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

**January 2022**

## 1. New Applications

### a. 21/CAG/0174 - Peer support Observational Ethnography – Theory in Context (POETIC) Study

| Name | Capacity |
|---|---|
| Dr Patrick Coyle | CAG vice-chair |
| Dr Katie Harron | CAG member |
| Professor Jennifer Kurinczuk | CAG member |

**Context**

**Purpose of application**

This application from the University of Nottingham set out the purpose of medical research to explore how mental health support workers integrate and work with the wider mental health team, and whether institutional logics support, compete with or conflict with peer support worker role implementation.

Peer support worker (PSW) roles are increasingly becoming an integral part of mental health systems in the United Kingdom. However, evaluations of peer support role

implementation consistently identify that organisational culture is the largest influence on the successful implementation of peer support worker roles. The study will focus on peer support workers who are employed at Nottinghamshire Healthcare NHS Foundation Trust. The co-investigator will undertake non-participant observation of peer support workers daily activities by concentrating on their interactions, behaviours, language, and dynamics with each other, other team members, and non-team members, e.g., non-NHS staff, service users, and family members, with a specific focus on understanding the peer support worker role in its context. Following this, the co-investigator will also interview a range of team members and elicit their perspectives about working alongside peer support workers and their role. In parallel, the co-investigator will also collect documents relating to the peer support worker role.

The applicants will use a qualitative and ethnographic approach to investigate how institutional logics may influence the implementation of peer support worker roles in a mental health organisation. The study will take place at two services within Nottinghamshire Healthcare NHS Foundation Trust. The applicants will observe peer support workers undertaking their daily activities, concentrating on their interactions, behaviours, language and dynamics with each other and with other team members and non-team members. The observations will be conducted for two to three days per week, with each period of observation lasting up to 6 hours. Those observed have been divided into two Groups; Group A – comprised of other NHS staff members from the same team, and Group B – comprised of anyone else, including other NHS staff not in the peer support worker's team, service users, informal carers, who may be present. The co-investigator will also conduct up to forty semi-structured interviews with participants, comprising of peer support workers and other Group A members. The applicants will also collect documents relating to the peer support worker role.

Support is sought as the observations will include observation of peer support workers encounters with each other, Group A members, and Group B members, e.g. at multi-disciplinary team meetings where all team members meet to discuss team issues, and/or PSWs discussing their day-to-day tasks with other staff members in the team office space, and/or PSWs delivering one-to-one sessions with service users. The types of conversations in the team office may include work-based discussions e.g. queries about tasks, duties, information technology-based questions, and upcoming meetings with service users. The observers may be exposed to confidential patient information during these 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.

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| **Cohort** | The cohort under investigation is peer support workers and other members of staff in the same NHS team as the peer support worker. 40 members of staff will be involved.<br><br>The confidential patient information potentially disclosed during observations will relate to service users of the two services at Nottinghamshire Healthcare NHS Foundation Trust. |
| **Data sources** | Incidental disclosures of confidential patient information may be made when the applicant observes multi-disciplinary team meetings and peer support workers undertaking their usual activities. |
| **Identifiers required for linkage purposes** | No items of confidential patient information will be retained for linkage. |
| **Identifiers required for analysis purposes** | No items of confidential patient information will be retained for 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. **A notice is to be placed on the websites for Nottinghamshire Healthcare NHS Foundation Trust and the University of Nottingham, to publicise the study. The text of these notices also needs to be provided to the CAG.**

The applicants provided the text of a notice, which would be placed on the Research into Recovery (RRT) website. The University of Nottingham, the Nottinghamshire Healthcare NHS Foundation Trust, and the Institute of Mental Health website will signpost the public to the RRT website. The RRT website provides one central resource that all potential parties are signposted to. The RRT website is partnership between the Nottinghamshire Healthcare NHS Foundation Trust and the University of Nottingham. The website notifies the public about mental health research being conducted in both the Trust and the University.

Members agreed that the notification did not sufficiently those whose confidentiality will be breached and the legal basis relied on. The CAG asked that the notification was revised to specify the patient group that will be observed and that support under Regulation 5 of the Control of Patient Information (COPI) Regulations (also known as 's251 support') has been granted.

2. **Patient and public involvement needs to be carried out with a representative group and feedback from this provided to the CAG.**

Further proportionate consultation was conducted with two members of Group B (mental health service users) and one member of Group A (mental health professional). Feedback was provided.

The CAG noted that the patient and public involvement carried out was small in scale, but proportionate to the scope of the study. Members 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 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. The notification needs to be revised to specify the patient group that will be observed and that support under Regulation 5 of the Control of Patient Information (COPI) Regulations (also known as 's251 support') has been granted. The revised notification is to be submitted within one month of the issuing of this outcome letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 13 December 2021.**
3. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information.

**Confirmed:**

The NHS Digital **2020/21** DSPT review for **the University of Nottingham** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (06 December 2021).

The NHS Digital **2020/21** DSPT review for **Nottinghamshire Healthcare NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (16 December 2021).

## b. 21/CAG/0159 - UK-REACH: United Kingdom Research Study into Ethnicity And COVID-19 outcomes in Healthcare workers

| Name | Capacity |
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| Dr Tony Calland MBE | CAG chair |
| Dr Martin Andrew | CAG member |
| Ms Sophie Brannan | CAG member |

**Context**

### Purpose of application

This application from the University of Leicester (with the controller for the activity confirmed to be the University of Leicester) sets out the purpose of the medical research which aims to examine if, how and why, ethnicity affects COVID-19 outcomes and the impact of COVID-19 on healthcare workers (HCWs). It is made up of five work packages (WP) which are briefly detailed below:

1. Work package 1: Linkage and analysis of anonymised healthcare worker regulator and human resource data to electronic healthcare records

2. Work package 2: Longitudinal consented cohort of healthcare workers

3. Work package 3: Policy analysis of the legal and ethical issues of linking HCW data to health outcomes

4. Work package 4: Qualitative study of HCWs' experiences of working during the pandemic

5. Work package 5: Stakeholder and public engagement

Only work package 1 is covered by this application. Within WP1, the primary aim is to determine whether COVID-19 diagnosis, hospitalisation and mortality rates differ between ethnic and occupational groups in HCWs. The study team will conduct both a broad analysis, encompassing all those registered as healthcare workers (HCWs) on 1 February 2020 in the UK, and a detailed sub-study analysis in those actively working during the COVID-19 pandemic, incorporating more granular ethnicity, occupation and exposure information.

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

## Confidential patient information requested

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

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| **Cohort** | Main study<br><br>All healthcare workers aged 16 yrs and over with an electronic staff record, or are registered at least one of the regulators (General Medical Council, Nursing and Midwifery Council, General Dental Council, General Pharmaceutical Council, General Optical Council, or |

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| | Health and Care Professions Council) as of 1st February 2020.<br><br>This equates to 1.5 million people.<br><br><u>HR Sub-Study</u><br><br>All healthcare workers aged 16 yrs and over with an electronic staff record, or are registered at least one of the regulators (General Medical Council, Nursing and Midwifery Council, General Dental Council, General Pharmaceutical Council, General Optical Council, or Health and Care Professions Council) as of 1st February 2020, that have worked at least one day over the course of the study period. |
| **Data sources** | <u>UK Healthcare Workers Cohort</u><br><br>1. The Department of Health and Social Care; ESR (Electronic staff records) for England and ESR (Electronic staff records) for Wales.<br><br>2. Professional registration databases i.e. General Medical Council, Nursing and Midwifery Council, General Dental Council, General Pharmaceutical Council, General Optical Council, or Health and Care Professions Council. **(This data has already been disclosed and linked, however it is still retained in identifiable format by DHCW in order for ESR data to be linked to the registrant data)**<br><br><u>Health Outcome Data from NHS Digital</u><br><br>1. GPES Data for Pandemic Planning and Research (COVID-19)<br><br>2. Covid-19 Second Generation Surveillance System (Pillar 1)<br><br>3. Covid-19 UK Non-hospital Antigen Testing Results (Pillar 2)<br><br>4. COVID-19 Hospitalization in England Surveillance System (CHESS) |

