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

APRIL 2019

1. NEW APPLICATIONS

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Ms Diana Robbins	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Clinical outcomes of a PPS program undertaken in a large UK cohort**

CAG reference: **18/CAG/0168**

IRAS project ID: **243889**

REC reference: **18/EE/0318**

Context

Purpose of application

This application from St George's University of London set out the purpose of medical research which aims to follow-up a cohort of patients who underwent voluntary cardiac screening with the voluntary organisation, Cardiac Risk in the Young (CRY). CRY is a charitable organisation that offer pre-participation screening to young adults aged between 14 and 35 years. Since 2008, CRY has screened over 100,000 patients with a health questionnaire and 12 lead electrocardiogram (ECG).

This proposes study aims to ascertain from those patients screened, how many went on to suffer a sudden cardiac arrest and/or sudden cardiac death via linkage of confidential patient information held within the CRY database with HES and ONS Mortality statistics databases held by NHS Digital. The findings will contribute to the ongoing research into the risks of sudden cardiac arrests and deaths in young apparently fit and healthy individuals. The research will build on a previous study (supported via CAG reference 16/CAG/0042), which followed up 5,000 patients within the CRY database.

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

Confidential patient information requested

Cohort

Patients aged between 14 and 35 years who underwent voluntary cardiac screening via Cardiac Risk in the Young from 2008 onwards. This will involve approximately 120,000 patients.

The following items of confidential patient information will be released from the Cardiac Risk in the Young database to St George's University London. Further disclosure from St George's University London to NHS Digital is then required to enable follow-up via HES and ONS Mortality information.

- Name,
- GP Registration,
- Date of birth,
- Date of death,
- Postcode (Unit Level),
- Gender,
- Ethnicity.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Clarify the figures quoted at page nine of the protocol around the incidence of sudden cardiac death in the USA. Submit a revised protocol document as necessary.**

The applicant provided a revised protocol document which addressed this point.

The Sub-Committee received the document and raised no further queries in this area.

2. **Justify why it is not feasible to contact patients in the CRY database in order to seek consent for the purposes of this specific research project.**

The applicant confirmed that consent was not feasible due to the size of the patient cohort to be included in the study.

The Group accepted the rationale provided and raised no further queries in this area.

3. **Provide a clear justification for each item of confidential patient information which has been specified as necessary for the application purposes. Response should confirm which items of confidential patient information would be disclosed to NHS Digital in order to facilitate linkage.**

The applicant explained that as the CRY database did not include patient NHS Numbers, they were requesting support to disclose full name, date of birth, sex and postcode to increase the probability of linkage. A unique study identifier would also be provided to enable the data returned from NHS Digital to be pseudonymised.

The Sub-Committee received the response and raised no queries in this area.

4. **Confirm whether the proposed activity will proceed as a research database or a specific project only. If proceeding as a research database, further information is required to explain in what format data will be stored, where this will be retained and what security and**

access arrangements would be in place. If the project will proceed as a specific project only, a revised application form should be provided which accurately reflects the project classification.

The applicant provided confirmation that the project would proceed as a research database. Analysis would be undertaken on an pseudonymised dataset.

The Sub-Committee received the response and raised no further queries in this area.

5. Clarify the retention period for the resulting linked dataset and confirm in what format this would be retained.

The resulting anonymised dataset would be retained for three years, in line with the data sharing agreement with NHS Digital. Any required retention beyond this point would be subject to a renewal request.

The Sub-Committee received the response and raised no further queries in this area.

6. Clarify how you intend to move away from support under the Regulations (exit strategy) for the project and the anticipated timeframe for this.

The applicant confirmed that all confidential patient information would be removed from the dataset following return of the pseudonymised dataset from NHS Digital. This would be linked to the wider study information by study specific identifier.

The Sub-Committee received the response and raised no further queries in this area.

7. Patient and public involvement and engagement activity should be carried out in order to test the acceptability of using confidential patient information without consent for the study purposes with an appropriate group. It is recommended that CRY be approached to see if it had an established group which could assist in this. Detail should be provided around the demographics of the group approached, how the activity was undertaken and what attendees were asked to consider, together with an overview of the findings. If the responses given are negative, the CAG will take this into account when considering whether support can be recommended, or whether further actions are necessary.

The applicant explained that a discussion had been undertaken with the CRY Chief Executive who explained that there was currently no engagement activity undertaken with the patients being screened. Further information was provided about the recent rollout of an online booking system for the screening appointments which provided an opportunity to consult with individuals making booking around the use of confidential patient information provided for research purposes. Attendees would also have the opportunity to provide further feedback when they attend their screening appointment.

Members commented that the response provided did not provide evidence of any engagement activity having been undertaken around the proposed activity as requested. However, the an overview was provided around how this activity could be progressed. The Group agreed that support would be recommended on a conditional basis that this patient engagement activity was progressed and feedback on the outputs provided at an interim six-month report. If the responses given were negative, this would be taken into account when considering whether support can continue, or whether further action is required.

8. **Patient notifications and dissent – further information is required to address the following points:**
   a. **Confirm whether the privacy notice supplied is intended to fulfil the dual purposes of fair processing (to comply with current data protection legislation) and patient notifications (in relation to the common law duty of confidentiality requirements),**
   b. **If so, the document should be revised to include details around how an individual can raise a specific objection to the use of their data in this study, including relevant contact details,**
   c. **If not, provide an overview of how the project would be promoted in the public arena and how a project-specific dissenting mechanism would be operated. Copies of ay documentation to facilitate this communications strategy would be required,**
   d. **Provide further details around how CRY promotes the research it supports via its newsletters.**

The applicant confirmed that the privacy notice which had been provided was intended to fulfil fair processing and transparency requirements in relation to the current data protection legislation together with patient notifications required to satisfy the common law requirements. This document was revised to include details around how an individual can raise a specific objection to the use of their data in this study, including relevant contact details.

The applicant further explained that CRY's mailing list was advertised at screening events and to the general public through various social media platforms including Twitter and Facebook. Subscribers receive to this list would receive the following communications: CRY monthly E-newsletter, raising awareness campaign emails, CRY update magazine (three times per year via post), CRY monthly fundraising E-newsletter, CRY medical conference and research news. Further information relating to research, screening, support, fundraising and medical information is also displayed on the CRY website which is advertised through the communication channels described.

The Sub-Committee received the response and revised website text. Members commented were unclear that the website text would be accessible to a wide public audience. As such, it was agreed that the information around the patient's right to object should be made more prominent at the beginning of the document to ensure this was clear. It was agreed that the revised text would be requested within one of this outcome to ensure that the changes were implemented ahead of the text going live on the public website. Support would be recommended on a conditional basis that this revised document was provided.

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 (Final)

1. The study-specific website text should be revised to relocate the information about a patient's right of object to an earlier place in the text. This revised document should be provided within one month of the date of this outcome letter.
2. Patient engagement activity should be progressed as part of the online booking system in order to explore the views around the use of confidential patient information provided as part of the screening programme for wider research purposes without seeking consent from the patients. Feedback around this activity is required at an interim report which should be provided within six-months of the date of this outcome.
3. Favourable opinion from a Research Ethics Committee (**Confirmed – 15 October 2018**).

4. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – St George's Hospital Medical School (covering St George's University of London) and NHS Digital have a published satisfactory reviewed grade on Version 14.1, 2017/18**).

Name	*Notes*
Dr Murat Soncul	Alternate Vice-Chair
Ms Sophie Brannan	CAG Lay Member
Mr Anthony Kane	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **At-Risk Registers Integrated into primary care to Stop Asthma crises in the UK (ARRISA-UK): A pragmatic cluster randomised trial with nested economic and process evaluations examining the effects of integrating at-risk asthma registers into primary care with internet-based training and support**

CAG reference: **18/CAG/0185**

IRAS project ID: **161432**

REC reference: **14/WA/1211**

Context

Purpose of application

This application from the University of East Anglia set out the purpose of medical research which aims to assess whether care provided to patients with asthma, which are at greater risk of hospital admissions and dying from their condition, can be improved via a GP-practice led intervention. The study has recruited 270 GP practices across England, Wales and Scotland in an attempt to identify approximately 10,000 patients who are at-risk of having severe asthma attacks. Half of these practices were randomised to receive a computerised alert message whenever one of the at-risk patients made contact with any member of the practice staff. Practice staff received training in how to manage the alert system, which included making urgent appointments, advising patients to take their medication and follow their written asthma action plans and pharmacists to ensure patients take their medication. The study will follow-up all patients within participating practices with an asthma diagnosis to ensure the intervention is workable for all patients and does not divert resources away from the wider asthma patient population.

