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

## July 2019

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## 1. NEW APPLICATIONS

| *Name* | *Notes* |
|---|---|
| Dr Patrick Coyle | CAG vice-chair |
| Dr Liliane Field | CAG member |
| Mr Andrew Melville | CAG member |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Application title:** **An evaluation of knee arthroplasty fixation in an evolving challenging population**
**CAG reference:** **19/CAG/0054**
**IRAS project ID:** **260499**
**REC reference:** **19/SC/0139**

**Context**

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to undertake a comparison of outcomes for patients undergoing cemented versus uncemented knee replacements in England.

The patient cohort will be identified by the National Joint Registry (NJR), which is a national audit programme commissioned by the Healthcare Quality Improvement Partnership. The NJR operates partially with support under the Regulations, via application 18/CAG/0146 and on a consented basis.

Northgate, processor for the NJR, will identify the relevant patient cohort within their dataset. Pseudonymised data from the NJR dataset will be disclosed to the applicant, with a corresponding NJR ID. Northgate will simultaneously disclose confidential patient information, together with NJR ID, to NHS Digital in order to facilitate linkage with the HES and ONS datasets, to collate inpatient data, patient reported outcome measures and mortality data. NHS Digital would disclose a pseudonymised linked dataset, with NJR ID back to the applicant. This would be linked with data from the NJR to create a pseudonymised data set for analysis. The applicant will see receive additional information on patients within the wider UK

nations who underwent a knee replacement within the study timeframe; however, this data will be provided in an anonymised format and will not be linked with wider datasets. This wider cohort is out of scope of the CAG application.

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

Confidential patient information requested

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

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|---|---|
| **Cohort** | All patients who have undergone a knee replacement since 01 April 2003 to 31 December 2018 who are registered within the National Joint Registry. Sample size is estimated at 1,087,611 patients. Data linkage will only be facilitated for patients in England. |
| **Data sources** | 1. Electronic Health records held within the National Joint Registry (NJR)<br>2. HES and ONS data held in electronic records by NHS Digital |
| **Identifiers required for linkage purposes** | 1. Surname<br>2. NHS Number<br>3. Date of birth<br>4. Postcode<br>5. Sex |
| **Identifiers required for analysis purposes** | 1. Sex |
| **Additional information** | The application set out a consented arm; this is not within the scope of the proposed support. |

**Confidentiality Advisory Group advice**

**1. The Group recommended that the first data linkage methodology, which involved de-identified data being released by Northgate and NHS Digital to the applicant for linkage via a study reference number, was operated for the study. Confirmation of this would be required prior to any final recommendation of support coming into effect.**

The applicant clarified in their response that they agreed with this suggestion. The data will be linked as per the data release project method outlined in the research protocol. The Group was satisfied with this response and raised no further queries.

**2. Confirm which datasets NHS Digital will be linking with the patient cohort.**

The applicant advised that NHS Digital would link the Office of National Statistics data (mortality), the patient reported outcome measure data (PROMs) and the admitted patient care records data (APC) with the NJR IDs provided from Northgate. The Group noted this information and raised no further queries.

**3. Provide justification to explain why it is not feasible to seek consent for this study.**

The applicant explained that it was not possible to obtain consent for this study, as the cohort included over 100,000 patients, who had already received their routine care. The Group accepted the rationale for not obtaining consent and raised no further queries.

**4. Clarify the scope of the patient cohort which would be identified by Northgate for inclusion in the study.**

The applicant advised that Northgate would only provide data of patients who underwent primary knee replacements and had consented for their data to be used for NJR research. This would form 92.4% of all knee replacements in their records. This would be approximately 100,000 knees. The Group noted this information and raised no further queries.

**5. The dissent process needs to be revised as follows;**

**a. Patients should be advised to contact the National Joint Registry directly in order to register their dissent,**

The applicant explained that the dissent process had been revised so that patients were asked to contact the NJR directly in order to register their dissent. Patients were able to contact the NJR by telephone, e-mail or via their website.

**b. Confirm how any dissent raised would be respected,**

Dissent would be respected by the NJR and the patient's personal details removed from the NJR database.

**c. Information about the study and how to dissent needs to be included on the NJR website at least six weeks before the data collection starts,**

The applicant advised that information about the application would be registered on the NJR website under the list of current projects.

**d. Copies of all website text would need to be provided for review.**

The NJR consent form and the wording about consent from the NJR website was provided for review. The Sub-Committee reviewed these documents and were satisfied that they were appropriate.

The Sub-Committee noted that the response to their query about dissent had not been adequately addressed and that it appeared that the applicant had misunderstood that a mechanism needed to be created and implemented for patients to dissent to inclusion in this application specifically, and not the NJR as a whole.

