Health Research Authority

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

**September 2019**

## 1. NEW APPLICATIONS

### a. 19/CAG/0135 - Derby Monitoring Study of Self-harm

| Name | Notes |
|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Dr Katie Harron | CAG Member |
| Mr Marc Taylor | CAG Member |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Context**

**Purpose of application**

This application from Derbyshire Healthcare NHS Foundation Trust set out the purpose of medical research which aims to undertake a series of studies on the epidemiology, clinical management, outcome and prevention of self-harm and suicide. The project is a multi-centre study carried out in collaboration with the University of Oxford and the University of Manchester.

The study includes all patients who present at the Derbyshire Healthcare NHS Foundation Trust having self-harmed. Patients are either included following completion of a study form by the treating clinician if they are seen by a member of the CAMHS or adult liaison psychiatry team during hospital attendance to undergo psychological assessment. The study team also check hospital records for wider self-harm attendees who do not undergo psychological assessment.

All patients included in the study are flagged within NHS Digital to enable ongoing mortality status follow-up to be carried out.

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

## Confidential patient information requested

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

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| **Cohort** | All patients aged six years and over attending the Royal Derby Hospital following an episode of self-harm, which is defined as an intentional act of self-poisoning or self-injury regardless of the motivation. This encompasses approximately 2,500 patients each year. |
| **Data sources** | 1. Emergency department patient records at Derby Teaching Hospitals NHS Foundation Trust,<br>2. Mental health patient records at Derbyshire Healthcare NHS Foundation Trust<br>3. ONS Mortality Dataset, NHS Digital |

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| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. Date of Birth<br>4. Postcode<br>5. Last known postal address |
| **Identifiers required for analysis purposes** | 1. Postcode – deprivation scoring<br>2. Gender<br>3. Ethnicity<br>4. Age in years |

## 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 how long confidential patient information would be retained for following the end of the study.**

The applicant clarified that confidential patient information would be retained up to 12 months following funding cessation and final participant recruitment, to allow for the final data quality checks and mortality linkage necessary to conduct final analyses, creation of final study reports and therefore achieve successful study closure. The applicant confirmed that they would ensure that during this time period, all appropriate research and support under the Regulations remained in place until confidential patient information is securely destroyed.

The Sub-Committee was assured by the applicant's clarification.

## 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. Prepare patient information materials for the child cohort and their parents/carer. These documents should be submitted for review within three months of the final outcome for this refreshed application.

2. The project manual should be updated in line with the wider study documentation. This should be provided for review within three months of the final outcome for this refreshed application.

3. An amendment should be submitted to request an extension to the duration of support in place for the activity should additional funding be provided past 31 March 2020.

4. All pre-existing conditions of support related to PIAG 4-06(FT2)/2006 remain applicable.

5. The pre-existing annual review cycle remains applicable, with the next annual review to be received 4 weeks before 20/02/2020, and then on an annual basis to this schedule.

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

7. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed: Derbyshire Healthcare NHS Foundation Trust, Derby and Burton NHS Foundation Trust and NHS Digital have confirmed 'Standards Met' grade.**

## b. 19/CAG/0072 - Validation of a novel scoring system to predict inpatient mortality in exacerbations of Chronic Obstructive Pulmonary Disease requiring assisted ventilation with supplementary longitudinal assessment of quality of life and other patient-centred outcomes over one year.

| Name | Notes |
|---|---|
| Dr William Bernal | CAG Alternate Vice Chair |
| Dr Tony Calland MBE | CAG Chair |
| Professor Barry Evans | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from Northumbria Healthcare NHS Foundation Trust sets out the purpose of medical research which aims to assist decision-making in the treatment of exacerbations in Chronic Obstructive Pulmonary Disease (COPD).

Exacerbations of COPD account for 12% of UK hospital admissions. During an exacerbation, the lungs may be unable to adequately clear carbon dioxide ("waste gas") and the blood becomes more acidic as it accumulates (termed respiratory acidaemia). Respiratory acidaemia has a high mortality and non-invasive ventilation (NIV) can be lifesaving.

Clinicians currently lack a simple method to accurately predict outcome and often overestimate the risk of death, resulting in under-use of NIV. The applicants aim to assist decision making by developing a simple prognostic tool, used to inform discussions about treatment options with patients/families, resulting in increased use of NIV in those who will benefit, and enhanced palliative care provision in those who will not.

The applicants collected survival and readmission data for up to 12 months post-discharge. Consent was not required from patients as the direct care teams at each site collected the patient information and only anonymised data was shared with the host site. The applicants had not accounted for the possibility that patients would be readmitted to a hospital that was not participating in the research, or die within the community, and now required the disclosure of confidential patient information from participating trusts to the host site, Northumbria Healthcare NHS Foundation Trust, for collation. The collated confidential patient information was then disclosed to NHS Digital and NHSWIS for linkage to Hospital Episode Statistics (HES) and Patient Episode Database Wales (PEDW) respectively, so that data including emergency department attendance, hospital admission, including to intensive care admission, length of stay and cause of/reason for admission can be accessed. De-identified data was then returned to the host site.

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

## Confidential patient information requested

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

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| **Cohort** | Male and female patients aged 35 years and over, diagnosed with Chronic Obstructive Pulmonary Disease. with an exacerbation complicated by respiratory acidaemia and which is treated with assisted ventilation. |
| **Data sources** | 1. Electronic patient records at participating Trusts in England and Health Boards in Wales<br>2. HES, NHS Digital<br>3. PEDW, NHS Wales Informatics Service |
| **Identifiers required for linkage purposes** | 1. NIVO study-specific ID<br>2. NHS number<br>3. Date of birth<br>4. Date of death<br>5. Postcode |

| | |
|---|---|
| **Identifiers required for analysis purposes** | 1. NIVO study-specific ID<br>2. NHS number<br>3. Date of birth<br>4. Date of death<br>5. Postcode<br>6. Admission Hospital<br>7. Gender<br>8. Ethnicity |

## Confidentiality Advisory Group advice

The applicant provided responses to the below query, which were reviewed by a Sub-Committee of the CAG.

1. **Further patient and public involvement and engagement activity should be carried out to test the acceptability of using confidential patient information without consent. Wider lay representatives who have previously been involved in the study should be approached to provide views. An overview of the activity undertaken, and feedback provided is required.**

The applicant provided transcripts of the consultations undertaken as part of the patient and public involvement and engagement activity carried out. The Sub-Committee noted the information provided and raised no further queries.

2. **Provide copies of the patient notices which will be displayed at Trust sites for information.**

3. **Wider communications should be made available via the websites of participating Trusts – provide confirmation to this point and copies of any documentation.**

In response to points 2 and 3, the applicant provided the posters and website text that will be used at the sites involved. The Sub-Committee reviewed these and requested that the phone number or email address of the relevant hospital department was included on the posters. The applicant provided assurance that this could be included and the Sub-Committee 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **Confirmed 06 July 2019.**

2. Confirmation of suitable security arrangements for organisations processing confidential patient information with support **(Confirmed: NHS Digital has a confirmed "Standards Met" grade on DSPT submission 2018/19. NHS Wales Informatics Service has a satisfactory CPIP Assurance Report. Northumbria Health Care (by NHS Digital 02 September 2019) has a confirmed "Standards Met" grade on DSPT submission 2018/19).**

## c. 19/CAG/0082 - Feasibility cohort study: Serum mid-luteal progesterone versus ultrasound for monitoring first-cycle clomifene citrate.

| Name | Notes |
|---|---|
| Dr Martin Andrew | CAG Member |
| Dr William Bernal | CAG Alternate Vice Chair |
| Mr David Evans | CAG Member |
| Mr Myer Glickman | CAG Chair |

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|---|---|
| Dr Harvey Marcovitch | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

## Context

### Purpose of application

This application from the University of Sunderland set out the purpose of medical research which aims to explore the feasibility of conducting a full retrospective cohort study to compare multiple pregnancy rates between those patients whose first cycle of treatment is monitored with ultrasound, and those who are not monitored with ultrasound.

Clomifene is a medication used to trigger the ovary to ovulate. Guidelines state that ultrasound should be used after clomifene is first given, to assess how many eggs have developed. Where there are multiple eggs, there may be an increased likelihood of multiple pregnancy, and the couple would be advised to avoid unprotected intercourse that month. This is because multiple pregnancies carry extra risks to mother and baby. The guidance to use ultrasound for this purpose is not based on any research evidence, as no evidence is currently available. Progesterone is a hormone produced in the ovary following ovulation. Using a blood test for progesterone can indicate if clomifene has successfully triggered ovulation, but gives no information about multiple pregnancy risk. The secondary aim is to assess the clinical and financial implications of using a blood test (progesterone level) as an alternative monitoring method.

This study will comprise various strategies of data collection from the medical records of patients who have completed treatment with clomifene. They will be split into two arms, monitored with ultrasound and not monitored with ultrasound, then the pregnancy outcomes will be compared based on the data gathered. This will be followed by an initial cost effectiveness analysis for each study arm.