This application has been submitted to the CAG to enable follow-up of patients at participating GP practices via administrative datasets held by NHS Digital. The application relates only to the sites in England. Information will be collected on A&E attendance, hospital admissions and deaths due to asthma. Practices will be followed up for a 12 month period. The applicants will also measure asthma control, medications prescribed, attendance for routine appointments and smoking cessation. This information will be used to calculate how much this costs and whether it improves (or interferes with) the care of other patients with asthma in the practices. The study also involves a consented qualitative element which will involve focus groups and interviews for patients and staff, to discuss thoughts about the at-risk registers, the training, and how it worked in practice. This element is out of scope for the CAG application as it will be operated on a consented basis.

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

Confidential patient information requested

Cohort

All patients with an asthma diagnosis across 222 English and 10 Welsh border GP practices recruited to the study. It is estimated that there will be 147,000 patients in total within this sample, of which, 10,000 will be at-risk of severe asthma attacks.

Confidential patient information will be disclosed from participating GP Practices to NHS Digital, via Harvey Walsh, in order to facilitate linkage with administrative datasets. The following items of confidential patient information are requested for the purposes set out:

- NHS Number – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Sex – sample validation and linkage.
- Date and cause of death (MM/YY format) – analysis,
- Registered GP practice code – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Confirm that the data transfer to NHS Digital would be carried out via secure network.**

The applicant provided confirmation that this was the case.

The Sub-Committee received the response and raised no further queries in this area.

2. **The patient notification documentation for the study should be revised to address the following points:**
   a. **The document currently labelled as the poster should be utilised as an information leaflet,**

The applicant provided confirmation that the document which was previously submitted as a poster would be utilised as a patient information sheet. The document was modified further to make it clearer and easier to understand, through the addition of diagrams and pictures, following advice from a Public and Patient Involvement (PPI) meeting and lay user group review. Details of this review process were provided for information purposes.

The Sub-Committee received the response and the revised document and raised no further queries in this area.

   b. **The patient's right to dissent should be made more prominent in the text via the inclusion of a heading,**

The applicant confirmed that an additional heading had been included in the document: "What to do if you want to opt out of your personal data being used in this way", to make patient's right to dissent more prominent.

The Sub-Committee raised no queries in this area.

c. **The reference to approval by the CAG should be revised to: The study has been approved by the Health Research Authority, following guidance from the Confidentiality Advisory Group (CAG), an independent body which provides expert advice on the use of confidential patient information',**

This revision was made as requested.

d. **A simpler document should be drafted as a poster, which provides a high-level description of the study and references the available information leaflet for further information.**

The applicant created a poster document as requested which provided references and sign-posting to the information sheet. It was also confirmed that the document was informed by guidance from members of the lay user group and the public and patient involvement meeting.

The Sub-Committee considered the new document. It was requested that this be revised to include information around the patient's right to object.

The applicant provided a revised document which addressed this point.

The Sub-Committee received the revised poster and raised no further queries in this area.

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed**).
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital has a published satisfactory reviewed grade on V14.1, 2017/18 and Harvey Walsh Ltd. have submitted a DSPT 2018/19 – NHS Digital confirmed by email 12/11 that standards have been met (equivalent of satisfactory rating on IGTK**).

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Mr David Evans	CAG Member
Dr Rachel Knowles	CAG Member
Ms Gillian Wells	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **The Sub30 feasibility study of a pre-hospital extra-corporeal membrane oxygenation (ECMO) capable advanced resuscitation team at achieving blood flow within 30 minutes of collapse in patients with refractory out-of-hospital cardiac arrest.**

CAG reference: **19/CAG/0024**

IRAS project ID: **244748**

REC reference: **19/LO/0035**

Context

Purpose of application

This application from the Barts Health NHS Trust set out the purpose of medical research which aims to evaluate the impact of early administration of Extracorporeal Cardiopulmonary Resuscitation (ECPR) to patients suffering cardiac arrest on survival outcomes. The active study will involve the recruitment of a six patients across a 12 month study period, who will receive ECPR within 30 minutes of the call for emergency services pre-hospital admission. This study aims to assess the feasibility and safety of operating this protocol in order to inform a future larger-scale trial.

The six active patients which will be included in the trial are being recruited under the emergency research provisions of the Mental Capacity Act 2005. The applicant has stated that the request for support under the Regulations does not extend to the active cohort of patients.

The applicants intend to create a control cohort of patients as a comparator group to the active patient cohort for analysis. The research team will send matching variables based on the active patient cohort to the London Ambulance Service to enable linkage with the dispatch data and cardiac arrest database. These variables will be used to match with wider patients managed by London Ambulance Service on non-study days to provide the researchers with a comparator cohort in order facilitate analysis. Whilst the variable included in this database have been limited, this will include date of incident, location of collapse (which may or may not be the patient's home address) and date of death as appropriate. The applicants are seeking support under the Regulations for the processing which would be undertaken by the London Ambulance Service and the subsequent disclosure of the database to the research team.

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

Confidential patient information requested

Cohort

All patients aged 18-65 years who suffer an out of hospital cardiac arrest and are attended by London Ambulance Service across the study duration (maximum 12 months) who were not included in the study as an active patient. Patients would be required to meet the standard inclusion criteria which have been established for active patient recruitment including receipt of bystander chest compressions within three minutes of collapse and remain in cardiac arrest at 20 minutes following the call to emergency services. Based on numbers of cardiac arrests attended in 2017/18, it is estimated that this patient cohort will include a maximum of 592 patients.

London Ambulance Service will perform matching on active patients based on age (closest match to five years), time of first LAS resource attendance on scene (closest match to five minutes) and presumption of the cardiac aetiology (cause) of the arrest. The following items of information will be released in relation to the matched comparator cohort:

- Location of the cardiac arrest – provided as GPS Location which will be converted into sector level postcode for analysis,
- Date of the cardiac arrest – analysis,
- Date of death – analysis,
- Age – analysis,
- Sex – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide a clear definition of the comparator control sub-group of patients which form the basis of the application to the CAG. This should also provide an estimate on the cohort size.**

The applicant explained that the comparator cohort was intended to be those patients that would have been eligible to be included in the active trial during the recruitment period. The estimated size of the cohort had been calculated using data from the London Ambulance Service Cardiac Arrest Annual Report 2017/18.

It was further explained that the comparator group was most closely approximated to a subset (those who were in refractory cardiac arrest at 20 minutes) of all the Utstein group (patients who suffer witnessed cardiac arrest of presumed cardiac aetiology and in a shockable rhythm). The applicant confirmed that in 2017/18, a total of 592 patients were in the Utstein comparator group; 335 were successfully resuscitated, and many within 20 minutes.

On this basis, the comparator group was estimated to include a minimum of 257 (502 minus 335) and a maximum of somewhere between 335 and 592 (but more likely to be closer to 335) patients.

The Sub-Committee received the response and raised no further queries in this area.

2. **Clarify what information will be collated on the comparator cohort and how this would be utilised in the overarching study analysis.**

It was clarified that the comparator cohort would be used to estimate the mortality in patients who do not receive ECPR. This information would be used to estimate the range of treatment effects and baseline mortality in any wider scale future trial. The applicant explained that they would match patients on a one to many basis' using matching with and without replacement in sensitivity analyses.

The Sub-Committee received the response and raised no further queries in this area.

3. **Provide specific justification to explain why it is not feasible to seek consent from the comparator cohort.**

The applicant advised that seeking consent in the comparator cohort was not feasible as it is estimated that the mortality rate in this sub-group of patients would be between 90% and 97% (based on the London Ambulance Service Cardiac Arrest database and the PARAMEDIC-2 study [N Engl J Med 2018; 379: 711] respectively).

