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

**08 October 2021**

## Present:

| Name | Capacity | Items |
|---|---|---|
| Dr Tony Calland MBE | CAG Chair | 1a, 1b, 2a |
| Dr Martin Andrew | CAG Member | 1a, 2a |
| Ms Sophie Brannan | CAG Member | 1b, 2a |
| Dr Harvey Marcovitch | CAG Member | 1a, 1b |

## Also in attendance:

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

## 1. New Precedent Set Review Applications – Research

## a. 21/CAG/0113 – A comprehensive assessment of peri-prosthetic fractures associated with the CPT® stem in a large teaching hospital over 16 years

### Context

### Purpose of application

This application from Nottingham University Hospitals NHS Trust set out the purpose of medical research that aims to define the incidence of Peri-prosthetic fractures (PPF) related to cemented collarless polished tapered stem (CPT®) design, by linking a retrospective consecutive series of patients who received the CPT® stem for primary THR at Nottingham University Hospitals NHS Trust to Hospital Episode Statistics (HES) data to identify all hospital admissions within the cohort with a femoral fracture. Applicants will also investigate if any particular risk factors can be identified.

PPF are a serious complication of total hip replacement (THR). Recent publications have suggested a higher prevalence of PPF with the CPT® stem compared to other polished taper stem designs and a higher revision rate for PPF in the UK National Joint Registry (NJR). Nottingham began using this stem design in 2009 and have not identified a significant cohort of patients suffering PPF, however, the true incidence may be unknown, as some patients may undergo fixation that is not recorded in the NJR.

Applicants will disclose confidential patient information alongside a pseudonymous ID to NHS Digital in order to link to HES to identify all A&E visits with coding related to femoral fracture during the lifetime of each implant. NHS Digital will return a pseudonymous dataset to the applicant, however this flow will still require support as the applicant will be able to re-identify the data. The applicant will link back to their clinical dataset using the pseudonymous ID. Once identified, the clinical team will review admission xrays and subsequent treatment xrays from Nottingham University Hospitals NHS Trust. After linkage, the dataset will be anonymised for analysis.

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 have received the CPT stem for primary THR in Nottingham University Hospitals NHS Trust<br><br>Between April 2009 and April 2020, n=2852 |
| **Data sources** | 1. Nottingham University Hospitals NHS Trust:<br>• Existing arthroplasty audit database (clinical database)<br>• Local imaging data<br><br>2. Hospital Episode Statistics (HES) – NHS Digital |
| **Identifiers required for linkage purposes** | To link to HES:<br><br>1. NHS number<br>2. Date of Birth<br>3. Postcode<br>4. Pseudonymous ID |
| **Identifiers required for analysis purposes** | 1. N/A – no confidential patient information required for analysis |
| **Additional information** | Pseudonymous ID will be added by the Trust.<br><br>Linkage key of pseudonymous ID numbers linked to NHS numbers will be kept on hospital intranet in secure folder this file will be password protected and accessible only by CI. direct care team only - no support required. |

## Confidentiality Advisory Group advice

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

### Public interest

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

## Practicable alternatives

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

- **Feasibility of consent**

The applicant reasons that consent is not a practicable alternative due to the large number of patients, the majority of whom are not under any active follow up, and a significant proportion may have passed away in the time since primary surgery. The Members accepted this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required to undertake linkage with HES data. It would not be possible to undertake linkage with anonymous or pseudonymous data, and therefore the Sub-Committee agreed that this would not be a practicable alternative.

## 'Patient Notification' and mechanism for managing dissent

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

The applicants have created a notification poster for Trust clinical areas and have also developed a website text. A study specific opt out option is available on these notifications, and the applicant will additionally not include patients who dissented to NJR, and will apply the national data opt out.

The CAG were content with the content of the notifications and the opt out options, however the description of who has reviewed the study should be amended to reflect the advisory role of CAG.