Treatment with clomifene is not a treatment regulated by the Human Fertility and Embryology Authority (HFEA) and the data collected will be from NHS patient records. There will be three possible ways in which departments can contribute data to the study. In some units, clinical staff will extract and anonymise the data and enter it into

the standardised Excel spreadsheet, which is then returned to the research team. An alternative method is that the clinical team will be provided with an audit package, which is completed by staff members to contribute to governance/educational needs within the department, as well as providing anonymised data back to the research team. The applicants will not require access to confidential patient information without consent if either of these methods is used. The applicants are seeking support to follow a third method of data collection, where the applicant will access confidential patient information in medical records on site at participating centres to record relevant non-identifiable patient data directly onto the research spreadsheet.

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

## Confidential patient information requested

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

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|---|---|
| **Cohort** | Female patients between 18 and 50 years of age who have completed treatment with clomifene. It is estimated 40 patients will be selected from each of the 17 sites. |
| **Data sources** | 4. Patient Health records held within the following participating Trusts:<br>a. Newcastle upon Tyne Hospitals NHS Foundation Trust<br>b. Gateshead Health NHS Foundation Trust<br>c. Liverpool Women's Hospital NHS Foundation Trust<br>d. University Hospital's Bristol NHS Foundation Trust<br>e. Manchester University NHS Foundation Trust<br>f. Nottingham University Hospitals<br>g. Derby Teaching Hospitals NHS Trust<br>h. University Hospitals of Derby and Burton<br>i. North Tees and Hartlepool NHS Foundation Trust<br>j. Isle of Wight NHS Trust |

| | |
|---|---|
| | k. Seven further hospital Trusts to be confirmed. |
| **Identifiers required for linkage purposes** | No items of confidential patient information will be required for validation or linkage purposes. |
| **Identifiers required for analysis purposes** | No items of confidential patient information will be extracted for analysis purposes. |
| | The applicants will have access to the complete record to enable relevant clinical information to be extracted for analysis; however, no items of confidential patient information will be collected for sample validation, linkage or analysis purposes. The only data retained and used in analysis will be anonymous clinical data, which will not contain any confidential patient information. |

## 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 how many of the participating trusts are unable to undertake the data collection and extraction processes on behalf of the researcher. This information is required to understand the scope of support which is required under the Regulations for the activity.**

The applicant advised that seven trusts had requested that she undertook the data collection and extraction process on their behalf.

The Sub-Committee raised no further queries.

2. **Further information about potential access by the applicant to information about Human Fertilisation and Embryology Authority (HFEA) regulated treatments is required;**

a. **Clarify the likelihood that patients treated with clomifene would have progressed to receive treatments that are regulated by the HFEA.**

The applicant explained that IVF and ICSI were not standard treatments for patients with ovulatory disorders. Therefore, only a small number of patients would be treated with clomifene and then progress onto other treatments that were regulated by the HFEA.

b. **Clarify if patients who had subsequently received HFEA regulated treatments would be excluded from the study or provide assurance that sections of the records containing information about HFEA regulated treatments will not be accessed.**

The applicant explained that it was likely that clomifene treatment would be documented separately to HFEA-licensed treatments in patients medical notes. If documents relating to clomifene treatment and HFEA-licensed treatments were held together, the applicant would ask the person responsible for holding the information to extract the relevant information. If this was not possible, then that patient would be excluded from the study.

The Sub-Committee noted the information provided above and raised no further queries.

3. **Advise if the consent forms completed by patients receiving HFEA regulated treatments will be checked to ascertain whether a patient had refused consent to be included in research.**

The applicant advised that the consent forms used by the HFEA, known as CD forms, relate only to data held by the HFEA. Clomifene is not a HFEA-licensed treatment, and therefore the CD form is generally irrelevant to this study.

In the event that a Trust had opted to use the CD form locally as an indication of consent for all fertility-related research, then this will be considered. The applicant did not expect this to happen often, as they had liaised with the local R&D approvals

processes for all Trusts involved in the study and none had indicated that they used the CD form for this purpose. If a patient had refused consent, then they would be excluded from the study.

If the CD form was held within the records relating to HFEA-related treatments, this would be requested from the person responsible for the records. The applicant would liaise with the local R&D approvals processor for all Trusts involved in the study, and none have indicated that they use the CD form

The Sub-Committee noted the information provided and raised no further queries.

4. **Information about the application, including how patients can register their dissent, needs to be included in relevant sections of the websites of the participating Trusts. Provide confirmation to this point and copies of any information materials which would be displayed.**

The applicant advised that they had decided not to make information available on the website, as it was unlikely that patients who had previously received treatment with clomifene would access the website of the fertility department that they were treated by and were therefore unlikely to see information about the study.

The Sub-Committee determined that this did not adequately address concerns about transparency, and asked that notifications were placed on the websites of participating Trusts.

The applicant provided a document, containing information about the study and how to dissent, which would be displayed on the websites of Trusts taking part in the study.

The Sub-Committee was satisfied by the revised poster and assurance that this information would be displayed on the websites of participating Trusts.

## 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 02 September 2019.**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. (**Not checked – the study will be carried out across 17 Trusts in England– security assurance would not be checked for all participating sites. Support is recommended on the basis that the applicant is responsible for seeking assurance that the appropriate security arrangements are in place at each site prior to processing any confidential patient information with support under the Regulations**).

## D) 19/CAG/0136 - Acute Leukemia in Pregnancy Registry Study

| Name | Notes |
|---|---|
| Ms Sophie Brannan | CAG Lay Member |
| Dr Tony Calland MBE | CAG Chair |
| Dr Harvey Marcovitch | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from the Hull and East Yorkshire Hospitals NHS Trust set out the purpose of medical research which aims to establish a research database focussed on women who were diagnosed with acute leukaemia or high-risk myelodysplasia in

pregnancy or who have later conceived after receiving previous treatment for either condition.

This is an observational study which aims to monitor and record the current treatment and outcomes of patients diagnosed with acute leukaemia during or prior to pregnancy since August 2009, and any new cases that are diagnosed during the period of the study with a view to informing a standardised approach to patient care. Patients will receive the treatment recommended by their doctor, the study will not alter the treatment pathway of participants. Prospectively diagnosed patients, or those still undergoing active treatment will be approached for consent by a member of their clinical care team. Patients who have been discharged and those who are no longer in active follow-up or contact with the clinical care team will not be approached for consent.

Research data collected during this study will not be released to other researchers or research organisations outside of the immediate study team for the duration of the study. Subject to further funding being obtained it is envisaged that the LIPS database and data collection will continue and may be expanded outside the UK. Request for access to the data for research purposes beyond the scope of the initial study will be managed by the Hull Health Trials Unit within the University of Hull.

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

## Confidential patient information requested

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

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| **Cohort** | Patients diagnosed with acute leukaemia or high-risk myelodysplasia during or prior to pregnancy since August 2009 across 24 Trusts in England and one Health Board in Wales who are no longer under active follow-up, have |

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|---|---|
| | been discharged from treatment or are known to be deceased. It is anticipated that there will be 50 patients within this cohort. |
| **Data sources** | 24 Trusts in England and 1 Health board in Wales |
| **Identifiers required for linkage purposes** | 1. Year of birth (mother)<br>2. Date of birth (child)<br>3. Date of death (mother and/or child)<br>4. Sex of child |
| **Identifiers required for analysis purposes** | 1. Year of birth (mother)<br>2. Date of birth (child – DD/MM/YY)<br>3. Date of death (mother and/or child – DD/MM/YY)<br>4. Sex of child |
| | The following additional cohorts will be included on the basis of informed consent:<br><br>• Current patients: defined as those who are receiving treatment and are now pregnant or those who have previously received treatment and are now pregnant,<br>• Historical patients: defined as those who had treatment whilst pregnant and are still in active follow-up or contact with the clinical care team or those who had an active acute leukaemia diagnosis and became pregnant post-treatment and are still in active follow-up or contact with the clinical care team. |

## Confidentiality Advisory Group advice

The applicant provided a response to the below queries, which were considered by a Sub-Committee of the CAG.

1. **Explain why the research database is not being established on a national basis, to include data from all Trusts and Health Boards in England and Wales.**

The applicant advised that the database was being set up on a national basis. Only hospitals with high intensity units treated acute myeloid leukaemia (AML) and Acute lymphoblastic leukaemia (ALL) in the UK, therefore only these units had been approached to take part. The applicants explained that they were willing to add additional sites if they also treated eligible patients.

The applicants planned to contact consultants and doctors across Trusts and Health Boards in England and Wales to raise awareness of the study. The study was also to be highlighted regularly to all UK haematologists at both national and international meetings throughout the study period, with the aim of optimising recruitment rates, but also to inform on its progress. The applicants also planned to publish news stories in suitable haematology related websites, such as Bloodwise. The study has also been adopted onto the NIHR portfolio, which the applicants hope will aid in further dissemination. The Sub-Committee noted the information provided and raised no further queries.

2. **Provide further information to explain how the retrospective patient cohort would be identified.**

The retrospective cohort was identified via screening of the Trust level Multidisciplinary Team database of patient diagnosis and mortality data. These searches were conducted by the consultant or other designated member of the clinical research team. Once a patient was identified, their case notes were checked for evidence of historic dissent and the NHS Message Exchange for Social Care and Health (MESH) for national opt-out against the use of their data for research purposes. If there was no evidence of opt-out then the clinical team began the data collection.

