1. New Applications

a. 20/CAG/0138 - Avon Community Acquired Pneumonia Study (Avon CAP): A Pan-Pandemic Acute Lower Respiratory Tract Disease Surveillance Study

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Martin Andrew</td>
<td>CAG Member</td>
</tr>
<tr>
<td>Dr Patrick Coyle</td>
<td>CAG Vice-Chair</td>
</tr>
<tr>
<td>Mr David Evans</td>
<td>CAG Member</td>
</tr>
<tr>
<td>Mr Marc Taylor</td>
<td>CAG Member</td>
</tr>
<tr>
<td>Dr Paul Mills</td>
<td>HRA Confidentiality Advice Service Manager</td>
</tr>
</tbody>
</table>

Context

Purpose of application
This application from the University of Bristol set out the purpose of medical research which aims to determine population-based incidence rates of hospitalized adults ≥18 of age with community-acquired lower respiratory tract infection (LRTI - including Community Acquired Pneumonia) in Bristol.
Acute lower respiratory tract disease (LRTD) encompasses pneumonia, lower respiratory tract infection (LRTI), acute bronchitis, exacerbation of underlying respiratory disease including asthma and chronic obstructive pulmonary disease (COPD). The healthcare costs of pneumonia throughout Europe before the COVID-19 pandemic was in excess of €10 billion per annum. In the UK, pneumonia affects 0.5 to 1% of adults each year, and the incidence of LRTI is considerably higher in patients ≥ 65 years of age.

Accurate incidence rates of acute LRTD and its disease subsets, such as pneumonia and LRTI, remain elusive and the impact of COVID-19 on respiratory disease burden is unclear. Accurate incidence rates of vaccine-preventable infection are required to assess the potential population-level impact of vaccination recommendations. On this basis, the applicants seek to conduct a study to measure the true burden of acute respiratory disease due to these pathogens during and after the COVID-19 pandemic within the limitations of currently available diagnostic testing.

This is a hospital based prospective surveillance study undertaken across two hospitals in Bristol. It is primarily a consented study, with the study team making every effort to consent patients into the study. However, there will be some patients who die or who are discharged before consent is attempted. For these patients the applicants seek support to collect confidential patient information at transfer these to the University of Bristol. The clinical data will be sent using a pseudonym to the University of Bristol, with the identifiers in a separate dataset. The identifiers will be used to prevent any ‘double counting’ of patients if seen at both hospitals within a short period of time. Those patients that are approached for consent and decline will not be included in the data sharing between Trusts under support.

A recommendation for class 1, 2, 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 | Patients aged 18 or over presenting at one of the participating NHS Trust with acute illness (i.e., present for 28 days or less) and evidence of acute Lower Respiratory Tract Disease from 01 August 2020. |
The applicants estimate that approximately 12,000 patients over 3 years will require processing of confidential patient information under support but will as far as possible seek consent and the true number may be less than this.

| Data sources | 1. North Bristol NHS Trust  
|             | 2. University Hospitals Bristol and Weston NHS Foundation Trust |
| Identifiers required for linkage purposes | 1. NHS number  
|                                                 | 2. Admission date  
|                                                 | 3. Date of birth  
|                                                 | 4. Postcode (sector level) |
| Identifiers required for analysis purposes | 1. Postcode (sector level)  
|                                                | 2. Gender  
|                                                | 3. Ethnicity  
|                                                | 4. Date of admission |
| Additional information | Date of birth will be recorded in the NHS database and will be used to calculate age at admission/death, etc. The patient age will be transferred to the University of Bristol IT domain. However, the date of birth will also be transferred to act as a second identifier within the dataset.  
| | Date of death will not be moved beyond the NHS IT domain. It will be used within this IT domain to calculate survival (days), age at death (etc.), and these values will be transferred to the University of Bristol domain. |

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 written evidence from each participating Trust how the staff undertaking research procedures fall within the National Data Guardian definition of the care team, as described above.
The applicants provided a joint letter from North Bristol NHS Trust and University Hospitals Bristol and Weston NHS Foundation Trust confirming that staff undertaking study activities on within this application project fall within the definition of the care team and therefore have a legal basis for processing the data.

The CAG were content with this explanation and raised no further issues.

2. **Provide confirmation that no identifiable patient information is shared with Pfizer.**

The applicant confirmed that the only demographic data that will be shared with Pfizer is gender, ethnicity and admission date (in least specific date format required for analysis). They further confirmed that name, NHS number, date of birth, postcode (sector level), date of death and date of discharge from hospital will never be shared with Pfizer.

The group acknowledged this confirmation.

3. **Provide confirmation that no identifiable patient information is shared outside the UK, for example with the USA**

The applicants confirmed that no identifiable information will be shared outside the UK, and will be in line with the previous response.

The CAG raised no further issues.

4. **Update the website text so to clearly separate the patient notification and privacy notice elements, as well as those whose data is processed under consent and those without consent. Consideration should be given to a layered approach to presenting this information, as well as to the text being reviewed by a lay group.**

The applicants provided updated website text which will be used, and confirmed that this has now adopted a layered approach with distinct pages for the consented and unconsented cohorts.

The CAG were content with the updated made.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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**

The following sets out the specific conditions of support.
1. Favourable opinion from REC 05 June 2020 (with the non-consented arm given favourable ethical opinion through an amendment on 08 October 2020).

2. Continual achievement of ‘Standards Met’ in relation to the relevant DSPT submission (or any future security assurance changes) for the duration of support. Evidence to be provided (through NHS Digital confirmation they have reviewed and confirmed the DSPT submission as standards met’ for the duration of support, and at time of each annual review.

The NHS Digital 2018/19 DSPT review for University of Bristol (Bristol Medical School) and North Bristol NHS Trust was confirmed as ‘Standards Met’ on the NHS DSPT Tracker (checked 21 October 2020).