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| | 5. Hospital Episode Statistics (HES) including all patient episodes, including elective but excluding maternity, from 1st February 2018 (24 months prior to study start date) to the most recent data available. This will enable assessment and adjustment of confounding comorbidities in the analyses.<br><br>6. Emergency Care Data Set (ECDS)<br><br>7. Civil Registration (Deaths) data.<br><br>8. ICNARC – applicant to confirm.<br><br>9. Personal Demographics Service<br><br><u>Health Outcome Data from SAIL</u> **(the below has already been linked under the COPI notice, and does not require support under Regulation 5)**<br><br>1. Outpatient referrals from primary care (OPRD)<br><br>2. GP primary care (WLGP)<br><br>3. Critical care dataset (CCDS)<br><br>4. Patient Episode Database for Wales (PEDW)<br><br>5. Welsh Demographic Service (WDSD)<br><br>6. Annual District Death Extract (WDDE)<br><br>7. Intensive Care National Audit (ICNC)<br><br>8. COVID-19 Pathology Test results (PATD)<br><br>9. COVID-19 symptom tracker dataset (CVST) |
| **Identifiers required for linkage purposes** | For linkage between the regulator data:<br><br>1. Family Name<br>2. Given Name<br>3. Other Names<br>4. Gender<br>5. Date of Birth<br>6. Postcode |

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| | 7. Address lines 1-5<br><br>For linkage to the health outcome data:<br><br>1. Unique Reference (SYSTEM_ID)<br>2. Family Name<br>3. Given Name<br>4. Other Names<br>5. Gender<br>6. Date of Birth<br>7. Postcode<br>8. Address lines 1-5 |
| **Identifiers required for analysis purposes** | <u>Main study</u><br><br>1. Ethnicity<br>2. Occupation<br>3. Age<br>4. Sex<br>5. Postcode to measure socioeconomic deprivation (is this modified for analysis)? Applicant confirming<br><br><u>HR Sub-Study</u><br><br>1. Ethnicity via religious belief, country of birth, immigration status and nationality. |

**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 applicant is asked to provide specific justification as to why "public interest" is an appropriate common law legal basis to transfer English and Welsh ESR data to DHCW.**

The applicant responded to say that the transfer of data from the ESR to DHCW is strictly limited to a set of identifiers including name, address and postcode. This information is derived from the Electronic Staff Record and is not derived from a health record nor has it been produced or prepared for the purposes of providing health care.

We have been asked to set out why public interest is an appropriate common law basis for this element of transfer. No common law duty of confidence attaches to this transfer which is limited for the express purpose of producing an anonymised linkage code. In relation to the GDPR we have set out that Article 6(1)(e) applies i.e. task in the public interest in that this transfer is in furtherance of government sponsored research for the purposes of preventing COVID-19 impacts in minority ethnic health care workers who have been disproportionately impacted by the pandemic.

The CAG was content with this response.

**2. Within one month, the applicant is asked to devise a specific notification mechanism which involves GMC and NMC newsletters and which allows the applicant to opt-out.**

The applicant responded to say that both the GMC and NMC inform their registrants that their data may be used for research purposes within their privacy notices. Additionally, the NMC informed registrants of the project in their 3 December 2020 and 21 January 2021 newsletters.

The CAG was content with this response.

**3. Within one month, the applicant is asked to create a study-specific opt-out mechanism, or if this is not possible, to provide a stronger justification as to why this cannot be done.**

With reference to a study-specific opt-out mechanism, the data flows were purposefully designed so that the research team did not have access to, and therefore, were unable to identify healthcare workers, to protect their confidentiality. By creating a study-specific opt-out mechanism, the research team would need to access identifiable data as the anonymisation process will need to be reversed. Healthcare workers who have opted out via the NHS national data opt-out will not be included in the study, and registrant/ESR data that cannot be linked to healthcare records will be deleted after linkage is complete, therefore those who have opted out of via the national data opt-out will also be excluded from this study. Additionally we do not have funding for creating an opt-out system.

The CAG was content with this response.

**4. The applicant is asked to confirm that DHCW do not retain any confidential data of individuals whose health outcome data cannot be linked.**

The applicant confirmed that DHCW do not retain confidential data of individuals whose health outcome data cannot be linked, once data is linked identifiable data is deleted within 7 days. DHCW will also be deleting all further identifiable data on those individuals who can be linked as per the same process, given that the aim is not to retain identifiable data. Identifiable data for future uses will be obtained via new agreements and appropriate legal bases for future use cases.

The CAG was content with this response.

**5. The applicant is asked to provide a letter of support from the Caldicott Guardian of the data controller, or equivalent from within the information governance function.**

The applicant provided a letter from Parmjit Gill, Information Assurance Service Manager and Data Protection Officer at the University of Leicester.

The CAG was happy with this.

**6. The CAG would like confirmation as to whether data will be collected from the Personal Demographics Service whose legal entity is NHS Digital.**

NHS Digital will use the Personal Demographics Service for the purpose of linking registrant data to healthcare data. However, this is not exported to the research team or SAIL (it is retained within NHS Digital) and so the research team do not have sight of this.

The CAG accepted this.

**7. The CAG would like confirmation as to whether data is collected from ICNARC, that is its own legal entity. If this is the case, please explain how this data is linked, as it will need to be included in the scope of support.**

The research team confirmed that they would not be collecting data from ICNARC; instead, data will be collected from Hospital Episode Statistics (HES). ICNARC data is available for the Welsh population and is linked within SAIL and available as a pre-linked anonymised dataset (no data collection at identifiable level from ICNARC), the access to the data for the project is therefore managed under an approval from SAIL project 1120 which subsequently links to data sharing agreements SAIL hold separately with ICNARC.

The CAG was happy to accept this explanation.

**8. The CAG would like to know if the postcode will be modified prior to analysis of deprivation score.**

The postcode will be modified prior to analysis of deprivation data; it will be replaced with Lower Layer Super-Output Area (LSOA) at the point of linkage and Townsend Deprivation score at the point of analysis.

The CAG accepted this.

**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**

1. Support under Regulation 5 Health Service (Control of Patient Information) Regulations 2002 will come into effect automatically following expiry of the COPI notice.

2. The National Data Opt Out will apply to processing of Confidential Patient Information under Regulation 5 to datasets requested via NHS Digital.

3. Favourable opinion from REC **Received 21 October 2020**

4. 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 applicant must ensure that NHS Digital confirmation of 'standards met' for organisations processing confidential patient information (Department of Health and Social Care, Digital Health and Care Wales, NHS Digital and the SAIL Databank i.e. Swansea University) is in place once support under Regulation 5 is active.**

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

| **Name** | **Capacity** |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Dr Martin Andrew | CAG member |
| Dr Harvey Marcovitch | CAG member |

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| Ms Caroline Watchurst | HRA Confidentiality Advisor |

## Context

### Purpose of application

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

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

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

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

### Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application

form and relevant supporting documentation as this letter represents only a summary of the full detail.

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| **Cohort** | All patients who have received the CPT stem for primary THR in Nottingham University Hospitals NHS Trust<br><br>Between April 2009 and April 2020, n=2852 |
| **Data sources** | 1. Nottingham University Hospitals NHS Trust:<br>• Existing arthroplasty audit database (clinical database)<br>• Local imaging data<br><br>2. Hospital Episode Statistics (HES) – NHS Digital |
| **Identifiers required for linkage purposes** | To link to HES:<br><br>1. NHS number<br>2. Date of Birth<br>3. Postcode<br>4. Pseudonymous ID |
| **Identifiers required for analysis purposes** | 6. N/A – no confidential patient information required for analysis |
| **Additional information** | Pseudonymous ID will be added by the Trust.<br><br>Linkage key of pseudonymous ID numbers linked to NHS numbers will be kept on hospital intranet in secure folder this file will be password protected and accessible only by CI. direct care team only - no support required. |

**Confidentiality Advisory Group advice**

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

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

The applicant provided updated notification documents in line with CAG suggestions on 12 November 2021, and the CAG were content with the response.