If the retrospective patients were still receiving follow-up, then these patients would be identified from lists of treated ALL and high-risk Myelodysplastic syndromes (MDS) patients, as well as the MDT diagnosis database. Consent would be sought from these patient's and support under Section 251 would no longer be required once consent had been obtained. The Sub-Committee noted the information provided and raised no further queries.

3. **Provide further information to justify the necessity of retention of the child's date of birth and date of deaths (mother and child) within the database once survival calculations had been undertaken.**

The applicant explained that, at the end of the initial study period and annually afterwards, the data would be exported from the data collection database, so that survival calculations could be made.

Once patients reached the 4-year follow-up time point, then data from the data collection database was used to create three new variables. These were; the child's age in weeks at death, the age of the mother at death and the child's age at 4-year follow-up, if the child was still living. The three variables would be used instead of the child's date of birth and date of death.

All other dates collected, such as scan and treatment dates, will be altered once patients have reached the 4-year follow-up time point. This dataset will then be added to a second long-term database, for which all cases will be recorded as a single site for the whole of the UK. This dataset will be used for any future data requests.

Once the data is in the 'long-term' database, the original data will be deleted from the data collection database. At this point it will be no longer be possible to remove the data for each patient from the long-term data as it will be fully anonymised. The Sub-Committee noted the information provided and raised no further queries.

4. **Provide copies of the text which would be displayed on both the Hull Health Trials Unit and Bloodwise websites.**

The applicant provided a copy of the text to be used on the Hull Health Trials Unit webpage. The applicant noted that they could not yet confirm the text to be used on the Bloodwise website, but that this was expected to be a summary of the project and would include a link to the Hull Health Trials Unit webpage. The Hull Health Trials Unit webpage would be the main source of information. The Sub-Committee noted the information provided and raised no further queries.

5. **Provide further information to explain how the national opt-out would be respected in the creation of the database.**

The applicant advised that no directly personal identifiable information, such as names and NHS numbers, would be collected in the database, therefore it was not possible for the research team to check whether patients had registered a national opt-out.

The applicants expected that all NHS Trusts would have a site level policy in place by March 2020 in order to be compliant with the national opt out and that the local policy of applying opt-outs would be followed. During site initiation, the sites would be instructed on which cases came under Section 251 support and would be asked to check local records at the NHS Trust for evidence of historic dissent to the use of their data in research. Sites would also be asked to check the records of all retrospective cases, from whom consent was not sought, for evidence of dissent using the NHS Message Exchange for Social Care and Health (MESH) for patient opt-out.

These checks would be performed prior to the disclosure of information for inclusion in the research database. The screening CRF had been amended so that the site had to confirm that checks had been completed before they were able to enter any data for a retrospective case where consent had not been obtained. The Sub-Committee noted the information provided and raised no further queries.

6. **A project-specific dissenting mechanism should be implemented – provide details of how this would be operated and how any objections raised would be respected.**

A flow diagram had been provided. This detailed how the project specific dissenting mechanism would be implemented. This diagram would also be given to sites during the site induction, to ensure that they were aware of their responsibilities.

The privacy notice had been updated and renamed to the 'Patient Notification and Privacy Notice.' The revised notice was submitted for review. The Sub-Committee noted the information provided and raised no further queries.

7. **Explore ways to engage with an appropriate patient group around the establishment of the database. It is recommended that Bloodwise be approached to see if they are able to facilitate contact with relevant patients and the public with experience in this area.**

The applicant advised that they would continue to explore ways of engaging with an appropriate patient group. The applicants had approached Bloodwise to discuss whether they could facilitate contact with relevant patients and the public.

Text, encouraging patients and the public to join a group to contribute to the development of the database and handling of the data, had been included in the Hull Health Trials Unit website text. The Sub-Committee noted the information provided and raised no further queries.

8. **Confirm whether specific approval is required from the Chief Medical Officer in relation to the termination data requested.**

The applicant confirmed that specific approval was not required from the Chief Medical Officer in relation to the termination data. E-mail correspondence between the applicant and the Department of Health and Social Care had been provided to support this. The Sub-Committee noted the information provided 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **Confirmed 02 August 2019.**

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 – Hull Health Trials Unit has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital e-mail 26 July 2019).**

## e. 19/CAG/0129 - Validation of a novel scoring system to predict inpatient mortality in exacerbations of Chronic Obstructive Pulmonary Disease requiring assisted ventilation with supplementary longitudinal assessment of quality of life and other patient-centred outcomes over one year.

| Name | Notes |
|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Mr Andrew Melville | CAG Lay Chair |
| Ms Diana Robbins | CAG Lay Chair |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from Royal Liverpool and Broadgreen University Hospitals NHS Foundation Trust set out the purpose of medical research which aims to use artificial intelligence to interpret Endovascular Aneurysm Repair (EVAR) x-rays performed in the Trust with a deep-learning algorithm to evaluate whether this could be used to interpret the x-rays.

The proposal is a proof of concept feasibility study. Abdominal aortic aneurysm (AAA) is a condition in which the largest blood vessel in the body becomes weak and forms a bulge. If it becomes large enough, the AAA can burst, often leading to death. Clinicians repair AAAs before they burst by undertaking EVAR, which is a standard treatment in the majority of patients. It is a keyhole technique that reinforces the aorta with a synthetic tube called a “stent-graft”. EVAR is a safer option in the short-term compared to traditional open surgery. However, in the longer term, 1 in 5 patients require further surgery to correct problems developing with the stent-graft such as loss of position and integrity of the stent-graft. Therefore, patients are followed up for life after EVAR with scans performed, usually on an annual basis, to look for signs of a failing stent-graft. Stent-grafts are visible on x-rays of the belly and by comparing series of images taken over time, it is possible to diagnose a myriad of stent-graft

problems including loss of positioning, disintegration of the stent-graft material as well as stent-graft distortion. But these changes can be subtle and difficult to spot, even to the trained human eye. As a result, patients undergo more detailed scans that carry a risk of kidney damage and radiation-induced cancer.

The applicant will identify a retrospective patient cohort who have undergone an EVAR procedure at the Royal Liverpool Hospital via the clinical database within the Liverpool Vascular and Endovascular Service. Radiographs which have been undertaken as part of routine post-EVAR surveillance will be obtained from the NHS PACS (Picture Archiving and Communication System). Support under the Regulations is sought for this initial patient identification process and the extraction of radiographs and supporting clinical information. This would be pseudonymised prior to use for analysis purposes at the University of Liverpool at the Institute of Ageing and Chronic Disease.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | All patients who underwent an Endovascular Aneurysm Repair procedure at the Royal Liverpool Hospital between 01 January 2005 and 31 December 2013. It is estimated that there will be 800 patients in the cohort. |
| **Data sources** | 5. Electronic Health records held within the Liverpool Vascular and Endovascular Service at the Royal Liverpool Hospital.<br>6. NHS PACS (Picture Archiving and Communication System) records at the Royal Liverpool Hospital. |

| | |
|---|---|
| **Identifiers required for linkage purposes** | 6. Name<br>7. NHS Number<br>8. Hospital ID<br>9. Date of Birth |
| **Identifiers required for analysis purposes** | Not applicable |
| **Additional Information** | Inclusion in the study requires a minimum of five-year post-procedure follow-up to be available. |

## 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. **The study poster needs to be revised as follows;**

a. **More details on the study, including how patient records would be used and the aims and potential benefit of the study, need to be incorporated.**

b. **A telephone number needs to be included for patients to register dissent.**

A revised poster, amended to reflect the above points, was submitted. A statement had also been added to explain that confidential patient information will be accessed without consent, along with an assurance regarding the experimental nature of the study and that routine care will not be affected.

A telephone number for patients to use to register dissent has also been added to the poster, alongside the e-mail address.

The Sub-Committee reviewed the poster and were satisfied with the revisions made.

2. **Clarify whether the analysis work will be solely carried out by the University of Liverpool, or if a commercial company will be involved at any stage.**

The applicant explained that the analysis wok would be conducted solely by the University of Liverpool, with no commercial involvement at any stage of the project. The Sub-Committee were satisfied by this assurance.

### 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 05 July 2019**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission. **(Confirmed for Royal Liverpool and Broadgreen University Hospitals NHS Foundation Trust)**

## f. 19/CAG/0105 - Partners at Care Transitions (PACT): Improving patient experience and safety at transitions of care - Assessing the feasibility of using the PACT intervention to improve safety and experience of the transition process in a randomised controlled trial setting.

| Name | Notes |
|---|---|
| Dr Martin Andrew | CAG Member |
| Ms Diana Robbins | CAG Lay Member |

| | |
|---|---|
| Ms Clare Sanderson | CAG  Alternate Vice-Chair |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

## Purpose of application

This application from the University of Leeds set out the purpose of medical research to improve the safety of experience of transitions from hospital to home for patients aged 75 years and over.

