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

March 2021

1. New Applications

a. 21/CAG/0012 - Expression and Reception of Gratitude in Healthcare: Analytical Ethnography

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Professor Lorna Fraser	CAG Member
Mr Marc Taylor	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from King's College London set out the purpose of medical research which aims to observe and describe the various ways in which gratitude is expressed, received and displayed in a healthcare setting, in the Royal Brompton Hospital. This study is an exploratory study that will inform subsequent phases of a wider project investigating gratitude in healthcare, and how it can enhance the wellbeing of those who give and receive it.

Gratitude is an emotion essential to supporting communicative human relationships. Expressions of gratitude form a significant source of patient feedback, but few healthcare providers use the data to implement change; however, when positive patient feedback is used effectively, increased staff morale brings quantifiable benefits. Analysis of staff and patient surveys shows an association between staff experience and patient experience, from which has in turn been linked to patient safety and clinical effectiveness. A positive organisational climate and supportive peer relationships enhance staff wellbeing, and this is an antecedent for improved patient care. The King's Fund has highlighted low morale as a significant problem in the NHS, with a major contributing factor being that staff feel undervalued. The study explores gratitude as a factor that feeds into a supportive climate that has the potential to significantly enhance morale. The project overall will generate advice and guidance for healthcare institutions who wish to better recognise and facilitate gratitude for the morale and subjective well-being of their staff and patients, and therefore improve the quality of care and patient safety.

Observations will be made of exchanges of gratitude between patients and visitors with members of staff, and between staff members on six identified wards at the Royal Brompton Hospital. Observations may be followed up with informal conversations or arranged interviews. Displays of gratitude that are visible in the Hospital (e.g. noticeboards displaying thank-you cards) will also be recorded. Photographs may be taken (with permission) of objects related to gratitude, but no identifiable information will be photographed. No confidential patient information will be recorded. The study is expected to consist of approximately 30 half-day observation sessions over a period of nine months, and a total of around 450 participants are expected to be observed.

All observations and interviews with patients, staff or visitors will be undertaken where possible with informed consent, however it is possible that the researcher may be incidentally exposed to confidential patient information. 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 consent where possible, observing from a distance to try to avoid overhearing where appropriate, ceasing observations when requested, and reminding all staff and patient participants to respect patient confidentiality during interviews and observations.

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.

Cohort	Applicants will observe approximately 450 participants, made up of patients over the age of 16, staff and visitors on specified wards. However these will be consented observations/interviews. Support for CAG purposes is provided regarding any patient whose confidential patient information may be incidentally disclosed without consent whilst these observations and interviews are taking place.
Data sources	Interviews and observations carried out in the participating NHS Trust: The Royal Brompton and Harefield NHS Foundation Trust
Identifiers required for linkage purposes	No items of confidential patient information will be collected for linkage purposes
Identifiers required for analysis purposes	No items of confidential patient information will be collected for linkage 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.

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. **Favourable opinion from the REC when available.**

The applicant has provided a favourable opinion letter from the REC on 4th March 2021.

2. **Please re-phrase the wording in the interview topic guide regarding this sentence;**
   '*Please bear in mind that we have a duty of confidentiality to patients and staff, so please refrain from mentioning identifiable information during the interview.'* to ensure it is clear that as part of the study no confidential patient information will be recorded or retained, and that if any is recorded, this will be deleted immediately. Please provide the updated document to the CAG within one month from the date of this letter.

The applicant has updated the document as advised by the Sub-Committee and provided the updated interview topic guide for review on 24th February. The Members were content that this request for further information had been met.

3. **The information sheets, consent forms, poster and other patient facing documents should state in plainer terms that no confidential information will be recorded or retained without consent. Please provide the updated documents to the CAG within one month from the date of this letter.**

The applicant has updated the patient facing materials as advised by the Sub-Committee and provided the updated documents for review on 24th February. The Members were content that this request for further information had been met, and were now pleased to recommend support.

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 4 March 2021

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: The **2019/20** NHS Digital DSPT reviews for **The Royal Brompton and Harefield NHS Foundation Trust** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 26 January 2021).

b. 20/CAG/0017 - Effectiveness of Differing Psychotherapies Offered in a Specialist Psychotherapy Service – a benchmarking study

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Dr Lorna Fraser	CAG Member
Mr Marc Taylor	CAG Member
Ms Katy Cassidy	HRA Confidentiality Advisor

Context

Purpose of application

This application from the University of Sheffield set out the purpose of medical research that seeks to determine how effective and durable psychotherapy is for patients presenting for specialist tertiary care psychotherapy.

Tertiary level psychotherapy services, often regional centres, cater for particularly complex and enduring presentations. This is because patients using these services have been non-responsive to interventions offered in Primary and Secondary care. Little research evidence is available regarding the effectiveness of tertiary care psychotherapy services and is therefore under-represented with regards to evidence compared to primary and secondary services. The applicants will carry out an in-depth statistical analysis of a pre-existing routine outcome data-set collected by a Specialist Psychotherapy Service (SPS) at Sheffield Health and Social Care NHS Foundation Trust, to collect evidence for local tertiary care services to establish how tertiary care services compare to existing benchmarks set by randomised controlled trials.