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

An email from NHS Digital confirming that standards were met was provided to the CAG on 21 January 2022.

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

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

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

The NHS Digital **20/21** DSPT equivalent review for **NHS Digital** was confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (checked 28 October 2021). The NHS Digital **20/21** DSPT review for **Nottingham University Hospitals NHS Trust** was confirmed as '**Standards Met'** by email to the CAG inbox (21 January 2022)

## d. 21/CAG/0133 - Mortality and morbidity outcomes after aorto-vascular surgery in patients with Marfan Syndrome: A UK experience

| Name | Capacity |
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| Professor William Bernal | CAG Alternate Vice Chair |
| Dr Sandra Duggan | CAG member |
| Mr Marc Tyalor | CAG member |
| Mr Anthony Kane | CAG member |

**Context**

### Purpose of application

This application from Barts Health NHS Trust sets out the purpose of medical research that seeks to investigate the UK incidence of aorto-vascular surgery in patients with Marfan Syndrome and patients' mortality outcome one-year after surgery.

Marfan Syndrome (MFS) is a genetic disease which affects the eyes, skeleton, heart and arteries. Although MFS affects multiple organ systems, cardiovascular manifestations are the most serious and life-threatening. Approximately 80% of adults MFS patients will have a dilated aortic root by 40 years, with aortic aneurysm and dissection the leading causes of morbidity and mortality. Improvements in diagnostics and medical and surgical interventions have increased life expectancy. However, the natural history and the influence of medical or surgical interventions in the UK population are not fully described. Further, the incidence of aorto-vascular surgery in this patient group is unknown, as MFS is not routinely documented in the National Institute of Cardiovascular Outcome Research (NICOR) national cardiac surgery

dataset and, therefore, there is currently no mechanism for exploring the aorto-vascular outcomes for this patient group.

The applicants will undertake a 10-year secondary analysis of linked national data, provided from the National Institute of Cardiovascular Outcome Research (NICOR), the Office of National Statistics (ONS) and HES data from NHS Digital, in order to identify the UK incidence and outcome of aorto-vascular surgery in patients with MFS. This includes associated hospital length of stay, mortality and morbidity rates, to provide information on the burdens that the aorto-vascular manifestations may place on the MFS population.

NHS Digital will be asked to identify patients with MFS within the HES database between January 2010 and December 2019. NHS Digital will then undertake linkage to HES and ONS datasets, and transfer the dataset to Barts Heart Centre (BHC) using secure electronic transfer. Research staff at BHC will then identify MFS patients who have aorto-vascular diseases from the data received from NHS Digital. Patients' NHS number, date of birth and date of surgery will then be transferred to NICOR to be linked to surgery specific data. NICOR is hosted by Barts Health NHS Trust and support is required for the transfer of confidential patient information between departments within the same organisation. NICOR will then transfer the linked dataset back to Barts Heart Centre and linked to the mortality and morbidity data, previously supplied by NHS Digital. Confidential patient information will be deleted from the dataset once the linkage is complete.

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

## Confidential patient information requested

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

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| **Cohort** | Patients aged 18 years and over, diagnosed with Marfan Syndrome and who had aorto-vascular surgery in England and Wales between 01 January 2010 and 31 December 2019.<br><br>The applicants advised that a sample size could not be estimated, as it was unknown how many patients with MFS underwent aorto-vascular surgery. |

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| **Data sources** | 3. HES and ONS data, held by NHS Digital<br>4. The National Adult Cardiac Surgery Audit within NICOR, held by Barts Health NHS Trust |
| **Identifiers required for linkage purposes** | 3. NHS number<br>4. Date of birth<br>5. Date of surgery |
| **Identifiers required for analysis purposes** | No identifiers will be retained in the dataset used for 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.

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. **Ways of minimising the flows of confidential patient information need to be explored with NHS Digital.**

The applicants explained that this issue had been explored in depth with NHS Digital and Data Protection officers at both Barts Health and Queen Mary University of London (QMUL) prior to making the CAG application. The applicants are confident that all feasible options have been considered and that the proposed option is the best option. All parties are happy with the proposed flow after considering several different options. The CAG noted this information and raised no further queries.

2. **Further steps need to be taken to promote the study:**

    a. **Information about the study needs to be included on relevant websites.**

    b. **The feasibility of displaying posters in relevant treatment areas should be explored.**

c. **The patient notification materials, including those being developed with ADUK, need to be provided for review.**

d. **The notification needs to include information on how patients can dissent to the inclusion of their data in this specific study.**

e. **The patient notification materials, including those being developed with ADUK, need to be provided for review.**

The applicants explained that they have created a patient notification poster, in collaboration with Aortic Dissection Awareness UK (ADUK). This was reviewed with the applicants newly-form patient and public involvement group. The poster contains information about the study and details on how patients can register dissent to the inclusion of their data. A QR code was also generated for easy access to the principal investigator's contact details.

Patient associations and charities, including ADUK, Marfan Trust and The Aortic Dissection Charitable Trust (TADCT) have agreed to display the poster on their websites.

The applicants have explored the feasibility of displaying posters in treatment areas and the Society of Cardiothoracic Surgery (SCTS) have agreed to send the poster to the audit leads of each cardiac centre in England and Wales. The CAG noted this information and raised no further queries.

3. **Further patient and public involvement needs to be carried out, covering the below areas;**

a. **The patient notification documents need to be reviewed.**

b. **As study-specific dissent mechanism needs to be created and feedback sought.**

c. **Patients with MFS need to be included in the patient and public involvement.**

The applicants explained that they have carried out further patient and public involvement (PPI) and have formed a PPI group specifically for the MFS studies. The

group is composed of six MFS patients with aorto-vascular manifestations, two relatives of patients affected by MFS and aorto-vascular disease and one member of the public with a chronic condition. They have all reviewed and approved the patient notification document (via email) and have been very supportive to the study-specific dissent mechanism.

The applicants also advised that 3 out of the 15 cardiac patients originally asked for their opinions have MFS and aorto-vascular manifestations. A further 10 MFS patients with aorto-vascular manifestations (including the 6 in our PPI group) were asked for their opinion as to whether they think it is appropriate to use already existing data without patient consent for research purposes and everyone agrees to it. This means that overall, 96% (24 out of 25) have expressed their support for such work. The CAG 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 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 17 September 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 **2020/21** DSPT review for **Barts Health NHS Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (23 September 2021)

## e. 21/CAG/0175 - The POETIC Study

| Name | Capacity |
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|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Professor Jenny Kurinczuk | CAG member |
| Dr Katie Harron | CAG member |

## Context

### Purpose of application

This application from the University of Nottingham set out the purpose of medical research to explore how mental health support workers integrate and work with the wider mental health team, and whether institutional logics support, compete with or conflict with peer support worker role implementation.

Peer support worker (PSW) roles are increasingly becoming an integral part of mental health systems in the United Kingdom. However, evaluations of peer support role implementation consistently identify that organisational culture is the largest influence on the successful implementation of peer support worker roles. The study will focus on peer support workers who are employed at Nottinghamshire Healthcare NHS Foundation Trust. The co-investigator will undertake non-participant observation of peer support workers daily activities by concentrating on their interactions, behaviours, language, and dynamics with each other, other team members, and non-team members, e.g., non-NHS staff, service users, and family members, with a specific focus on understanding the peer support worker role in its context. Following this, the co-investigator will also interview a range of team members and elicit their perspectives about working alongside peer support workers and their role. In parallel, the co-investigator will also collect documents relating to the peer support worker role.