Transitions of care from hospital to home can be risky, especially for older people with multiple health conditions. Previous research has suggested that the post-discharge period may be improved by better involving patients and families in their care. This study forms part of a programme of research which aims to develop an intervention to improve the safety and experience of transitions from hospital to home for people aged 75 years and over. In this study a feasibility cluster Randomised Control Trial will be conducted to explore the feasibility of using the intervention and trial methodology. As the applicants have progressed through this programme of work they have identified a problem in accessing accurate routine readmission data, as the way in which hospitals code discharge information does not always accurately record whether patients were admitted from and discharged to their own home, rather than a nursing or care home. This programme of work is designed to assist patients discharged home, therefore the applicants intend to assess the extent to which this coding issue will affect the accuracy of the primary outcome measure for the target population.

In order to test the processes as part of the full cluster Randomised Control Trial, the applicant first intends to identify the most efficient, cost effective and accurate way of identifying readmission data for patients who are discharged to their own homes rather than other usual places of residence, such as nursing homes. Information Services in each Trust will create a list of 10 patients per participating ward who are aged 75 years or over, consecutively admitted to the participating ward, and discharged from anywhere in the hospital to ‘usual place of residence’ as per hospital coding. Confidential patient information on these patients will be shared with a Trust research nurse. The research nurse will then check the medical records and categorise patients as discharged to either their own/a relative’s home, a nursing home, intermediate care

or another residence. This data will be aggregated at ward level and all personal information removed before the data is shared with the research team.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | 100 male and female participants, aged 75 years and over, admitted to 10 participating wards. |
| **Data sources** | Electronic and paper records held in participating Trusts. |
| **Identifiers required for linkage purposes** | 5. NHS Number<br>6. Hospital ID Number<br>7. Date of birth<br>8. Postcode (unit level)<br>9. Address of patients' usual residence<br>10. Date of admission to hospital<br>11. Ward admitted to |
| **Identifiers required for analysis purposes** | The applicant confirmed that no items of confidential patient information were required for analysis purposes |

## Confidentiality Advisory Group advice

The CAG reviewed the applicants' response to the below query.

1. **A mechanism should be established to inform patients about the research study and provide a means for dissent to be raised against their data being accessed in this manner. Copies of any documentation to support this should be provided for consideration.**

The applicant provided a poster, which outlined the aims of the study, how confidential patient information would be used and explained how patients could dissent from inclusion. The Sub-Committee reviewed this and determined that a leaflet should also be created to support the poster. The leaflet needed to expand on the information provided in the poster and provide a clearer explanation of how minimal the impact on privacy would be.

A leaflet was created by the applicant and submitted for review. The Sub-Committee reviewed this leaflet and determined that the information provided to patients was now suitable. No further queries were raised.

Amendment request

The applicant submitted an amendment alongside the response to provisional to remove one of the named sites from the scope of support under the Regulations.

The Airedale NHS Foundation Trust would no longer take part in the element of the study which required support under the Regulations. The request was considered by the CAG who recognised that the request reduced the scope of support required under the Regulations. The applicant confirmed that the site may take part in the wider elements of the study which did not require a recommendation of support under the Regulations.

The CAG received the amendment submission which had been provided to ensure an accurate audit trail in relation to the sites which were participating in the study. No further action was required.

## 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 27 June 2019.**

2. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit submission. **(Confirmed: Leeds Teaching Hospitals NHS Trust (by NHS Digital email 12 July 2019) and Mid Yorkshire Hospitals NHS Trust (by NHS Digital email 09 August 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

### f. 19/CAG/0148 - Parents' and children's informed and voluntary consent to heart surgery

| Name | Notes |
|---|---|
| Dr William Bernal | CAG Alternate Vice Chair |
| Ms Sophie Brannan | CAG Lay Member |
| Dr Tony Calland MBE | CAG Chair |
| Ms Katy Cassidy | Confidentiality Advisor |

## Context

### Purpose of application

This application from University College London set out the purpose of medical research to explore the views and experience of children referred for heart surgery. Children and their parents will be observed before and after surgery, and they will be interviewed post-surgery. Forty clinical staff will also be interviewed and selected discussions between staff and families will be recorded. Interviews will also be audio-recorded and transcribed. Wards, out-patient clinics and multi-disciplinary team (MDT) meetings, where the care of the patient will be discussed, will also be observed. Patients recruited into the study, their families/carers and staff will be consented for the above aspects.

The applicant explained that, due to the nature of multi-disciplinary meetings, it is possible that researchers will be present when doctors talk about patients who are not in the study. The researchers will not make any written notes of confidential information of patients who are not enrolled in the study. Medical meetings will not be audio-recorded.

Regarding the observation of daily activities in the wards and outpatient clinics, those present will be informed that they are being observed and of their right to opt out. Some families and children might find it difficult to opt out from being observed by directly saying this to the researcher or to a member of the staff. Red-stop cards will be provided, which they can display as an alternative to opt out. The researchers will wear a ‘Researcher’ badge, and display posters and give handouts to inform them about the research.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | 220 participants in total.<br><br>60 - patients between 6 and 15 years of age, who have undergone heart surgery at Great Ormond Street Hospital NHS for Children and Evelina Children's NHS Hospital. The age limit is for child participants is 15 years at the time of recruitment. The reason for not setting an upper age limit is that parents and healthcare staff are also participants.<br><br>120 - Parents/guardians<br><br>40 – staff |
| **Data sources** | 10. MDT meetings and ward observations at Great Ormond Street Hospital NHS for Children and Evelina Children's NHS Hospital. |
| **Identifiers required for linkage purposes** | No items of confidential patient information are required for linkage purposes. |
| **Identifiers required for analysis purposes** | No items of confidential patient information are required for analysis purposes. |
| **Additional Information** | The applicants do not require access to confidential patient information without consent for the purposes of the study analysis. Support is being sought in case of incidental disclosures during multi-disciplinary team meeting observations. |

## Confidentiality Advisory Group advice

1. **Patients and their families need to be given the opportunity to opt-out of both the ward observations and the observation of the MDT while their case was discussed needs to be retained. Confirmation that the researchers will leave the MDT meeting while patients who had opted-out were discussed needs to be provided.**

The applicant advised that patients and their families would be given the opportunity to opt-out of both the ward observations and the observation of the MDT. The applicants also agreed that they would leave the MDT meeting while patients who had opted-out were discussed.

The Sub-Committee noted the information provided and raised no further queries in this area.

2. **The poster and leaflet need to be amended to explain both the ward and MDT meeting observations, and advise how patients can opt-out.**

The applicants provided a leaflet and poster, which explained the meeting observations and how patients can opt-out. The Sub-Committee reviewed these documents 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **Confirmed 18 February 2019**

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 for Great Ormond Street Hospital NHS for Children and Guy's and St Thomas' NHS Foundation Trust.**

## g. 19/CAG/0112 - Assessment of the de-identification algorithm in UKCRIS

| Name | Notes |
|---|---|
| Dr Martin Andrew | CAG Member |
| Dr Patrick Coyle | CAG Vice Chair |
| Mr David Evans | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to investigate the efficacy of the de-identification algorithm used in Clinical Records Interactive Search (CRIS) at Oxford Health NHS Foundation Trust.

CRIS extracts data from NHS Trusts' electronic health records for research purposes. A key step in making these data available to researchers is the robust de-identification of data to protect patients' right to privacy. The data in CRIS contains both structured and unstructured fields. While de-identifying structured fields, such as the field labelled 'patient name', is easy, de-identifying free text, such as clinical notes and correspondence, is much harder. Mistakes can occur for many reasons,

such as misspellings. In CRIS, the de-identification is currently done using a bespoke algorithm. The algorithm finds all words it considers personal identifiers and masks them with “ZZZZ”. The efficacy of this de-identification algorithm has not been explicitly studied to date. This is a problem, since it means that the patients and Trusts can only be offered estimated information about the robustness of the de-identification.

This project aims to fill this knowledge gap by assessing performance of the de-identification algorithm used in CRIS. This is done by comparing a sample of historic unmasked free text notes with the same notes which have been de-identified by the algorithm. The applicants will use an SQL query to sample the CRIS database for 500 randomly selected, adult patients. For each of the participants, the researchers will access two free-text patient notes and filenames for any attachments in their record in CRIS. The de-identified data will then be manually compared with the original notes, which have the identifiers intact. The patient identifiers present in the text and instances where the algorithm has masked or not masked an identifier, or mistakenly masked a word that is not an identifier will help the applicants determine how well the algorithm de-identifies patient data. The data analysis will be conducted entirely on these fully anonymous counts. The applicants will assess the performance of the algorithm using two measures: recall and precision. Recall describes what portion of the identifiers were masked. Precision describes what portion of the masked words were truly identifiers.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | 500 randomly selected patients, male or female, aged 18 years and above, who are included on the CRIS database at Oxford Health NHS Foundation Trust. Two records will |

| | |
|---|---|
| | be identified undergo accuracy checking for each patient included in the study. |
| **Data sources** | 1. Electronic Health records held within Oxford Health NHS Foundation Trust |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Hospital ID number<br>4. Date of birth<br>5. Postcode- unit level |
| **Identifiers required for analysis purposes** | 1. Postcode - unit level |

## 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 further information on how the study findings will be disseminated, particularly to other Trusts using the system.**

The applicants planned to disseminate their findings to the other Trusts using CRIS via the CRIS National Governance Group. This group meet twice and year and provided oversight on the governance model for CRIS. The findings would also be disseminated at a talk or poster presented at the annual CRIS conference, which is attended by CRIS users and representatives from the Trusts using CRIS. A summary of the findings would also be posted on the CRIS network website. The Sub-Committee noted the proposed methods of dissemination and raised no further queries.

