Minutes of the meeting of the Confidentiality Advisory Group

27 October 2022 via Zoom

Present:

Name	Role
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG Vice Chair
Dr Martin Andrew	CAG Member
Dr Malcolm Booth	CAG Member
Dr Sandra Duggan	CAG Member
Dr Rachel Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Ms Diana Robbins	CAG Member

Also, in attendance:

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

Mr Will Lyse	HRA Approvals Administrator
Mr Iain Adams	Observer (HRA Staff – Complaints Support Manager)

1. Introduction, apologies, and declarations of interest

The following conflicts of interest were declared.

- Conflict of Interest – CAG Member Dr Rachel Knowles declared a conflict of interest with item 3c. Dr Knowles remained in the meeting but did not participate in the development of the recommendation provided by the CAG

2. Support decisions

Secretary of State for Health & Social Care Decisions

No non-research applications were discussed at the **22 September 2022** meeting.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **22 September 2022** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- Published 22 September Full

3. New Applications

a. 22/CAG/0149 - Progression of Diabetic Retinopathy from referral to treatment or vision loss: External Validation, update and net clinical benefit of a Multivariable Prediction Model

Purpose of application

This application from the University of Birmingham set out the purpose of medical research that seeks to determine whether a model developed in primary care to identify patients at high risk of developing diabetic retinopathy can also be used in hospitals.

Diabetic retinopathy (DR), is a complication of diabetes at the back of the eye and is the fourth leading cause of preventable vision loss in the UK. Patients with diabetes are screened regularly for signs of early DR by the Diabetic Eye Screening Programme (DESP). However, when a patient develops clinical signs of advanced retinopathy, they are referred to Hospital Eye Services (HES) or surveillance clinics for closer observation and treatment to prevent vision loss. The number of patients with diabetes is increasing each year, with a consequent rise in numbers of patients with DR. This, in combination with under-resourced NHS causes an overburdening of HES, resulting in delays in patients being seen and a higher risk of harm to patients. Data from general practice has been used to develop a model to identify patients who are at a high risk of progressing to DR which requires treatment. The applicants are now seeking to test whether the same model can be used in hospital services and surveillance clinics.

A retrospective review of patients with diabetes will be undertaken. At two of the three participating trusts, the identification of patients and data extraction will be undertaken by the direct care team. At South Tyneside and Sunderland NHS Foundation Trust the identification and data extraction will be undertaken by research staff. Support is only required for activity taking place at this Trust. An anonymised dataset will be extracted and sent to the University of Birmingham for analysis.

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

Confidential patient information requested

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

Cohort	Patients aged 12 years and over diagnosed with Diabetic Retinopathy 800 patients from South Tyneside and Sunderland NHS Foundation Trust will be included.
Data sources	1. Patient records at South Tyneside and Sunderland NHS Foundation Trust
Identifiers required for linkage purposes	1. NHS Number 2. Date of birth 3. Date of death
Identifiers required for analysis purposes	No identifiers will be retained for analysis

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG noted a lack of clarity around the number of patients to be recruited. The CAG queried whether the research team would stop recruitment once they reached their target number.

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 CAG requested clarification on whether the research team would apply small number suppression, due to the small number of children involved in the study.

- **Feasibility of consent**

The applicants noted that the patient cohort will include those at a high risk of developing co-morbidities. The mortality rate amongst this group is also high. Patients would be unlikely to respond to a letter of invitation. The sample needed to be as representative of the patient population as possible and the applicants sought to help those at high risk, who were most unlikely to respond.

The CAG was content with the justification that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Research staff require access to confidential patient information held in patient records at South Tyneside and Sunderland NHS Foundation Trust in order to identify suitable patients and extract an anonymised dataset.

An anonymised dataset will be extracted from the patient records. The data extraction at South Tyneside and Sunderland NHS Foundation Trust will be undertaken by data extractors employed by R&D, who are not considered to be members of the direct care team by the Caldicott Guardian at the Trust.

CAG was content that use of anonymised data was not a practicable alternative.

'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 object 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 will be displayed which will contain information on how patients can dissent.

The National Data Opt-Out will be applied.

The CAG requested that hard copies of the patient notification were displayed within clinics. Members also asked that the applicants consider how patient notification materials can be made available to those with visual impairments, e.g. by providing large-print versions of the materials.

It was noted that the language used within the patient notification was not lay friendly. The CAG asked that the posters were revised for simplicity and clarity, and

that acronyms were either explained or removed. Members asked that contact details including phone number and address were provided on the poster, should patients have queries or wish to opt-out.