The applicants will use a qualitative and ethnographic approach to investigate how institutional logics may influence the implementation of peer support worker roles in a mental health organisation. The study will take place at two services within Nottinghamshire Healthcare NHS Foundation Trust. The applicants will observe peer support workers undertaking their daily activities, concentrating on their interactions, behaviours, language and dynamics with each other and with other team members and non-team members. The observations will be conducted for two to three days per week, with each period of observation lasting up to 6 hours. Those observed have been divided into two Groups; Group A – comprised of other NHS staff members from the same team, and Group B – comprised of anyone else, including other NHS staff not in the peer support worker's team, service users, informal carers, who may be present. The co-investigator will also conduct up to forty semi-structured interviews with participants, comprising of peer support workers and other Group A members. The applicants will also collect documents relating to the peer support worker role.

Support is sought as the observations will include observation of peer support workers encounters with each other, Group A members, and Group B members, e.g. at multi-disciplinary team meetings where all team members meet to discuss team issues, and/or PSWs discussing their day-to-day tasks with other staff members in the team office space, and/or PSWs delivering one-to-one sessions with service users. The types of conversations in the team office may include work-based discussions e.g. queries about tasks, duties, information technology-based questions, and upcoming meetings with service users. The observers may be exposed to confidential patient information during these 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** | The cohort under investigation is peer support workers and other members of staff in the same NHS team as the peer support worker. 40 members of staff will be involved.<br><br>The confidential patient information potentially disclosed during observations will relate to service users of the two services at Nottinghamshire Healthcare NHS Foundation Trust. |
| **Data sources** | Incidental disclosures of confidential patient information may be made when the applicant observes multi-disciplinary team meetings and peer support workers undertaking their usual activities. |
| **Identifiers required for linkage purposes** | No items of confidential patient information will be retained for linkage. |
| **Identifiers required for analysis purposes** | No items of confidential patient information will be retained for 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. **A notice is to be placed on the websites for Nottinghamshire Healthcare NHS Foundation Trust and the University of Nottingham, to publicise the study. The text of these notices also needs to be provided to the CAG.**

The applicants provided the text of a notice, which would be placed on the Research into Recovery (RRT) website. The University of Nottingham, the Nottinghamshire Healthcare NHS Foundation Trust, and the Institute of Mental Health website will signpost the public to the RRT website. The RRT website provides one central resource that all potential parties are signposted to. The RRT website is partnership between the Nottinghamshire Healthcare NHS Foundation Trust and the University of Nottingham. The website notifies the public about mental health research being conducted in both the Trust and the University.

Members agreed that the notification did not sufficiently those whose confidentiality will be breached and the legal basis relied on. The CAG asked that the notification was revised to specify the patient group that will be observed and that support under Regulation 5 of the Control of Patient Information (COPI) Regulations (also known as 's251 support') has been granted.

2. **Patient and public involvement needs to be carried out with a representative group and feedback from this provided to the CAG.**

Further proportionate consultation was conducted with two members of Group B (mental health service users) and one member of Group A (mental health professional). Feedback was provided.

The CAG noted that the patient and public involvement carried out was small in scale, but proportionate to the scope of the study. Members 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 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 notification needs to be revised to specify the patient group that will be observed and that support under Regulation 5 of the Control of Patient Information (COPI) Regulations (also known as 's251 support') has been granted. The revised notification is to be submitted within one month of the issuing of this outcome letter.

2. Favourable opinion from a Research Ethics Committee. **Confirmed 13 December 2021.**

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

   **Confirmed:**

   The NHS Digital **2020/21** DSPT review for **the University of Nottingham** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (06 December 2021).

   The NHS Digital **2020/21** DSPT review for **Nottinghamshire Healthcare NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (16 December 2021).

## f. 21/CAG/0176 - Organisational & Cultural issues in the maintenance of Patient Safety

| Name | Capacity |
|---|---|
| Kathleen Cassidy | Confidentiality Advisor |

**Context**

### Purpose of application

This application from the University of Nottingham set out the purpose of medical research that seeks to explore the organisational and cultural factors that contribute to effective safety management when a high secure patient is managed outside of the secure setting.

Security plays a primary role within a forensic environment, as it maintains the safety of patients, staff and the general public and allows the patient to experience the most beneficial therapeutic environment because of the reduction in risk of harm. The primary risk of security breaking down is when systems interact. System interactions includes movement between departments, from hospital to community, from prison to hospital and between hospitals. This application has been created to look at how safety is maintained when high secure patients are managed outside of the secure setting during leaves of absence, which happen to enable patients to access healthcare such as treatment at hospital, to attend court or to attend a leave trial at a medium secure hospital, to be transferred to prison, or for leave on compassionate grounds. Leave of absences (LOAs) are classed as a high-risk activity because of the absence of structural aspects of security, that is, the locks, the fences, the CCTV, the alarms and the additional staff. In addition to this, the act itself exposes or potentially exposes these patients to the public, which can present opportunities for psychological and physical harm towards the patient, general public and staff. This also risk damaging the reputation of the hospital and the confidence from the public that the hospital has ability to contain these risks. The LOAs of high-risk patients are meticulously planned, looking at both historical and dynamic risks. This activity involves multidisciplinary team planning and also working in partnership with other organisations such as Ministry of Justice, courts, police, general hospital staff and their security staff, etc. Thus, there are also different staff with roles involved in the activity, for example, the actual LOA itself is often led by a nurse with several healthcare assistants with the numbers determined by the risks that the individual patient is deemed to pose. Thus, in order for this activity to be carried out smoothly several organisational and cultural aspects need to be

considered to understand how the aspects interact in order to maintain safety. Although these activities rarely go wrong, it is important to consider this activity from a safety perspective, in order to understand how to learn from the aspects that contribute to the maintenance of safety during such activities when they work well.

The applicants will conduct interviews with staff and management from different wards and departments that are involved in the maintenance of safety during the planning and implementation of LOAs from high secure forensic hospitals. Ethnographic observations will be completed in person in the setting, this will be opportunistic in the respect of LOAs, briefings, debriefings and serious incident feedback meetings involving LOAs that take place in the data collection time frame from January 2022 to the end of December 2022. The applicants will also review current policies, protocols and procedures relating to LOAs. Reviews of incident reports will also be undertaken by the researchers. Support is sought as the applicants may be exposed to confidential patient information when undertaking ethnographic observations. No patient information will be recorded by the researchers, as the study is exploring safety management processes only.

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** | The cohort involved are staff at Broadmoor Hospital, West London NHS Trust |
| **Data sources** | 5. Interviews and observations conducted with staff at Broadmoor Hospital. |
| **Identifiers required for linkage purposes** | No patient information is required for linkage purposes. |

| | |
|---|---|
| **Identifiers required for analysis purposes** | No patient information is required for analysis purposes. |
| **Additional information** | The applicants have ticked “Name” in Q37, however have clarified that this is not be required for the study. Patient names will not be documented in field notes and will be redacted from interview data. |

**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. **Advise whether the audio recordings could be transferred by NHS mail account or by another acceptable file transfer service.**

2. **If the recordings need to be transferred physically, please advise if the recordings could be encrypted.**

The applicant advised that the transcribing would be undertaken at Broadmoor. The transcriptions will be reviewed by Dr Hafferty before it is emailed to the applicant’s secure Nottingham University email account. Personal data will be removed and the remaining data transferred with the unique identifier code. The only information transported in the locked briefcase will be the consent forms. The information was noted and accepted.

**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 January 2022**

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 2020/21 DSPT reviews for University of Nottingham and West London NHS Trust were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 07 December 2021)

## 2. New Amendments

### 18/CAG/0038 – A randomised controlled trial to evaluate invitation to community-based low dose computed tomography (LDCT) screening for lung cancer versus usual care in a targeted population at risk.

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

**Amendment request**

This study from the Leeds Teaching Hospitals NHS Trust aims to test targeted Low Dose Computed Tomography (LDCT) scans screening in community settings concentrating on deprived areas of Leeds. The intention is to randomise 55-80 year old smokers or ex-smokers to intervention or usual care groups prior to approach. The intervention group will be invited to an assessment for a Lung Health Check (including LDCT screening for high-risk people) framed as a pilot health service.

