear about this in their scope, (b) update the patient information materials accordingly and (c) provide justification why consent for use of data is not practicable.

The applicants are advised to seek further advice from the Confidentiality Advice Team prior to resubmitting, and can contact Paul Mills (paul.mills@hra.nhs.uk; 020 7972 2470).

Practicable alternatives

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

- **Feasibility of consent**

Members felt that seeking consent for the mailout and the CCG data collection was impracticable, given the applicant's justification that this will involve a large number of women and the services do not have the capacity to undertake this activity

Please note the information above regarding the NHAIS information from all eligible women for the trial.

- **Use of anonymised/pseudonymised data**

It was agreed by that the use of anonymised/pseudonymised data is impracticable for the activities requested, and the applicants are unable to complete these without confidential patient information.

'Patient Notification' and mechanism for managing dissent

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

The group wishes to commend the applicants on clear patient information. These were clear and informative to participants. It is understood that these may change in light of the detail above but the group requested that any information regarding CAG that is kept is revised to correctly detail the role of CAG.

It was noted the opt out process described by the applicant was a result of the Patient and Public Involvement and Engagement undertaken. The group were content with this and wish to praise the applicants on a good demonstration of listening to, and acting on, the discussion held with user groups.

Patient and Public Involvement and Engagement

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

The group applauds the comprehensive Patient and Public Involvement and Engagement work that has been undertaken for this project. As detailed above around opt outs it is particularly noteworthy that this was not just seen as an exercise to do, but that the applicants listened to the valuable comments of the attendees.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised applications submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. Provide much more clarity on the scope of activities that require support, particularly the historical collection referred to in the protocol.

2. Consider clarifying and simplifying the flow charts to demonstrate where support is required, and the data flows involved. Consider splitting these out into simplified flows for each aspect that requires support.

3. Consider the impact of the “Managing non-response: establishing the ICO and CAG position document”, and how to take forward this when considering the scope of support requested.

4. Update the patient facing material in light of the decisions taken in point 3 above.

5. Where patient facing material makes reference to the role of the CAG, ensure that it is referenced in the correct legal framework

5. 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