The CAG requested for the patient notification to state that there would be no change to standard treatment if patients were to dissent from 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 applicants advised that a patient and public involvement pre-application meeting had been held in March 2021. Seven patients with sight threatening diabetic retinopathy attended the meeting, alongside a lay person with experience of research in young persons and a GP representative. Feedback from the views obtained were provided in pages 30-32 of the Protocol.

Whilst the CAG noted that some patient and public involvement had been conducted, members asked that further engagement was undertaken with additional groups specifically about the use of patient data without consent. Feedback from this was to be provided to the CAG, as a response to provisional.

Exit strategy

An anonymised dataset will be extracted from patient records.

The CAG was content with the exit strategy proposed.

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. Please clarify whether recruitment will stop once the target number has been reached.

2. Please specify whether small number suppression will be applied.

3. The patient notification materials need to be revised as follows:

    a. The patient notification materials need to be revised for simplicity and clarity.
    b. All acronyms should be explained or removed.
    c. Contact details need to be provided.
    d. A statement that patient care will not be affected should patients opt-out from the study needs to be included.
    e. Please provide the updated patient notification materials

4. Ongoing patient and public involvement need to be undertaken specifically about the use of patient data without consent, as per the advice in this letter.

Specific conditions of support (provisional)

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

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

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

    NHS Digital 2021/22 DSPT review for **South Tyneside and Sunderland NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (31/10/2022)

b. 22/CAG/0155 - Using AI and Data Analysis to Better Predict Cardiovascular Disease

Purpose of application

This application from Manchester Metropolitan University set out the purpose of medical research that seeks to identify digital signatures that relate to cardiovascular disease risk.

Prediction models are widely used in clinical practice. The NHS currently uses QRISK to quantify the risk of acute coronary syndromes (ACS) or stroke in primary care in patients not previously diagnosed with cardiovascular disease. QRISK demonstrates a good capacity to discriminate between those at a higher or lower risk, but it should be possible to improve performance by using computer aided analysis of patient data to develop understanding of the interaction between different indicators of risk and how they cluster in patients that suffer heart attacks.

Patients will be identified from records at Salford Royal Infirmary, part of the Northern Care Alliance NHS Foundation Trust, and Wythenshawe Hospital and Manchester Royal Infirmary, part of Manchester University NHS Foundation Trust. The data will be collated into a single dataset by research staff at Salford Royal Infirmary. Once linked, the dataset will be anonymised and uploaded to the Northern Care Alliance NHS Foundation Trust

The anonymised dataset will be analysed by staff at Northern Care Alliance NHS Foundation Trust and Manchester Metropolitan University.

A recommendation for class 1,4,5 and 6 support were 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	5000 patients. 2200 – 2500 patients aged 18 years and over who experienced ACS between 01 April 2015 – 31 March 2018 and were treated Manchester Royal Infirmary or Wythenshawe.

	2200 – 2500 validation cohort of patients treated between 01 April 2018 – 31 March 2021
Data sources	1. Primary healthcare data held in Salford integrated record 2. Secondary healthcare data held in electronic patient records at Northern Care Alliance NHS Foundation Trust and Manchester University NHS Foundation Trust 3. MINAP data from Wythenshawe and Manchester Royal Infirmary for patients that have a Salford postcode 4. BCIS data from Wythenshawe and Manchester Royal Infirmary for patients that have a Salford postcode
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth 4. GP Registration 5. Postcode – unit level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – sector level 3. Gender 4. Ethnicity 5. Age at time of clinical event

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 noted a lack of clarity on why section 251 support was sought. Furthermore, the CAG requested clarity on the overarching outcome of the study

and how the data collected would be used. The CAG asked that the specific outcome measures that the data would be used to answer were provided.

The CAG requested clarification on exactly how and for what purpose the results of the Artificial Intelligence analysis would be used. What were the exact questions that the research is hoping to answer? This is of importance to CAG as part of their assessment in whether there is public interest to be gained by the breach of the common law duty of confidentiality, described in this application.

The CAG noted the term ‘better recovery’ within the written application and requested for clarification on what this meant.

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 CAG noted that the participants date of birth and postcode was required for the study. Patients’ age and either the index of multiple deprivation or lower super output area should be used instead. If these alternatives cannot be used, please provide a justification as to why not.

- **Feasibility of consent**

The applicants advised that consent was not feasible as patients will have been treated for acute coronary syndromes up to 8 years ago and not all patients will still be alive. The applicants also seek to avoid biasing the sample and to collect data from as many eligible patients as possible.