This amendment requests collaboration with the “4 in the lung run” (4ILTR) study. The 4ITLR is investigating using geo-demographic segmentation as a tool to guide approach strategies for people at risk of lung cancer. The applicants are requesting to collaborate with the 4ILTR team at the University of Nottingham in order to replicate this work in the YLST cohort, and undertake analysis of lung cancer risk by geo-demographic segmentation tool on the YLST cohort. Aggregate data for lung cancer risk distribution will be calculated and shared with the 4ILTR team. No confidential patient information will be shared with the 4ILTR team at the University of Nottingham. However, an amendment to ‘s251’ support has been requested in order to update the purposes of the YLST application.

This amendment also sought support to extract smoking codes from the primary care database at an additional earlier timepoint, in order to provide an interim assessment of the impact of a baseline round of screening with co-located smoking cessation. The YLST has existing support in place to extract participant smoking codes from GP records at the end of the study.

This amendment also sought support to allow assessment of the rates at which study participants (both intervention and control populations) have accessed smoking cessation services from One You Leeds (OYL) during the study period. ‘S251’ support is required for Reed Wellbeing (on behalf of OYL) and YLST Database in Leeds Institute for Data Analytics to disclose confidential patient information (YLST unique ID, NHS number and Date of birth from YLST and Patient name, Address, Date of birth and OYL unique ID from OYL) to NHS Digital in order for NHS Digital (as a trusted third party) to link the cohort together and provide information back to Reed Wellbeing (on behalf of OYL) - YLST unique ID and OYL unique ID only. This will determine which participants in YLST (both in the intervention and control group) have engaged with OYL over the course of the study to date. OYL would then supply pseudonymous information regarding the people followed in YLST who they saw during this time period, alongside YLST unique ID.

This amendment clarified that York Trials Unit will no longer have a role in the analysis of final outcome data following Professor Rhian Gabe’s move from the University of York to Queen Marys University of London (QMUL) in 2019. This does not impact upon the studies data flows, as analysis will be undertaken remotely through the Virtual Research Environment hosted by Leeds Institute for Data Analytics.

This amendment also clarified that the original application stated support was requested for linkages with ONS Mortality data held by NHS Digital and the National Cancer Registration and Analysis Service (NCRAS) originally held at Public Health England (PHE). This is in order to receive cause and date of death, and lung cancer diagnostic and outcome data respectively. This amendment clarifies that 's251' support is in place to disclose confidential patient information from the YLST Database in Leeds Institute for Data Analytics to NHS Digital in order to link with ONS Mortality data and NCRAS data (now retained at NHS Digital), and provide the applicant with date of death and other outcome data. The clarification was required because although this was clear in the original application, it was not explicitly stated in the original outcome letter, and it was felt clarification was required in this case.

**Confidentiality Advisory Group advice**

The amendment was considered by the CAG Chair, who was content with the changes requested, noting that most related to changes that did not involve any additional disclosures of confidential patient information arrangements, and the additional new data flows requested were acceptable.

**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**

   **Leeds Teaching Hospitals NHS Trust, University of Leeds – IRC, CFH Docmail LTD, and Reed Wellbeing Ltd, and NHS Digital have confirmed 'Standards Met' on DSPT 2020/21 (by check of DSPT tracker 13 December 2021)**

2. Confirmation of a favourable opinion from a Research Ethics Committee; **Confirmed 04 January 2022**

## 22/CAG/0004 – Mass evaluation of lateral flow immunoassays for the detection of SARS-CoV-2 antibody responses in immunosuppressed people

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

### Context

#### Amendment request

This application from Imperial College London aims to evaluate the detection of SARS-CoV-2 antibodies at a population level in immunosuppressed individuals. 's251' support is currently in place to allow the disclosure of confidential patient information (full name, address including postcode, mobile phone number and date of birth) from NHS Digital to Ipsos Mori for the purpose of inviting individuals to the study.

This amendment sought support to include transplant recipients into the study. NHS Blood and Transplant will identify 40,000 potential patients from the UK Transplant Registry. 's251' support is requested to allow NHS Blood and Transplant to disclose the NHS numbers of these patients to NHS Digital. NHS Digital will apply the national data opt out. 's251' support is also requested to allow NHS Digital to identify the contact details of these individuals, and disclose confidential patient information (full name, address including postcode, mobile phone number and date of birth) to Ipsos Mori for the purpose of inviting transplant recipients to the study.

### Confidentiality Advisory Group advice

The amendment requested was considered by Chair's Action. The Chair was content to support this amendment.

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

### Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold **Confirmed:**

   The NHS Digital **20/21** DSPT reviews for **Ipsos Mori and NHS Blood and Transplant** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (confirmed by email to CAG inbox 31 December 2021)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 06 January 2022**

## 20/CAG/0084 – PIONEER: The UK Health Data Research Hub for Acute Care

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request
This application has 's251' support to allow transfer of confidential patient information from West Midlands Ambulance NHS Trust to University Hospitals Birmingham NHS Foundation Trust to establish the PIONEER research database.

The PIONEER team have been asked by SAGE and the National Vaccine Taskforce to assess the vaccine response to hospitalised COVID, including in the wake of new variants, and to determine potential adverse outcomes requiring hospital assessment after vaccine boosters. This will require linking national vaccine data from NHS Digital for patients within the PIONEER research database.

Therefore, this amendment sought support for University Hospitals Birmingham NHS Foundation Trust to disclose confidential patient information to NHS Digital, in the form of the NHS number of patients in the PINOEER database who either presented with COVID-19 symptoms or those of an adverse reaction to the vaccine from 8th September 2020. 's251' support is also sought for NHS Digital to link to COVID-19 Vaccine status and COVID-19 Vaccine adverse reaction datasets and for the applicants to receive confidential patient information (postcode and date of birth) alongside clinical vaccination data. Once data are returned from NHS Digital, the UHB PIONEER team will link (using NHS number and Postcode) the vaccine status and any adverse reaction data back to the extracted cohort. The data will then be anonymised before it is loaded into a Trusted Research Environment (TRE) for analysis.

The applicants have provided a flow chart, and updated patient notification documents, which were presented to CAG for review.

**Confidentiality Advisory Group advice**
The amendment requested was considered by Chair's Action. The Chair considered the amendment was reasonable and was supportive of the request.

**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 **20/21** DSPT reviews for **University Hospitals Birmingham NHS Foundation Trust**, **West Midlands Ambulance Service NHS Trust** and **NHS Digital** were confirmed as '**Standards Met'** on the NHS Digital DSPT Tracker (confirmed by email to the CAG inbox 05 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed (REC considered no review required)**

## 21/CAG/0081 – neoWONDER: Neonatal Whole Population Data linkage to improving long-term health and wellbeing of preterm and sick babies

| Name | Capacity |
|---|---|
| Professor William Bernal | CAG Alternate Vice-Chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

This application from the Neonatal Data Analysis Unit (NDAU) at Imperial College London aims to improve the lifelong health and wellbeing of babies born preterm and/or with surgical conditions by linking existing data from the National Neonatal Research Database (NNRD) with routine health, educational and environmental datasets in England and Wales to evaluate the long-term impact of neonatal interventions.

This amendment sought support to clarify the linkage process regarding PICANet and CRIS datasets. Support is already in place for the disclosure of confidential patient information from NNRD, PICANet and CRIS to NHS Digital for linkage. This clarification of process is to limit transfer of information to NDAU for matched cases only rather than entire datasets. Specifically the amendment is to allow NHS Digital to disclose the PICANet and CRIS dummy study ID's that match NNRD records back to NDAU, in order for NDAU to further disclose the PICANet and CRIS dummy study ID's

back to PICANet and CRIS. This will enable PICANet and CRIS to only disclose pseudonymous data about relevant patients rather than their entire datasets.

Summary of data flow:

1) NNRD, PICANet and CRIS send NHS number, sex, date of birth, unique study ID to NHS Digital for matching **(already has 's251' support)**

Note- the study IDs will be dummy IDs generated specifically for this study versus any generic CRIS/PICANet ID number.