It was further explained that, to limit the study to only those patients who could be consented would mean that contact could only be made with survivors and thus preclude a mortality estimate. The data would also be used to estimate potential recruitment rates in London for a future study and whether the geographical distribution of cardiac arrests would require more than one study car in a future study.

The Sub-Committee received the response and raised no further queries in this area.

4. **Confirm when the anonymisation process would be carried out in order to establish an exit strategy from support under the Regulations. It was noted that date of death and the GPS postcode would need to be removed as part of this process.**

The agreed exit strategy from support under the Regulations was clarified by the applicant. This would be to delete that date of death, GPS postcode and date of cardiac arrest after the analysis had been completed and within 12 months of the End of Study (as defined in Section 7.9 of the Research Protocol v2.0 dated 23 January 2019).

The applicant would retain the anonymised identifier (the CAD [Computer Assisted Dispatch] reference from London Ambulance Service) to enable any future audit of analyses, if required by regulators and if those regulators had appropriate permissions to process such data.

The Sub-Committee received the response and raised no further queries in this area.

5. **The study website should include specific information around the comparator sub-cohort of patients which would be included in the study, together with details of how patients can object to the use of their data in this manner. Provide drafted text to be displayed for information purposes.**

The applicant confirmed that the omission of information about the comparator group on the study website was an oversight which had now been corrected. The revised text was provided for review, together with confirmation that this had gone live on the public-facing website.

The Sub-Committee was satisfied with the revised text and raised no further queries in this area.

6. **Provide copies of the trial information sheets and posters for review.**

Copies of all of the trial information leaflets that had been approved by the REC were included in the original application submission.

The applicant advised that an additional information leaflet had been prepared for ambulance crews who may also attend the cardiac arrest when patients were not recruited if they are subsequently asked questions by family and friends of the patients. This was provided for review.

It was further explained that, following discussions with the communications departments of all the collaborators, the applicant also intended to coordinate a press release by the three organisations. This would point interested persons to the study website. The applicant explained that the rationale for this was to enable any future enquiries about the study (which is potentially conducted in public places) to be redirected to this initial document and then decline to comment further about any specific scenario. The draft press release was provided for review together with the Standard Operating Procedure about Social Media and Publicity.

The Sub-Committee received the response and raised no further issues in this area.

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

The applicant provided confirmation to this point.

The Sub-Committee received this response and raised no further issues in this area.

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 (Final)

1. Favourable opinion from a Research Ethics Committee (**Confirmed**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Ambulance London Service NHS Trust and Barts Health NHS Trust both have published satisfactory reviewed grades on V14.1, 2017/18**).

Name	*Notes*
Ms Clare Sanderson	Alternate Vice-Chair
Dr. Liliane Field	CAG Member
Mr. Myer Glickman	CAG Member
Mrs Diana Robbins	CAG Lay Member
Ms Clare Sanderson	Senior Confidentiality Advisor

Application title: **Patient perceived outcomes after Sub-acromial Decompression surgery #1**

CAG reference: **19/CAG/0048 (Resubmission of 19/CAG/0016)**

IRAS project ID: **258258**

REC reference: **19/NW/0150**

Context

Purpose of application

This application from the University of Liverpool sets out the purpose of medical research which aims to evaluate local practice and explore the outcomes of arthroscopic sub-acromial decompression surgery (to release a ligament from the front of the shoulder blade) from a patient's perspective via targeted questionnaire.

All patients who underwent the surgical procedure at Leighton Hospital, within the Mid Cheshire Hospitals NHS Foundation Trust, during 2016 and 2017 will be invited to take part in the questionnaire. An application has been made to the CAG to seek support under the Regulations to support the disclosure of confidential patient information from medical records to facilitate the invitation process. The Student Investigator, whilst an employee of Mid Cheshire Hospitals NHS Foundation Trust, is not considered to be part of the direct care team for this patient population. Patients will provide their consent to participate in the study.

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

Confidential patient information requested

Cohort

All living patients aged 18 years and over who underwent primary arthroscopic sub-acromial decompression surgery at Leighton Hospital in the calendar years 2016 and 2017 will be invited to participate in the study. It estimated that fewer than 100 patients will meet the inclusion criteria.

The following items of confidential patient information are required to identify and validate the patient sample to be invited to participate in the study and to facilitate the invitation process:

- Name,
- Hospital ID,
- Full Address and Postcode.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's response to the request for further information in correspondence.

1. **Confirm that the feedback documents provided from the patient engagement activity includes responses from all patients who were present at the session, to evidence that all were supportive of the project proceeding via the described methodology.**

The applicant confirmed that the test of acceptability questionnaire was submitted to the whole cohort of the post-operative shoulder class at Leighton Hospital and that all questionnaires were submitted to the CAG for review.

The Sub-Committee received the response and raised no further queries.

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**).
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed - Mid Cheshire Hospitals NHS Foundation Trust has a satisfactory reviewed grade on V14.1, 2017/18**).

Name	*Notes*
Dr Tony Calland MBE	Chair
Dr William Bernal	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Outcomes of patients undergoing lower limb vascular procedures in the National Vascular Registry**

CAG reference: **19/CAG/0005**

Context

Purpose of application

This application from the North Bristol NHS Trust set out the purpose of undertaking a service evaluation in order to describe the longer term patient outcomes after lower limb vascular surgery in England. Clinical and demographics risk factors for poor outcomes will also be investigated. It is intended the findings of the service evaluation would enable clinicians and patients to be better informed and to facilitate future research.

Patients who have undergone lower limb vascular surgery will be identified within the National Vascular Registry (NVR), which is commissioned by the Healthcare Quality Improvement Partnership (HQIP) as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP). Patients undergoing elective surgery are included in the NVR via consent. For patients undergoing emergency surgery, support under the Regulations is in place via application CAG 5-07(f)/2013 to include these individuals in the registry. The NVR will disclose confidential patient information, together with a study-specific ID, to NHS Digital to facilitate linkage with HES and ONS. Wider clinical information from the NVR will be released to the applicant with the same study-specific ID attached. NHS Digital will undertake the wider linkage and release information to the applicant with the study-specific ID attached. The applicant will link the two pseudonymised datasets for analysis.

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

Confidential patient information requested

Cohort

All patients recorded in the National Vascular Registry who underwent lower limb vascular surgery from 01/01/2014 to 31/12/2016. The inclusion criteria cover 40,890 procedures; however, the number of patients may be lower if they have undergone multiple procedures during the inclusion timeframe.

The following items of confidential patient information will be disclosed from the National Vascular Registry to NHS Digital to facilitate linkage:

- NHS Number,
- Date of Birth,

- NVR patient ID.

Confidentiality Advisory Group advice

A Sub-Committee of the CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide a letter of confirmation from the North Bristol NHS Trust that is has confirmed the project's categorisation as a non-research service evaluation and supports the activity proceeding on this basis.**

The applicant provided an email from the Clinical Trials Manager within the Research & Innovation Department of North Bristol NHS Trust confirming that the project has been appropriately categorised as non-research service evaluation. This is in addition to the confirmation included with the original application from the Clinical Effectiveness department that the service evaluation project is registered with them.

The Sub-Committee received the assurance and raised no further issues in this area.

2. **Provide assurance that appropriate project support and supervision was in place for the project from a more senior clinician.**

A letter of confirmation was provided from Professor Rob Hinchliffe, Clinical Professor of Vascular Surgery, North Bristol NHS Trust and University of Bristol, that he was supervising and supporting the project.

The Sub-Committee received the assurance and raised no further queries.

3. **Confirm where the resulting linked pseudonymised dataset would be retained for analysis.**

The applicant confirmed that the resulting dataset would be retained at North Bristol NHS Trust.

The Sub-Committee received the response and raised no further queries in this area.

4. **Provide details of the study-specific communications strategy established together with the National Vascular Registry, together with an overview of the project specific dissenting mechanism. Copies of any documentation to support this should be provided.**

The applicant provided copies of email correspondence with National Vascular Registry Manager, which detailed the communications strategy and dissenting mechanisms. It was confirmed that these mechanisms had been additionally approved by HQIP.

It was explained that studies which made use of NVR data at an individual patient-level would be included within the NVR privacy notice which was made available on the website.

Further information was requested from the applicant around this response as it was unclear from the weblink provided, where this information would sit.