Patients accessing the SPS are invited to complete an outcome measure, the OQ-45, at the start of treatment, monthly, at the end of treatment and as follow-up from psychotherapy at the SPS. The changes in the questionnaire score will be used as an indicator of the effectiveness of an intervention. Patient outcomes data, along with other relevant demographic information, age, gender, employment status, is routinely recorded within an electronic database. Patients who indicate they do not wish to share their clinical records for health purposes, or decline questionnaire participation, are omitted from this process. The applicants will use this dataset for analysis. They will also request individual electronic patient

records in order to extract additional information on medication use, previous psychological therapy input, diagnosis, carecluster. The dataset will be imported into the service outcomes database. Support is sought as the student investigator, who is not part of the direct care team, will carry out the anonymisation of the dataset, before it is exported to the University of Sheffield through the data-gatekeeper identified for this study. Following verification that data is fully anonymised, data will be forwarded to the research team for data analysis.

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

Confidential patient information requested

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

Cohort	Patients aged between 18 and 80, who have attended a specialist psychotherapy service. The applicants anticipate that 1000 patients will be included.
Data sources	1. Electronic patient records at Sheffield Health and Social Care NHS Foundation Trust 2. The outcomes evaluation database at Sheffield Health and Social Care NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Date of birth
Identifiers required for analysis purposes	No identifiers will be retained 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. **Members asked that a data flow diagram was provided, clarifying the "NHS Electronic records' which will be accessed. Members also queried whether primary care data would be included and whether the data source used was complete enough to provide the required information.**

The applicant provided a data flow diagram.

The applicant clarified that the NHS electronic records required will be those held by Sheffield Health & Social Care NHS Foundation Trust. Primary care data will not be accessed, and the applicants anticipated that the required information will be reported within Sheffield Health & Social Care NHS Foundation Trust secondary care clinical notes. The applicants confirmed that they expected that this data would be sufficient enough to run the proposed regression analyses.

The CAG noted a concern with step 2 in the data flow diagram. This states that 'This will include notes from the Specialist Psychotherapy Service specifically, and also notes from any other SHSC NHS Trust service that patients have accessed. This information will then be incorporated into the 'extrac_V1' spread sheet.' It was not clear whether a truly anonymised dataset would be created, which was safe to share freely with others. If there was a possibility that the dataset remained disclosive, then the dataset would need to be described as 'de-identified' throughout the dataflow, as a signal that the output continues to require protection.

2. **Patient and public involvement must be undertaken to explore the views of patients around the use of their confidential patient information. The Group suggested contacting a mental health charity, such as MIND, to facilitate this. Feedback from the patient and public involvement is to be provided to the CAG for review. Details should be provided around the format of the activity, the demographics of those involved and the information which was provided together with an overview of the feedback which was provided.**

The applicants explained that they had approached MIND, who declined to be involved as they determined that the Sheffield branch did not provide a suitable platform for conducting patient and public involvement. The applicants discussed the study with two expert-by-

experience consultants, who worked for Sheffield Health & Social Care NHS Trust. Feedback from this discussion was provided.

The applicants also planned to conduct on-going patient and public involvement during the course of the study, including presenting the study at a patient involvement group, SHSC Sun:Rise. The applicants noted that this meeting may be delayed due to the Covid-19 pandemic.

3. **A poster offering an opt out is to be displayed in the Sheffield service for a period of 4-6 weeks before data extraction takes place. The poster needs to contain information on how patients can register their dissent. Notices should also be placed on appropriate websites.**

The applicants provided a poster, to be displayed in the host service for 4-6 weeks prior to the planned extraction. This poster was refined using feedback from patient and public involvement will input from the Communications Department at (Sheffield Health & Social Care NHS Trust. The applicants also planned to use the poster content in a patient notice to be placed on the SHSC Specialist Psychotherapy Service website.

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. The dataflow diagram needs to be revised to describe the dataset as 'de-identified.'

2. Favourable opinion from a Research Ethics Committee. **Confirmed 17 January 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: **2019/20** DSPT **for Sheffield Health and Social Care NHS Foundation Trust has been reviewed as 'Standards Met'** (confirmed by email to CAG inbox on 8 March 2021).

c. 19/CAG/0047 - Development and validation of a risk assessment tool for self-harm in prisoners.

Name	Capacity
Dr Patrick Coyle	CAG Vice-Chair
Dr Liliane Field	CAG Member
Dr Rachel Knowles	CAG Member
Ms Diana Robbins	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to develop a tool that will identify the risk of repeat self-harm amongst prisoners within three months post ACCT closure. Assessment, Care in Custody and Teamwork (ACCT), is a risk management plan, which is used to collect important information for prisoners considered at risk of self-harm and suicide, to assist in reducing self-harm and suicide in prisons.

The proposed study has three elements, for the CAG is only being asked to consider the initial part in relation to the development of the tool for which routinely collected data from prison healthcare records and ACCT documentation will be used to create a statistical model to predict repeat self-harm. The second phase of the study will be a qualitative phase working with staff and prisoners on a consented basis and the third phase will involve testing the tool in a cohort of prisoners at the end of their ACCTs.

The cohort to be included within the first phase of the study will be identified from a dataset which was created in an historical study. This original dataset contains 14,111 ACCT reviews opened between 2004 and 2017 in four prisons at the North of England [HMP NewHall (females), HMP Wealstun, HMP Hull and HMP Leeds]. The dataset contains pseudonymised prison number, date the ACCT was opened and closed, the location where it was opened, reason for opening and closing the ACCT, and post-closure review date. The applicant is seeking support under the Regulations to access the wider clinical records of a sub-cohort of 1,000 patients enrolled in this previous study. The applicant will reverse the pseudonymisation

process in order to access the individual prison ID numbers of patients, to enable access to the wider patient records held within the medical record system, SystmOne, which is a known clinical records system.