The sentence; *'This study has been reviewed and given a favourable opinion by the NHS, Cardiff Research Ethics Committee, and has been reviewed and approved by the Health Research Authority, the Confidentiality Advisory Group'*

Should be altered to the following; '*This study has been reviewed and given a favourable opinion by the NHS, Cardiff Research Ethics Committee, and has been reviewed and supported by the Health Research Authority, following advice from the Confidentiality Advisory Group'*

## Patient and Public Involvement and Engagement

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

The applicant has informally asked a number of primary arthroplasty patients whether they would be happy for their details to be used in collection of data to test the safety of implants and they universally were happy for this. The Trust R&D department has additionally undertaken general patient and public involvement which supports the use of historic data in this way for research purposes. The applicant is in the process of building a specific patient and public involvement group. Most patients eligible for this study have previously consented to NJR data recruitment and an expectation inherent in this that there information will be stored on the NJR systems and potentially used in studies involving NJR data.

The Members were content with the rather limited study specific patient and public involvement undertaken to date, on the basis that all of the patients have consented to their data being used by the NJR and the researchers are part of the direct care team. As the applicant is in the process of building a study specific patient and public involvement group, the Sub-Committee considered that this work should continue, and the applicant should provide a report on the study specific patient and public involvement undertaken at the first annual review.

## Exit strategy

Once linkage has been undertaken, identifiable data will be deleted and analysis will be on an anonymised dataset. A key is retained, however this is stored separately from the dataset by direct care team only. The Members were content with this exit strategy.

## Confidentiality Advisory Group advice conclusion

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

In order to complete the processing of this application, please respond back to all of the request for further information within one month.

## Request for further information

1. Please amend the notification documents as described above to reflect the advisory role of CAG, and provide updated versions for review.

2. Please provide evidence of NHS Digital review of Nottingham University Hospitals NHS Trust 20/21 DSPT, as per standard condition of support below.

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

### Specific conditions of support

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

1. Please provide a report on the study specific patient and public involvement undertaken at the time of the first annual review.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 09 June 2021**.

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. **Pending:**

   The NHS Digital **20/21** DSPT equivalent review for **NHS Digital** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 28 October 2021). The NHS Digital **20/21** DSPT review for **Nottingham University Hospitals NHS Trust** was **pending.**

## b. 21/CAG/0141 – Exploring an Advanced Practice programme for children and young people's healthcare: a realist evaluation

**Context**

### Purpose of application

This application from University of Northumbria set out the purpose of medical research that aims to examine if, how, why and in what circumstances an Advanced Practice programme, delivered by nurses, works (or not) for Children and Young People's (CYP) healthcare.

Research into Advanced Practice (AP) within the context of nursing reports benefits that include reducing waiting times, improving access to care, and cost efficiencies and service sustainability. However there are limitations, including research predominantly concentrating on adults, and not acknowledging the fact that CYP have stark differences in healthcare needs. Additionally Research in the context of CYP is largely from other countries, which does not take into account the healthcare systems in the UK. The researcher will collect qualitative data during consented interviews with healthcare professionals. This is outside the scope of CAG support.

'Section 251' support is required for the researcher, who is not considered part of the direct care team, to incidentally view confidential patient information during reviews of service performance data (incident reporting and/or commendation reporting), and service audits at Northumbria Healthcare NHS Foundation Trust. Patient information is not the subject of the research. The researcher will also undertake a case note review, without patient consent. No confidential patient information will be collected. 25 case notes will be identified by the direct care team, and reviewed by the researcher, who is not considered direct care team. The researcher will look for evidence of 'quality of care' delivered by the Advanced Practice programme, and will not record any confidential patient information.

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** | 25 case notes of Children and/or Young People (Ages) 0-18yrs –directly exposed to the care offered by the Advanced Practice programme within the case site clinical area at Northumbria Healthcare NHS Foundation Trust,<br><br>Treated between November 2020 and November 2021 and selected retrospectively |
| **Data sources** | 1. Northumbria Healthcare NHS Foundation Trust<br><br>• Routine Service Performance Data (audits, incident reports /commendations pertaining to the Advanced Practice programme<br><br>• Case notes – both paper and electronic |

| | |
|---|---|
| **Identifiers required for case note review** | 3. Medical notes will be reviewed |
| **Identifiers required for analysis purposes** | 2. No confidential patient information collected for analysis |
| | A key between a pseudo ID and the identifying information will be kept by direct care team only. |

## Confidentiality Advisory Group advice

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

### Public interest

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

However the Sub-Committee did not feel the case for the public interest was well made. They were unclear if 25 records would be enough of a sample to draw a useful conclusion, noting that although the breach of confidence only relates to 25 people, they were doubtful that the public interest in the outcome of only 25 justifies the breach of confidence.