The NHS Digital 2018/19 DSPT review for University Hospitals Bristol and Weston NHS Foundation Trust was confirmed as ‘Qualified Assurance – Trust has not achieved 95% staff undertaking security awareness training’ on the NHS Digital DSPT Tracker (checked 21 October 2020). Please note the specific condition of support. All staff at organisation that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support.

b. 20/CAG/0137 - Best Care for Abdominal Emergencies - The BCAE Study. A retrospective single, centre cohort study of patients with intestinal emergencies

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Tony Calland MBE</td>
<td>CAG Chair</td>
</tr>
<tr>
<td>Dr Martin Andrew</td>
<td>CAG Member</td>
</tr>
<tr>
<td>Ms Sophie Brannan</td>
<td>CAG Member</td>
</tr>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
<tr>
<td>Dr Paul Mills</td>
<td>HRA Confidentiality Advice Service Manager</td>
</tr>
</tbody>
</table>
Context

Purpose of application
This application from Portsmouth Hospitals NHS Trust sets out the purpose of medical research that aims to improve the quality of care for all patients with an abdominal emergency, irrespective of whether they have a laparotomy or not. The study aims to provide mortality rates for different treatment options, and analysis of short and long term outcomes. The study is a single-centre retrospective cohort study, and will use data from electronic patient records collected at Portsmouth Hospitals Trust NHS as part of routine patient care.

Abdominal emergencies are common, and patients often need life-saving emergency surgery; laparotomy. This procedure is high risk with 10% mortality rate. However, patients who do not have a laparotomy are not well characterised and do not receive the prioritised care patients having surgery do, even though their condition is no less severe. There are two additional groups of patients admitted with abdominal emergencies: patients having keyhole surgery (laparoscopy) and patients for whom any treatment would be futile and would benefit most from an end of life care pathway. Further research is needed to investigate the management of all patients with intestinal emergency, to optimise care for each group of patients.

This study will use electronic hospital records from Portsmouth Hospitals NHS Trust to retrospectively identify all patients admitted with an abdominal emergency over a six year period, using ICD-10 diagnosis, OPCS-4 procedure codes from the Patient Administration System (PAS) and TheatreMan™ and National Emergency Laparotomy Audit (NELA) data, all of which is held locally at Portsmouth Hospitals NHS Trust. The cohort will be extracted from records that are collected as part of routine clinical care, by a member of staff who is not part of the direct care team. The applicant plans to identify patient and admission characteristics of 4 groups of patients (laparotomy, laparoscopy, nonsurgical treatments, and end of life care). The confidential patient information of patients who don’t meet the criteria will not be seen or extracted. The patients identified will be screened to remove those who have registered with the NHS national data opt-out. The resulting dataset will form the final study cohort. The main data extraction phase will then take place using patients’ NHS numbers to extract patient demographics, (age, gender, date of death), their primary (and subsequent admissions) with diagnoses and procedures, and their vital signs, blood tests and surgery specific data for their intervention episode into linked datasets. The linked datasets will then be pseudonymised and identifying characteristics (name, address, date of birth) replaced by a study identification number (ID), by the Portsmouth Hospitals NHS Trust research data manager before it leaves the hospital’s systems. Age at first intervention will be recorded as it is required for the analysis, as will date of death. The key to the pseudonymisation will be deleted once the data has been extracted.

The pseudonymised datasets will be transferred with a Trust issued encrypted device from the Portsmouth Hospital NHS Trust research server onto the University of Portsmouth research server via a University of Portsmouth encrypted laptop.
As part of the response to provisional, the applicant will modify date of death after analysis to less identifiable formats, and at this point the study will no longer require support under Regulation 5.

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.

<table>
<thead>
<tr>
<th><strong>Cohort</strong></th>
<th>All adult patients admitted to Portsmouth Hospital NHS Trust with acute abdominal intestinal conditions over the study period (6.5 years: 01 December 2013 – 28 February 2020)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lowest age 16, no upper age limit.</td>
</tr>
<tr>
<td></td>
<td>An approximate total of &lt;5,800 patients with an intestinal emergency and &lt;3,400 patients undergoing surgery.</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria:</td>
</tr>
<tr>
<td></td>
<td>- Must have an acute intestinal condition, based on their ICD-10 codes and OPCS-4 codes</td>
</tr>
<tr>
<td></td>
<td>- Must be &gt;= 16 years of age at the time of admission</td>
</tr>
<tr>
<td></td>
<td>- Have at least one full set of vital signs recorded on the day of admission</td>
</tr>
<tr>
<td></td>
<td>- Have at least one full set of routine blood tests recorded on the day of admission</td>
</tr>
</tbody>
</table>
Exclusion criteria:
- Maternity admissions during/after pregnancy
- Patients admitted or undergoing intestinal surgery for a second time or more

<table>
<thead>
<tr>
<th>Data sources</th>
<th>1. Portsmouth Hospitals NHS Trust - electronic patient records collected as part of routine patient care (will be screening all general adult wards, excluding maternity)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Identifiers required to extract electronic data and create study ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Name</td>
</tr>
<tr>
<td>2. NHS Number</td>
</tr>
<tr>
<td>3. Hospital ID</td>
</tr>
<tr>
<td>4. GP registration</td>
</tr>
<tr>
<td>5. Date of Birth</td>
</tr>
<tr>
<td>6. Date of Death</td>
</tr>
<tr>
<td>7. Postcode</td>
</tr>
</tbody>
</table>

(These identifiers are extracted and used to link to clinical datasets within Portsmouth Hospital)

<table>
<thead>
<tr>
<th>Identifiers required for analysis purposes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date of Death</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis will be undertaken by University of Portsmouth. All data will be pseudonymised at the point of extraction and the national opt-out will be applied. Identifying characteristics (name, address, date of birth) will be replaced by a study identification number (ID)</td>
</tr>
</tbody>
</table>

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.