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

Confidential patient information requested

Male and female adult prisoners (age 18 years old and above) that were on an ACCT following a self-harm episode (including threats of self-harm) between 2004 and 2017 in four prisons at the North of England [HMP NewHall (females), HMP Wealstun, HMP Hull and HMP Leeds, Prison categories (A to C)]. 1000 patient records would be accessed in order to establish the cohort of 750 to be included in phase one of the study.

The only item of confidential patient information required is Prison ID – the applicant has clarified that this identifier is used within the clinical records system, SystmOne, to identify individual patients. Gender and ethnicity would also be utilised in 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. **Evidence of compliance with the standard of conditions of support detailed below is required prior to any final recommendation of support coming into effect.**

Favourable opinion from the REC was given on 02 April 2020. Greater Manchester West Mental Health NHS Foundation Trust has a 19/20 DSPT reviewed as 'Standards Met' by NHS Digital, confirmed as review complete on 24 February 2021. The applicant called the CAT team to confirm this on 8 March 2021. It is understood that this DSPT covers processing at HMP Wealstun. It is noted there are amendments planned for this study, which can now be submitted.

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 02 April 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.

   Confirmed:
   The NHS Digital **19/20** DSPT review for **Greater Manchester West Mental Health NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 10 March 2021)

d. 20/CAG/0021 - Increasing cervical cancer screening uptake in Yorkshire: Testing the effectiveness of a behaviour change intervention in deprived and non-deprived populations

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Patrick Coyle	CAG Vice-Chair
Professor Lorna Fraser	CAG Member
Mr Tony Kane	CAG Member
Dr Rachel Knowles	CAG Member
Dr Harvey Marcovitch	CAG Member
Ms Caroline Watchurst	HRA Confidentiality Advisor
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application from University of Leeds set out the purpose of medical research which aims to pilot and test the effectiveness of a new low-cost behaviour change intervention to increase uptake of cervical screening in Yorkshire. This randomised controlled trial will test two interventions individually and combined; (a) Implementation intention-based intervention, (b) a motivational based intervention, (c) both these interventions combined, and (d) usual care control. The study will investigate if the intervention reduces inequality by increasing screening in low uptake groups.

Early identification of cervical cancer risk could prevent a large number of deaths. The NHS Cervical Screening Programme is the central strategy for reducing cervical cancer mortality. However, screening uptake rates are falling, particularly in women aged 25-49 years and remain low in deprived groups. The behaviour change techniques included in this intervention have been shown to effectively encourage a wide range of positive health behaviours, including medical screening. By applying these techniques to encourage cervical cancer screening uptake, this low cost intervention has three potential benefits; Increased early detection and therefore increased patient survival, Reduced inequalities – screening uptake is particularly low in areas of socioeconomic deprivation, and it is hoped that this study will help reduce these inequalities by encouraging screening in low uptake groups, and substantial cost savings for the NHS.

The cohort is 16,000 individuals living in North East and Yorkshire region, who will be sent an invitation to take part in cervical cancer screening from the National Cervical Cancer Screening programme within the next 48 hours. NHS Digital will extract a list of individuals who are due to be sent an invitation to take part in cervical cancer screening in the following 48 hours from the Cervical Screening Administration Service (CSAS) database, using the National Health Application and Infrastructure Services (NHAIS) database. NHS Digital will remove any individuals who have registered with the National Data Opt Out, along with anyone who has requested not to be invited to take part in the study (Information will be available on certain websites providing an opt out option prior to the intervention date). The remaining women will be randomised to one of the four conditions of the randomised controlled trial. A document with randomisation order will be provided by the research team to NHS Digital. NHS Digital will then provide the list of eligible participants in the format; Name, NHS number, Address including postcode, and randomised study condition, to Capita Intelligent Communications (CIC), the mailing service used by the Leeds Cervical Screening Administration Service mailing centre. The study information sheet along with the intervention materials, as described in the application will be sent by CIC to the participants, approximately 48 hours after the initial screening letter is sent from the cervical screening service.

Participants are free to decide not to take part (i.e., not to use the intervention materials) should they wish. Participants will also be able to opt out from having their uptake data used in the study,

by contacting NHS Digital. Screening uptake data will be extracted on a one-off basis at the end of the trial (16 weeks post-screening invitation) by NHS Digital, by linking the list of patients who were sent the intervention with data on cervical cancer screening uptake (using the NHAIS database, or replacement, both held at NHS Digital) using NHS number, date of birth and address. Date of birth will be modified to age group, and postcode will be modified to deprivation score by NHS Digital. All identifiers will be removed from the dataset, and NHS Digital will send the anonymised dataset to the researchers at the University of Leeds. At no stage of the research will the University of Leeds research team have access to confidential patient identifiable information. NHS Digital are acting as data processor on behalf of Public Health England, the data controller for all cervical screening data in England.

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	At the timepoint of data extraction to create the cohort; 16,000 Individuals aged 24.5-64 who are eligible for cervical cancer screening and who are due to receive a screening invitation in the following 48 hours from the National cervical cancer screening programme, located within North East and Yorkshire region. At the timepoint of receiving study information; the cohort will have received their cervical cancer screening invitation in the previous 48 hours. This data extraction is planned to take place in February or March 2021.
Data sources	1. Cervical Screening Administration Service (CSAS) through National Health Application and Infrastructure Services (NHAIS) Database (held by NHS Digital)

	2. Data on cervical cancer screening uptake; through National Health Application and Infrastructure Services (NHAIS) Database (held by NHS Digital), or the replacement database, also held at NHS Digital. There is a new database in development to replace NHAIS, support will cover either source.
Identifiers required to extract and disclose to Capita	1. Name 2. NHS number 3. Address including postcode 4. Study intervention condition
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Address including postcode 4. Study intervention condition
Identifiers required for analysis purposes	1. Study intervention condition 2. Age group (modified from date of birth) 3. Deprivation score (modified from postcode) This data will be extracted on a one-off basis, 16 weeks post screening invitation by NHS Digital, and can be considered anonymous.
Additional information	The research team at the University of Leeds will not receive any identifiable information.