2) NHS Digital send back to Imperial College the study dummy IDs from PICANet and CRIS that match to NNRD records **(seeking permission in this amendment)**

3) NDAU then send back to PICANet and CRIS the respective study IDs so that they know for which cases they should send pseudonymised clinical data (without NHS number, only study IDs) back to NDAU. **(seeking permission in this amendment)**

4) PICANet and CRIS will send to Imperial College pseudonymised clinical data (without NHS number) (**already has 's251' support)**

5) NDAU will match these clinical data from PICANet and CRIS to the NNRD and transfer to ONS SRS to be linked to wider health and education data. (**already has 's251' support)**

**Confidentiality Advisory Group advice**
The amendment requested was considered by Alternative Vice-Chair's Action, who was supportive of the request, noting that this clarification was a less disclosive method than the original proposal.

**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: As there are more than 5 organisations processing confidential patient data these will not be individually checked by the CAT team, and it is the responsibility of the applicant to ensure the DSPTs for these organisations have been assessed as 'standards met' by NHS Digital**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no need to review 03 November 2021**

## 20/CAG/0122 – The Prognostic Performance of the Enhanced Liver Fibrosis Test in UK Patients with Chronic Liver Disease Assessed 20 Years After Recruitment to the EUROGOLF study (EVenti)

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |

**Context**

### Amendment request

The application provides a legal basis for the retention of the existing data held by the Royal Free London NHS Foundation Trust and to allow the disclosure of confidential patient information between NHS Digital and the Royal Free London NHS Foundation Trust for the purposes of linkage. The aim of the study is to determine the value of using the enhanced liver fibrosis test (ELF) as part of an evaluation of liver disease risk in middle life.

The original CAG outcome letter incorrectly stated that the identifiers disclosed to NHS Digital were Name, date of birth and gender. However, this was an administrative error on the part of the Confidentiality Advice Team (CAT) and should have read NHS number, date of birth and gender, as these were the identifiers requested by the applicant and considered by CAG. This is confirmed to the applicant by an email from Paul Mills in April 2021. This change has already been updated on the CAG registers.

This amendment request was requested by Paul Mills, in order to allow the applicant to additionally send Study ID to NHS Digital, which will reduce the number of identifiers flowing back to them. NHS Digital already have 's251' support in place to undertake linkage to HES, Cancer registry and ONS mortality records. However, this amendment request is to clarify additionally that NHS Number, date of birth and gender will now be removed before disclosing the data back to the applicant alongside study ID, which is less disclosive than the original proposal. 's251' support remains in place for the flow of information back, as this contains date of death, and the applicant additionally has a means to re-identify the data received from NHS Digital, by linking to the local database containing study ID.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team. No queries were raised regarding this amendment, as it is less disclosive than the original design, and 's251' support is already in place for the flow of confidential patient information between these organisations.

**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 **20/21** DSPT reviews for **Royal Free London NHS Foundation Trust and NHS Digital**

were confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 21 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 10 May 2021**

## 17/CAG/0176 – A Risk-adjusted and Anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneursyms: The UK Complex Aneurysm Study (UK-COMPASS)

| Name | Capacity |
|---|---|
| Ms Clare Sanderson | CAG Alternate Vice-Chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

This application from the Royal Liverpool and Broadgreen University Hospitals NHS Trust was supported to examine how the different treatments for abdominal aortic aneurysm compare in terms of clinical benefit and the utilisation of NHS resources. The study will link data between NHS Digital, imaging data from Trusts and the National Vascular Registry for both initial collection and follow up over a five-year period.

This amendment contains some changes that are relevant for the REC only, and are not relevant to CAG support, including an extension to the recruitment duration of the consented cohort.

The amendment to CAG sought support for the team at Liverpool University Hospitals NHS Trust to disclose study pseudonym, NHS number and date of birth (via nhs.net or letter clearly marked “Confidential Addressee only” on the envelope) to the lead consultant surgeon (direct care team) in participating external NHS Trusts, regarding approximately 1.5% of patients included in the study, for the

purposes of query resolution. The applicants will request pseudonymous information back about treatment, including;

- Date of operation (aneurysm repair)
- Exact type of operative technique utilised
- Emergency or elective nature of operation
- Complications encountered at the time of the operation, if any.

The applicants estimate the number of patients will be no more than 4 from any single NHS Trust.

The purpose of the amendment is to ensure the applicants are able to ask NHS Trusts for clarification on the nature of surgical operation when there is a discrepancy between HES data and National Vascular Registry data, to ensure the data do not have to be discarded.

**Confidentiality Advisory Group advice**
The amendment requested was considered by the Alternative Vice-Chair, who was content to recommend support for this amendment.

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

## Specific conditions of support

The following sets out the specific conditions of support.

1. Confirmation provided from the IG Delivery Team at NHS Digital to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold: **Confirmed:**

   The NHS Digital **20/21** DSPT review for **Liverpool University Hospitals NHS Foundation Trust and NHS Digital** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 13 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed 15 December 2021**

## ECC 7-05(g) 2011 -TARN (Trauma Audit and Research Network)

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

The Trauma Audit and Research Network (TARN) have existing support to retain patient NHS numbers and dates of birth to support specific activities as a national clinical audit in England and Wales. The specific activities that require these identifiers include supporting the flow of Best Practice Tariff, to assist data completeness across hospitals, and elements of outcome prediction modelling that require data linkage with ONS to obtain true 30 day patient outcomes.

NHS Wales have launched a Major Trauma Network (MTN) in South Wales. The MTN will consist of a Major Trauma Centres (MTC) which will be based in the University Hospital of Wales (UHW) alongside Trauma Units (TU) within each of the six health boards in South Wales. The network went live in September 2020.

Anonymised patient related datasets to allow the above analysis are available via the Secure Anonymised Information Linkage (SAIL) databank hosted by Swansea University in partnership with DHCW and TARN, which is separately hosted. Access to confidential patient information is required in order to link the separate datasets between these two organisations. In this amendment TARN are seeking to extend the purposes of their current support to cover the Trauma Evaluation Analysis and Research Cymru (TEAR Cymru) project which is a separate project to the previously supported Cardiff University application. This project will involve trauma data evaluation for the SWTN/Swansea University, and additional retrospective and prospective data is required to support this non-research project.

Confidential patient information will be disclosed from TARN to SAIL via DHCW, which acts as their 'Trusted Third Party (TTP) for anonymisation and encryption. The data required to perform this linkage is NHS Number, DOB and gender. DHCW will replace the commonly-recognised identifiable items (including name, address and date of birth) for each person with an encrypted code and sends this, along with minimal information (on gender, area of residence and week of birth) to SAIL.

The TEAR Cymru project will have a duration of 5 years which require quarterly refreshes of SAIL data. TARN will send 1 quarterly refresh of data to SAIL and all projects approved to use TARN data will use data from this extract. The amendment will allow TARN to provide an evidence base for public service delivery and for decisions which are likely to significantly benefit the quality of life of people in the Wales.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team, who raised no queries regarding this amendment. 's251' support was already in place for these data flows between organisations. This support is for an additional project, however the amendment is no more disclosive that the support already provided.

**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 2020/21 DSPT review for Trauma Audit and Research Network was

confirmed as ‘Standards Met’ on the NHS Digital DSPT Tracker (checked 21 January 2022)

A CPiP is in place for Digital Health and Care Wales.

## CAG 5-07(f)/2013 – National Vascular Registry

| Name | Capacity |
|---|---|
| Dr Patrick Coyle | CAG vice-chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

### Context

#### Amendment request

This audit application from the Royal College of Surgeons of England has support to establish a National Vascular Registry (NVR). Support is already in place to allow access to NHS number, date of birth and postcode.

This amendment sought support for the NVR to collect additional clinical information on patients undergoing lower limb vascular procedures in NHS hospitals, whose details are already collected in the NVR IT system. The additional data items will be collected using the Research Electronic Data Capture (REDCap) software, for the purposes of supporting NHS vascular services to undertake quality improvement (QI) activities. No additional confidential patient information will be collected, and the flows of data remain the same. There are currently 13 NHS vascular centres who have volunteered to be part of the QI initiative. These centres are all located in England. However, if successful, other vascular centres in England and Wales might enrol.