This letter summarises the outstanding elements set out in the provisional support letter, and the applicant response. The applicant response was considered by a sub-committee of the CAG.
1. Clarify if full address or postcode alone is required for identification of the cohort and linking with internal clinical databases?

The applicant clarified that postcode alone would be required. The CAG were content with this response.

2. Provide justification for why it is not practicable for the CI to identify the study cohort and perform internal linkages, and so avoid a breach in the common law duty of confidentiality?

The applicant has detailed the reasons why the CI is unable to identify the cohort, including that the CI doesn’t have experience of working with the computer systems used, which are complex and require a skilled data manager to access them. The members accepted this justification.

3. Provide a full justification as to why full date of death cannot be changed after analysis to a less identifiable format?

The applicant responded that date of death was essential for analysis and provided reasons for this. On further questioning regarding why the date of death was required to be stored for 10 years rather than modified after analysis, the applicant responded that despite the importance of possibly using the dataset for future research, they have agreed that date of death will be deleted from the archived dataset when the study is completed. Prior to deletion, the applicants will modify date of death to calculate if a patient has died at 30-days, 90-days and 1-year from index hospital admission. Year of death will also be retained to allow for some seasonal analysis. The CAG accepted this response.

4. Ensure that a study specific dissent mechanism is in place for the study

The applicants have ensured that there is a study specific dissent mechanism which is on the website, plain English summary, and poster. In the applicants response only an email address is mentioned, but it is noted a telephone number is also provided.

5. The patient notification materials (website, ‘plain English summary’ and poster) need review to ensure it is clear to a lay person how data is collected. The materials need to clearly show that the data is pseudonymised at the hospital site. The notification materials also need to contain a clear study specific dissent mechanism, and be provided to CAG for review.
The CAG were content with the provided amended documents.

6. Please confirm if the national data opt out is currently in operation at Portsmouth Hospitals NHS Trust.

The applicant confirmed that this is in operation at Portsmouth Hospital NHS Trust and the CAG accepted this response.

**Security assurances**

During the initial sub-committee discussion members considered that the flow of data from Portsmouth Hospital NHS Trust to University of Portsmouth to be identifiable, given the inclusion of date of death, and requested the applicant gain DSPT assurances from NHS Digital for the University of Portsmouth. As part of the response discussion the applicant argued that this flow is not considered identifiable and cited 19/CAG/0132 as a precedent.

CAG members further considered this argument and reviewed the cited precedent. CAG members agreed that the applications were very similar, and both should be handled in the same manner. At the time of considering 19/CAG/0132 there was considerable confusion as to whether date of death on its own was considered an identifier. However, taking into account the context of these studies, the other clinical information and demographics that is also being transferred, the CAG considers date of death to be an identifier. As such, a legal basis is required for the flow of data from Portsmouth Hospital NHS Trust to University of Portsmouth, and requested the applicant gain DSPT assurances from NHS Digital for the University of Portsmouth. The applicants of 19/CAG/0132 will be contacted with the same advice.

However, the CAG do note that waiting for a DSPT for University of Portsmouth may delay preparatory work that can be undertaken at Portsmouth Hospital NHS Trust. As such this current support only applies to activities at Portsmouth Hospital NHS Trust. Once NHS Digital DSPT assurances for University are in place the applicant should notify the Confidentiality Advice Team who will issue further correspondence to confirm that support is extended to the transfer of data including date of death to University of Portsmouth.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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.
However, security assurances are required to be in place at University of Portsmouth before support can be recommended for the transfer of the pseudonymised dataset for the purposes of analysis.

**Specific conditions of support**

The following sets out the specific conditions of support.

1. Support is in place to allow named members of staff, who are not part of direct clinical care team, to extract the patient cohort from electronic patient records at Portsmouth Hospitals NHS Trust. Support for the transfer of confidential patient information from Portsmouth Hospitals NHS Trust to University of Portsmouth for the purposes of analysis is not supported, and is dependent upon NHS Digital review of the Data Security and Protection Toolkit (DSPT) for University of Portsmouth being confirmed as ‘standards met’.

2. Favourable opinion from a Research Ethics Committee.  
   **Confirmed 12 November 2020**

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

   - The NHS Digital 2019/20 DSPT review for Portsmouth Hospitals NHS Trust (RHU) was confirmed as ‘Standards Met’ on the NHS DSPT Tracker (checked 22 October 2020).

   - The NHS Digital DSPT review for University of Portsmouth is pending, and will be required to be provided in order to support the transfer of the dataset for analysis to University of Portsmouth.

c. **20/CAG/0136 - A randomised controlled trial assessing the effectiveness and cost effectiveness of thrice weekly, extended, in-centre nocturnal haemodialysis versus standard care using a mixed methods approach: NightLife**

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Patrick Coyle</td>
<td>CAG Vice-Chair</td>
</tr>
</tbody>
</table>
Context

Purpose of application
This application from University of Leicester sets out the purpose of medical research that aims to test the clinical and cost effectiveness of thrice weekly, extended hours nocturnal dialysis compared to standard dialysis care thrice weekly during the day. The study is a pragmatic, multi-centre, consented, randomised controlled trial with a health economic analysis.

Kidney dialysis is a lifesaving treatment for around 24,000 patients in the UK. However haemodialysis (HD) can have extensive physiological, psychological and sociological impacts on patients. This is due to the side effects of haemodialysis and also the scheduling of treatment times, which results in patients ‘losing’ three days a week. Unsurprisingly, patient-reported quality of life is low, with many patients unable to continue paid employment. Studies suggest that people who have their dialysis overnight may feel better and may be able to live a life which is closer to normal. There is, however, a need for further evidence to establish the effectiveness and cost-effectiveness of nocturnal extended dialysis compared with daytime dialysis.