Confidentiality Advisory Group advice

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

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. Please provide a favourable opinion from REC when available

Favourable opinion from the REC was provided to CAG on the 25th Match 2021.

2. **Please provide assurances from NHS Digital regarding the 19/20 DSPT submission for Capita Business Services**

Received by email to the CAG inbox on 26th February 2021.

3. **Please confirm if a pseudonym is received by the University of Leeds from NHS Digital, within one month from the date of this letter.**

The applicant provided responses on 3rd March 2021 detailing that the data will be fully anonymised and therefore no pseudonym identifiers will be included in the dataset transferred to the University of Leeds by NHS Digital. The members were content with this response.

4. **Please undertake further patient and public involvement and engagement activities with a selection of women who are eligible to be invited for cervical cancer screening, to discuss the use of confidential patient information without consent, and provide any evidence of the outcomes of these events, within one month from the date of this letter.**

The applicant has undertaken a further online survey of 100 women eligible for cervical cancer screening to better understand their opinions about using confidential patient information without consent. A summary of the outcomes of this work was provided for CAG review. The majority of women were supportive. The Members were content with this response and found the patient and public involvement work undertaken to be excellent, and very informative.

5. **Please could the notification materials displayed prior to NHS Digital sending the list of eligible people to Capita be displayed beyond the University of Leeds lab group webpage and the Yorkshire Cancer Research website, to ensure the fullest coverage possible. Please consider this and provide a response within one month from the date of this letter.**

The applicant confirmed that the link to the notification materials will be shared on the School of Psychology's University social media accounts as well as on the lab page website and Yorkshire Cancer Research website in order to ensure the fullest coverage possible. The CAG was content with this response.

6. **Please update the privacy notice with reference to Article 6(1)(e) of the General Data Protection Regulations (GDPR), and provide the updated document to the CAG within one month from the date of this letter.**

The applicant has updated the privacy notice as requested and provided the document to CAG for review. The Members were content with the updated version.

7. **Please provide an updated Patient Information Sheet with the wording *'this letter or'* removed.**

The applicant has updated the privacy notice as requested and provided the document to CAG for review. The Members were content with the updated version.

8. **Please provide confirmation that contact details for an individual at NHS Digital will be provided in order for people to opt out of the study, and that this individual will have the knowledge to process any requested opt-outs.**

The applicant confirmed that this is correct; the contact details for an individual at NHS Digital will be provided in the privacy notice and the patient information sheet. This person will keep a list of these individuals and will remove any opt outs at the same time that National Data opt out individuals are cleansed from the list of eligible participants. Prior to the study taking place, NHS Digital will be given the full information about what is involved in the study and we will ensure that the contact involved in the study has the knowledge to process any opt outs. The members were content with this explanation.

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 25 March 2021**

2. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the

'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

Confirmed:

- The NHS Digital **19/20** DSPT equivalent review for **NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 February 2021).
- The **19/20** DSPT submission for **Capita Business Services** was confirmed as 'Standards Met' by NHS Digital email to CAG inbox (received 26 February 2021).
- **University of Leeds 8E218 – SEED** does not require a DSPT for this application, as no identifiers are processed at this organisation.

e. 20/CAG/0100 - Study of lung transplant in cystic fibrosis through linkage between the UK Cystic Fibrosis Registry and the UK Cardiothoracic Transplant Registry

Name	Capacity
Dr Tony Calland MBE	CAG Chair
Dr Malcolm Booth	CAG Member
Ms Sophie Brannan	CAG Member
Mr David Evans	CAG Member
Dr Paul Mills	HRA Confidentiality Advice Service Manager

Context

Purpose of application

This application, from London School of Hygiene & Tropical Medicine, sets out the medical purpose to undertake data linkage and research into lung transplants in Cystic Fibrosis.

Cystic fibrosis (CF) is one of the most common inherited diseases and affects around 10,500 people in the UK. The most seriously affected organ in CF is the lung and people with CF experience long-term deterioration in lung function. Lung transplantation is a treatment option for people with CF who have end-stage lung disease, with the aim being to improve both quality and quantity of life.

The applicants wish to link data held within the Cystic Fibrosis Registry and NHS Blood and Transplant (Cardiothoracic Transplant Registry). Identifiers, without clinical data, from each

registry will be sent to NHS Digital to enable common pseudonyms to be generated. The pseudonymised IDs will be transferred to London School of Hygiene & Tropical Medicine from NHS Digital, as will the clinical data from each registry, where the data from each registry will be linked. The actions of Cystic Fibrosis Registry is undertaken through participant consent, whereas section 251 support will be required for the actions of NHS Blood and Transplant.

The resultant data will be used for research purposes by the team to investigate how people with CF progress along the transplant pathway from joining the waiting list to transplant and to death on the waiting list or post-transplant, the impact of lung transplantation on life expectancy for people with CF, how patient characteristics are associated with the risks and benefits of lung transplant and how patient and donor characteristics affect post-transplant outcomes.