2. **Advise whether there are any plans to repeat the study with amended methodology to see if the results can be improved.**

The applicants explained that the outcomes of this study would be used to guide the development of the de-identification algorithm, however the first published outcomes

will be of the system as it is prior to the commencement of the study. The applicants intended to run similar studies in multiple Trusts and the methodology used in this study may be amended to see if it can be improved. The Sub-Committee raised no further queries.

3. **A project specific communication mechanism needs to be created. This also needs to include a process for patients to dissent to this project specifically. Provide an overview of the mechanism together with any documentation to support this.**

The applicant explained that leaflets would be posted on notice boards at locations providing secondary mental health care around Oxfordshire and Buckinghamshire. The same information would also be displayed on the 'news' section of the Trust website prior to the data sampling. The Trust had also committed to including information about the project in their social media. These postings will include an e-mail and postal address for patients to register dissent or request further information. The draft leaflet was provided for review. The Sub-Committee raised no further queries.

4. **Provide further information on the feedback received during the review of the project by the CRIS oversight committee.**

The applicant explained that the project was discussed at the CRIS Oversight Group in October 2018. At that time, the Overnight Group advised that the applicants seek advice from CAG about whether the project was research or service evaluation.

The applicants met with a member of the Oversight Group more recently. The member agreed that the potential benefit to patients justified the use of the opt-out model. The member also encouraged the applicants to increase the patient and public involvement and engagement to be carried out in order to gain a wider opinion. The Oversight Group will also assist in forming the focus group used accelerate and improve the patient and public involvement and engagement for this project, as described below. The Sub-Committee noted the information provided and raised no further queries.

5. **Further patient and public involvement needs to be carried out with service users at the Trust. An overview of the activity undertaken should be provided, together with details of the information provided to patients and the feedback provided around the study, with a focus on use of confidential patient information without consent.**

The applicants explained that they planned to expand the patient and public involvement and engagement for this project by creating a new focus group. This group will consist of CRIS team members, research staff, lay people and service users. The aim of the focus group will be to open up the discussion about the rationale for carrying out the study and its feasibility, and to gain a collection opinion on the justifiability of the project and the opt-out model used. The applicants hoped to recruit between 6 and 10 members and to hold the first meeting in Autumn 2019.

The applicants had recently met with a member of the Oversight Group as well as a service user to seek initial advice regarding patient and public involvement and engagement. The Sub-Committee noted the information provided 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **Confirmed 19 August 2019.**

2. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit submission. **(Confirmed: Oxford Health NHS Foundation Trust ('Standards Met' 2018/19 by NHS Digital email dated 01 July 2019).**

## h) 19/CAG/0137 - National Cancer Patient Experience Survey 2019

| Name | Notes |
|---|---|
| MS Sophie Brannan | CAG Lay Member |
| Dr Patrick Coyle | CAG Vice Chair |
| Professor Barry Evans | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

## Purpose of application

This application from NHS England set out the purpose of administering patient surveys to evaluate services provided to cancer patients in 2019. This would enable comparisons between Trusts, for commissioners, providers and patients (all of whom could access the published results), would allow for monitoring of improvements in services, drive further improvements, and provide NHS England with an up to date overview of cancer patient experience across England.

The purpose of collecting and analysing data via this survey is to:

- Secure continuous improvement by building on the results of previous surveys, enabling local providers and Cancer Alliances to assess their performance improvement with other providers,
- Enable commissioners to assess local improvements in cancer patient experience,
- Provide NHS England and NHS Improvement with an up to date overview of cancer patient experience across England,
- Provide NHS England and NHS Improvement with data on each participating Trust and the areas on which quality improvement needs to be focused,
- Enable patients to make informed choices about where to go for cancer treatment via publishing the provider level analysis on publicly available websites.

The Cancer Patient Experience Survey (CPES) 2019 fieldwork period will begin at the end of September 2019 and there is an aspiration to close fieldwork in January 2020,

rather than at the end of March as in previous years, to enable more timely reporting of outputs.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | All adult patients (aged 16 and over), with a primary diagnosis of cancer, who have been admitted to hospital as inpatients for cancer related treatment, or who were seen as day case patients for cancer related treatment and were discharged between 1st April 2019 and 30th June 2019 would be included in the survey. This is estimated to cover 125,000 cancer patients. |
| **Data sources** | 1. Electronic patient records at participating Trusts in England |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS number<br>3. Full address<br>4. Sex<br>5. Ethnic group<br>6. Date of birth<br>7. ICD10 code<br>8. Admission and discharge dates<br>9. Speciality code<br>10. Referring CCG<br>11. Admission type<br>12. Site treated at. |

| | |
|---|---|
| **Identifiers required for analysis purposes** | 1. Sex<br>2. Age<br>3. Ethnic group<br>4. ICD10 code<br>5. Admission and discharge dates<br>6. Speciality code |

## 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 further details on how any opt-outs recorded at Trust level would be applied, and whether Picker Institute Europe would be provided with any details on patients who opted-out and a justification for this latter approach if this approach was to be used.**

The applicants advised that the Trusts were sent dissent posters, leaflets and wording to be used on their websites to advertise the 2019 survey during the sampling frame of 01 April to 30 June. These materials included contact details for the patient to contact the Trust if they wished to opt-out of the survey. Trusts were required to maintain a record of patients who dissented and remove them from the patient list prior to submission to Picker, to ensure that Picker were not provided with the details of these patients.

During the fieldwork stage, patients were able to opt-out of inclusion by contacting the Picker Freephone, by returning a blank questionnaire or by contacting the Trust. In these three options, Picker would be informed of the patients details to ensure that they were correctly identified and removed from the list of patients. The Sub-Committee reviewed this information and raised no further queries regarding the opt-out process.

2. **Provide details on whether the issue of access to confidential patient information prior to consent being sought was discussed during the**

**public and patient involvement and engagement activities carried out and provide any relevant feedback.**

Patients that volunteered for cognitive interviews were given an overview of the survey methods i.e. that the questionnaire is sent to all cancer patients treated within a specific time frame. These patients were provided with the survey materials, which made it clear that their personal details had been provided by the NHS Trust that treated them. None of the volunteers had expressed concern with consent or the use of patient information for the purpose of carrying out this survey.

The applicants advised that NHS England had not received any such concerns from engagement with stakeholders or patients in recent years, including meetings with the Cancer Patient Experience Advisory Group (CPEAG).

The applicants advised that out of the 123,512 patients included in the 2018 survey, there were 10 calls from patients who were exercising a formal right to erasure request under GDPR. All 10 requests were actioned as soon as practically possible and within one calendar month. 1 patient raised a complaint about their data being shared with Quality Health, as they were registered under the National Data Opt-Out programme. This was raised with and responded to directly by the NHS Trusts concerned.

The Sub-Committee noted the information provided and raised no additional queries.

3. **Provide further details on the survey advisory group to be set up for the 2019 survey, including whether the issue of access to confidential patient information prior to consent being taken will be discussed with this group.**

The meeting of the CPEAG on the 4th June was the last to meet prior to the 2019 survey's fieldwork. No concerns regarding access to confidential patient information without prior consent were raised.

A new advisory group was in the process of being set up. This will include representatives from Trust staff, patients, cancer charities, Cancer Alliances and Clinical Commissioning Groups. The first meeting of this group was scheduled for 23 September 2019, which is after the mailing for the 2019 iteration of the survey are due to start. The applicants will ensure that discussion of access to confidential patient information without consent is added to the agenda of this meeting, which will aid the applicants in preparing for the 2020 survey. The Sub-Committee noted the information provided and raised no further queries.

4. **Confirm the retention duration for confidential patient information, both for patients who had agreed to the retention of their data and those who had not.**

The applicant confirmed that confidential patient information, name, date of birth, address and NHS number, will be securely deleted on 31st August 2021 for all patients that opt-out of receiving future surveys. All patient materials stating the deletion date have been updated and now consistently provide this date.

Confidential patient information for patients that opted into receiving future surveys will be securely stored and reviewed after 20 years. This retention period allows patients to be followed up in the future regarding their health and health care. This information is potentially useful in understanding the long-term effects of cancer and cancer treatment. At 20 years, the applicants will assess the need and usefulness of this data and decide accordingly to either securely delete the data or store the data for an agreed additional number of years. A revised covering page for the questionnaire had been provided, highlighting this change. The Sub-Committee noted the information provided and raised no further queries.

5. **Clarify the number of reminders to complete the survey that patients would receive.**

The applicant clarified that patients would be sent a maximum of two reminders, in addition to the initial contact. The first mailing packet sent included the questionnaire and covering letter. Non-responders were then sent a reminder letter three weeks later. Finally, another questionnaire and covering letter was sent after another three

weeks to those that have yet to respond. A total of three contacts were made with patients. The Sub-Committee noted the information provided and raised no further queries.