The applicant explained that as the application had not yet received a recommendation of support, the information had not been updated on the public-facing website. It was explained that an additional heading would be included in the document to list details of studies making use of patient-level NVR data.

Members agreed that evidence that this link had been updated to display this study information was required within three months of support coming into effect.

The NVR Registry Manager has advised that it would not be possible to operate a study-specific objection mechanism on behalf of the applicant. However, it was explained that the NVR operates a specific objection mechanism which enables patients to dissent to their inclusion in the registry. It was also advised that patients who registered a national objection mechanism would be excluded from the Registry.

The Sub-Committee received this response and commented that whilst it was ideal that a project-specific objection mechanism could not be operated, it was recognised that the applicant was unable to operate this directly without support from the NVR. Members accepted the proposed methodology around patient objection.

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 Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support (Final)

1. The project-specific text should be published on the National Vascular Registry website – provide evidence that this information has gone live within three months of the date of this outcome letter.
2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – NHS Digital (processor) has a published satisfactory reviewed grade on V14.1, 2017/18**).

Name	*Notes*
Dr Tony Calland MBE	Chair
Mr Myer Glickman	CAG Member
Mr Andrew Melville	CAG Lay Member
Dr Murat Soncul	Alternate Vice-Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Determination of genetic, transcriptomic and proteomic pharmacological targets for the treatment of ovarian cancer**

CAG reference: **19/CAG/0008**

IRAS project ID: **214527**

REC reference: **18/WA/0324**

Context

Purpose of application

This application from the Leeds Teaching Hospitals NHS Trust set out the purpose of medical research which aims to gain further understanding around the genetic blueprint defects and pathways leading to abnormal protein expressions in patients with ovarian cancer. This project aims to address both of these strategies by providing surplus archival ovarian cancer tissue samples with anonymised case-specific demographic annotations to a commercial partner who is funding the project, TriStar. In turn, TriStar will distribute this material to pharmaceutical companies actively engaged in ovarian cancer drug development programmes, whilst returning a replica of all the material collected and processed to Leeds, where it will be made available for academic research programmes.

The application has been submitted for review by the CAG to seek support under the Regulations to enable the patient cohort to be identified from records held at Leeds Teaching Hospitals NHS Trust and to facilitate the extraction of the pseudonymised data set which will be shared with the study partner TriStar. Archival diagnostic tumour samples will also be provided to the TriStar study partner – these will be linked to the pseudonymised dataset. A link file will be maintained at the hospital Trust site, to enable any returned surplus samples to be returned to the correct patient record.

Eligible patients will be identified by the main applicant in the first instance from the CoPath database (pathology diagnosis reporting software). These cases will be retrieved from the archive by a biomedical scientist appointed solely for the study purposes. The main applicant will be responsible for determining which patients from the overarching sample had sufficient diagnostic tissue stored in the archive to be eligible for inclusion in the study. The biomedical scientist will then access the PPM+ database (patient information storage database) in order to extract the relevant clinical information to support the samples. The main applicant will retain an independent, link-anonymised database which contains the study numbers and patient identifiers.

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

Confidential patient information requested

Cohort

Female patients who received a surgical resection for a range of ovarian cancers and were treated at the Leeds Teaching Hospitals NHS Trust. 500 patients will be included in the study from existing records spanning a 25 year time period.

The following items of confidential patient information will be extracted from CoPath records to enable the identification of the associated tissue samples and to create the anonymised clinical database to be used to support analysis:

- NHS Number – sample validation and linkage,
- Date of birth – converted to years for analysis,
- Date of death – used to calculate survival time for analysis,
- Sex – sample validation,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's response to the provisionally supported outcome in correspondence.

1. **Confirm whether the Chief Investigator is considered to be part of the direct care team for the patient cohort in order to establish the scope of support which is required under the Regulations.**

The applicant provided confirmation that he was considered to be part of the clinical care team, which had been verified by the Research Governance Manager at Leeds Teaching Hospitals NHS Foundation Trust.

The Sub-Committee received the response and raised no further issues in this area.

2. **If not considered to be part of the direct care team, clarify how long the Chief Investigator would retain the linkage key, in order to establish a timeframe for the exit from support under the Regulations.**

This query was no longer applicable due to the above classification.

The Sub-Committee received the response and raised no further queries.

3. **Clarify how the 500 patients to be included in the study would be identified, including how many patient records would need to be accessed in order to achieve the target cohort of eligible patients.**

The applicant confirmed that there may be a requirement to access more than 500 records in order to identify the relevant patient sample; however, a strategy had been employed to ensure that only those patients with sufficient archival tissue sample are included in the study. The applicant also confirmed that patient's would be identified from PPM+ system, rather than CoPath, which included a less detailed patient record.

The Sub-Committee received the response and raised no further issues in this area.

4. The website site should be revised to address the following points:

a. The language should be reviewed to ensure that this would be accessible to a lay audience,
b. Reference to CAG Approval should be replaced with '…and the Health Research Authority at the recommendation of the Confidentiality Advisory Group…',

These points were addressed in the revised document.

c. The closing date for patient objection should be revised – the lead in time should be extended to allow meaningful period for dissent to be raised.

The applicant confirmed that the dissenting mechanism would be extended to the point that the samples are extended to the point samples are sent to TriStar, which will be an additional four months and would patient dissent to be respected.

The Sub-Committee received these responses and raised no further issues in this area.

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 (Final)

1. Patient and public involvement and engagement activity should be undertaken on an ongoing basis to seek views on the study progress, findings and the subsequent dissemination. Feedback should be provided at the time of annual review around additional activity undertaken in this area and the feedback provided. If the responses given are negative, the CAG will take this into account when considering whether support should continue, or whether further actions are necessary.
2. Favourable opinion from a Research Ethics Committee (**Confirmed**).
3. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Leeds Teaching Hospitals NHS Foundation Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

Name	*Notes*
Dr Tony Calland MBE	Chair
Dr Lorna Fraser	CAG Member
Mr Myer Glickman	CAG Member
Mr Andrew Melville	CAG Lay Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **ECG Parameters predicting Adverse Events in Congenital Heart Disease**

CAG reference: **19/CAG/0049 (Previously: 18/CAG/0162)**

IRAS project ID: **250076**

REC reference: **18/NS/0107**

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research which aims to investigate whether there is a way to predict which children and adults who have previously undergone surgery for congenital heart disease are at higher risk of developing abnormal heart rhythms (arrhythmias), including ventricular tachycardia (VT), ventricular fibrillation (VF) and sudden cardiac death. This is a retrospective record review only. Records from the congenital heart disease database at the Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust, will be accessed to extract a pseudonymised dataset to be used in the study analysis.

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

Confidential patient information requested

Cohort

Male and female deceased patients, who underwent surgery at Newcastle upon Tyne Hospitals NHS Foundation Trust to treat congenital heart disease between 01/01/1965 and 01/01/2021.

Access to the complete medical records is required. The following items of confidential patient information are required for the purposes described:

- NHS Number – linkage,
- Date of birth – analysis,
- Date of death – analysis,
- Sex – analysis,
- Ethnicity – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Provide further information to explain why the consenting process which had been described for the research database was not considered a practicable alternative to seeking support under the Regulations in relation to the living patient cohort for inclusion in this proposed activity.**

The applicant confirmed that sufficient numbers had now been recruited to the research database and therefore it is only the patients who have died whose data we wish to use.

It was explained that, at the point where this initial application was made, there were insufficient patients recruited to the research database. Patients are recruited to this at routine clinic appointments and not required to make extra attendances.

The applicant explained that since the initial application was made, it had become apparent that there are other ECG parameters that were relevant to measure in this population e.g. PR interval and QRS fragmentation. It was clarified that the power calculations do not suggest any further numbers of notes, above those requested, need to be looked at in order to appropriately investigate these measurements in a similar fashion

The Sub-Committee received the response and the revised scope of the application request. No issues were raised in this area.

2. **Assurance is required that the consent which has been taken from the patients for the described research database provided an appropriate legal basis, in relation to the common law duty of confidentiality, to legitimise the student investigator's access to confidential patient information include in patient records for the purposes of this study.**

The applicant confirmed with the Information Governance at Newcastle upon Tyne NHS Foundation Trust, that student investigators were regarded as part of the research team in terms of the consent taken from patients for the research database. Furthermore, students involved in Research and accessing data have in place a Research Passport with the Trust validating their access.