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

Cohort	People with CF in the UK who have data recorded in the UK Cardiothoracic Transplant Registry up to and including 2019. People without CF and lung transplant donor who have data recorded in the UK Cardiothoracic Transplant Registry, upto and including 2019.
Data sources	1. NHS Blood and Transplant 2. NHS Digital
Identifiers required for linkage purposes	1. NHS Number 2. Date of Birth 3. Gender
Identifiers required for analysis purposes	1. Date of Death

Additional information	The applicants state that The Cystic Fibrosis Registry data is collected under consent, and so is not part of this support.

Confidentiality Advisory Group advice

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

1. **Clarify the size of the patient cohort from the UK Cardiothoracic Transplant Registry for which data will be processed under support.**

The applicant explained that the UK Cardiothoracic Transplant Registry contains data on approximately 9500 patients registered to either the lung or heart-and-lung transplant waiting list, 5000 recipients of a transplant involving the lungs (a subset of the 9500), and 5000 deceased donors that enabled these transplants.

The CAG were content with the response.

2. **Revise the patient notification statement to clearly detail the procedure for patients to opt out of the use of their data.**

The applicant provided a supporting document detailing a unified approach to opt out with a single point of contact. Both the UK Cystic Fibrosis Registry website and the NHSBT website will each provide a brief statement with a link to the main study website and to a specific page on "Information for individuals in the data. The opt-out text now gives step-by-step instructions on how to request for data to be removed, and what will happen after this request has been made. Patients who have given their consent to contribute their data to the UK CF Registry can withdraw at any time, but there is no precedent for allowing patients to withdraw from individual studies for which data requests have been approved by the Registry Steering Committee. Therefore, following further discussion, the Cystic Fibrosis Registry prefers not to provide a direct statement about opting out on their own website.

Members noted the updated notification statements regarding patient opt out as well as the position taken with the UK Cystic Fibrosis Registry website following discussions. No concerns were raised about this.

3. **Clarify how patient notification materials will reach the non-CF patients.**

The applicant noted that non-CF patients are included in the UK Cardiothoracic Transplant Registry and will be able to discover the study via the NHSBT website. The non-CF patients include those awaiting and receiving lung transplants for a variety of reasons and conditions. The non-CF participants are therefore a diverse group, and as such they are not easily

reached collectively via patient groups, for example. In addition to providing information on the registry websites and on the study website, the study will be made known via Twitter, with links made to NHSBT (@NHSBT) and the Cystic Fibrosis Trust (@cftrust) therefore teaching their followers.

The group raised no concerns and were content with the response.

4. **Detail how patient notification materials and opt out mechanisms for when children reach the age of majority will be addressed**

The applicant stated that the data used for this study will be a one-off and not updated over time. Therefore, for individuals whose childhood data are included, their adult data will not be included. However, these individuals may still wish for their childhood data to be removed. This is explained in the study website section on "Information for individuals in the data".

The information on opting out from the study is given in sections for adults, parents/guardians of children, and people whose childhood data may be included but who have now reached the age of majority.

The CAG were content with the 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 16 September 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.

   Confirmed:

   The NHS Digital 19/20 DSPT review for **London School of Hygiene and Tropical Medicine, NHS Digital** and **NHS Blood and Transport** was confirmed as **'Standards Met'** on the NHS Digital DSPT Tracker (checked 30 March 2021)

2. New Amendments

a. 20/CAG/0045 - An evaluation of a water fluoridation scheme in Cumbria: A population based comparative cohort study of systemic and topical fluoride exposure

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Manchester seeks to assess the effects and costs of systemic and topical exposure to water fluoridation following a reintroduced Water Fluoridation scheme on a cohort of contemporary children. The study currently has support in place to allow the disclosure of confidential patient information from research records collected by the research team at the University of Manchester to the NHS BSA for linkage to dental health data and to NHS Digital for linkage to HES.

On the original application it was stated that data for dental general anesthetics would be accessed through HES data held by NHS digital. However this data is additionally held by North Cumbria Integrated Care NHS Foundation Trust (NCIC), and the Trust have agreed to provide this data instead of NHS Digital. Therefore this amendment sought support for a change in data processor from NHS Digital to North Cumbria Integrated Care NHS Foundation Trust, and a change in data flow to allow the disclosure of confidential patient information from research records collected by the research team at the University of Manchester to North Cumbria Integrated Care NHS Foundation Trust for linkage to data for dental general anesthetics, replacing the flow of identifiers going to NHS Digital for linkage with HES, as this is no longer required.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT raised no queries regarding this amendment.

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 **19/20** DSPT review for **University of Manchester** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 February 2021) and The NHS Digital **19/20** DSPT reviews for **NHS Business Services Authority and North Cumbria Integrated Care NHS Foundation Trust** were confirmed as 'Standards Met' by email to the CAG inbox (on 26 February 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 16 February 2021

b. 20/CAG/0046 - An evaluation of a water fluoridation scheme in Cumbria: population based comparative cohort studies of topical fluoride exposure alone

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the University of Manchester seeks to assess the effects and costs of topical fluoride exposure alone following a reintroduced Water Fluoridation scheme on a cohort of contemporary children. The study currently has support in place to allow the disclosure of confidential patient information from research records collected by the research team at the University of Manchester to the NHS BSA for linkage to dental health data and to NHS Digital for linkage to HES.

On the original application it was stated that data for dental general anesthetics would be accessed through HES data held by NHS digital. However this data is additionally held by North Cumbria Integrated Care NHS Foundation Trust (NCIC), and the Trust have agreed to provide this data instead of NHS Digital. Therefore this amendment sought support for a change in data processor from NHS Digital to North Cumbria Integrated Care NHS Foundation Trust, and a change in data flow to allow the disclosure of confidential patient information from research records collected by the research team at the University of Manchester to North Cumbria Integrated Care NHS Foundation Trust for linkage to data for dental general anesthetics, replacing the flow of identifiers going to NHS Digital for linkage with HES, as this is no longer required.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The CAT raised no queries regarding this amendment.