This study is being undertaken in 3 workstreams. Workstream 1 and 3 are outside of scope of this support. Workstream 2 is in scope and applicants will undertake observations and interviews in 9 NHS haemodialysis units over the course of the NightLife study. Applicants will use a mixed methods approach to provide an evaluation of the study processes. This will include an assessment of whether the implementation is given per protocol and identification of contextual factors that influence its implementation and adoption. Collection and monitoring of quantitative data collected as part of the main study and a mixture of ethnographic methods which are the subject of this application (observations, interviews and document collation) will be used to generate qualitative data.

It is expected that 2-3 visits per dialysis unit at different time-points will take place (e.g. pre-intervention, during the training period and during nocturnal haemodialysis delivery). Each observation period will last approximately 6-8 hours, to include a nightshift and handovers. The observations and interviews will comprise of observing both standard and nocturnal
haemodialysis practice in different dialysis units, exploring staff and patient engagement and experiences, and identifying barriers and facilitators to nocturnal haemodialysis. Copies of relevant documentation may be collected. Observations and interviews will be undertaken by study researchers from University of Leicester over the course of 42 months. All staff and patient interviews will be undertaken with written informed consent, and all staff and patient observations will be undertaken with verbal consent. However it is possible that observations of individuals may indirectly involve others. Support under the regulations is required in case of accidental disclosure of confidential patient information regarding a non-consented patient during either observations or interviews with staff and consented patients. The researchers have put in a number of safeguards to protect patient confidentiality including consenting where possible, and avoiding making any records of confidential patient information. Eligible participants will be approached by a member of the clinical team.

Applicants are mindful of the impact of the post COVID-19 on undertaking observations in dialysis units and interviews with staff and patients. They will comply with local Trust requirements. It may be possible to undertake observations as planned, however for periods when restrictions do not allow observations on a unit, applicants will rely more heavily on interview data, which may be conducted remotely (via telephone or approved video-conferencing software, e.g. Microsoft Teams or Google Hangouts).

A recommendation for class 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.

<table>
<thead>
<tr>
<th>Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td>For CAG purposes support is only given regarding patients in haemodialysis units, not for NHS staff or family members of patients.</td>
</tr>
</tbody>
</table>

The cohort requiring support are: patients treated on haemodialysis units who are not consented into this study, whose information may be incidentally disclosed.
During observations and interviews carried out by researchers of:

- 20-40 Patients established on haemodialysis for >3 months (i.e. prevalent dialysis patients)
- Relatives or visitors accompanying patients (that fulfil RCT eligibility criteria) to haemodialysis sessions
- 20-40 Clinical and non-clinical staff working at haemodialysis units participating in the Nightlife study

### Data sources

Interviews and observations carried out in 9 participating dialysis units around the UK who are participating in the NightLife RCT:

- University Hospitals Leicester NHS Trust
- Northamptonshire Healthcare NHS Foundation Trust
- University Hospitals of North Midlands NHS Trust (Stoke)
- University Hospitals Birmingham NHS Foundation Trust (Heartlands Hospital)
- University Hospitals Birmingham NHS Foundation Trust (Queen Elizabeth Hospital)
- Sheffield Teaching Hospitals NHS Foundation Trust
- King's College Hospital NHS Foundation Trust
- Cambridgeshire and Peterborough NHS Foundation Trust
- Cardiff and Vale University Health Board

### Identifiers required for linkage purposes

1. No items of confidential patient information will be collected for linkage purposes

### Identifiers required for analysis purposes

1. No items of confidential patient information will be collected for analysis purposes

### 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. Please describe the process of, and clarify what is meant by, ‘verbal consent’ for the observations.
The applicant described the process and it was agreed by the Sub-Committee that this could be considered verbal consent rather than an opt out mechanism only.

2. **Please can you confirm that the patients have given permission for relatives or others to be interviewed about them.**

   It was clarified by the applicant that relatives interviews would not be 'about' the patient but rather the process of dialysis. The CAG were content with this response.

3. **Please can clinical staff be reminded as part of the staff interviews of their duty of confidentiality, and ask for non-consented patients not to be referred to by name or in an identifiable way?**

   The response from the applicant agreed with this suggestion, and this will be implemented as part of the study. The CAG were satisfied with the response.

4. **Please provide a PPI opinion on the lack of description surrounding potential incidental disclosure of confidential patient information in the patient facing documents.**

   The applicant described that this has been discussed with the Patient and public representative, and she felt that adding further information regarding potential incidental disclosure would be confusing for patients. The CAG accepted this response, and noted that despite there being only one patient representative who had been consulted this was proportionate for the study.

5. **Please provide a PPI opinion on the verbal consent methodology, and whether this should rather be referred to as an opt out opportunity.**

   The patient representative felt that the verbal consent methodology could remain as described, and the CAG were content with this considering the answer to question 1.

6. **Please provide confirmation from PPI representatives that they would consider it proportionate for the researcher to continue with the observations on the rest of the ward if verbal consent was not given or a patient opted out.
The patient representative described the bay set up in most dialysis units would make it reasonable to exclude a whole bay if a patient opted out of being observed. She commented that the units are large, and it would be possible for a researcher to move away from the area appropriately. The researchers added that dissent would never be overridden. The CAG accepted this response.

Confidentiality Advisory Group advice conclusion
The CAG agreed that the minimum criteria under the Regulations appeared to have been met, 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

The following sets out the specific conditions of support.

1. Favourable opinion from a Research Ethics Committee.
   Confirmed 10 December 2020

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the ‘Standards Met’ threshold. See section below titled ‘security assurance requirements’ for further information: Security assurances are required for the 9 sites where the observations take place. Support will be based on confirmation that the DSPT at the site will be complied with and that no identifiable information will be kept onsite or removed from the site. However, as this is more than 5 organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.
2. New Amendments


<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Tony Calland MBE</td>
<td>CAG Chair</td>
</tr>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
</tbody>
</table>

Context

Purpose of application

This research database created by the University of Cambridge, contains mammographic images to be used as a resource for the development, testing and creation of artificial intelligence algorithms. There is currently support in place to allow research staff to undertake the processing of confidential patient information from patient records at Cambridge University Hospitals NHS Foundation Trust, in order to provide the applicants at the University of Cambridge with an anonymised dataset.