The Sub-Committee received the assurance and raised no further questions in this area.

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

The applicant confirmed that this was the case.

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 (Final)

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

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Newcastle upon Tyne Hospitals NHS Foundation Trust has a satisfactory reviewed grade on V14.1, 2017/18**).

Name	*Notes*
Dr Tony Calland MBE	Chair
Dr Malcolm Booth	CAG Member
Miss Sophie Brannan	CAG Lay Member
Mr David Evans	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Translational Research in Pulmonary Hypertension at Imperial College (TRIPHIC)**

CAG reference: **19/CAG/0040 (Replacement of CAG 4-09(a)/2013)**

IRAS project ID: **253767**

REC reference: **19/LO/0086**

Context

Background to Submission

The TRIPHIC research database received a recommendation of support under the Regulations on 18 September 2013. The purpose of the project was to establish a research database from established datasets at Imperial College Healthcare Trust which were linked with datasets at NHS Digital (then the HSCIC). The database included information on approximately 2000 patients who had been referred to the National Pulmonary Hypertension Service at Imperial over the preceding decade.

Purpose of this Application

This application from Imperial College Healthcare NHS Trust set out the purpose of medical research through the ongoing retention of the TRIPHIC research database for a further five-year duration in line with the refreshed research database application which had been submitted for ethical review, in line with NHS REC Standard Operating Procedure requirements.

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

Confidential patient information requested

Support under the Regulations currently extends to the following sub-cohorts of patients:

1. living patients who previously donated biological samples and were then discharged prior to the introduction of TRIPHIC (n=374),
2. living patients with CMR images who were also discharged (n=177),
3. a further 152 patients remain under care of the Pulmonary Hypertension Service and are being approached directly, seeking face-to-face TRIPHIC consent during clinical follow-up.

The following items of confidential patient information are required for the purposes set out:

NHS Number – sample validation and linkage,
Date of birth – sample validation, linkage and analysis,
Date of death – sample validation, linkage and analysis,
Sex – analysis,
Ethnicity – analysis.

Confidentiality Advisory Group advice

A Sub-Committee of the main CAG considered the applicant's response to the request for further information detailed in the provisionally supported outcome in correspondence.

1. **Further consideration should be given to how the approach to retrospectively included patients around their ingoing inclusion in the TRIPHIC database should be made.**

a. **The ICO guidance around managing non-response should be considered – this can be found on the HRA website at the following link: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/**

The applicant explained that, as referenced within the previous outcome letter, members of the clinical care team would continue to directly approach patients who remain within the active care of the pulmonary hypertension service for their TRIPHIC consent. It was explained that 26 of the 152 active patients who previously donated biological samples had already provided their consent and the others will be approached during standard clinical appointments, either at local outreach clinics or at Hammersmith Hospital.

The applicant advised that there were two reasons why patients no longer under the active care of the pulmonary hypertension team were important for the ongoing research studies and therefore continue to be included in the TRIPHIC database.

Firstly, after previously consenting to donate biological samples and allow access to their clinical data for research, the patients (n=374) were discharged either because they did not have pulmonary hypertension or were diagnosed with pulmonary hypertension due to left heart or lung disease. These represent novel disease control and comparator groups that have made a significant contribution to the applicant's recent research. Secondly, patients were discharged after undergoing clinical investigations and the results, (e.g. CMR images, n=177) underpin ongoing research.

The applicant explained that the value of the samples and/or clinical results for future research studies was reliant on the continuing inclusion of contemporaneous patient information in the TRIPHIC database.

The applicant expressed thanks to the CAG for bringing to their consideration the means of approaching retrospectively included patients about their ongoing inclusion in the TRIPHIC database.

It was advised that the applicant's knowledge of consent via post and the level of response/non-response was limited to one example where members of staff in the NIHR-Imperial Clinical Research Facility sought to re-consent active pulmonary hypertension patients following a substantial protocol amendment. They approached 49 participants, 33 (67%) responded within 1-14 weeks and 16 (33%) failed to respond. The non-response might be even greater among discharged patients but the applicant had no compelling evidence to support this.

On the basis of the non-response guidance and the evidence from the previous consenting attempt, the applicant confirmed that they would conduct a pilot experiment, seeking postal consent for ongoing inclusion on the TRIPHIC database in a subset of 40 individuals discharged after donating blood

samples. If the non-response rate was high (i.e. >50%), the applicant proposed adopting an opt-out mechanism instead. This would involve members of the clinical care team writing to discharged patients (draft letter provided); informing them of their participation in the Pulmonary Hypertension Biobank at Imperial College and/or TRIPHIC database; their ongoing contribution to research in pulmonary vascular disease; and the existence of an established opt-out mechanism should they wish to withdraw from the database. Apart from the draft letter, the applicant did not envisage amending any of the other information delivered to patients.

The Sub-Committee received the response and recognised the applicant's decision to progress a pilot consenting phase. Members acknowledged that the applicant was aware of the risks involved here; however, it was reiterated that any patients who did not respond to the consent request would need to be removed from the TRIPHIC database. The Group agreed that feedback around the consenting pilot would be requested from the applicant at the time of next annual review. It was also agreed that a condition would be added to the support around the removal of non-responders from the database.

b. A clear overview of how this approach would be made, whether this would seek formal consent or opt-out and how the methodology was in line with the above guidance would be required.

The applicant reiterated that they would be guided by the outcome of the consenting pilot here and if non-response rate was found to be too high, the applicant would change the approach to an opt-out methodology.

The Sub-Committee received the response and recognised that follow-up would be provided in line with the above point.

c. Copies of any documentation to support this process should also be provided for consideration.

The applicant provided copies of the revised information materials, which had also received a favourable ethical opinion from the REC. A drafted information letter was also provided, if the methodology should be changed to an opt-out mechanism.

The Sub-Committee received the documentation and raised no queries in this area.

2. Confirm whether, and how, the vital status of patients would be checked prior to any approach being made about involvement in the database.

It was confirmed that the clinical care team routinely confirmed the up to date contact details, vital status and GP of patients before making contact and they would follow the same procedure before writing to discharged patients about their involvement in the TRIPHIC database and ongoing research. Local electronic records (CERNER system at Imperial College Healthcare NHS Trust) and nationally available information would be accessed, including life status, on the NHS Spine which would be confirmed with the patient's GP before writing to them.

Members received the assurance and raised no further queries in this area.

3. Provide further justification to support ongoing retention of confidential patient information in relation to sub-group of patients known to be deceased.

The applicant explained that the research value of donated samples and/or clinical results from deceased patients was dependent on linkage to contemporaneous confidential patient information such as diagnosis, drug therapies and comorbidities.

Some deceased patients had a history of heritable disease and other family members were often included in the TRIPHIC database, either as active patients or as unaffected relatives undergoing regular screening by the Pulmonary Hypertension Service. As such, there were also occasions when the clinical care team retrospectively amend the pulmonary hypertension diagnosis of deceased patients. For these reasons, it is necessary to retain deceased confidential patient information. However, it was clarified that users of the TRIPHIC database can only access pseudonymised information and were unable to identify participants.

The Group was assured by the rationale provided and raised no queries in this area.

4. Consider whether the items confidential patient information requested within the application are sufficient to facilitate the approach to patients.

The applicant confirmed that the confidential patient information requested within the database application was sufficient to enable staff in the clinical domain to identify specific patients and then approach them about their involvement in the database and ongoing research.

The Sub-Committee received the assurance and raised no queries.

5. Provide details of any wider study communications strategy which is promoting the database with patients and the wider public.

The applicant confirmed that they continued to inform patients about the research activity that they participate in at Hammersmith Hospital, including the TRIPHIC database. It was explained they had recently written a 'Research Update in Pulmonary Hypertension' that demonstrates the value of their samples and data. This was available in the News section of the NIHR-Imperial Clinical Research Facility website and the National Pulmonary Hypertension Service was incorporating it in a newsletter for patients.

In addition to presentations at National and International Scientific meetings and publications in high ranking journals, members of staff have promoted the TRIPHIC database and their research during interviews published in 'emphasis**'** (a magazine for supporters of the Pulmonary Hypertension Association UK) and in articles published in 'Advances in Pulmonary Hypertension' (the Official Journal of the Pulmonary Hypertension Association USA).