The CAG was content with the justification that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to facilitate the linkage across datasets. An anonymised data set will be used for analysis.

CAG was content that use of anonymised data was not a practicable alternative.

‘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 object 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 applicants advised that they intend to carry out patient notification and to implement a project-specific dissent mechanism but have not yet created the materials. The information sheet will be designed in collaboration with a patient advisor. The information sheet will be disseminated with Research for the Future participants.

The National Data Opt-Out will be applied.

The CAG requested clarification on how the patient notification materials will be made available. Details on the dissent mechanism, how this would be applied and how patients could dissent the use of their data.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public are 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 advised that they have engaged with patients and the public via a co-creation methodology, facilitated by Research for the Future. Patients with CVD were surveyed. All responders were in favour of the project.

The CAG requested that discussions with the Patient and Public Involvement groups, specifically about the use of confidential patient information without consent, needed to be carried out.

Exit strategy

An anonymised data set will be used for analysis.

The CAG queried whether the applicants would retain any confidential patient information or whether the identifiable data would be deleted once the anonymised dataset had been created. If confidential patient information would be retained, details on how this would be held and how any further uses of the data would be handled, were needed.

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.

Following advice from the CAG, the Health Research Authority recommended that the application was **deferred**.

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 application submission, which addresses the below

1. Clarify why section 251 support is needed and the overarching aims of the study, including how the data collected would be used and the specific outcome measures that the data would be used to answer.

2. Please provide clarification on exactly how and for what purpose the results of the Artificial Intelligence analysis would be used. What were the exact questions that the research is hoping to answer?

3. Provide a definition of the term “better recovery.”

4. Patients’ age and either the index of multiple deprivation or lower super output area should be used instead of date of birth and full postcode. If these cannot be used, please provide a justification as to why not.

5. Details on the dissent mechanism, how this would be applied and how patients could dissent to use of their data.

6. Please provide the patient notification / information sheet and details on how the materials will be distributed.

7. Please provide feedback from the consultation with the Patient and Public Involvement group about the use of confidential patient information without consent.

8. Clarify whether any confidential patient information will be retained or if the identifiable data would be deleted once the anonymised dataset had been created. If confidential patient information would be retained, details on how this will be held and how any further uses of the data will be handled, need to be provided.

c. 22/CAG/0156 - General Health Outcomes in Subfertile Men: a UK register-based cohort study

Purpose of application

This application from UCL Institute of Child Health set out the purpose of medical research that seeks to establish whether men with known subfertility are at a greater risk of developing chronic malignant and non-malignant health outcomes compared to men from the general population.

Infertility, defined as the inability of a sexually active couple to achieve pregnancy within one year, has substantial effects on human health at both population and individual levels. Assisted Reproductive Technology (ART) has increased the chances that infertile men will become fathers. However, the implications of the underlying infertility on the affected individuals remains uncertain. Research in the USA and Scandinavian countries has suggested that men's reproductive health may reflect their physical health, and male infertility may be a risk factor for the subsequent development of both malignant and non-malignant disease, as well as early death. Fertility evaluation could be an opportunity to improve men's overall health and identify risk factors for the development of diseases later in life. Little is known about how generalisable these findings are to other populations. The applicants seek to explore whether national administrative health data can be used to investigate the long-term health of men with fertility problems.

Staff at the Human Fertilisation and Embryology Authority (HFEA) will identify the male partners of women who have undergone ART from patient records that they hold. Confidential patient information will be disclosed to NHS Digital for linkage to Health Episode Statistics (HES) and ONS Mortality data, and the National Cancer Registration Dataset. The linked dataset will be pseudonymised by use of a unique study member number.

NHS Digital will also identify a control group, of male individuals of similar age, from the Personal Demographics Services Dataset. Two controls will be identified for everyone patient in HFEA dataset. NHS Digital will conduct linkage to HES and ONS mortality data and the NCRAS dataset. A pseudonymised dataset will be disclosed to UCL Institute of Child Health. The pseudonymisation key will be held at NHS Digital, therefore the dataset held by UCL Institute of Child Health can be considered to be effectively anonymised. NHS Digital will retain a file containing confidential patient information for both cohorts.