Amendment request

This amendment sought support for a number of changes to the database. The name of database has changed to “The Cambridge Cohort - Mammography East-Anglia Digital Imaging Archive (CC-MEDIA)”. A new data processor has been added; Norfolk and Norwich University Hospital NHS Foundation Trust (NNUH) will now also send anonymised datasets to the applicants. This is to increase the generalisability of the data, and will allow for more extensive and reliable testing of AI algorithms to take place at the University of Cambridge.

The following changes requested in this amendment are the result of a collaboration with an experienced member of staff to develop this technically challenging study. The requested adjustments have been made to ensure that all women who attended routine screening are able to be included, and information is able to be linked between different sites. This has resulted in updating the identifiers used, the data extracted, as well as the eligibility definition for women who will be included. An updated data flow diagram has been provided, which encompasses these changes; the addition of NNUH, additions to the identifiers extracted (Accession number, Cryptic NHS number, Episode Record ID, Previous NHS number, Site,
Screening office (last + next) and Study date), a new route to the Database Access Committee (DAC) review for pre-existing collaborations, and the addition of breast screening staff undertaking the data extraction. An updated document has been provided regarding data fields for collection, which includes ethnicity in order to test for potential inherent bias computer algorithms could display. Updated DICOM headers are provided, and the applicant has confirmed these will remain not identifiable. The cohort of women has been expanded to allow inclusion of those who have re-entered routine 3 yearly mammographic screening from high / moderate risk screening, and additionally women who took part in the Age X trial. This changes the cohort age range from 50-70, to age 47 and above. There is no upper age limit, as women can self-refer after age 70 every 3 years.

The following information is provided to CAG as notification only, as no changes have been requested to the support provided. As suggested by the CAG in the outcome letter dated 11 June 2020, the database access Committee will contain a lay member and a member of the breast screening department at the Cambridge University Hospitals NHS Foundation Trust (CUH). The applicants additionally confirm in this amendment that the database will be re-considered for support after 5 years, as agreed in the outcome letter dated 11 June 2020. Patient facing documents (a lay summary and posters) have been updated with the described changes and provided to CAG. These will be displayed online on both the university departmental webpage and the breast screening office webpage. An updated protocol v1.3 has been provided which encompasses the changes described in the amendment form, including the addition of new investigators from NNUH.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair. It was felt that the amendment was justified, and the additional identifiers do not make the dataset any more disclosive. The data flows are appropriate and the updated patient facing materials noted.

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

The following sets out the specific conditions of support.
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**

The 2018/19 NHS Digital DSPT review for **Cambridge University Hospitals NHS Foundation Trust (RGT)** was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 11 November 2020). The 2019/20 DSPT is yet to be reviewed by NHS Digital.

The 2019/20 NHS Digital DSPT review for **Norfolk & Norwich University Hospitals NHS Foundation Trust (RM1)** was confirmed as ‘Standards Not Fully Met (Plan Agreed)’ on the NHS Digital DSPT Tracker (checked 11 November 2020). Please note the updated specific condition of support below.

**Norfolk & Norwich University Hospitals NHS Foundation Trust** should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 24 November 2020**

b. 19/CAG/0196 – Evaluating prescribing safety indicators embedded in computerised clinical decision support software OptimiseRx

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Patrick Coyle</td>
<td>CAG Vice Chair</td>
</tr>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
</tbody>
</table>

**Context**

**Purpose of application**

This study from the University of Manchester seeks to evaluate the effectiveness of the computerised clinical decision support system OptimiseRx on improving prescribing safety in general practices and the associated costs to the NHS. The applicants have existing support to allow ResearchOne and NHS Digital to generate a SALT link key to facilitate linkage between primary care data from GP practices and HES, ONS and IMD datasets at NHS Digital. NHS number was required for this linkage but was going to be sent in a pseudonymised format from TTP/ResearchOne to NHS Digital.
Amendment request
This amendment request seeks support for the full NHS number to be sent to NHS Digital from TTP/ResearchOne instead of in pseudonymised format due to a new system implemented by NHS Digital. An updated flow diagram has been provided.

The applicants also wish to expand the time window for selecting GP practices. They plan to use data from GP practices that have started using OptimiseRx from September 2013 up to end of February 2019, rather than February 2014 to September 2017 as originally stated. By expanding the time frame, the applicants will improve the statistical power of their analyses as they will be including data from more patients. The applicants are interested in potentially hazardous prescribing in the 24 months before the date at which the GP practice started using OptimiseRx, and also 12 months after implementation. Therefore this amendment will allow the applicant to investigate prescribing trends from September 2011 until February 2020.

Confidentiality Advisory Group advice

The amendment requested was considered by Chair’s Action. The Vice-Chair considered the amendment request was reasonable and justified, and noted the applicant already has support for NHS number to be used for linkage purposes. He was content to recommend 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

The following sets out the specific conditions of support.

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 – NHS Digital has a confirmed ‘Standards Met’ grade on DSPT submission 2019/20 by check of DSPT tracker 01 December 2020
• Confirmed - The Phoenix Partnership (TPP) has a confirmed ‘Standards Met’ grade on DSPT submission 2019/20 by check of DSPT tracker 01 December 2020

• Confirmed - University of Manchester has a confirmed ‘Standards Met’ grade on DSPT submission 2018/19 by check of DSPT tracker 01 December 2020 (2019/20 is being reviewed)

2. Confirmation of a favourable opinion from a Research Ethics Committee. Confirmed 2 December 2020

c. 16/CAG/0066 – Hospital Alerting Via Electronic Noticeboard (HAVEN)

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
</tbody>
</table>

**Context**

**Purpose of application**

This study from Oxford University Hospitals NHS Foundation Trust aims to produce a hospital-wide IT system that enables a continuous risk assessment in all hospital patients, and predicts those at risk of deterioration. Support is currently in place to cover the disclosure of confidential patient information from Oxford University NHS Foundation Trust to the HAVEN research team.