The Sub-Committee received the response and raised no queries in this area.

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 (Final)

1. All pre-existing conditions of support related to CAG 4-09(a)/2013 remain applicable.
2. The pre-existing annual review cycle remains applicable, with the next annual review to be received four weeks before 18/09/2019, and then on an annual basis to this schedule.
3. Feedback around the consenting pilot should be provided at the time of next annual review, including an overview of how many patients responded to the request and those which were lost. Confirmation should also be provided at that time around whether the patient approach would continue on a consenting basis, or whether adoption of the opt-out mechanism has been agreed.

4. Patients who do not respond to the consent approach in the pilot study would need to be removed from the database. Confirmation should be provided at the time of next annual review around this.
5. Favourable opinion from a Research Ethics Committee (**Confirmed**).
6. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Information Governance Toolkit (IGT) submission (**Confirmed – Imperial College Healthcare NHS Trust has a published satisfactory reviewed grade on V14.1, 2017/18**).

2. NEW AMENDMENTS

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Confidentiality Enquiry into Patient Outcome and Death**

CAG reference: **PIAG 4-08(b)/2003**

Amendment Request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes this year. This amendment covered the first which is 'In hospital management of out of hospital cardiac arrests'. The methodology follows the standard retrospective case identification case note review as previous reviews, but the topic is new.

It was confirmed that there are approximately 30,000 treated out of hospital cardiac arrests in the UK each year. Among these patients, 27.5% (8250) experience return of spontaneous circulation and 8.4% survive to hospital discharge. The applicant confirmed that a sample size of approximately 1000 patients will be selected from the identified patients for clinician questionnaire dissemination and case note review. The number of cases included will be limited to a maximum of 10 per hospital.

Confidentiality Advisory Group Advice

The amendment request was reviewed by the Vice-Chair who noted that the request was for an extension to apply the same methodology that had been previously used and for which the applicant already had support.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Confidentiality Advisory Group agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific Conditions of Support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – National Confidentiality Enquiry into Patient Outcome and Death (NCEPOD), Version 14.1, 2017-18, reviewed grade of satisfactory confirmed by email 06/07/2018).**

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **National Confidentiality Enquiry into Patient Outcome and Death**

CAG reference: **PIAG 4-08(b)/2003**

Amendment Request

In line with the original application, the applicant had been commissioned by HQIP to undertake two confidential reviews of case notes this year. This amendment covered the second which is 'Dysphagia in Parkinson's Disease'. The methodology follows the standard retrospective case identification case note review as previous reviews, but the topic is new.

Parkinson's disease (PD) is a neurodegenerative disease which is increasingly prevalent. It is more common with increasing age. Parkinson's UK estimated the number of cases of PD in the UK to be 145,519, and estimate this to increase and have almost doubled by 2065. Dysphagia has been defined as difficulty moving food from the mouth to the stomach.

The aim of the review is to examine the pathway of care of patients with Parkinson's disease (PD) who are admitted to hospital when acutely unwell. In particular, to identify and explore multidisciplinary care and review organisational factors in the process of identifying, screening, assessing, treating and monitoring the ability to swallow.

Data will be collected on patients aged 16 and older admitted to hospital with an ICD10 code for Parkinson's Disease over an eight week period, from Monday 7th January (00:00) – Sunday 3rd March (23:59) 2019. It is anticipated that approximately 80% of patients with Parkinson's Disease will also have dysphagia.

The anticipated sample sizes of each type of data collected are as follows:

- Organisational questionnaire – 300,
- Clinician questionnaires – 500,
- Case note review – 500.

Confidentiality Advisory Group Advice

The amendment request was reviewed by the Vice-Chair who noted that the request was for an extension to apply the same methodology that had been previously used and for which the applicant already had support.

Confidentiality Advisory Group Conclusion

In line with the considerations above, the Confidentiality Advisory Group agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific Conditions of Support

2. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – National Confidentiality Enquiry into Patient Outcome and Death (NCEPOD), Version 14.1, 2017-18, reviewed grade of satisfactory confirmed by email 06/07/2018).**

Name	*Notes*
Dr Tony Calland MBE	Chair
Dr Harvey Marcovitch	CAG Member
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **The UK Renal Registry: A Research Database**

CAG reference: **16/CAG/0064**

IRAS project ID: **199545**

REC reference: **16/NE/0042**

Amendment request

The amendment requested the following changes:

- Change to the Chief Investigator to Dr Katharine Evans,
- Revisions to the data flows which underpin the research database, to ensure these align with the flows supported under the linked non-research application 16/CAG/0153, which provides the data for this application,
- Updates to the supporting project protocol to reflect the following:
    - The study numbers have now been updated to include an estimate of the number of patients reported with Acute Kidney Infection,
    - Explicitly describe the collection of patient reported data, which was previously reflected in the main application,
    - Changes to the study group structure have been described in the 'Prioritisation of ideas for research' section,
    - The involvement of the Patient Council in data release from the research database has been updated to reflect that the Council would informed of all proposals which have been approved for data release,
    - Inclusion of further examples within the section 'Types of Research undertaken by the UK Renal Registry' to add quality of life, symptoms and activation.

Confidentiality Advisory Group advice

The amendment request was considered by a Sub-Committee of the Confidentiality Advisory Group. Members recognised that the research database was populated with data which was collected for audit purposes under the linked reference 16/CAG/0153. The revised the data flow chart which had been provided reflected the scope of support which was in place for this linked non-research application. The Group accepted the updated data flow chart and raised no queries.

Members acknowledged that the revisions which had been made to the research database protocol provided further clarity in certain areas and brought the document in line with the wider detail which had been included in the initial application form. The wider areas of interest for applicants utilising the database for research purposes were accepted.

The Sub-Committee noted the change to the Chief Investigator and raised no queries in this area.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – UK Renal Registry has a satisfactory reviewed grade on V14.1, 2017/18**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed**).

Name	*Notes*
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **Prevalence of hip femoroacetabular impingement (FAI) syndrome in the general population**
CAG reference: **18/CAG/0151**

Amendment request

The amendment requests support under the Regulations for the following changes to the study:

- Extension the duration of support under the Regulations to September 2019.
- To allow access to pseudonymised X-Rays to study collaborators at the University of Warwick, which already have access to the associated data,
- To allow access to pseudonymised X-Rays and data to study collaborators in the Netherlands. These named collaborators were also added to the wider study contacts.

Confidentiality Advisory Group advice

The amendment request was considered by the Chair's Action. The delays experienced by the applicant during the initial application process were noted and it was agreed that on this basis, the extension to the duration of support under the Regulations was appropriate. The wider access to the pseudonymised analysis data by wider study collaborators at the University of Warwick and in the Netherlands was acknowledged. The applicant had made clear that the wider study collaborators would not be able to access confidential patient information in relation to the cohort. The CAG was content to provide a recommendation of support to the amendment.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements (**Confirmed – Project specific Data Security and Protection Toolkit has been reviewed as Standards Met – confirmed by NHS Digital email 15/11/2018**)
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed**).

Name	*Notes*
Ms Clare Sanderson	Alternate Vice-Chair
Miss Katy Cassidy	Confidentiality Advisor
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: A case-control evaluation of the NHS Breast Screening Programme

CAG reference: ECC 6-05 (e)/2012

REC reference: 12/LO/1241

IRAS reference: 91136

Amendment request

The amendment has been submitted in order to extend the duration of support under the Regulations to 31 December 2023, in line with revised funding.

The applicants have experienced significant delays in obtaining the required data from the data holders, and this additional time will ensure that the project aims are satisfied and the data is fully utilised for the objectives for which it was sought.

Confidentiality Advisory Group advice

The amendment request was considered by the Chair's Action. The Chair noted that support was originally given until 1 January 2016 and requested further information on the delays experienced by the applicant.