#### Confidentiality Advisory Group advice

The amendment requested was considered by the Vice-Chair. He considered that as this amendment is about collecting extra data items to assess the quality of care, in particular, to assess where delays in treatment occur, that it does not involve any extra identifiers being collected. A different interface will be used to collect data, however, no additional confidential patient information will

be collected this way. The Vice-Chair considered that this amendment will allow a very important quality issue to be assessed, and was content to recommend support.

**Confidentiality Advisory Group advice conclusion**

In line with the considerations above, the CAG agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the 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 **20/21** DSPT review for **The Royal College of Surgeons of England** was confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 18 January 2022)

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

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

This study from King's College Hospital aims to create a new dataset to aid in developing a predictive tool to estimate the degree of pregnancy-associated progression and adverse pregnancy outcomes in women with Chronic Kidney Disease (CKD), including those with rare renal disease. Two renal datasets, the National Registry of Rare Kidney Diseases (RaDaR) and the UK Renal Register (UKRR), will be linked with two pregnancy data sets, Hospital Episodes Statistics and Maternity Services Data Set, by NHS Digital. The linked data will form a new dataset.

This amendment sought support to extend the duration of the support required until 31 December 2023, due to delays experienced.

**Confidentiality Advisory Group advice**
The amendment requested was considered by the Confidentiality Advice team (CAT), 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 NHS Digital **20/21** DSPT reviews for **NHS Digital**, **King's College Hospital NHS Foundation Trust** and **The Renal Association** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed 01 November 2021**

## 18/CAG/0126 – Connected Health Cities: Data linkage of urgent care data

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

## Context

### Amendment request

The applicants have existing support to create a research database, in which routine NHS data from a number of providers of emergency and urgent care (EUC) in the Yorkshire and Humber region is collected and linked to provide a coherent picture of EUC demand in the region. The initial period was for 60 months, between 2011 and 2015, and this was extended to include records until the end of 2017. The scope of support was also extended in 2017 to include data from mental health records held by Sheffield Health and Social Care NHS Foundation Trust.

The data linkage has been completed, however the applicants are now seeking support to delay the deletion of the patient identifiers until 31 December 2022, which will allow them to undertake further data linkages, for which a separate new CAG application has been submitted (22/CAG/0019).

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team (CAT), 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 NHS Digital **20/21** DSPT reviews for **Sheffield Teaching Hospitals NHS Foundation Trust**, and **University of Sheffield School of Health and Related Research** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed non substantial 13 January 2022.**

## 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. The applicant also informed the CAG that the Chief Investigator has changed from Dr Sahra Ali to Dr David Allsup.

### 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 as part of previous amendment submission - 7 January 2021**

## 19/CAG/0013 – Cerebrovascular accident and Acute coronary syndrome and Peri-operative Outcomes Study

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

Support is in place for the disclosure of specified confidential patient information from SSNAP at King's College London and Myocardial Ischaemia National Audit Project (MINAP) from the National Cardiovascular Outcomes Research team at Bart's Health NHS Trust to NHS Digital to facilitate linkage with HES and ONS for the purpose of medical research which aims to better understand the link between poor surgical outcomes for patients who have previously suffered a heart attack or stroke.

This amendment is to amend the data sources and data flows to remove the SSNAP data, as SSNAP have been unable to take part in the project. No confidential patient information from SSNAP has been processed. The linkage has been undertaken between MINAP, HES and ONS only.

**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 NHS Digital 20/21 DSPT reviews for **University of Nottingham and NHS Digital** were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial 24 January 2022**

## 19/CAG/0164 – Investigation of gender mortality differences in children admitted to UK Paediatric Intensive Care Units

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request
This application from the University College London Great Ormond Street Institute of Child Health seeks to investigate why girls admitted to Paediatric Intensive Care Units (PICU) in England and Wales have a higher mortality rate than boys. Support is in place to allow NHS Digital to link PICAnet data to HES and ONS mortality data.

This amendment sought support to extend the duration of support until 28 February 2023, to ensure analysis is completed.

**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 NHS Digital 20/21 DSPT reviews for University of Leeds – SEED and University of Leeds – LASER (which cover PICANet), and NHS Digital were confirmed as 'Standards Met' on the NHS Digital DSPT Tracker (checked 24 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed non substantial 17 January 2022**

## 20/CAG/0020– Healthcare Usage of Bariatric/Metabolic Surgery

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

## Context

### Amendment request

This research from King's College London seeks to assess the overall long-term healthcare usage of bariatric and metabolic surgery. Support is currently in place to allow members of the research team, who are not members of the direct care team, to process confidential patient information held in patient records at King's College Hospital NHS Foundation Trust, and for the disclosure of confidential patient information from King's College Hospital NHS Foundation Trust to NHS Digital for data linkage to HES data.

This amendment sought support to extend the duration of support until 30 June 2022, to enable to the analysis to be completed.

### 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 NHS Digital **20/21** DSPT reviews for **King's College Hospital NHS Foundation Trust** and **NHS Digital** were confirmed as 'Standards Met' (by check of the DSPT tracker 24 January 2022)

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed non substantial by email 17 January 2022**

## 21/CAG/0070 – The DAMPen-D study: Improving the Detection, Assessment, Management, and Prevention of Delirium in Hospices - Co-design and feasibility study of a flexible and scalable implementation strategy to deliver guideline-adherent delirium care

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

**Amendment request**

This application aims to establish whether it is feasible to collect sufficient outcome data, explanatory process data, and cost data, in a future effectiveness evaluative study in palliative care settings. Support is in place to allow members of the research team from the University of Hull, who are not members of the direct care team, to access confidential patient information, held in paper or electronic records, for the three participating hospice sites in order to extract an anonymised dataset.

This amendment sought support for the addition of a new data processor, in the form of a fourth study site - St Catherine's Hospice, Scarborough. A letter for support from the site has been provided. This is to ensure the study collects the amount of data required, as staff shortages at the original sites is making study participation more difficult.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team (CAT), 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: Security assurances are required for the sites where processing of confidential patient information will take place. Support will be based on confirmation that the DSPT at the site will be complied with. However, as this is 5 or more organisations, these will not be individually checked by the Confidentiality Advice Team, and it is the responsibility of the applicant to ensure that appropriate security assurances are in place.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed no review required 16 December 2021**

## 21/CAG/0108 – What clinical outcomes are associated with the 'joint care' for teenagers and young adults with cancer? Short title: BRIGHTLIGHT_2021

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |
| Dr Tony Calland MBE | CAG chair |
| Dr Murat Soncul | CAG alternative vice-chair |

**Context**

### Amendment request

This application from University College London Hospital NHS Foundation Trust (UCLH) aims to administer patient surveys to help determine if there are clinically significant differences in outcomes in 2021 for teenagers and young adults (TYA) with cancer receiving 'joint care' compared to all or no care in a teenagers and young adults Principal Treatment Centre (TYA-PTC).

Support is currently in place to allow the disclosure of confidential patient information from participating NHS Trust teenage and young adult multidisciplinary teams (TYA MDT) to Quality Health to enable a patient survey to be distributed, and also for Quality Health to disclose survey data linked to identifiable information for all invitees, to NHS Digital, in order to link to National Cancer Registration and Analysis Service (NCRAS) data, and provide applicants with a pseudonymised dataset for analysis. This supported data flow is regarding English patients and Trusts. The original application specified an additional data flow for Welsh sites would be included, and this amendment is to clarify the Welsh data collection.

This amendment sought support to include the University Hospital of Wales Cardiff as an additional participating site. This site is the only Principal Treatment Centre in Wales, so applicants will be able to include most of the teenage and young adult cancer patient in Wales. The data flow for Welsh patients is the same for the first part – so support is required for the disclosure of confidential patient information from the University Hospital of Wales Cardiff to Quality Health to enable a patient survey to be distributed. However, the next step includes an additional data processor for Welsh sites. Support is also requested for Quality Health to disclose survey data linked to identifiable information for all invitees, to Welsh Cancer Intelligence and Surveillance (WCISU) in order to link to the Welsh cancer registry data, which already includes PEDW data, and provide applicants with a pseudonymised dataset for analysis.