6. **The patient information materials need to be revised as follows;**

    a. **Patients need to be informed of the items of confidential patient information may be shared onwards and which organisations the information may be shared with.**

    b. **Confirm that the helpline number is up to date.**

    c. **References to Quality Health need to be removed.**

A revised questionnaire and covering letters were provided. This had been amended to remove references to Quality Health and to specify that no confidential patient information would be shared onwards with research organisations. The organisations involved were not specified within the text as there are a wide range of organisations that may request to use the data. All requests would be considered on a case by case basis.

The applicant explained that Picker were currently in the process of issuing a new number for the helpline. Once this was issued, then the questionnaire and covering letters would updated accordingly. The first mailings were scheduled to take place in early October 2019, and the telephone number would be finalised in September. The Sub-Committee noted the information provided and raised no further queries.

**Security Assurance**

The applicant explained that confirmation remained outstanding in respect of Greens Ltd., the organisation acting as processor to facilitate distribution of the surveys. As the security assurance had been confirmed for the Picker Institute Europe, the applicant requested whether support could be recommended for the early stage of the survey cohort sampling, which involved Picker only. It was agreed that support

would be recommended for the early stage of the application, covering the disclosure of confidential patient information from NHS Trusts to Picker Europe to enable the patient cohort to be established. It was agreed that the final outcome would be reissued at the point appropriate security standards are confirmed in respect of Greens Ltd.

### 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. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **(Confirmed – Picker Institute Europe (by NHS Digital email 17 July 2019) and Greens Limited (by NHS Digital email dated 01 October 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

## h. 19/CAG/0114 - Evaluation of adults admitted to hospital with community acquired pneumonia and non-cystic fibrosis bronchiectasis: a multicentre, retrospective observational cohort study.

| Name | Notes |
|---|---|
| Dr Martin Andrew | CAG Member |
| Dr William Bernal | CAG Alternate Vice Chair |
| Dr David Evans | CAG Member |
| Mr Myer Glickman | CAG Member |
| Dr Harvey Marcovitch | CAG Member |

| | |
|---|---|
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

## Purpose of application

This application from the University Hospitals Birmingham NHS Foundation Trust set out the purpose of medical research which aims to evaluate the utility of biomarkers that predict clinical outcomes and evaluate the association between morphology of underlying lung disease and clinical outcome, for patients admitted to hospital with community acquired pneumonia (CAP) and non-cystic fibrosis (non-CF) bronchiectasis.

This multicentre, retrospective observational cohort study will include all adult patients admitted with CAP and non-CF bronchiectasis to one of three hospital sites within the University Hospitals Birmingham NHS Foundation Trust between 2010 to 2017. Routinely collected clinical data will be extracted from electronic patient records. No additional interventions/procedures will be performed.

Initial data extraction will be facilitated by the trusts clinical coding team. Characteristics which are not extractable by the clinical coding team will be collected manually by review of electronic patient records by a designated member of the research team. Source data obtained from electronic patient records will be recorded using an Excel spreadsheet. The master file containing confidential patient information collected in the study will be kept on a server accessible only via a Trust computer, encrypted and protected by password. A separate dataset used for statistical analyses, derived from the master file, will be stored in pseudonymous format and protected by password. A member of the research team will perform pseudonymisation for the purposes of statistical analysis. Only pseudonymised data will be exchanged between authorised individuals for data analysis. NHS.NET email (encrypted) will be used for data exchange.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | A maximum of 700 patients, aged 18 years and over, admitted to Birmingham Heartlands Hospital, Good Hope Hospital and Solihull Hospital between 01/01/2010 – 01/01/2017 with a primary diagnosis of CAP and co-morbid non-cystic fibrosis bronchiectasis. |
| **Data sources** | 7. Electronic and paper Health records held within University Hospitals Birmingham NHS Foundation Trust |
| **Identifiers required for linkage purposes** | 1. Hospital ID number<br>2. Date of death |
| **Identifiers required for analysis purposes** | 1. Hospital ID number<br>2. Date of death<br>3. Gender |

## Confidentiality Advisory Group advice

The applicant's response to the provisionally supported outcome was considered by a sub-committee of the CAG.

1. **A study flow chart, clearly describing the flow of information from extraction by the clinical coding team through to the point of pseudonymisation needs to be provided.**

The applicant submitted a study flow chart. The applicant clarified that the data was pseudonymised on receipt and no data was stored alongside the patient

identification number. The patient identification number was stored only in the master file, alongside the pseudonym, so that the appropriate patient record could be located and the data extracted. The data extracted from the records was stored with the pseudonym only.

The Sub-Committee raised a query regarding who accessed confidential patient information in order to populate the spreadsheet, and asked that this was clarified. The applicant advised that only the researchers working on the study would access confidential patient information to extract the required data. The Sub-Committee noted the information provided and raised no further queries.

2. **The items of data to be retained in the master file and the pseudonymised spreadsheet need to be clarified, including any items of confidential patient information. Clarify if dates of birth and death are retained, or if age by year and age at death will be retained.**

The applicant clarified that only the patient identification number and pseudonym were retained in the data file. All other data items were stored in the pseudonymised spreadsheet.

Patients' dates of death were retained in order to analyse 30-day mortality, which was one of the primary outcomes of the study. Patients' date of birth was not collected or stored, but age at presentation and gender was collected and retained. Patients' age at death was not collected. The Sub-Committee noted this information and requested that the time from admission to death was retained, rather than date of death.

The applicant advised that patients' date of death was preferred over time from admission to death. If the time until death was stored, then the investigator would need to calculate and document the time from admission until death, which may lead to errors. If date of death was stored then the time until death, including whether this occurred within 30 days, could be calculated digitally. The date of death could also be referred back to when data accuracy was checked, but errors would be more difficult to detect if time until death was used. The Sub-Committee accepted this justification and raised no further queries.

3. **The length of time that the master file and pseudonymised spreadsheet will be retained need to be clarified.**

The applicant explained that the master file and pseudonymised spreadsheets would both be retained for three years. The Sub-Committee noted this and raised no further queries.

4. **Further details on the patient and public involvement carried out with the Clinical Research Ambassador Group need to be provided, including the topics discussed and any feedback received.**

The application provided a document which detailed their discussions with the Clinical Research Ambassador Group (CRAG) and the feedback given. The Sub-Committee noted this and raised no further queries.

5. **Further patient and public involvement is required. Contact needs to be made with patient groups for those with chronic lung disease to seek their opinion of the study design and the use of confidential patient information without consent.**

The applicant advised that the CRAG included patients with respiratory conditions. The group members who attended the meeting were asked to provide feedback on the potential importance of the study. The applicants had also met with the Solihull 'Breathe Easy' group, which was a third sector community support group for patients with respiratory disease. Feedback from this meeting was also provided. The Sub-Committee noted the information given and raised no further queries.

6. **A patient notification mechanism needs to be created. An overview of the communications strategy needs to be provided to the CAG, including any copies of the material used to promote the study.**

The applicants provided a study poster, to be used for patient notification. This also contained information on how patients could dissent. The poster would be displayed in respiratory clinics, where patients with respiratory conditions were followed up. This included waiting rooms and clinic rooms of the respiratory departments at Birmingham Heartlands, Good Hope and Solihull Hospitals. The Sub-Committee noted this information 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **Confirmed 9 May 2019**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **(Confirmed – University Hospitals Birmingham NHS Foundation Trust has a confirmed 'Standards Met' grade on DSPT submission 2018/19 by NHS Digital email dated 27 June 2019).**

## i. 19/CAG/0110 - Investigating all-cause mortality in the substance misuse treatment population

| Name | Notes |
|---|---|
| Dr Malcolm Booth | CAG Member |
| Dr Patrick Coyle | CAG Vice Chair |
| My Myer Glickman | CAG Member |
| Ms Katy Cassidy | Confidentiality Advisor |

## Context

### Purpose of application

This application from Derbyshire Healthcare NHS Foundation Trust set out the purpose of medical research which aims to investigate identified risk factors associated with patients dying from drug related death, whilst also attempting to predict their impact on early mortality.

The rising rate of drug-related deaths has precipitated a need for greater understanding of the factors that influence them. The applicant aims to investigate the epidemiology of all service users, clinical outcomes, and the risk factors associated with service user deaths in treatment or up to a year after discharge. A cohort study design will be implemented, analysing data routinely collected for patient care in Derbyshire Healthcare NHS Foundation Trust Substance Misuse Services (SMS) from 2012 to 2020, supplemented by mortality follow-up data from NHS Digital.