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 **19/20** DSPT review for **University of Manchester** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 05 February 2021) and The NHS Digital **19/20** DSPT reviews for **NHS Business Services Authority and North Cumbria Integrated Care NHS Foundation Trust** were confirmed as 'Standards Met' by email to the CAG inbox (on 26 February 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 18 February 2021

c. 19/CAG/0185 - Understanding Multidisciplinary approaches and Parental Input in perinatal mortality Review

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The application currently has support in place to allow the incidental disclosure of confidential patient information to the researcher during the observation of perinatal mortality review meetings.

This amendment is to include a further Trust at which these observations will take place.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The team raised no issues with this amendment.

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:
   Newcastle upon Tyne Hospitals NHS Foundation Trust (RTD) has a confirmed 'Standards Not Fully Met (Plan Agreed) grade on DSPT submission 2019/20 (by check of NHS Digital DSPT tracker on 01 March 2021). Please note the updated specific condition of support below.

Newcastle upon Tyne 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 non-substantial by email 10 November 2020.

d. 18/CAG/0054 - Lung cancer screening study using low dose CT to support the development of blood tests for early cancer detection

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This study investigates the feasibility of introducing low dose computed tomography (LDCT) screening to a group of adults at high risk of lung cancer. The study has support to allow the research team access to GP record systems in order to identify and invite potential participants to the study. The study also has support to analyse the data of both those who attend and those who do not.

This amendment sought support for one additional external contractor to access the trial database for the purpose of system maintenance, which may lead to confidential patient information becoming visible as fixes are processed. The contractors are appointed via honorary contracts with UCL which bind these individuals to the same duty of confidence as substantive UCL staff.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, as a previous amendment request for maintenance of the trial database was considered by a Sub-Committee and supported on 14 October 2019. A second amendment considering the same issue was

supported on 17 August 2020. The CAT recognised that the maintenance of the trial database was an essential element to ensuring the supported project can successfully proceed.

It was noted that the Confidentiality Advisory Group (CAG) had already determined that the project had a medical research purpose which was strongly in the public interest. The CAT recognised that the Sub-Committee had previously determined that database maintenance was not listed as a medical purpose in its own right within section 251(12) of the NHS Act 2006, however the Group was assured that the necessary processing for this task was essential to achieving the overarching medical research purpose of the study.

The CAT understood the rationale provided and were content to provide a recommendation of support to the project.

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 – DSPT 2019/20 have been confirmed with 'Standards Met' grades for University College London Hospitals NHS Foundation Trust, University College London - School of Life and Medical Sciences, and Amazon Web Services (by check of the DSPT tracker on 05 March 2021).

   CFH Docmail Ltd has not has a 2019/20 DSPT assessed by NHS Digital, but this amendment relates to urgent software maintenance and therefore the CFH Docmail DSPT is not relevant to this amendment. The applicant is advised to request a review of the CFH Docmail Ltd 2019/20 DSPT from NHS Digital if they are still a data processor for this application.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed within the scope of existing ethical opinion

e. 20/CAG/0028 - Small Area Health Statistics Unit Research Database

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Imperial College London is a research database focusing on research of environmental health risks. Support is currently in place to allow the disclosure of confidential information to SAHSU for linkage and research purposes, from various sources.

This amendment seeks support for the addition of General Practice Extraction Service (GPES) as a data source, which is held by NHS Digital. The same identifiers as in the original support will be requested with other GPES non-identifiable data items. SAHSU will be requesting the date and the cause of death to identify individuals who have died of COVID-19, if this linkage has already been done by NHS Digital. No linkage will be undertaken with the other health datasets SAHSU currently hold in their database. SAHSU will use the GPES data to look at long term exposure to air-pollution and COVID-19 mortality and to quantify the effect of pre-existing conditions on COVID-19 mortality. The privacy notice will be amended to include the GPES data flow.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The team understood the justification for this amendment and raised no queries.

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 **19/20** DSPT review **for Imperial College - UK Small Area Health Statistics Unit** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (by email sent to the CAG inbox 10 March 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 26 February 2021**

f. 19/CAG/0136 - Acute Leukemia in Pregnancy Registry Study

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from the Hull and East Yorkshire Hospitals NHS Trust aims to establish a research database focused on women who were diagnosed with acute leukaemia or high-risk myelodysplasia in pregnancy or who have later conceived after receiving previous treatment for either condition.

This amendment sought support to extend the duration of support required until May 2022, due to delays experienced due to the Covid-19 pandemic.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment.

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 CAT team has not undertaken a check of the security assurances at each site, as the study has support for over 5 participating organisations. This is the responsibility of the applicant to ensure that these are in place.

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed non substantial 7 January 2021

g. CAG 8-06(b)/2013- National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit Programme - Secondary Care Clinical Audit

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

The National Asthma and COPD Audit Programme's secondary care audit currently has support for the collection of audit data for all admissions of adults to hospital with asthma attacks (ages 16+) and acute exacerbation of COPD (ages 35 +) in England Scotland and Wales, on a continuous basis.

The applicants sought support in this amendment for an additional exclusion criteria to be added to the COPD audit, and to include additional ICD-10 codes in the inclusion criteria for the COPD audit in order to ensure the accurate capture of all eligible patients for the COPD audit.