The applicants explained that this case-control study was designed to be repeated two-yearly in order to ensure that the effectiveness of the programmes was maintained. Previous case-control studies had experienced three-year delays in receiving all data and Information Governance permissions, and the applicants had anticipated that similar delays would be experienced during this study. The first case-control studies were due to be completed within the five-year programme of the first Policy Research Unit. Due to delays in obtaining the required data, those studies were in the analysis phase eight years later. The applicants advised that they anticipated that, now the case-control studies had taken place once, they would be able to progress more swiftly, and so had requested an extension for a further five years.

The applicants explained that the causes of the delays in obtaining the data were not straightforward. The applicants first application for data coincided with organisational changes, such as the establishment of Public Health England in April 2013 and NIGB was replaced by CAG at the same time. These led to uncertainty regarding data release. New conditions, such as Information Governance Toolkit compliance, were introduced, which needed to be met before any data was released. The application for the main phase dataset was also delayed due to organisational changes. The Office for Data Release (ODR) was also established, resulting in new application forms and new policies.

Furthermore, the introduction of the “Type 2 Objections” to NHS data led to further delays whilst the logistics of removing the data of people who logged these objections was worked through by ODR and NHS Digital.

Overall, the time taken to obtain pilot study data from application to receipt was 18 months. The time taken to obtain all England data from application to receipt was 23 months.

The Chair reviewed the information provided by the applicant and was assured by the explanation given for the delays.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Barts Cancer Care showed a satisfactory reviewed grade on V14.1 of the IG Toolkit)**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed: Acknowledgment of Non-Substantial Amendment from REC/HRA provided)**

Name	*Notes*
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **Clinical Practice Research Datalink Service (CPRD)**

CAG reference: **ECC 5-05 (a)/2012**

REC Reference: **05/MRE04/87**

Amendment Request

The amendment is seeking support under the Regulations to include information from the National Asthma and Chronic Pulmonary (NACAP) Disease audit. The NACAP audit is commissioned by the Healthcare Quality Improvement Partnership (HQIP) and operates with support under the Regulations via reference 19/CAG/0001 (Previously CAG 8-06(b)/2013). The Royal College of Physicians facilitates the audit on behalf of HQIP.

The data linkage will be undertaken by NHS Digital, acting as processor, which follows the standard agreed process which was in place for the overarching CPRD application. Confidential patient information would be disclosed from Crown Informatics Service, which acts as processor for the audit, to NHS Digital which would facilitate the linkage process to the wider CPRD records. Only pseudonymised data would be subsequently disclosed to CPRD to be made available to researchers applying to use the database.

Confidentiality Advisory Group Advice

The amendment was considered via Chair's Action. The data flows and linkage mechanism proposed were in line with the standard agreed mechanism for the CPRD for which support was already in place. It was recognised that data collection for the adult asthma audit had not commenced; however, support was requested under the Regulations to enable this linkage to be undertaken when this audit data was available. A letter of support had been provided by HQIP, as controller for the audit activity, for the linkage to CPRD.

The Chair was content to provide a recommendation of support to the inclusion of the National Asthma and Chronic Pulmonary (NACAP) Disease audit dataset within the CPRD master dataset list as it was recognised that the linkage to supplementary primary care data would be valuable to those researchers undertaking research into asthma and COPD.

A draft of revised patient notification material to be displayed by CPRD and was provided for consideration. The Group raised no queries around the text provided for the CPRD.

An interim notification mechanism had been proposed in relation to the patient information and notification materials which supported the audit programme. The applicant had suggested that, until the linkage between the NACAP audit and CPRD datasets was implemented as a standard linkage, the data flow would not be explicitly detailed within the patient information materials. It was proposed that the data flow be considered within the scope of the generic terms of 'other organisations' or 'third parties'.

The Group commented that the proposed interim arrangement did not provide clear information to patients around where their data was being disclosed or how this would be used. It was further noted

that the incorporation of an intermediary step to update patient notification and information materials, would duplicate the activity required to revise documentation and could potentially lead to outdated information being provided to patients in relation to the audit. The CAG agreed that the patient notification and information materials which supported the NACAP audit would require revision from the outset to clearly explain that data collected within the audit would be linked, via NHS Digital, to the CPRD database.

The CAG agreed that support would be recommended on a conditional basis with a requirement that the revised patient notification and information materials for the National Asthma and Chronic Pulmonary (NACAP) Disease audit were updated within a three-month period to accurately reflect the disclosure and linkage to CPRD. It was clarified that the revised documentation should be submitted as an amendment to the overarching audit application, 19/CAG/0001, to ensure that an accurate record of the patient facing documents was maintained on file.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. The patient notification text and patient-facing information materials which support the National Asthma and Chronic Pulmonary (NACAP) Disease audit should be revised to provide clear information around the disclosure of information to NHS Digital for the purposes of linkage with CPRD. Revised documentation is required within three months of the date of this outcome letter and should be provided by HQIP in connection to the audit application.
2. Confirmation of suitable security arrangements via IG Toolkit submission (**Confirmed – NHS Digital has a satisfactory reviewed grade on V14.1, 2017/18**).
3. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – covered within the overarching CPRD REC favourable opinion**).

Name	*Notes*
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **UK Renal Registry**

CAG reference: **16/CAG/0153**

Amendment request

The amendment sought support for the following changes to the registry activity:

1. Data flows with Public Health England – this data flow is already supported; however, the amendment seeks to reduce the items of confidential patient information disclosed to support this data flow. This will now be facilitated on NHS Number, Date of birth and Gender only (with UKRR ID), removing the following items: Hospital Number and full name (forename/initial/surname).

2. Addition of the following new data flows:

a. NHS England – monthly transfer of Renal Replacement Therapy (RRT) and Acute Kidney Injury data (AKI) which will include NHS Number, date of birth, postcode and gender,

b. NHS Wales Informatics Service – to facilitate linkage with the PEDW dataset to mirror follow-up which is in place via NHS Digital for English patients. This data flow would involve the disclosure of the following items of confidential patient information: UKRR ID number, NHS Number, date of birth, gender and postcode.

The amendment also describes the inclusion of Your Health Survey Information; however, it is clarified that patients completing the survey provide consent to the transfer of their information to their renal care unit and the UK Renal Registry, so this element is out of scope for the CAG consideration.

Confidentiality Advisory Group advice

The amendment requested was considered by a Sub-Committee of the CAG. The reduction in the items of confidential patient information required to facilitate linkage with Public Health England was acknowledged.

The addition of the data flow to NHS England would be used for strategic planning, purchasing and evaluation of specialised services for which NHS England has a national commissioning responsibility. The applicant confirmed that a data sharing agreement with NHS England would be established and reviewed annually to ensure the continued need for the data flow to NHS England. The Group was assured by the rationale provided to support the data flow and raised no queries in this area.

Members recognised that the proposed disclosure with the NHS Wales Informatics Service would enable the same follow-up of Welsh patients as was currently in place via NHS Digital for English patients. The applicant had provided confirmation within the amendment form that data linkage via NHS Digital to the HES and ONS datasets had been fully established. No queries were raised in this area.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

Specific conditions of support

1. Confirmation of suitable security arrangements (**Confirmed – UK Renal Registry, Public Health England and NHS England have published satisfactory reviews on V14.1, 2017/18 of the IGTK. NHS Wales Informatics Service has an existing CPIP Assurance Report**)

Name	*Notes*
Dr Tony Calland MBE	Chair
Miss Kathryn Murray	Senior Confidentiality Advisor

Study title: **SLAM IG Clinical Dataset Linking Service**

CAG reference: **ECC 3-04(f)/2011**

REC number: **08/H0606//71**

Amendment request

The amendment is seeking support under the Regulations to link the established patient cohort with HES maternity data around offspring birth date and delivery outcomes.

The proposed data linkage does not require any further processing of confidential patient information or disclosures, as the required information is already held in a pseudonymised format by the applicant; however, support is required to facilitate the additional processing and linkage to this information which was collated with support under the Regulations.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. It was recognised that the applicant had already held the required HES maternity data, which was provided by NHS Digital. Whilst the information is in a pseudonymised format, support under the Regulations is required for the additional processing and linkage.

The applicant explained that the Data Sharing Agreement with NHS Digital would be updated to reflect the wider use of the HES maternity data and additional processing to link the patient cohort.