Data available on SystmOne from 2012 will be extracted by the Trust's IT department on to excel spreadsheets for further analysis by the research team using statistical software. Data from PARIS, the Trust's electronic patient record system for mental health services, will be extracted for patients who had accessed mental health services, in order to obtain more detailed information on mental health diagnoses and treatment. Any variables missing from the patient data will be manually checked on SystmOne or PARIS by a researcher assigned to the project. Information held on SystmOne and PARIS relates only to patients seen within Derbyshire Healthcare NHS Foundation Trust. The SMS Recovery Lead, working within Derbyshire Healthcare NHS Foundation Trust, will provide routinely collected demographic and sociodemographic information on service users who died whilst in treatment or within 12 months of discharge or disengagement across Derby City and Derbyshire. The Multi-Agency Drug-related Deaths Panel, administrated by Derby Local Authority, will also share information collected from the police and ambulance services and coroner's reports on drug-related deaths in the region. The applicant confirmed that no items of confidential patient information will be shared from Derbyshire Healthcare NHS Foundation Trust to the Multi-Agency Drug-related Deaths Panel. Confidential patient information will be shared with NHS Digital to be linked with Office of National Statistics mortality data in order to obtain cause of death information for all service users who

die in or subsequent to substance misuse service engagement, to ensure a full dataset.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | 24,300 female and male patients aged 18 or more years of age, who are previous or active service users of Derbyshire Healthcare NHS Foundation Trust Substance Misuse Services (SMS) between 01/01/2012 and 31/12/2020. |
| **Data sources** | 1. Electronic Health records held within Derbyshire Healthcare NHS Foundation Trust<br>2. ONS mortality data held by NHS Digital<br>3. Multi-Agency Drug-related Deaths Panel held by Derby Local Authority |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. Hospital ID number<br>4. Date of Birth |
| **Identifiers required for analysis purposes** | 1. Name<br>2. NHS Number<br>3. Hospital ID number<br>4. Date of Birth<br>5. Date of Death<br>6. Postcode (unit level)<br>7. Gender<br>8. Occupation |

| | |
|---|---|
| | 9. Ethnicity |

## Confidentiality Advisory Group advice

The applicant's response to the provisionally supported outcome was considered by a sub-committee of the CAG.

1. **Confirm the legal basis which supports the disclosure of information from the Multi-Agency Drug-Related Death Panel to the Derbyshire Healthcare NHS Foundation Trust.**

The applicant advised that the disclosure of information from the Multi-Agency Drug-Related Death panel was necessary in order for the Trust to perform their official functions. Data was also shared in the public interest. The Trust were following guidance from the National Treatment Agency for Substance Misuse on how to conduct local reviews through partnerships involving stakeholders such as drug treatment providers, the police, ambulance service, mental health services and probation. The Group accepted this clarification and raised no further queries.

2. **Clarify whether information from the Multi-Agency Drug-Related Death Panel to is linked with patient records as part of standard clinical practice, or confirm whether support under the Regulations is required to facilitate this linkage for the purposes of this study alone.**

The applicant explained that this data was linked as part of standard clinical practice and so support under the Regulations was not required to facilitate this linkage. The Group noted this explanation and raised no further queries.

3. **It is unclear whether the dataset created is pseudonymised or anonymised;**

    a. **Clarify whether the SystmOne ID is retained in the dataset used for analysis.**

**b. If so, explain the necessity of including this data item, as its inclusion may mean that the dataset is identifiable, as those working in the same organisation would be able to link the dataset to confidential patient information.**

The applicant advised that the SystemOne ID will be retained in the dataset until the dataset was amalgamated and cleaned. The ID was retained so that data can be linked for individual patients across multiple years. The applicants may also need to revisit the original patient record in order to resolve any inconsistencies or complete any gaps in data. The ID was also retained so that data for patients who asked to be withdrawn could be removed.

Once the dataset was finalised and ready for analysis, the SystemOne ID will be removed and replaced with a study ID. The dataset will then be completely anonymised and linkages to the patient record will no longer possible. The Group noted this information and raised no further queries.

**4. Provide a copy of the study document to be displayed on the Derbyshire Healthcare NHS Foundation Trust website**

The applicant provided the Patient Information Notice which would be displayed on the Trust website. The Group noted this 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 (Final)

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 4 September 2019.**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed - Derbyshire Healthcare NHS Foundation Trust (NHS Digital e-mail 19 August 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

### i. 19/CAG/0105 - Partners at Care Transitions (PACT): Improving patient experience and safety at transitions of care - Assessing the feasibility of using the PACT intervention to improve safety and experience of the transition process in a randomised controlled trial setting.

| Name | Notes |
|---|---|
| Dr Martin Andrew | CAG Member |
| Ms Diana Robbins | CAG Lay Member |
| Ms Clare Sanderson | CAG Alternate Vice Chair |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

**Purpose of application**

This application from the University of Leeds set out the purpose of medical research to improve the safety of experience of transitions from hospital to home for patients aged 75 years and over.

Transitions of care from hospital to home can be risky, especially for older people with multiple health conditions. Previous research has suggested that the post-discharge period may be improved by better involving patients and families in their care. This study forms part of a programme of research which aims to develop an intervention to improve the safety and experience of transitions from hospital to home for people aged

75 years and over. In this study a feasibility cluster Randomised Control Trial will be conducted to explore the feasibility of using the intervention and trial methodology. As the applicants have progressed through this programme of work they have identified a problem in accessing accurate routine readmission data, as the way in which hospitals code discharge information does not always accurately record whether patients were admitted from and discharged to their own home, rather than a nursing or care home. This programme of work is designed to assist patients discharged home, therefore the applicants intend to assess the extent to which this coding issue will affect the accuracy of the primary outcome measure for the target population.

In order to test the processes as part of the full cluster Randomised Control Trial, the applicant first intends to identify the most efficient, cost effective and accurate way of identifying readmission data for patients who are discharged to their own homes rather than other usual places of residence, such as nursing homes. Information Services in each Trust will create a list of 10 patients per participating ward who are aged 75 years or over, consecutively admitted to the participating ward, and discharged from anywhere in the hospital to 'usual place of residence' as per hospital coding. Confidential patient information on these patients will be shared with a Trust research nurse. The research nurse will then check the medical records and categorise patients as discharged to either their own/a relative's home, a nursing home, intermediate care or another residence. This data will be aggregated at ward level and all personal information removed before the data is shared with the research team.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | 100 male and female participants, aged 75 years and over, admitted to 10 participating wards. |

| | |
|---|---|
| **Data sources** | Electronic and paper records held in participating Trusts. |
| **Identifiers required for linkage purposes** | 12. NHS Number<br>13. Hospital ID Number<br>14. Date of birth<br>15. Postcode (unit level)<br>16. Address of patients' usual residence<br>17. Date of admission to hospital<br>18. Ward admitted to |
| **Identifiers required for analysis purposes** | The applicant confirmed that no items of confidential patient information were required for analysis purposes |
| **Additional information** | The overarching research programme will operate on a consented basis and is out of scope for the CAG application. |

## Confidentiality Advisory Group advice

The CAG reviewed the applicants' response to the below query.

1. **A mechanism should be established to inform patients about the research study and provide a means for dissent to be raised against their data being accessed in this manner. Copies of any documentation to support this should be provided for consideration.**

The applicant provided a poster, which outlined the aims of the study, how confidential patient information would be used and explained how patients could dissent from inclusion. The Sub-Committee reviewed this and determined that a leaflet should also be created to support the poster. The leaflet needed to expand on the information provided in the poster and provide a clearer explanation of how minimal the impact on privacy would be.

A leaflet was created by the applicant and submitted for review. The Sub-Committee reviewed this leaflet and determined that the information provided to patients was now suitable. No further queries were raised.

Amendment request

The applicant submitted an amendment alongside the response to provisional to remove one of the named sites from the scope of support under the Regulations.

The Airedale NHS Foundation Trust would no longer take part in the element of the study which required support under the Regulations. The request was considered by the CAG who recognised that the request reduced the scope of support required under the Regulations. The applicant confirmed that the site may take part in the wider elements of the study which did not require a recommendation of support under the Regulations.

The CAG received the amendment submission which had been provided to ensure an accurate audit trail in relation to the sites which were participating in the study. No further action was required.

## 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 27 June 2019.**

2. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit submission. **(Confirmed: Leeds Teaching Hospitals NHS Trust (by NHS Digital email 12 July 2019) and Mid Yorkshire Hospitals NHS Trust (by NHS Digital email 09 August 2019) have confirmed 'Standards Met' grade on DSPT 2018/19).**

## j. 19/CAG/0129 - Deep learning applied to plain abdominal radiographic surveillance after Endovascular Aneurysm Repair (EVAR) of Abdominal Aortic Aneurysm (AAA).

| Name | Notes |
|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Mr Andrew Melville | CAG Lay Member |
| Ms Diana Robbins | CAG Lay Member |
| Ms Katy Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from Royal Liverpool and Broadgreen University Hospitals NHS Foundation Trust set out the purpose of medical research which aims to use artificial intelligence to interpret Endovascular Aneurysm Repair (EVAR) x-rays performed in the Trust with a deep-learning algorithm to evaluate whether this could be used to interpret the x-rays.