Members commented that the public benefit was not clear from the application, for example, the following statement is vague; '*..contribute to theory surrounding the operations of an Advanced Practice programme established for CYPs healthcare'*. The CAG were not clear how the mentioned theory will help patients.

In the absence of any patient and public involvement to support the application, the Members did not feel they could agree that this activity was in the public interest. The CAG will await the REC opinion regarding the ethical values and benefits.

### Scope

It appears that the researcher requires ‘s251’ for two separate breaches of the common law duty of confidentiality. One is a random selection of 25 casenotes identified by the direct care team, and provided to the researcher to access on-site. This is clear to Members. The other

breach of confidentiality is the incidental disclosure of confidential patient information during review of service performance data (incident reporting and/or commendation reporting), and service audits. However, the Members were not clear whether in this second stream the researcher sees the entire casenote or just the report on the incident. This needs to be clarified, as it is currently not clear exactly what confidential patient information will be viewed without consent.

The Sub-Committee noted that the CAG have not been told the site where the selected patients are treated. Northumbria Healthcare runs a number of hospitals and community services. The CAG consider that whether the subjects come from one or several sites is pertinent to where notification should appear and patient and public involvement conducted; for example, if it is just North Tyneside Hospital that may be simple, but if the research includes community services it might not be.

## Practicable alternatives

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

- **Feasibility of consent**

The applicant has provided three reasons for why consent is not a practicable alternative;

1. Some participants may have been international visitors to the area, presenting as a one-off occurrence therefore tracking those persons to gain consent could be difficult.

2. The general return rate of consent in conducting a retrospective case note review in this way is highly likely to be significantly low.

3. Uninvited contact could cause considerable stress to patients and their families.

The CAG accepted the justifications provided that consent is not a practicable alternative.

- **Use of anonymised/pseudonymised data**

Confidential patient information is not collected as part of the study, but will be viewed during the undertaking of a case note review. It is not possible to review case notes without viewing confidential patient information. The Members were content this could not be undertaken in a less disclosive manner, as the applicant confirmed the notes would be both paper and electronic meaning an automated data collection was not possible.

## ‘Patient Notification’ and mechanism for managing dissent

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

As a response to queries, the applicant has reasoned that any poster developed would not be seen by the relevant cohort, as the study design is retrospective. However one has been developed for the wards. No suggestions have been made of other ways to display information which could reach the cohort, for example on any websites or social media. The content and placing of the notification poster has not been discussed with any patient and public involvement participants.

The clinical team will ensure that if any person has any dissent recorded, their notes will not be included for review. The national data opt out will also apply. A specific study opt out is offered on a poster in response to queries.

The Members felt that the poster could contain more information. They also felt that further notification in addition to the poster should be provided, and the point made above about which site(s) the cohort will be drawn from is relevant, because this might affect how notification is undertaken.

Patient and public involvement groups could inform on the content of the poster, and any additional placing of notifications to ensure the cohort might see it. This could potentially include social media advertisement, as the age group is 0-18.

The Members were content with the opt out options described.

## Patient and Public Involvement and Engagement

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

The applicant is in the process of establishing an external expert reference group. It is proposed between five to eight people will form this group, inclusive of service user representation. However, this has not yet been undertaken. Therefore there is currently no support from patients and the public regarding the specific breach in the common law duty of confidentiality (case note review of 25 children and young people by a researcher who is not considered part of direct care team, and review of incidents/audits).

The Sub-Committee commented that the results of patient and public involvement would be required before ‘s251’ support can be provided. This will need to evidence the acceptability of this use of confidential patient information without consent. This will help the CAG to consider the public interest in the activity. In addition, the notification should be discussed with a patient and public involvement group, as described above. It is noted that the five to eight promised participants will include ‘service users’. However the Members will require more details about

who makes up the external expert reference group. The Sub-Committee wished to know particularly about how the applicant will undertake patient and public involvement with children and young persons as well as parents. The CAG commented that given the direct care team might well be a paediatric unit, the applicant could explore how to carry out some patient and public involvement with children and young people, with their input.

## Exit strategy

The information collected will be anonymous for analysis. A key is retained, but this is retained by the direct care team only. The case note review will be part of phase 2, and is expected to be completed approximately July 2022. 'Section 251' support required until then.