**Amendment request**

This amendment sought support for the addition of two new data processors. Applicants requested to add Royal Berkshire NHS Foundation Trust and South Warwickshire NHS Foundation Trust as participating sites, and require support under the Regulations to cover the disclosure of confidential patient information from Lancashire Teaching Hospitals NHS Trust to the HAVEN research team. These additions are to demonstrate that HAVEN is generalisable outside of Oxfordshire.
This amendment also notified CAG that the study data extraction procedures have now changed to enable application of the National Data Opt-Out at all sites. This has changed due to the implementation of the National Data Opt-Out since the study was first supported.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT was supportive of the addition of two new data processors.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT 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

The following sets out the specific conditions of support.

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 –

   - The NHS Digital 2018/19 DSPT review for Oxford University Hospitals NHS Foundation Trust (RTH) was confirmed as ‘Standards Not Fully Met (Plan Agreed)’ on the NHS Digital DSPT Tracker (checked 08 October 2020). Please note the updated specific condition of support below. The 2019/20 DSPT has not yet been reviewed.

   Oxford University Hospitals NHS Foundation Trust (RTH) should achieve the security assurance action plan as agreed with NHS Digital. All staff involved in processing information under this application reference should be aware of the precise scope of support and its boundaries and have successfully completed local security awareness training before processing any information under support.

   - The NHS Digital 2018/19 DSPT review for Royal Berkshire NHS Foundation Trust (RHW) was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 08 October 2020). The 2019/20 DSPT has not yet been reviewed.
• The NHS Digital 2019/20 DSPT review for South Warwickshire NHS Foundation Trust (RJC), is confirmed as standards met (by email to CAG inbox on 08 December 2020)

2. Confirmation of a favourable opinion from a Research Ethics Committee
   Confirmed: 17 April 2020

   d. 19/CAG/0035 – Updating cancer survival index trends for England and Wales to 2016

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Tony Calland MBE</td>
<td>CAG Chair</td>
</tr>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
</tbody>
</table>

Context

Purpose of application

This application from the London School of Hygiene and Tropical Medicine aims to update trends in the index of survival from all cancers combined in England and Wales, up to 10 years after diagnosis. Support is currently in place to allow the disclosure of specified confidential patient information from the National Cancer Registration and Analysis Service at Public Health England (PHE) and the Welsh Cancer Intelligence and Surveillance Unit to the Cancer Survival Group at the London School of Hygiene and Tropical Medicine for analysis, regarding a cohort of all adult patients aged 15 – 99 years, who were diagnosed with a first, primary invasive cancer from 1971 to 2016. This is expected to include over 10 million patients.

Amendment request

The amendment request seeks to add two additional years on to the dataset received from PHE, to include a cohort of all adult patients aged 15 – 99 years, who were diagnosed with a first, primary invasive cancer from 1971 to 2018. This is due to the time elapsed since original support was provided.
The applicant has confirmed there are no other change to the application.

**Confidentiality Advisory Group advice**

The amendment requested was considered by Chairs action. The Chair was content to support the collection of the additional two years of data from 2017 and 2018 from PHE. It is important to ensure all data to this project is as up to date as possible and since there is no change to the protocol or identifiers collected, it was commented that continuing support was justified.

**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**

The following sets out the specific conditions of support.

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:** The NHS Digital 2018/19 DSPT review for Cancer Survival Group-London School of Hygiene & Tropical Medicine was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 08 December 2020). The 2019/20 DSPT has not yet been reviewed, but applicant has requested.

2. Confirmation of a favourable opinion from a Research Ethics Committee.

   **Confirmed non substantial by email from REC 04 December 2020**

   e. CAG 8-02 (a)/2014 Assuring Transformation: Data collection by Clinical Commissioning Groups to populate patient registers and reporting
CAG 8-02 (b)/2014 Data collection by NHS England Area Teams responsible for commissioning secure mental health and child and adolescent mental health services to populate patient register and reporting.

CAG 8-02 (c)/2014 Assuring Transformation: Enhanced Quality Assurance Process Data flow (Disclosure by HSCIC to NHS England)

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Tony Calland MBE</td>
<td>CAG Chair</td>
</tr>
<tr>
<td>Dr Patrick Coyle</td>
<td>CAG Vice-Chair</td>
</tr>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
</tbody>
</table>

Context

Purpose of application

A suite of three applications had been presented by NHS England, on behalf of Clinical Commissioning Groups, to reflect the different data flows involved in the initiative known as ‘Assuring Transformation’. The overarching purpose of these data flows was stated to ensure that a commissioner is always monitoring the overall management of patient care through the activity of ‘case management’. Case management had been defined at time of original consideration as activities by certain roles to ensure the continuity and quality of care delivered by healthcare providers over the period of the patient’s care and to ensure the appropriate support is provided.

Details around the final support provided were set out in the letter dated 10 December 2014, and additional amendment letters.

The application is currently supported up to 31 March 2021.
Amendment request

The amendment requested an extension to the duration of support in place for the application indefinitely.

The original intention of the application was that Assuring Transformation (AT) would be time-limited and would be stood down once the applicants had worked with NHS Digital to reconcile the Mental Health Services Data Set (MHSDS) and AT datasets. However the process has been more complex than anticipated and so support is requested for a duration amendment whilst the applicants continue to work with NHS Digital to enable the AT dataset to be reconciled gradually with MHSDS. The aim is no longer for AT to be stood down; the aim is now for AT to be the primary data source, with data pulled from MHSDS where possible. A letter of support for the duration amendment has been provided from NHS Digital, and extensive justification provided as an appendix to the amendment.