The proposal is a proof of concept feasibility study. Abdominal aortic aneurysm (AAA) is a condition in which the largest blood vessel in the body becomes weak and forms a bulge. If it becomes large enough, the AAA can burst, often leading to death. Clinicians repair AAAs before they burst by undertaking EVAR, which is a standard treatment in the majority of patients. It is a keyhole technique that reinforces the aorta with a synthetic tube called a “stent-graft”. EVAR is a safer option in the short-term compared to traditional open surgery. However, in the longer term, 1 in 5 patients require further surgery to correct problems developing with the stent-graft such as loss of position and integrity of the stent-graft. Therefore, patients are followed up for life after EVAR with scans performed, usually on an annual basis, to look for signs of a failing stent-graft. Stent-grafts are visible on x-rays of the belly and by comparing series of images taken over time, it is possible to diagnose a myriad of stent-graft problems including loss of positioning, disintegration of the stent-graft material as well as stent-graft distortion. But these changes can be subtle and difficult to spot, even to

the trained human eye. As a result, patients undergo more detailed scans that carry a risk of kidney damage and radiation-induced cancer.

The applicant will identify a retrospective patient cohort who have undergone an EVAR procedure at the Royal Liverpool Hospital via the clinical database within the Liverpool Vascular and Endovascular Service. Radiographs which have been undertaken as part of routine post-EVAR surveillance will be obtained from the NHS PACS (Picture Archiving and Communication System). Support under the Regulations is sought for this initial patient identification process and the extraction of radiographs and supporting clinical information. This would be pseudonymised prior to use for analysis purposes at the University of Liverpool at the Institute of Ageing and Chronic Disease.

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

## Confidential patient information requested

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

| | |
|---|---|
| **Cohort** | All patients who underwent an Endovascular Aneurysm Repair procedure at the Royal Liverpool Hospital between 01 January 2005 and 31 December 2013. It is estimated that there will be 800 patients in the cohort. |
| **Data sources** | 1. Electronic Health records held within the Liverpool Vascular and Endovascular Service at the Royal Liverpool Hospital.<br>2. NHS PACS (Picture Archiving and Communication System) records at the Royal Liverpool Hospital. |
| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. Hospital ID<br>4. Date of Birth |

| | |
|---|---|
| **Identifiers required for analysis purposes** | Not applicable |
| **Additional information** | Inclusion in the study requires a minimum of five-year post-procedure follow-up to be available. |

## 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. **The study poster needs to be revised as follows;**

a. **More details on the study, including how patient records would be used and the aims and potential benefit of the study, need to be incorporated.**

b. **A telephone number needs to be included for patients to register dissent.**

A revised poster, amended to reflect the above points, was submitted. A statement had also been added to explain that confidential patient information will be accessed without consent, along with an assurance regarding the experimental nature of the study and that routine care will not be affected.

A telephone number for patients to use to register dissent has also been added to the poster, alongside the e-mail address.

The Sub-Committee reviewed the poster and were satisfied with the revisions made.

2. **Clarify whether the analysis work will be solely carried out by the University of Liverpool, or if a commercial company will be involved at any stage.**

The applicant explained that the analysis wok would be conducted solely by the University of Liverpool, with no commercial involvement at any stage of the project. The Sub-Committee were satisfied by this assurance.

### 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 05 July 2019**

2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission. **(Confirmed for Royal Liverpool and Broadgreen University Hospitals NHS Foundation Trust)**

## 2. NEW AMENDMENTS

### a. 16/CAG/0021 - Effectiveness and Cost-effectiveness of 'Usual Care' versus 'Specialist Integrated Care': A Comparative Study of Hospital Discharge Arrangements for Homeless People in England

| Name | Notes |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

### Amendment Request

The amendment requested an extension to the duration of support to 30 November 2019.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group which acknowledged that delays experienced in the receipt of data from NHS Digital had led to the duration extension request. The Group was content to provide a recommendation of support to the amendment.

It was recognised that support would only be in place until 30 November 2019, at which time the applicant would be required to provide an end of study closure report to enable the application entry on the register of approved applications to be expired.

### Confidentiality Advisory Group advice 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 DSPT Toolkit submission (**Confirmed - University College London, School of Life and Medical Sciences has 'Standards Met' confirmed by NHS Digital on 01/08/2019)**.

2. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmation of non-substantial amendment received 04/08/2019)**

## b) 16/CAG/0029 - The Empress Study Cancer diagnosis via Emergency Presentation: a case-control study

| Name | Notes |
|---|---|
| Ms Clare Sanderson | CAG Alternate Vice Chair |

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|---|---|
| Miss Kathryn Murray | Senior Confidentiality Advisor |

### Amendment Request

The amendment requested support to change the data storage arrangements by removing University of Leeds as processor and replacing with this with the University of Hull (Hull Health Trials Unit).

### Confidentiality Advisory Group advice

The amendment request was considered by Chair's Action. The Group noted that the change in processing arrangements did not appear to increase the risk to patient data privacy or security. It was recognised that the University of Hull (Hull Health Trials Unit) had confirmed security assurance via the Data Security and Protection Toolkit submission.

### Confidentiality Advisory Group advice 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 DSP Toolkit submission (**Confirmed – University of Hull (Hull Health Trials Unit) has a confirmed 'Standard Met' grade by NHS Digital email dated 25 July 2019**).

2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed – 02 September 2019**)

## b. 17/CAG/0011 - Genetic mechanisms in polyposis of the bowel.

| Name | Notes |
|---|---|
| Dr Murat Soncul | CAG Alternate Vice Chair |

| | |
|---|---|
| Ms Katy Cassidy | Confidentiality Advisor |

### Amendment Request

The applicants had initially applied for support under Section 251 and its Regulations to include a cohort of deceased patients. The number of deceased patients was capped at 20, and the applicants have confirmed that this number will not be exceeded. So far, the applicants have recruited 10 deceased patients and are seeking support to extend the end date of the study until 31 August 2020, to allow more time to meet the recruitment target.

The applicants intend to recruit 350 patients into the entire cohort, and are also extending the timescale of the study so that this target is met. However, living patients are consented into the study, and are outside the scope of the application for Section 251 support.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The rationale for extending the duration of the study was accepted.

### Confidentiality Advisory Group advice 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 Data Security and Protection Toolkit submission **Confirmed for Cardiff University**

2. Confirmation of a favourable opinion from a Research Ethics Committee **Confirmed 07 August 2019**

## c. 15/CAG/0143 - National Prostate Cancer Audit – PROMS/PREMS

| Name | Notes |
|---|---|
| Dr Murat Soncul | CAG Alternate Vice Chair |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

## Amendment Request

The amendment request sought to extend the scope of the patient cohort to be invited to participate in the prostate cancer audit patient reported outcomes survey to include those individuals who had received a diagnosis from 01/04/2018 onwards.

## Confidentiality Advisory Group advice

The amendment request was considered via Chair's Action. It was recognised that the extension to the patient cohort would enable the applicant to continue ongoing evaluation of patient reported outcomes and experiences in relation to those patients more recently diagnosed with prostate cancer. The applicant had confirmed that there would be an initial six-month extension to the cohort, with a view to further extension.

A letter of support for the amendment had been provided from the Healthcare Quality Improvement Partnership (HQIP) as controller for the activity. The applicant had also provided an update to the text displayed on the public website, which referenced the extended patient cohort.

## Confidentiality Advisory Group advice 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 Data Security and Protection Toolkit submission (**Confirmed – Quality Health Ltd, 'Standards Met' assessment on 2018/19 submission confirmed by NHS Digital email on 24 July 2019**)

## d. ECC 3-06(m)/2009 - Prognostic factors in Prostate Cancer

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

### Amendment Request

The amendment request set out the below changes to the existing scope of support:

1. Addition of identifiers

Support is currently in place for the following items of confidential patient information to be used for linkage purposes: name, hospital ID, date of birth and date of death.

The amendment seeks to include: NHS Number, former cancer registration identifiers and postcode. These additional identifiers will be used for the purposes of linkage. Change of data sources – cancer registration and mortality data

Previously follow-up cancer registration and mortality information had been provided to the study by numerous local cancer registries which have subsequently been disbanded over the duration of the study. The applicant is requesting that this data is now provided by NHS Digital (England) and Welsh Cancer Intelligence and Surveillance Unit (Wales), utilising the above items of confidential patient information for linkage purposes.

2. Extension to cohort size

The original application covered an anticipated patient cohort of 2,500 patients. The applicant is seeking to extend this to accurately reflect the cohort of 3,500 included within the project.

3. Change to study coordinator

The amendment also set out a change to the project manager, naming Ms Holly Sandu as the new project lead.

## Confidentiality Advisory Group advice

The amendment request was considered by Chair's Action. It was recognised that the proposed changes which had been set out in the request had become necessary due to the changes in the structure of cancer registration services since the project commenced. The CAG was assured that the additional items of confidential patient information requested were necessary to facilitate accurate linkage with the cancer registration and mortality datasets held by NHS Digital and WCISU.

The Group further noted that the increased sample size had been requested to reflect more accurately the number of prostate cancer patients which were eligible for inclusion in the project.

The addition of the new project lead was noted as an administrative change which did not require a recommendation of support.

## Confidentiality Advisory Group advice 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 – Barts Cancer Centre and NHS Digital have confirmed DSPT 'Standards Met' grade. WCISU has achieved the appropriate standard on CPIP assurance report).**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **(Confirmed – received 17 July 2019).**

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|---|---|
| Signed – Chair | Date |
| | |
| Signed – Confidentiality Advice Team | Date |
| | |