Information specific to this application needed to be provided on the NJR website. The information about consent should link to the NJR research portfolio, so that patients can check for any projects that may relate to them and which they would prefer to dissent from. The same information about the application and how to dissent needed to be included on the website of the Nuffield Department of Orthopaedics.

The applicant provided a further response to these queries. He explained that it was not possible for patients to dissent from this study specifically and not from the NJR as a whole. All patient data was used by the NJR to produce its annual registry report, which included a breakdown of cemented and cement less knee replacements. This is similar to the information that the applicant aimed to produce, but not stratified by age and gender.

The applicant confirmed that information about this specific project will be made available on the NJR website under the section titled “Research Project Portfolio.” The applicant had also discussed the project with the Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences (NDORMs) communication team, who have agreed to create a page on the NDORMs website about the study and with details of the dissent process, the email and telephone contact details of the NJR help team and the NJR website information. The applicant advised that that page would be available prior to the study commencing.

The Sub-Committee noted the rationale given and raised no further queries.

**6. Clarify that the response provided to Q11 of application filter page, which stated that confidential patient information would not be accessed outside of the care team without consent, was in error.**

The applicant advised that this was an error, and the answer should have been recorded as “yes.” The Group accepted this clarification.

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

The applicant confirmed that the legal basis for processing data under GDPR being relied upon in this application are Article 6(1)(E) – tasks in the public interest and Article 9(1)(J) – research purposes. The Group noted this information and raised no further queries.

## Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

## Specific conditions of support

1. Favourable opinion from a Research Ethics Committee. **Confirmed 26 June 2019**
2. Confirmation from the IGT Team at the Health and Social Care Information Centre of suitable security arrangements via Information Governance Toolkit (IGT) submission. **(Confirmed – NHS Digital has a reviewed "standards met" grade on the Data Security and Protection Toolkit).**

| *Name* | *Notes* |
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| Dr William Bernal | CAG Member |
| Dr Malcolm Booth | CAG Member |
| Mr. David Evans | CAG Member |
| Mrs Diana Robbins | CAG Lay Member |
| Dr Murat Soncul | CAG Alternate Vice Chair |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Application title:** **The 'OxMIV' violence risk assessment tool: an external validation study in patients referred to Early Intervention in Psychosis services using routine documentation in Electronic Patient Records.**
**CAG reference:** **19/CAG/0092**
**IRAS project ID:** **257332**
**REC reference:** **19/LO/0498**

**Context**

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to assess the accuracy of a tool which is used to assess the risk of patients, who are under the care of the community mental health teams as part of the Early Intervention in Psychosis program, turning violent.

The OxMIV tool has previously been trialled in Sweden and the applicant wishes to test its efficacy in England. It utilises data which is routinely collected by clinicians to predict the likelihood of patients turning violent. This study aims to test the accuracy of the tool's estimations on a historic patient cohort. To achieve this, routine information from electronic healthcare records for patients who were previously treated under the Oxford Health NHS Foundation Trust's Early Intervention in Psychosis (EIP) services will be accessed in order to calculate the OxMIV score. Police and health care records will then be checked for evidence of subsequent violence which will be utilised to evaluate the accuracy of the tool.

The applicant will require access to patient's medical records for the 12-month period following the EIP referral to examine for incidents of violence. Access to police records for the same duration would also be required to establish a complete picture of patient violence following the intervention.

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

Confidential patient information requested

Cohort

1300 consecutive referrals EIP referrals, up to May 2018, within the Oxford Health NHS Foundation Trust will be accessed in order to identify approximately 1000 eligible patients for inclusion.

Access to the complete patient record will be required in order to identify eligible patients for inclusion in the study and to enable wider data required for analysis to be extracted. The following items of confidential patient information are specifically required for the purposes set out below:

- Name – sample validation and linkage,
- Date of birth – sample validation and linkage,
- Date of Early Intervention Service referral – analysis,
- Sex – analysis.

**Confidentiality Advisory Group advice**

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

1. **Confirm whether the OxMIV tool will be applied to all 1000 patients included in the study.**

The applicant explained that in order calculate the predictive accuracy of the OxMIV tool, information on the ratings made by the tool for both the individuals who went on to develop the outcome of interest, and those who did not is required. It was confirmed that it was not possible to establish the accuracy of the tool without both types of information. Therefore, the tool would be applied to all 1000 individuals included within the study, regardless of whether or not they developed a violent outcome.

The Sub-Committee was assured by the clarification provided.