## Confidentiality Advisory Group advice conclusion

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

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

## Further information required

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

1. Please provide further information regarding the public benefit of this activity.

2. Please clarify the scope of support, relating to if, during the review of service performance data (incident reporting and/or commendation reporting), and service audits, the researcher will have sight of the entire medical record or not.

3. Please provide further information about which site or sites within Northumbria Healthcare NHS Foundation Trust the cohort will be from.

4. Please provide an updated patient notification strategy, which has further notification options in addition to the poster. The content of notifications should be discussed with a patient and public involvement group, as well as discussing where to display notifications in order that the cohort might see the information.

5. Please undertake patient and public involvement to evidence the acceptability of this use of confidential patient information without consent, and outside of the direct care team. The notification should be discussed with a patient and public involvement group, as above. Please provide details about who makes up the external expert reference

group. Please ensure children and young persons are involved in patient and public involvement as well as parents.

6. Please provide a Favourable Opinion from the REC (as per standard CAG conditions of support). This is not required to be in place before CAG review any re-submission, but will be required prior to final 's251' support being provided.

Once a new application is received the information will be reviewed at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

## 2. New Precedent Set Review Applications – Non-Research

### a. 21/CAG/0146 - Stroke risk after traumatic brain injury (TBI)

**Context**

**Purpose of application**

This non-research application from University of Birmingham sets out the medical purpose of identifying predictors of stroke risk post Traumatic Brain Injury (TBI). The applicant aims to link the Trauma Audit Research Network (TARN) and Secure Anonymised Information Linkage (SAIL) datasets to create a single dataset including comprehensive hospital data and long-term primary care data.

TBI is a global health problem; worldwide, >60 million people experience a TBI each year and incidence is rising. TBI has been found to be an independent risk factor for stroke. However, it is unclear which TBI patients have increased stroke risk. Stroke is a leading cause of death and disability; therefore, understanding predictors of stroke risk post-TBI is important to inform stroke prevention in this population.

NHS number is required to link TARN and SAIL data. Data will be linked by SAIL Databank's Trusted Third Party, Digital Health and Care Wales (DHCW). Following the linkage, data will be anonymised and disclosed to the University of Birmingham for analysis.

A recommendation for class 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.

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|---|---|
| **Cohort** | The population will be:<br><br>- adults (≥18 years)<br>- diagnosis of TBI (any severity)<br>- resident in Wales<br><br>The sample size will be all patients within the TARN/SAIL databases who meet the above inclusion criteria. (approximately 160,000). |
| **Data sources** | 1. University of Manchester: Trauma Audit Research Network (TARN)<br>2. Swansea University: Secure Anonymised Information Linkage (SAIL) databank |
| **Identifiers required for linkage purposes** | 4. NHS number<br>5. TARN Unique record ID |
| **Identifiers required for analysis purposes** | 3. Age<br>4. Gender<br>5. Ethnicity<br><br>Dataset will be effectively anonymous for analysis |
| **Additional information** | Disclosure of clinical data from TARN to SAIL (File 2) does not require support as this does not contain any identifying information. |

## Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

## Public interest

The Members were agreed that there is a strong public interest toward supporting this application, particularly given a previous review that TBI patients have increased risk of stroke, for what is clearly a medical purpose. However it was clear that the purposes of this application did not fall within the definition of non-research purposes of the management of health and social care services, and it was felt that the purpose of this application was clearly medical research. Therefore, the CAG were not assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006, in the context of this non-research application. This is expanded upon below.

## Scope

The application has been submitted as a non-research application. This was a result of the applicant decision that the linkage element of the application is not specifically research in itself. However the purpose of undertaking the linkage appears to be medical research, in order to identify predictors of stroke risk post TBI, to then inform stroke prevention in this population.

the HRA decision tool was undertaken during the 08 October 2021 precedent-set meeting, by the applicant, after prompting from the Confidentiality Advice Team (CAT). Applicants had not undertaken the tool before submitting to CAG. The HRA decision tool has informed the applicant that this application can be submitted as non-research, however the CAG disagree with this assessment. The applicant has reported as part of the tool, that the results will not be generalisable, however the purposes described in the application do appear to be generalisable, as the applicant has described using the results to inform stroke prevention in a TBI population. The CAG also commented additionally that the application does not seem to have any element of service evaluation. The Sub-committee recognised that the applicants had sought advice on this matter, however, they considered that this application is unequivocally an exercise undertaken for the purposes of supporting medical research.