The Group recognised that the CRIS database was a valuable research resource and was assured that there was a wider public interest to be achieved from undertaking research into maternity outcomes for mental health patients. Support was recommended for the amendment.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed – South London and Maudsley NHS Foundation Trust has a satisfactory reviewed grade on Version 14.1, 2017-18).**
2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – Linkage covered in overarching REC opinion).**

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Miss Katy Cassidy	Confidentiality Advisor
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: **BRIGHT LIGHT: Do specialist services for teenagers and young adults (TYA) with cancer add value?**

CAG reference: **ECC 8-05(d)/2011**

IRAS reference: **81684**

REC reference: **11/LO/1718**

Amendment request

The amendment has been submitted to obtain support to undertake secondary data analysis on the dataset created by the applicants, under their previous support.
The applicants undertook an assessment of the historic consent which was in place and noted that patients had not been informed that their data may be used for additional relevant analysis about their experiences of cancer and care.

Following an amendment in 2017, the applicants were required to delete all patient contact details and so are unable to contact patients directly to re-consent for this purpose.

Pseudonymised data are held and processed at UCL/UCLH linked to study identifiers. the items of confidential patient information included are date of birth, date of diagnosis and date of death (where relevant). Broad diagnosis categories using the Birch criteria are used so young people with rarer cancer types cannot be identified.

All data processing will be undertaken at UCLH, UCL and the University of Leeds. All proposed secondary analysis is submitted to the core and/or executive team for peer review to ensure this aligns to the recent James Lind Alliance research priorities for Teenage and Young Adult Cancers to ensure analysis carried out is an unanswered research question identified by young people, their carers and professionals.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action.

The applicants had collected a significant amount of data from 1,114 young people newly diagnosed with cancer between 2012 and 2014. This included clinical, NHS and patient-reported outcomes and experience data. These data were collected to answer the specific question on whether specialist services added value. However, the applicant had explained that the number of other research questions these data could answer had become more apparent.

The Chair noted that the data set concerned was already pseudonymised so there could be no further breach of confidentiality. It was acknowledged that the patients had indicated that they were supportive of the use of their tissue specimens in any analysis beneficial to future cancer sufferers, and the Chair determined that it was reasonable to assume that they would also be supportive of their pseudonymised data being used in the same way.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Confirmation of suitable security arrangements via IG Toolkit submission. **(Confirmed: University College London Hospitals NHS Foundation Trust has a satisfactory reviewed score for IGT v14.1)**
2. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmed: Favourable Opinion issued by London-Bloomsbury REC on 7 March 2019)**

Name	*Notes*
Dr Patrick Coyle	Vice-Chair
Miss Sophie Brannan	CAG Lay Member
Ms Diana Robbins	CAG Lay Member
Miss Katy Cassidy	Confidentiality Advisor
Miss Kathryn Murray	Senior Confidentiality Advisor

Application title: UK Surveillance of Primary Congenital Hypothyroidism in Children

CAG reference: ECC 3-04(k)2011

IRAS project ID: 76106

REC reference: 11/EE/0152

Amendment request

In this amendment the applicants are seeking support to link data collected for the UK Surveillance of Primary Congenital Hypothyroidism (CHT) in Children with prescription (NHS Business Services data), hospital episodes data, death registrations and National Congenital Anomaly and Rare Disease Registration Service (NCARDRS) data at Public Health England (PHE).

The existing support included the retention of NHS numbers until the children were 11 years of age in order to enable linkage to routine outcome data for the cohort. The original application did not specify which linkages would be made, and this amendment has been submitted to clarify the linkages.

NCARDRS has existing support, under application reference CAG 10-02(d)/2015 to access the prescribing data, hospital episodes data and death registrations. The applicants will disclose the NHS numbers, sex and date of birth of children resident in England at birth and/or when new-born screening took place, and who are included in the UK CHT Surveillance study, to NCARDRS, who will link data from each dataset to each child.

NCARDRS will disclose the current vital status, details of prescribed medications, in-patient, out-patient and A&E attendance episode data, a list of congenital abnormalities and the results of the new-born hearing screening back to the applicants.

The applicants are also seeking support for NCARDRS to disclose confidential patient information to the New-born Hearing Screening Programme (NHSP), held by Northgate Solutions for PHE NHSP, in order to link to the results of new-born hearing screening.

The applicants explained that they expected data linkage to be possible on NHS number alone, except for one child whose NHS number was unknown, and were requesting support to provide NCARDRS with the date of birth, sex, ethnicity, district postcode, child's screen date and results, and child's disease category and date of diagnosis, and a unique ID for each child. These additional items of confidential patient information would be disclosed to confirm that the linkage is correct.

When the data linkage process has been confirmed as successful, support was also sought to transfer the UK CHT Surveillance Study dataset, including confidential patient information, for ongoing retention by Public Health England within the scope of support which is in place for the NCARDS dataset. The applicants stated that this will enable them to delete the identifiers held within the UCL Data Safe Haven after the analyses were complete, or after 2023, whichever is earlier, and remove the need for continuing support under the Regulations for the study.

The amendment submission, had also requested support to the patient cohort with education outcomes at age 7-11 years within the National Pupil Database, held by the Office of National Statistics (ONS). The applicant confirmed that the data flows to support this linkage were not yet known. As such, the applicant confirmed that this element was removed from the amendment request pending confirmation of the linkage process.

Confidentiality Advisory Group advice

The amendment request was considered by the Sub-Committee, who were content to recommend support for the disclosure of confidential patient information to Public Health England for linkage to NCARDRS.

The Sub-Committee noted that, although there is only one subject without an NHS number, ascertainment is so important that it is appropriate to provide the other identifiers to NCARDRS to verify the NHS numbers. Members accepted the argument that the date of birth, sex, ethnicity and postcode needed to be provided for validation.

The Sub-Committee noted that NCARDRS provided the CHT study with patients' date of death when the linked data was returned. Members stated that date of death was an item of confidential patient and agreed that support under the Regulations was required to support this disclosure.

The text on the BPSU website was to be updated to reflect the change in data collection. The updated text referred to patients contacting the research team in order to opt-out, and Members asked if the contact details from the original text would still be included. A web-link was provided to the Confidentiality Advice Team, which confirmed that the contact details for the applicant were included on the BPSU website, for patients to request an opt-out.

Members queried whether this information would be replicated within the PHE and the British Thyroid Foundation websites.

The applicant explained that PHE had standardised webpages and that an approvals process needed to be completed before information about this application could be included. If the data linkage was approved by PHE, then the Office for Data Release and NCARDRS will include the application on the public register, which is the preferred form of notification for unconsented data studies. The applicant intended to apply for inclusion on the PHE website after the application to CAG had been completed.

The applicant intended to approach PHE about writing a blog for their website, which would also include a link to the BPSU webpage, NCARDRS and PHE ODR.

The British Thyroid Foundation website has a short page about research, which contains information about this application and a link to the BPSU website. The applicant stated that they would approach BPSU regarding including information about the study linkage extension. The applicant noted that it was preferable to direct patients to one page to ensure information was given consistently.

The Sub-Committee accepted the explanation for not updating the PHE and BTF websites directly, and noted that updating the information to include a link to the BPSU website was appropriate. The Sub-Committee asked that an update on this was provided at Annual Review.

Members recognised that the data flows to support linkage with the National Pupil Database at the Department for Education were not yet known and accepted the applicant's request to remove this from the scope of this amendment. A separate amendment submission was required in future at such time as the data flows to support this were clarified.

The Sub-Committee noted that the applicant was a member of the Confidentiality Advisory Group. This presented a potential conflict of interest, but the member had no involvement in the consideration of this amendment.

Confidentiality Advisory Group conclusion

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Health Research Authority.

Specific conditions of support

1. Support is not extended to the linkage to the National Pupil Database, held by the Office of National Statistics, at this stage.
2. An update should be provided at the time of annual review around the progress which has been made to update the patient notification materials available via the BPSU, British Thyroid Foundation and Public Health England websites.
3. Confirmation of suitable security arrangements via IG Toolkit submission. **(University College London, School of Life and Medical Sciences EE133902-SLMS has a satisfactory reviewed score for v14.1 2017/18, Public Health Public England X25 has a satisfactory reviewed score for v14.1 2017/18, Northgate Public Services has a satisfactory reviewed score for v14.1 2017/18)**
4. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed Favourable Opinion from Cambridge South REC)**