This amendment does not seek to change the data flows or confidential patient information collected. However, the data flow diagrams have been provided for ease of review. The inclusion and exclusion criteria for the adult asthma audit will not change and no additional patient identifiers beyond what has already been agreed will be collected for either the asthma or COPD audit.

The amendment also seeks to notify the CAG about making automated real-time reports publicly available. Currently, automated reports are available via the NACAP web tool (www.nacap.org.uk, provided by Crown Informatics Limited) which are updated every 15 minutes using the data entered by hospitals, with no input from the audit team required to generate these. Over the next two years NACAP will be working to develop this automated real time reporting capability to produce additional automated reports, and making them publicly available so that all necessary stakeholders, including patients and carers, have access to them and can work with hospitals to drive improvement and change. This element does not require additional CAG support as this is in line with the original purposes of the application, and therefore is already within the scope of the current approval. The real time reports will not contain any identifiable data.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team.

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 Secretary of State for Health and Social Care.

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 **19/20** DSPT review for **Royal College of Physicians, Imperial College London - School of Public Health Medical Trials and Research, Crown Informatics** and **NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 17 March 2021)

h. 20/CAG/0147 - Global Consortium Study of Neurological Dysfunction in COVID-19 - paediatric substudy (Short title: GCS-NeuroCOVID paediatric substudy)

Name	Capacity
Ms Caroline Watchurst	HRA Confidentiality Advisor

Context

Amendment request

This application from Birmingham Women's and Children's NHS Foundation Trust aims to quantify neurological symptoms and diagnoses in paediatric patients with confirmed or presumed COVID-19 who are admitted to hospital.

This amendment sought support to add a number of additional NHS Trusts as data processors for the application. The sites are listed in an additional document provided with this amendment. The applicant has also provided an updated protocol alongside this amendment, which includes no further changes to CAG support.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries.

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. Support is provided for occasions where confidential patient information is processed by a researcher who is not a member of the direct care team. Support under Regulation 5 is not required if this is performed by a member of the direct care team. This condition will remain for the duration of the study.

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 Trusts where patients are identified will be required to have security assurances in place. However, as there are more than five organisations, the CAT team will not check each one individually; it is the responsibility of the applicant to ensure these are in place.

3. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 March 2021**

i. 17/CAG/0050 - Educational Outcomes in Children Born after ART

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support for disclosure specified confidential patient information from NHS Digital to the Office for National Statistics to facilitate linkage with the National Pupil database. In September 2020, the applicants were given support to Add the Department for Education (DfE) as an additional data processor in order to undertake linkage of the assisted reproductive therapy (ART) database (this database has its own support under CAG reference ECC 4-03(g)/2012).

Following discussions with NHS Digital and the DfE, the applicants have submitted this amendment to clarify some details:

- The applicants are seeking to include "other name" as an additional linkage variable, alongside forename and surname. The dataset held by NHS Digital will contain this variable. It will be included in the data flow from NHS Digital to DfE but excluded from the dataset made available to the UCL research team.

- Patients' birth weight, multiple birth indicator, and maternal month & year of birth will flow from NHS Digital via the DfE (alongside the previously approved individual

identifiers to be used for linkage), for onward deposition into the ONS Secure Research Service (SRS). These are potential confounding variables, held by NHS Digital, that will be included in the final pseudonymised analysis dataset. The additional data items will be disclosed from NHS Digital to the DfE alongside the individual identifiers to be used for linkage. The DfE will subsequently include these variables, together with educational outcome data for the cohort, in the pseudonymised dataset that will flow from the DfE to the ONS-SRS for access by the UCL research team for analysis in the ONS-SRS.

- Pseudonymised fertility treatment data for the study cohort will flow from UCL to the ONS-SRS, rather than from the HFEA to the ONS-SRS as specified in the previous data flow diagram.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG agreed that the amendment was in the public interest.

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

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 – UCL School of Life and Medical Sciences Data Safe Haven, NHS Digital and the Office for National Statistics have confirmed standards met grades for 2019/20)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 12 March 2021.**

j. 20/CAG/0044 - Revision Hip and Knee Replacement: Evaluation of Clinical, Psychological and Surgical Outcomes

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow the disclosure of confidential patient information from the National Joint Registry (NJR) to NHS Digital for linkage to PROMs, HES and ONS datasets.

In this amendment, the applicants are seeking to revise the data flows, as NHS Digital have updated their internal patient linkage methodology to the Master Patient Service (MPS). Under the current support, the disclosure of confidential patient information from Northgate Public Services (NPS) to the NJR to NHS Digital for linkage to HES, PROMS and ONS datasets will form Stage 1.

However, instead of the pseudonymised dataset, including the NJR ID, being sent to the NPS, the NPS will disclose confidential patient information from the NJR to NHS Digital. NHS Digital will use these identifiers to link to the HES, PROMS and ONS datasets, and generate a cohort of patients who are not already in the NJR, and the send the complete, pseudonymised dataset directly to the University of Oxford (rather than to the NJR, who then send the dataset to the University). The NJR will also send pseudonymised joint replacement records with the Study ID directly to the University of Oxford. NHS Digital will retain the NJR identifiers until MPS is available, when the identifiers will be used to undertake a second linkage to the PROMS dataset.

Once the MPS is available for the PROMS dataset, a second stage will be added. NHS Digital will repeat the linkage to the NJR cohort, using the same identifiers used in Stage 1. NHS Digital will send two fields, the PROMS_SERIAL_NO and Study_ID to the University of Oxford as a look up table.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the NJR will be enhanced by data from HES that is missing from the NJR at resent because patient data from Trusts has not submitted to the NJR through error. The new service from NHS Digital will enable much more accurate matching of the NJR data to PROMS allowing much greater accuracy in the audit.