A discussion between CAT, the applicant and the HRA queries line is underway to clarify if this can be considered a non-research application, or whether a research application is required for CAG, alongside a REC application. The Sub-Committee consider that a research application to CAG should be required.

For the re-submission, the applicant is advised to complete a research application form to CAG, and the sub-committee are content to review again via the precedent set pathway.

The Members wish to state that they are very supportive of this application in principle and they do not wish to delay this important research. The applicant is advised to re-submit as soon as possible, and to contact the CAT for advice if required regarding re-submission.

## Practicable alternatives

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

- **Feasibility of consent**

The applicant has reasoned it is not practicable to consent the thousands of patients in the TARN audit, as it would not be feasible to obtain consent from this large number of people. Furthermore, obtaining consent would require accessing personal, identifiable information such as contact details and full name. The Sub-Committee agreed with this justification.

- **Use of anonymised/pseudonymised data**

Confidential patient information is required for linkage, and Members were content that this could not be undertaken using anonymous or pseudonymous data. The applicants are using a well-established 'split file' approach for linkage.

## 'Patient Notification' and mechanism for managing dissent

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

The applicant has submitted the application with a design which makes no attempt to inform people who contribute data to TARN or SAIL databases specifically about this project. However, the applicant reasons that both TARN and SAIL have processes in place inform their cohorts that their data may be used for research purposes. However this is not relevant, as this has been submitted as a non research application.

The applicant has asked TARN and SAIL about whether it would be possible to display a study specific notification, and apply a study specific opt out, but no response has yet been supplied. SAIL and TARN do have opt out options from their respective datasets and these will be respected. It is not clear if the national data opt Out will be applied.

The Members considered that it is not acceptable to have no study specific notification for this project. The applicants are required to develop a project-specific plan for notification. This should at least include notification on the TARN and SAIL websites, and perhaps use of a stroke charity or TBI charity to help inform where notification could be displayed so the cohort might see it. The Sub-Committee commented that the patient and public involvement group may be able to help with this.

The Members felt that a study specific opt out before the disclosure from TARN to SAIL could be applied, however the CAG felt they needed to see the responses from TARN surrounding opt-out before making a judgement.

## Patient and Public Involvement and Engagement

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

This project is funded by the National Institute for Health Research (NIHR) Surgical Reconstruction and Microbiology Research Centre (SRMRC) based at the University of Birmingham. The SRMRC has a dedicated patient and public involvement group for trauma patients. This application has been discussed with the patient and public involvement group. The group understood why it was not practical to seek consent to use confidential information from all patients and felt that the use of confidential information in the proposal was minimal and reasonable.

The CAG commented that this was satisfactory, as the applicants had approached a patient and public involvement group of the relevant patient population to discuss the unconsented use of confidential patient information for linkage, with positive views being reported.

## Exit strategy

The exit strategy is anonymisation, at the time point of DHCW deleting NHS number. It is currently unclear how long with this take, and the applicant is checking with DHCW. The length of time support required for should be clarified in a re-submission if possible, however the CAG were content with the clear exit strategy.

## Confidentiality Advisory Group advice conclusion

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

Following advice from the CAG, the Secretary of State for Health and Social Care recommended that the application was deferred.

## Further information required

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

1. Please re-submit this application as a research application, alongside a corresponding application to REC.

2. Please develop a project-specific plan for notification as described above.

3. A study specific opt out should be applied if possible. A re-submission should include the responses from TARN surrounding opt-out, including clarity over whether the National Data opt out would be applied.

Once a new application is received the information will be reviewed at the next available CAG meeting. Deadlines for future CAG meetings are available on the HRA website and you should contact the Confidentiality Advice Team to book the application onto the next available meeting.

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| *Minutes signed off as accurate by correspondence from Dr Tony Calland, MBE, CAG Chair* | | *21 December 2021* |
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| | | |
| Signed – Officers of CAG | | Date |
| | | |
| Caroline Watchurst | | *20 December 2021* |
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| | | |
| Signed – Confidentiality Advice Team | | Date |
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