A recommendation for class 1, 4 and 6 support were 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	Male partners of women who underwent non-donor assisted reproductive procedures for male subfertility in England and Wales between 01 August 1991- 31 September 2009. Total sample size: 500,000
Data sources	1. NHS Digital held datasets: a. Linked Health Episode Statistics (HES) b. ONS Mortality data c. National Cancer Registration Dataset d. Personal Demographics Service e. Civil Registration records 2. Human Fertilisation and Embryology Authority held datasets
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Date of birth 4. Postcode – district level
Identifiers required for analysis purposes	1. Date of birth 2. Postcode – district level 3. Gender 4. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

- **Minimising flows of identifiable information**

The data flow diagram showed that two datasets including confidential patient information would be retained, one held by NHS Digital and the other by The Human Fertilisation & Embryology Authority. Should the applicants wish to use these datasets for other research, an amendment to the section 251 support will need to be submitted.

- **Feasibility of consent**

The applicants cited that size of the cohort. The applicants also noted that the HFEA will not have up to date contact details for all patients and that seeking to obtain patient contact details would require that researchers accessed a larger amount of confidential patient information. The applicants also noted that they sought to include as many patients as possible and to avoid bias. Seeking consent from patients may introduce bias.

The CAG was content with the justification that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

NHS Digital require access to confidential patient information to undertake the data linkage of HFEA supplied data to datasets held by NHS Digital.

CAG was content that use of anonymised data was not a practicable alternative.

‘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 object 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 patient notification material was provided. This will be made available on the study website. This document stated in the first section under “Can I choose whether to take part in the study?” states that “No, this is not possible.” However, there is a section below “Can I opt out of being included?” This details that patients can opt-out by contacting the Chief Investigator or the HFEA. The notification needs to be revised.

The CAG highlighted a typographical error within the patient notification. It was stated that the applicant will share de-anonymised data. The CAG requested the word ‘de-anonymised’ was amended to ‘anonymised’.

Patient and Public Involvement and Engagement

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

The study research group sought views on the proposed study via a short anonymous survey publicised via the British Fertility Society, the Fertility Network UK, the Human Fertilisation and Embryology Authority, the National Institute of Health Research (NIHR) as well as the study website and social media (Twitter, Facebook, Instagram). 26 responses were received, and a summary of responses were given in the CAT Advice Form.

The survey did not seek views around the use of confidential patient information without consent. The applicants have now added a question specific to processing of confidential patient information under s251 support.

The applicants are also planning a social media campaign to take place in October/November 2022. The content to be used is currently being designed.

The CAG requested that the construction of the patient and public involvement group encompasses individuals who have infertility and that the structure and wording of

questions encourages response. The CAG recommends this through conducting sessions either in a group setting or through individually targeted letters with questionnaires attached.

Once the patient and public group is created, the CAG requested for the group to review the patient notification materials.

Exit strategy

A pseudonymised dataset will be sent from NHS Digital to UCL Institute of Child Health.
The pseudonymisation key will be held at NHS Digital and UCL researchers will not have access to it at any point. The dataset shared with UCL will only contain the unique identifiers generated as part of the pseudonymisation process and the dataset will therefore be effectively anonymised.

The CAG was content with the exit strategy proposed.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. The patient notification materials need to be revised as follows:
    a. The ‘de-anonymised’ typographical error needs to be amended.
    b. The contradictory information about patient opt-out needs to be revised.

2. The following needs to be undertaken, with regards to patient and public involvement:

    a. The patient and public involvement group needs to include individuals affected by infertility. Patient and public involvement needs to be conducted, via groups sessions

and/or by individually targeted letters with questionnaires attached.

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. **Favourable Opinion Confirmed (09 August 2022)**

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 2021/22 DSPT review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (31/10/2022)

   Pending:

   NHS Digital 2021/22 DSPT reviews for **Human Fertilisation and Embryology Authority (HFEA)** were confirmed as 'Pending' on the NHS Digital DSPT Tracker (31/10/2022)

d. 22/CAG/0157 - Do we miss a common subset of Primary Aldosteronism in which there is cyclical or exaggerated diurnal variation in secretion?

Purpose of application

This application from Queen Mary University of London set out the purpose of medical research to determine whether a form of primary aldosteronism exists which causes a cyclical or exaggerated diurnal variation in secretion and whether 24-hour urine measurements help in detecting people with PA.

Hypertension (high blood pressure) can lead to heart attacks and stroke. Many people with hypertension have 'essential' hypertension, for which no underlying cause has been identified. Around 10% of patients with hypertension have primary aldosteronism (PA), an excess production of the hormone aldosterone, which causes the body to inappropriately retain salt. PA can be treated with surgery or medications, however only around 1% of patients with PA are diagnosed with the condition and better ways of identifying the condition need to be developed. Gene mutations in the adrenal gland affect the rhythm with which aldosterone is produced and may cause fluctuations in aldosterone production throughout the day. PA may have been missed in patients whose aldosterone levels fluctuate. The applicants aim to identify patients with a potentially missed diagnosis of PA by studying 24-hour urine samples.