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: Northgate Public Services (by NHS Digital email dated 08 January 2021) and NHS Digital (by check of the NHS Digital DSPT Tracker) have confirmed 'Standards Met' grade on DSPT 2019/20).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 05 February 2021.**

k. 18/CAG/0071 - Avoiding Cardiac Toxicity in lung cancer patients treated with curative-intent radiotherapy to improve survival

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to identify suitable patients from electronic radiotherapy records held at each institution by members of the clinical care team and to disclose confidential patient information to Public Health England for linkage with the National Cancer Registration and Analysis (NCRAS) dataset.

The project was planned to end on 30/03/2020, however the COVID outbreak has severely impacted on the progress of the study. The applicants are seeking to extend the end date of the project by 18 months, to 30/11/2021.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team, who agreed that the extension was in the public interest.

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 2019/20 DSPT review for Public Health England was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (26 February 2021).

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   Confirmed 28 January 2021

I. 17/CAG/0030 - UKSAFE

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants advised that their data sharing agreement with NHS Digital is due to expire on 30 March 2021. They are seeking to extend the duration of this data sharing agreement for a further year and also require an extension to their support under s251. The additional time is required in order to make any additional changes to the analyses that have already been completed, in respect of peer reviewer comments from academic journals and external peer review comments on the NIHR final study report.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The Team agreed that the extension was in the public interest.

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 Secretary of State for Health and Social Care.

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 University of Oxford - Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Big Health Data and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 04 March 2021)

m. 20/CAG/0087 - Research database for Cambridgeshire & Peterborough NHS FT (CPFT)

Name	Capacity
Ms Kathleen Cassidy	HRA Confidentiality Advisor

Context

Amendment request

The applicants have existing support to allow Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) to link confidential patient information from the CPFT database to HES and ONS data at NHS Digital and the National Pupil Database at the Department for Education.

The existing support states that patients NHS number, name, date of birth and postcode will be used to link the CPFT data to HES and ONS at NHS Digital. NHS Digital have asked that patient name is not used, and that sex/gender is used instead to verify that the correct patients are linked.

For the linked from CPFT to the National Pupil Database, currently patient name, date of birth and postcode is used. The Department for Education have asked that sex/gender is also used, to match the standard linkage methods used by DfE.

The applicants also clarified that the postcodes used for linkage will be date-stamped, i.e. marked with start and end dates. This is because the use of postcode information for linkage requires dates for accuracy, in that people live at particular postcodes for defined periods of time.

The applicants confirmed that all identifiers are used for linkage only and will be removed from the database before researchers are allowed access.

Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The Group agreed that the changes made were in the public interest.

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 DSPT reviews for **Cambridgeshire and Peterborough NHS Foundation Trust, NHS Digital** and **Department for Education** were confirmed as **'Standards Met'** on the NHS DSPT Tracker **(checked 11 February 2021)**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **REC confirmed that review was not required on 22 February 2021.**

3. Annual Review Approvals

CAG Reference	Application Title
CAG 8-06(b)/2013	National Asthma and Chronic Obstructive Pulmonary Disease (COPD) Audit Programme (NACAP)
ECC 1-06(c)/2011	National Gastrointestinal Cancer Audit Programme (Oesophago-Gastric Cancer)
19/CAG/0154	The CANDID study: Understanding how to improve making, communicating and recording a medical (differential) diagnosis in the acute care setting through institutional, legal and ethical drivers
PIAG 1-05(j)/2007	A national population-based case-control study of the genetic, environmental and behavioural causes of breast cancer in men
PIAG 3-07(j)/2002	Long-term consequences of chronic diseases and their treatments
PIAG 1-07(d)/2004	British Regional Heart Study (men)
PIAG 4-07(h)/2002	British Regional Heart Study (men)
CAG 8-02(a)/2014	Assuring Transformation
CAG 8-02(b)/2014	Assuring Transformation
CAG 8-02(c)/2014	Assuring Transformation
CAG 9-08(e)/2014	The EPIC- Norfolk prospective population study
17/CAG/0030	Is it safe to completely disinvest in TJR follow-up or will this expose harm?
17/CAG/0033	Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis
15/CAG/0196	Tracking the impact of gestational age on health, educational and economic outcomes: a longitudinal record linkage study (TIGAR)
ECC 1-03(d)/2012	National Gastrointestinal Cancer Audit Programme (Bowel Cancer Audit)
18/CAG/0142	SEARCH:A population based study of genetic predisposition to breast, OVARIAN & endometrial cancer
19/CAG/0214	Understanding the scale and nature of avoidable harm in prison healthcare
19/CAG/0145	Transfusion Medicine Epidemiology Review

17/CAG/0174	UTMoST Study
PIAG 4-06(c)/2006	Long-term sequelae of radiation exposure from computed tomography in children and adolescents
17/CAG/0184	UK collaborative clinical audit of health care for children and young people with suspected epileptic seizures (Epilepsy12)
17/CAG/0204	CRIS Linkage with the Office for National Statistics Census Data
CAG 9-08(a)/2014	SLaM CAMHS Linkage with DfE National Pupil Database
PIAG 2-07(c)/2004	The Manchester Self-Harm Project
19/CAG/0162	Accuracy, impact and cost-effectiveness of prehospital clinical early warning scores for adults with suspected sepsis

Signed – Chair	Date
Signed – Confidentiality Advice Team	Date