Confidentiality Advisory Group advice

The amendment request was considered by the Chair team. The Chair team was supportive in principle of the amendment to allow more time for the correct identification and analysis of patients suffering from autism spectrum disorder and learning difficulties. It was noted that these patients are among the most vulnerable in society and often there are safeguarding needs in addition to treatment or care for their primary disability, and the public interest was therefore very strong.

However, the Chair team were concerned that an indefinite extension would lose any pressure to continue to look for solutions. With this in mind the chair team would like to review the extension yearly via annual review. At the next annual review, the chair team requested a report to the CAG providing a progress report on further solutions and a plan for moving forwards with an estimated time to complete the targets.

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 Secretary of State for Health and Social Care.
Specific conditions of support

The following sets out the specific conditions of support.

1. Support is extended on condition that the applicant provides a progress report, and a plan for achieving workable solutions at the next annual review, including estimated times to complete targets. Support is initially extended until this time, at which point consideration will be made for continued support.

2. Confirmation of suitable security arrangements via IG Toolkit submission.

- The NHS Digital 2018/19 DSPT review for NHS England were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 1 December 2020), the 2019/20 DSPT is currently under review

f. 20/CAG/0049 – PREDICT Study: RaDaR and UKRR Linked Dataset

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Tony Calland MBE</td>
<td>CAG Chair</td>
</tr>
<tr>
<td>Dr Patrick Coyle</td>
<td>CAG Vice Chair</td>
</tr>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
</tbody>
</table>

Context

Purpose of application

This study from King’s College Hospital aims to create a new dataset to aid in developing a predictive tool to estimate the degree of pregnancy-associated progression and adverse pregnancy outcomes in women with CKD, including those with rare renal disease. Two renal datasets, the National Registry of Rare Kidney Diseases (RaDaR) and the UK Renal Register (UKRR), will be linked with two pregnancy data sets, Hospital Episodes Statistics and Maternity Services Data Set, by NHS Digital. The linked data will form a new dataset. The study currently has support to link the records of at least 750 pregnant women with Chronic Kidney Disease in England, which was an estimated number.
Amendment request

This amendment request is to clarify the cohort numbers, as the applicants now have a more accurate estimate. Approximately 60,000 individuals who meet the criteria have been identified as part of the UK renal registry. The identifiers of these individuals will be shared with NHS Digital, with the expectation that up to approximately 10% of these records may be linked with pregnancy datasets held by NHS Digital. This means the cohort could be up to approximately 6000 pregnant women instead of an estimated 750+, however this is still an estimate and the applicants will not know the number until linkage has taken place. Data from a larger number of women will enable increased confidence in study findings and make them more generalisable.

The protocol and patient facing materials have not been altered due to this amendment request, as neither contained information on numbers of linked records expected.

Confidentiality Advisory Group advice

The amendment requested was considered by the Chair, who commented that the public interest in this amendment was substantial. It was felt that investigation of the optimum care of this patient group is extremely important, and that larger cohort numbers would give additional statistical power to the project and therefore is an additional benefit. The Chair was therefore happy to agree to the amendment.

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

The following sets out the specific conditions of support.

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:
The NHS Digital 2019/20 DSPT review for NHS Digital, and The Renal Association were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 03 November 2020).

The NHS Digital 2018/19 DSPT review for King’s College Hospital NHS Foundation Trust was confirmed as ‘Qualified Assurance – Trust has not achieved 95% staff undertaking security awareness training’ on the NHS Digital DSPT Tracker (checked 03 November 2020). Please note the updated specific condition of support below.

All staff at King’s College Hospital NHS Foundation Trust that are involved in processing information under this application reference should have successfully completed local security awareness training before processing any information under support.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 10 December 2020

   g. 15/CAG/0119 (ECC 5-05 (f)/2012) – MBRRACE-UK – Delivering the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP)

<table>
<thead>
<tr>
<th>Name</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Tony Calland MBE</td>
<td>CAG Chair</td>
</tr>
<tr>
<td>Ms Caroline Watchurst</td>
<td>HRA Confidentiality Advisor</td>
</tr>
</tbody>
</table>

Context

Purpose of application

This Healthcare Quality Improvement Partnership (HQIP) commissioned activity from University of Oxford set out the purpose of the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) which is a national programme that aims to assess quality and stimulate improvement in safety and effectiveness in maternal, newborn and infant healthcare by systematically enabling clinicians, managers and policy makers to learn from adverse events. Support under the Regulations was given to cover access to confidential patient information from ONS and NHS Trusts. Patients treated
between 1 Jan 2009 and 31 March 2017 are included, and this has since been extended until 30 September 2021.

The Confidentiality Advice Team undertook an assessment of the 2020 annual review for the application, which was received in April 2020. A query was raised around the retention of an administrative data set which held confidential patient information in relation to all reported maternal deaths since 1 Jan 2009, as it was unclear whether there was existing support for ongoing retention of this data.

Support under the Regulations had previously been provided to the applicants to additionally retain identifiable data about all women who died as a maternal death from 1st January 2009 onwards, in an amendment outcome letter dated 19 July 2018, with the specific condition of support:

‘Support is recommended for the ongoing retention, by the University of Oxford (on behalf of HQIP), of the maternal deaths dataset for a period of one year from date of this letter. During this time HQIP and the applicant are required to explore and establish a more appropriate arrangement/organisational location for the ongoing retention of this data. A report is required by the time of next annual review, at the latest, on the substantive progress which has been made to achieve this.’

The annual review provided on 11th April 2019 was supported for a further year, until the April 2020 submitted annual review, at which time point the condition of the amendment specified above was explored with the applicant to ensure a legal basis for the retention of the database.

It was explained that a trusted third party, NHS Digital, had been approached for this retention. No retention arrangement had been secured with NHS Digital, and it has further been confirmed that NHS Digital are unable to retain this data. The applicant is now in discussions with the Office for national Statistics (ONS). The applicant has therefore submitted the proposed amendment to extend the scope of support so that the MBRRACE-UK collaboration could retain this data set up to 30 September 2021 in line with the current funding of the overarching MBRRACE-UK programme.