2. **Clarify the source of third-party data, in relation to the parents and siblings of the patient cohort, and the extent of information to be included in the analysis dataset.**

It was explained that there were three pieces of information required to complete the OxMIV tool that relate to family information. These were parental drug/alcohol use (yes/no), parental violent crime (yes/no) and sibling violent crime (yes/no). This information would be extracted from the electronic health record in the same manner as the other items for OxMIV, and if present would likely be located within the family or personal history sections of the assessment.

The applicant confirmed that no identifiable information about these family members was required i.e. the information is not triangulated with any sources of information relating to that family member themselves. It was further confirmed that these three parameters would be treated in exactly the same manner as all the other parameters within the OxMIV tool for the

purposes of analysis, i.e. any link to the identifiable index individual will be deleted prior to data analysis.

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

3. **Provide assurance that the laptop computer to be used in data transfer will be appropriately encrypted.**

The applicant confirmed that the laptop used in all data collection activities would be protected by Whole Disc Encryption.

Confirmation was received by the Sub-Committee.

4. **Feedback from the initial meeting of the project-specific patient and public involvement group is required. Provide details around the demographics of the group and the format of the initial meeting, together with an overview of discussions held and the views expressed by the group around the project and proposed methodology.**

A detailed overview was provided by the applicant around the initial patient and public group, which was held on 11 June 2019. The group consisted of five individuals (three females >40 years of age, and two males <30 years of age). Of these, two have personal experience of recent engagement with Early Intervention in Psychosis (EIP) services, one is currently engaged with EIP services, one is a carer for someone with a severe mental illness, and one has lived experience of a relevant disorder and engagement with non-EIP mental health services.

Following the meeting, which was supplemented by further written information about the specific issues, feedback regarding the use of confidential information was collated.

Of the individuals with personal lived experience, none raised concern about the approaches employed by the study and the use of data without consent. A common comment was noting the potential value to patients of the overall work to develop a tool that was particularly strong at assigning low risk status. One individual commented that they thought the reasons for not contacting 1000 people to gain consent were well explained. Another individual commented on the potential benefits to patients, families and the wider community of the work, as well as for health services, and felt that this made the ‘sacrifice’ of using data without consent worthwhile, and that the safeguards in place to minimise the risks of this seemed appropriate and the overall approach was acceptable.

One individual group member who is a carer did raise some issues. These were that they were unsure whether the ‘ends justified the means’, and it was reported that they felt that effort should be made to contact the 1000 people to both inform them of the study activity and consent them. This individual was concerned at how statistical methods to account for missing predictor data could be reliable and felt that it was unfair to ‘label’ people based on this data, and group violent offences together when there was a spectrum of severity.

The Sub-Committee received the feedback from the patient and public involvement activity. It was recognised that the feedback which had been provided was detailed and covered both positive and negative views from attendees. Members commented that the negative views

expressed around the project were quite significant and agreed that it would be beneficial for the applicants to undertake further patient and public involvement and engagement activity to ensure that these concerns were not shared more widely. It was agreed that support would be recommended on the basis that further patient and public engagement activity was carried out to explore views about the project. Feedback would be required at the time of first annual review.

5. **Provide copies of the additional information which would be provided to patients in the patient packs for consideration.**
6. **Provide copies of the text to be displayed on the University and Trust websites for consideration.**

The applicant confirmed that the poster document which had been provided in the initial submission would be made available at base sites, in patient information packs and online. It was also confirmed that a privacy notice, in order to meet the GDPR requirements would be displayed on the University of Oxford website. This document was provided for information.

The Sub-Committee received the clarification and supplementary document.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

**Specific conditions of support (Final)**

1. Support extends to the processing of confidential patient information from records at the Oxford Health NHS Foundation Trust only. An alternative legal basis has been established to legitimise access to and extraction from the Thames Valley Police database.

2. Support extends to the use of confidential patient information and supporting clinical information extracted from medical records at Oxford Health NHS Foundation Trust within the scope of this project only. Data cannot be used by the applicant or the Thames Valley Police for any wider purposes.

3. Wider patient and public involvement and engagement activity should be carried out to test the acceptability of the project and its methodology with a wider group. Feedback about the activity undertaken and the views expressed is required at the time of first annual review. If the views provided were negative, the CAG would take this into account when considering whether support can continue or whether further work is required.