Patients will be consented into the study. Suitable participants will be recruited from endocrinology and hypertension clinics, either referred from their responsible clinicians or by interrogation of the databases of patients in these clinics. This will be undertaken by the direct care team and is outside the scope of support. Patients who had taken part in previous research but did not meet the criteria for PA may also be recruited. Similarly, some participants will also be recruited from previous results sourced from laboratory databases. These two recruitment methods will require processing of confidential patient information by research staff. Once suitable patients have been identified, they will be contacted by post for consent to take part in the research. If patients do not respond to the postal contact within one month, they will be followed up by telephone. Patients participation will proceed on a consented basis.

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

Confidential patient information requested

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

Cohort	Patients with suspected PA who did not meet the diagnostic threshold for PA Patients with diagnosed PA and with previous aldosterone samples of <277 pmo/L Patients with fluctuating aldosterone results that indicate variability in production

	Total sample size: 100
Data sources	1. Patient records, records from previous research and laboratory databases held at Barts Health NHS Trust
Identifiers required for linkage purposes	1. Name 2. NHS number 3. Hospital ID number 4. Full postcode
Identifiers required for analysis purposes	1. Name 2. Date of birth 3. Gender 4. Ethnicity

Confidentiality Advisory Group advice

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

Public interest

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

Scope

The CAG noted that some participants were recruited from the endocrinology and hypertension clinics. Members requested clarification on whether these individuals were the same as the lab group.

The CAG requested clarity on why it was necessary to recruit patients from previous studies and whether this was because the applicants were concerned, they could not recruit sufficient numbers from the clinics.

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 seek to identify patients from old research records in order to capture a larger, more varied population. Patients identified via this method will be approached for consent.

The CAG was content with the justification that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Researchers require access to confidential patient information in order to identify and make contact with eligible patients.

CAG was content that use of anonymised data was not a practicable alternative.

'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 object 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 applicants provided a poster which will be displayed within Endocrinology and Hypertension clinics.

The patient invitation letter contained a section advising patients that they can opt-out. This contained the following text "If you are unhappy about the way we used your information to contact you, please let us know, or if you would like to object formally, you can contact the Patient Advisory Liaison Team. The National Data Opt-Out will be applied.

The CAG was satisfied with the proposed 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.

The applicants advised that they have discussed this application with patients participating in their other PA research studies. Views on what patients thought about researchers looking at their data without consent for the purpose of identifying suitable patients. All feedback was very encouraging and there were no objections.

The CAG noted that the Patient and Public Involvement group was constructed from patients of previous similar studies. However, the CAG requested that the applicant construct their own group of stakeholders, for example by approaching people within the outpatient clinics waiting room and asking them to review the notification materials. The CAG also recommended contacting cardiovascular and heart disease charities, asking them to review the notification.

The CAG requested that the language used within the patient's notification materials was reviewed by the Chief Investigator, Academic Supervisor and Patient and Public Involvement group, to help simplify the language used.

Exit strategy

Patients will be consented into the study. For patients who do not respond to the initial contact, the letter will be followed up by a phone call within one month. If there is no response, then the confidential patient information collected to facilitate contact will be discarded.

The CAG was content with the exit strategy.

Confidentiality Advisory Group advice conclusion

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

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

Request for further information

1. Clarify whether the participants recruited from the endocrinology and hypertension clinics are the same as the lab group.

2. Clarify why patients need to be recruited from previous studies.

3. A patient and public group needs to be created. The CAG also advised contacting cardiovascular and heart disease charities and request that they review the information.

4. The patient notification materials need to be reviewed by the Chief Investigator, Academic Supervisor and Patient and Public Involvement group, to help simplify the language used.

Specific conditions of support (provisional)

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

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

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   NHS Digital 2021/22 DSPT review for **Barts Health NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (31/10/2022)

   Pending:

   NHS Digital 2021/22 DSPT reviews for **Queen Mary University of London** were confirmed as 'Pending' on the NHS Digital DSPT Tracker (31/10/2022)

4.Any other business

- The Chair informed CAG that the office report and Chairs report had been circulated and if the members had any questions to contact CAT or the Chair.
- The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Dr Tony Calland, MBE	07/11/2022
Dr Patrick Coyle	02/11/2022

Signed – Confidentiality Advice Team	Date
William Lyse	07/11/2022