**Amendment request**

This amendment sought support under the Regulations for MBRRACE-UK to continue to hold the identifiable data about all women who died as a maternal death from 1st January
2009 onwards until a trusted third party arrangement can be identified, or until **30 September 2021** (whichever is earlier).

The applicants argue that it is in the public interest the retain these identifiers, in the event that it is necessary to identify specific women in the future for, for example, a retrospective review of the care that they received.

**Confidentiality Advisory Group advice**

The amendment requested was considered by Chairs action. It was commented that there is a very strong public interest in this amendment, involving patient safety. The chair was happy to extend the period of data retention of confidential patient information as requested, and requested an update as to the progress of finding a trusted third party in six months.

**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 Secretary of State for Health and Social Care.

**Specific conditions of support**

The following sets out the specific conditions of support.

1. Please provide an update regarding the progress of finding a trusted third party to retain the dataset in six months from the date of this letter.

2. Confirmation of suitable security arrangements via IG Toolkit submission.

   **Confirmed – Nuffield Department of Population Health, University of Oxford (EE133863-MSD-NDOPH-NDPH) has a confirmed ‘Standards Met’ grade on DSPT submission 2019/20** and **University of Leicester - College of Life Sciences (EE133832-CMBSP) has a confirmed ‘Standards Met’ grade on DSPT submission 2018/19** (Confirmed by check of the DSPT tracker 09 December 2020).
Context

Purpose of application

This application has been submitted by the Trauma Audit and Research Network (TARN) for non-research purposes. The application currently has support under Regulation 5 for the change of controller of the confidential patient information which was collated under the National Clinical Audit of Specialist Rehabilitation following Major Injury (NCASRI) from HQIP to TARN.

Amendment request

This amendment is seeking support to retain the NCASRI dataset which contains identifiers for the purposes of future linkage for one year, and was submitted as requested by the Confidentiality Advice Team (CAT) after review of the Annual review submitted November 2020 as a response to a condition of support.

A report was provided for CAG review regarding the ongoing public interest in retaining the dataset in case this dataset is required to link to other datasets in the future. The applicants commented that there is no single NHS system that currently identifies patients with complex rehabilitation needs and the level of service that they eventually receive. By maintaining the NCASRI dataset including identifiers, this will allow further data linkage to provide this evidence, which could help identify any gaps in service provision and provide opportunities to improve access to specialist rehabilitation for patients.

Confidentiality Advisory Group advice
The amendment requested was considered by the Chair’s Action. The report and the amendment request were sent to the CAG Chair for review. The Chair accepted the justifications provided by the applicant regarding the retention of the NCARSI dataset for one year, and for this retention to be reconsidered at each annual review. However it was commented that if several annual reviews go by without identifiers being used, then the case for retention weakens and there is a possibility that support for the retention of identifiers may be expired and the CAG may require the dataset to be anonymised. A condition was applied regarding this.

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 Secretary of State for Health and Social Care.

Specific conditions of support

The following sets out the specific conditions of support.

1. The retention of confidential patient information as part of the NCARSI database is supported until the next annual review only, and this will be considered on an annual basis.

2. Confirmation of suitable security arrangements via IG Toolkit submission. Confirmed -The NHS Digital 2019/20 DSPT review for Trauma Audit and Research Network- was confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 16 December 2020)
# 3. Annual Review Approvals

<table>
<thead>
<tr>
<th>CAG Reference</th>
<th>Application Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>19/CAG/0172</td>
<td>SEARCH: A population based study of genetic predisposition to breast, ovarian and endometrial cancer</td>
</tr>
<tr>
<td>19/CAG/0164</td>
<td>Investigation of gender mortality differences in children admitted to UK Paediatric Intensive Care Units</td>
</tr>
<tr>
<td>19/CAG/0149</td>
<td>Mammographic Predictors of Cancer Recurrence after Breast Conservation and Adjuvant Endocrine Therapy</td>
</tr>
<tr>
<td>19/CAG/0181</td>
<td>CQC Maternity Pilot Annual Review</td>
</tr>
<tr>
<td>19/CAG/0084</td>
<td>Developing Diagnostic and Prognostic Algorithms Using Digital Pathology and Artificial Intelligence</td>
</tr>
<tr>
<td>17/CAG/0107</td>
<td>WMUK Rory Morrison Registry</td>
</tr>
<tr>
<td>17/CAG/0152</td>
<td>Barts Health NHS Trust (NICOR) UK Transcatheter Aortic Valve Implantation (TAVI) Registry</td>
</tr>
<tr>
<td>CAG 5-07(f)/2013</td>
<td>National Vascular Registry</td>
</tr>
<tr>
<td>14/CAG/1025</td>
<td>Death Notification of participants at HSCIC</td>
</tr>
<tr>
<td>14/CAG/1012</td>
<td>NIHR Critical Care Health Informatics Collaborative</td>
</tr>
<tr>
<td>19/CAG/0185</td>
<td>Understanding Multidisciplinary approaches and Parental Input in perinatal mortality Review</td>
</tr>
<tr>
<td>17/CAG/0176</td>
<td>A Risk-adjusted and Anatomically Stratified Cohort Comparison Study on Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms: (UK-COMPASS)</td>
</tr>
<tr>
<td>18/CAG/0119</td>
<td>Comprehensive Patient Records (CPR) for Cancer Outcomes, CPR Workstream 5 Patient Reported Outcome Measures (PROMs)</td>
</tr>
<tr>
<td>ECC 1-03(FT2)/2010</td>
<td>Prospective Study of Outcomes in Sporadic versus Hereditary breast cancer (POSH)</td>
</tr>
<tr>
<td>Signed – Chair</td>
<td>Date</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Signed – Confidentiality Advice Team</td>
<td>Date</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>