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

5. Confirmation from the IG Delivery Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (DSPT) submission (**Confirmed – University of Oxford Medical Sciences Division, Standards Met confirmed 21/06/2019 and Oxford Health NHS Foundation Trust, Standards Met confirmed 01/07/2019**).

| *Name* | *Notes* |
|---|---|
| Dr William Bernal | CAG Alternate Vice-Chair |
| Ms Sophie Brannan | CAG Lay Member |
| Dr Tony Calland MBE | CAG Member |
| Professor Barry Evans | CAG Member |
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Application title:** **Enhanced surveillance of neonatal herpes simplex disease in UK and Irish infants less than 90 days of age.**
**CAG reference:** **19/CAG/0077**
**IRAS project ID:** **116856**
**REC reference:** **19/WA/0066**

**Context**

Purpose of application

This application from the Royal Alexandra Children's Hospital, Brighton & Sussex University Hospitals NHS Trust set out the purpose of medical research, where the applicants are seeking to determine whether infants who receive prompt treatment for Herpes simplex virus (HSV) have a better outcome that those whose treatment is delayed.

The applicants aim to study all cases of neonatal HSV in infants under 90 days of age in the UK and Ireland over a 2-year period between 2019 - 2021. Paediatricians will be asked to notify the applicants of cases of neonatal HSV as they occur via a routine reporting source called the British Paediatric Surveillance Unit (BPSU). The usual BPSU methodology will be followed. The condition will be included on the BPSU "Orange Card" sent to members monthly by e-mail. The investigator will then send the study questionnaire directly to the reporting clinician. The questionnaire asks for clinical details of the case and for minimal identifiers. The questionnaire can be completed online, via the REDCap system, or sent by secure email.

The study will also investigate how each child has been in the year following their diagnosis. Reporting clinicians will be sent a follow-up questionnaire after one year by the study team (this will be sent via a secure link to a REDCap questionnaire, or to secure nhs.net email if preferred). The case will have been assigned a unique study number by the BPSU: The reporting clinician will be given this number as a point of reference, in case they identify more than one case during the study period. This unique number and DOB only will be referred to when requesting follow-up information.

The applicants intend to collaborate with the RCOG UKOSS (UK Obstetric Surveillance System) to ensure that obstetric data are complete. The applicant confirmed that

confidential patient information will not be shared with RCOG UKOSS. UKOSS has confirmed that, for all BPSU studies including this one, anonymous data (including names, hospital numbers, maternal DOB, etc.) is not collected / recorded. Their sole role is to facilitate contact with reporting clinicians in relevant local hospitals (there is one UKOSS reported for each hospital). The applicants will then liaise directly with the local team, using only infant and maternal DOB to link cases in order to request missing obstetric information.

HES/ONS data on cases of neonatal HSV will be requested to ensure the completeness of the data collected (i.e. to ensure that the number of cases reported via the BPSU system is equivalent to the number reported by these sources). This will provide reassurance that information on all cases of neonatal NHS during the study period have been captured; this is particularly important given the small number of cases expected. No confidential data will be disclosed to NHS Digital: cases will be linked using name of hospital, age & sex of baby only.

Local laboratories will be contacted by the study team in the uncommon event that there is incomplete information provided on the BPSU questionnaire (for example, HSV typing & CSF cell counts). The study team will contact the laboratory via telephone (to identify a senior lab member) and then an email will be sent by nhs.net mail to this team member, requesting missing data. Cases will be linked using the minimal patient identifiers, including DOB / date of sample.

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

Confidential patient information requested

Cohort:

Infants of 90 days or younger diagnosed with Herpes Simplex Virus infection between 2019-2021. It is estimated that between 90 – 130 cases would be reported over the two-year period. This is anticipated to be June 2019-June 2021.

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

- NHS number – sample validation and linkage,
- Hospital ID number – sample validation and linkage,
- Date of birth - sample validation, linkage and analysis,
- Date of death - sample validation, linkage and analysis,
- Hospital name and postcode - sample validation and linkage,
- Gender - sample validation, linkage and analysis,
- Postcode (district level) – analysis
- Ethnicity - analysis

**Confidentiality Advisory Group advice**

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

1. **The Group requested further information regarding the rationale for collecting certain patient identifiers, specifically patients' date of death and patient postcode.**

The applicant explained that collecting patients' date of death would provide a consistent method of calculating patients age at death. The applicant advised that some clinicians interpreted date of birth as day 0 of life, while others considered this to be day 1, therefore using 'age at death (in days) may lead to inaccuracies when calculating age at death.

The applicant confirmed that patients' postcodes would not be collected. The name and postcode of the admitting hospital was collected instead. This was collected in a regional format, for the purposes of analysing geographical distribution of HSV disease.

The CAG noted the information provided and raised no further queries.