This amendment also sought support to allow Quality Health to apply an additional check of the national data opt-out prior to sending out questionnaires, as not all Trusts yet have the capability to apply the national data opt-out, and the applicants wish to be sure that no questionnaire is sent out to somebody who has registered a national data opt-out. This is in addition to the local opt-out methodology agreed in the original CAG application, and in addition to individual Trusts applying the national data opt-out, where they are able. The applicant confirmed that the local opt-out options would still apply at each site (as agreed in CAG outcome letter), and therefore if a person opted out of this study only, the dissent options described to CAG would still stand, and their data would not be sent to Quality Health. If the Trust is able to apply the national data opt-out prior to sending to Quality Health this would also still be done. The amendment is to ensure a secondary layer of ensuring the national data opt-out is applied prior to sending out the letters, as the national data opt-out is not yet fully operational in every Trust.

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Chair and the Alternative Vice-Chair. The Chairs were content to recommend support for the addition of a Welsh site, as this

is acceptable and indeed something that was expected. In relation to the additional National Data Opt-Out check undertaken by Quality Health, the Chairs commented that this is the ideal process in addition to Trust's checking their local opt-outs, and were content to recommend support. The Chair commented that because the National Data Opt-Out is not yet fully operational in all Trusts (due to a delay triggered by Covid-19) the applicants wish to have a "belt and braces" approach to ensure that no patient who has opted out is sent a questionnaire. The Chair considered this to be a very reasonable and sensible option.

**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:**

   Due to the number of organisations involved it is the responsibility of University College London Hospitals NHS Foundation Trust as controller, to ensure that all organisations processing confidential patient information without consent meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised about a practice. This will not be individually checked by the Confidentiality Advice Team (CAT), as there are more than 5 organisations involved.

   Regarding Welsh security assurances – Caldicott Principles into Practice Outturn reports (CPiP)s are in place for both the Welsh Cancer Intelligence and Surveillance (WICSU) – covered by Public health Wales NHS Trust, and University Hospital of Wales Cardiff – covered by Cardiff and Vale, confirmed 16 December 2021.

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 21 January 2022**

## 19/CAG/0119 – MATTS (Major Trauma Triage Tool Study)

| Name | Capacity |
|---|---|
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

**Context**

### Amendment request

This study aims to develop a new and more accurate triage tool to be used by paramedics when assessing patients for signs of major trauma. Support is currently in place to allow access to confidential patient information included in patient medical records onsite at participating ambulance and hospital trusts by research paramedics to facilitate linkage and extract pseudonymised data for analysis.

The original CAG fully supported outcome outlines support for the data collection for phase 3 of the MATTS project. However at the time point 's251' support was initially provided, only the timeframe for the cohort in phase 2 data collection was confirmed. The phase 2 cohort was defined as;

*Patients of any age who are attended by Emergency Medical Services (EMS) following non-trivial injury within a participating trauma network across the following ambulance services, between November 2019 and February 2020.*

The cohort timeframe for phase 3 data collection was not confirmed in the original letter of support, as the applicant did not yet know when this data would be collected.

This amendment is to confirm that the timeframe for the cohort in phase 3 data collection will be between 1st October 2021 and 31st May 2022, and therefore the patient cohort for phase 3 is defined as;

*Patients of any age who are attended by Emergency Medical Services (EMS) following non-trivial injury within a participating trauma network across the following ambulance services, between 1 October 2021 and 31st May 2022.*

**Confidentiality Advisory Group advice**

The amendment requested was considered by the Confidentiality Advice Team, as the CAG have already supported the data collection for phase 3 as part of the initial

application. This amendment is to clarify the timeframe for the data collection for phase 3. No queries were raised as part of 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: **Not checked due to the number of sites involved in the study. Support is recommended on the basis that it is the applicant's responsibility to ensure that the required security assurance standards have been met at each site prior to processing any confidential patient information with support under the Regulations.**

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 17 January 2022**

## 3. Annual Review Approvals

| | |
|---|---|
| 18/CAG/0064 | National Bone and Joint Infection Registry |
| 14/CAG/1043 | SOCCER |
| PIAG 4-07(j)/2002 | Multicentre randomised controlled trial of 'once only' flexible sigmoidoscopy in prevention of colorectal cancer morbidity and mortality |
| PIAG 3-04(FT3)/2006 | Population Flexible Sigmoidoscopy Screening - Demonstration of a high uptake nurse-led programme. |
| 19/CAG/0012 | Long term outcomes in Hirschsprungs Anorectal Malformations |
| 17/CAG/0075 | Incidence of JSLE in CYP and their Access to Care in the UK and ROI |

| | |
|---|---|
| PIAG 4-08 (d)/2003 | National Confidential Inquiry into Suicide and Homicide by People with Mental Illness |
| 19/CAG/0220 | Linked de-identified research database for congenital anomaly outcomes |
| 19/CAG/0060 | Lancashire ANCA vasculitis and Glomerulonephritis study |
| 19/CAG/0002 | Outcome of resuscitated term babies with no heart rate at 10 minutes |
| 20/CAG/0084 | PIONEER |
| 20/CAG/0127 | Oxford Vascular Study |
| 16/CAG/0153 | The UK Renal Registry |
| 17/CAG/0020 | Clinical & biological factors associated with relapsed neuroblastoma |
| 19/CAG/0013 | CAPO Study |
| 19/CAG/0023 | Naevoid Melanoma |
| 14/CAG/1018 | CEMARC |
| 17/CAG/0174 | Risk-benefit and costs of UKR compared to TKR |
| PIAG 1-07(d)/2004 | British Regional Heart Study (men) |
| PIAG 4-07(h)/2002 | ONS Longitudinal Study |
| 19/CAG/0191 | Glucocorticoid induced adrenal suppression in the UK & Ireland |
| 20/CAG/0157 | The Oxford Risk Factors And Non-invasive imaging Study |
| 16/CAG/0024 | ADDITION - 10 year follow up (IRAS ID160001) |
| 16/CAG/0026 | ADDITION Plus 10 Year Follow Up (IRAS ID 173399) |
| 19/CAG/0150 | T1D vascular complications |
| 19/CAG/0127 | CRIS Linkage with the HIV and AIDS Reporting System |

| | |
|---|---|
| ECC 1-06(c)/2011 | National Gastrointestinal Cancer Audit Programme (Oesophago-Gastric Cancer) |
| 19/CAG/0008 | TriStar ovarian cancer project (version 1) |
| 17/CAG/0055 | CRIS Linkage with DWP Employment and Benefits Data |
| PIAG 4-06(c)/2006 | Long term sequlae of radiation exposure from computed tomography in children and adolescents. |
| 19/CAG/0198 | Evaluation of aid to diagnosis for DDH in general practice, Version 1 |
| 20/CAG/0101 | Fish and Chips |
| 17/CAG/0153 | NICOR CtE Registries |
| 19/CAG/0145 | Transfusion Medicine Epidemiology Review (CR9/2014) |
| 20/CAG/0063 | A population-based comprehensive lymphoma registry |
| 20/CAG/0104 | POST-BOX (Workpackage 1) |
| 20/CAG/0111 | Under 16 Cancer Patient Experience Survey |

| | | |
|---|---|---|
| Signed – Chair | | Date |
| | | |
| *Minutes signed off as accurate by CAG Chair Dr Tony Calland MBE, Vice Chair Dr Patrick Coyle, and Alternate Vice Chairs Ms Clare Sanderson, Professor William Bernal and Dr Murat Soncul* | | *04th April 2022* |
| | | |
| Signed – Confidentiality Advice Team | | Date |
| *Caroline Watchurst Confidentiality Advisor* | | *28th March 2022* |