2. **The Group asked for clarification regarding the length of time that confidential patient information would be stored for.**

The applicant explained that anonymised clinical information would be stored for a period of 20 years, in line with Medical Research Council guidance. Confidential patient information would only be stored for as long as necessary to ensure that de-duplication of cases was completed. The total data collection period was three years and one additional year for analysis. The data would then be destroyed in with Brighton & Sussex University Hospitals NHS Trust policy.

The CAG noted the information provided and raised no further queries.

**Confidentiality Advisory Group advice conclusion**

The CAG agreed that the minimum criteria under the Regulations appeared to have been met and that there was a public interest in projects of this nature being conducted, and therefore advised recommending support to the Health Research Authority, subject to compliance with the specific and standard conditions of support as set out below.

**Specific conditions of support**

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

2. Confirmation from the IGT Team at NHS Digital of suitable security arrangements via Data Security and Protection Toolkit (IGT) submission **(Brighton And Sussex University Hospitals NHS Trust – Standards met confirmed by NHS Digital email on 26 July 2019).**

## 2. NEW AMENDMENTS

| *Name* | *Notes* |
|---|---|
| Dr Patrick Coyle | Vice-Chair |
| Miss Katy Cassidy | Confidentiality Advisor |

**Application title:** **Evaluating variation in special educational needs provision for children with Down syndrome and associations with emergency use of hospital care**
**CAG reference:** **16/CAG/0015**
**IRAS project ID:** **177370**
**REC reference:** **15/LO/2086**

### Amendment request

The amendment form set out a request to extend the end date of the project from 31 December 2018 until 31 December 2021. The applicant explained that they had experienced delays in obtaining data access approvals and required this additional time in order to complete the study.

### Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair agreed that the extension to the study was justified, given the difficulty the applicants had experienced in obtaining the required data.

### Confidentiality Advisory Group conclusion

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

### Specific conditions of support

1. Confirmation of suitable security arrangements via DSPT submission. **(Confirmed - University College London - School of Life and Medical Sciences was confirmed as 'Standards Met' by NHS Digital via email on 13 June 2019).**
2. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmed – 11 January 2019).**

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

**Application title:** **Prolonged Effects of ART: A Record Linkage study (PEARL)**
**CAG reference:** **16/CAG/0053**

**IRAS reference:** **177855**

**REC reference:** **16/CAG/0222**

**Amendment request**

This amendment form set out a request to amend the planned data flow for this linkage study. Support is in place for NHS Digital to use patients' NHS number to match women in the HFEA registry data to women in CPRD mother-baby data set. The applicants intend to change this so that NHS Digital use NHS numbers to link all women in the HFEA registry to all women in the CPRD primary care dataset.

This change has been made on the advice of the Controller, the University of Oxford, as the previous wording did not accurately describe the linkage. NHS Digital will conduct the linkage and match all women in the HFEA registry to all women in the CPRD primary care dataset. The restriction to the CPRD Mother-Baby dataset occurs later, as this is done by CPRD not NHS Digital. The data that will be released to the researchers at the University of Oxford remains unchanged.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Chair. The Chair determined that the change to the data flows was reasonable and was happy to support the amendment.

**Confidentiality Advisory Group conclusion**

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

**Specific conditions of support**

1. Confirmation of suitable security arrangements via DSPT Toolkit submission. **(Confirmed – University of Oxford – Medical Science Division – Nuffield**

**Department of Population Health was confirmed as 'Standards Met' by NHS Digital via e-mail on 08 July 2019)**

2. Confirmation of a favourable opinion from a Research Ethics Committee **(Confirmed 01 July 2019)**

| *Name* | *Notes* |
|---|---|
| Miss Kathryn Murray | Senior Confidentiality Advisor |

**Application title:** **Research to identify measures of quality and safety of healthcare**
**CAG reference:** **15/CAG/0005**
**IRAS project ID:** **167242**
**REC reference:** **10/H1102/25**

**Amendment request**

The amendment request sought support to change the location of the server equipment which hosted the project database to a new Imperial College facility located at the Virtus data centre.

**Confidentiality Advice Team advice**

The amendment requested was considered by the Confidentiality Advice Team. It was noted that the described change of data storage location was an administrative change. The applicant had provided evidence of the relevant security assurance via NHS Digital email confirmation of 'Standards Met' grade for the Data Security and Protection Toolkit.

**Confidentiality Advisory Group 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**

1. Confirmation of suitable security arrangements via Data Security and Protection Toolkit submission (**Confirmed – Imperial College London, Faculty of Medicine, School of Public Health (Primary Care and Public Health, Dr Foster Unit**).
2. Confirmation of a favourable opinion from a Research Ethics Committee (**Confirmed**).

Signed – Chair Date

Signed – Confidentiality Advice Team Date