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

**January 2021**

## 1. New Applications

### a. 20/CAG/0157 - The Oxford Risk Factors And Non-invasive imaging Study: ORFAN

| Name | Capacity |
|---|---|
| Ms Clare Sanderson | CAG Alternative Vice-Chair |
| Professor Barry Evans | CAG Member |
| Mr Tony Kane | CAG Member |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |

## Context

### Purpose of application

This application from the University of Oxford set out the purpose of medical research which aims to develop and validate novel imaging biomarkers to predict future heart attacks and other cardiovascular complications. This is a multi-arm study, with arm 4 only relevant to this application. Following the COVID-19 pandemic, the ORFAN study will additionally ascertain COVID-19 status (suspected or confirmed). The influence of COVID-19 infection on the outcome measures of the study will be explored.

Obesity is a known risk factor for cardiovascular disease (CVD). Body fat accumulation is associated with increased metabolic risk and it is now recognised that not only body fat quantity but also adipose tissue (AT) quality determines increased CVD risk. CT scans provide a reliable, accurate and non-invasive way to assess body adiposity. Increased volume of AT as measured by CT is independently associated with increased CVD risk in large clinical cohorts; similarly, increased epicardial AT volume is an independent predictor of cardiovascular event in subjects undergoing coronary CTA. Developing imaging biomarkers for assessing body adiposity could potentially provide a useful screening tool for the primary or secondary prevention of CVD.

A substantial proportion of Covid-19 patients have suffered adverse cardiovascular outcomes. If applicants can identify patients at risk for rapid deterioration during acute Covid-19 infection by quantifying the background vascular inflammation and the tendency of micro-thromboses, this will enable deployment of appropriate therapeutic measures (e.g. anticoagulation) and guide allocation of NHS resources.

NHS Trust direct care teams will identify retrospective patients with eligible scans. They are assigned a unique study ID, and the minimum required identifiers extracted alongside this ID are sent to;

NHS Digital, for the purposes of linkage with HES, ONS, and other datasets as detailed below, including the emergency care dataset, medicines dispensed in primary care, and covid-19 hospitalisations,

Barts Health NHS Trust, on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR), for the purposes of linkage with clinical outcomes, such as heart attack

Kings College London, on behalf of the Sentinel Stroke National Audit Programme (SSNAP), for the purposes of linkage with clinical outcomes, such as stroke,

Participating NIHR Biomedical Research Centres (BRC's) for the purposes of linking with baseline clinical data extracted from the Electronic Patient record (EPR) of associated participating trust.

The above parties will perform the data linkage, will modify date of birth and date of death and will delete identifiable data, with only the unique study ID remaining. The linked datasets will be sent to the ORFAN study team, at University of Oxford. The third parties that

performed the data linkage will keep the linkage file for 10 years to update the relevant outcomes on an annual basis, to avoid individual NHS Trusts having to send identifiers to the third parties multiple times.

The scans are pseudonymised with the unique study ID by the direct care team and securely sent to University of Oxford. The direct care team will also screen electronic health records for health outcomes. Participating trusts also send health outcomes alongside the unique study ID to the ORFAN study team, at university of Oxford. The ORFAN team will link the datasets received from NHS Digital, NICOR, SSNAP and the NIHR BRCs, with the clinical data including the scans from the participating Trusts.

75,000 retrospective patients data will be collected over a 2 year period from when CAG support is provided. The data collected will span different time points as each participating Trust, as they commenced CT services at different times. However no patient with a scan prior to 2010 will be included.

A recommendation for class 1, 4 & 6 support was requested to cover 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** | 75,000 retrospective patients in the UK (England and wales only for the purposes of CAG) who have undergone clinical CTA's or unenhanced CT chest, abdomen and pelvis scans at participating NHS Trusts.<br><br>The timescale for inclusion in the ORFAN study Arm 4 is different for each collaborating NHS Trust, however no patient with a scan before 2010 will be included in the study.<br><br>Inclusion criteria detailed in the application |
| **Data sources** | 1. NHS Digital; (HES, ONS, Medicines dispensed in primary care, Emergency care dataset, Covid-19 hospitalisations – datasets as detailed below)<br>a. Hospital Episode Statistics (HES) – Accident and Emergency dataset |

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|---|---|
| | b. HES – Admitted patient care dataset<br>c. HES - Outpatients<br>d. HES – Critical care<br>e. Emergency Care Data Set (ECDS)<br>f. Medicines dispensed in Primary Care (NHSBSA data)<br>g. Civil Registration (Deaths) - Secondary Care Cut<br>h. COVID-19 Hospitalization in England Surveillance System<br>i. HES:Civil Registration (Deaths) bridge<br><br>HQIP is the data controller for the below datasets, however the legal entity where identifiers are sent are;<br><br>2. Barts Health NHS Trust (on behalf of the National Institute for Cardiovascular Outcomes Research (NICOR)<br><br>3. Kings College London, on behalf of the Sentinel Stroke National Audit Programme (SSNAP)<br><br>4. NHS Trusts participating – PACS radiology systems and electronic patient records at;<br>• Oxford University Hospitals<br>• Royal United Hospitals Bath<br>• Milton Keynes University Hospital<br>• University Hospitals of Leicester<br>• Barts Health<br>• Royal Brompton and Harefield<br>• Leeds Teaching Hospitals<br>• Royal Papworth Hospital<br>• Cambridge University Hospitals<br>• Guy's and St Thomas' NHS Foundation Trust<br>• New Cross Hospital<br>• Royal Wolverhampton NHS Trust<br>• Sandwell & West Birmingham Hospitals<br>• Queen Elizabeth Hospital Birmingham<br>• University Hospitals Birmingham NHS Foundation Trust<br>• University Hospital of Manchester Foundation Trust |

| | |
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| | 5. NIHR Biomedical Research Centres (BRCs) that operate at Trusts with collaborating clinical teams – data extracted from electronic patient record (EPR) of the associated local trust<br>• Oxford<br>• Royal Brompton and Harefield<br>• Leicester<br>• Leeds<br>• Cambridge<br>• Barts |
| **Identifiers required for linkage purposes**<br><br>**Minimum required as confirmed with each data processor** | **NHS Digital**<br>1) NHS Number<br>2) Date of birth<br>3) Postcode (if NHS Number is not available)<br>4) Name (if NHS Number is not available)<br><br>**NICOR**<br>1) NHS Number<br>2) Date of birth<br>3) Postcode<br><br>**SSNAP**<br>1) NHS Number<br>2) Date of birth<br>3) Postcode (if NHS Number is not available)<br>4) Name (if NHS Number is not available)<br><br>**NIHR BRCs**<br>1) NHS Number<br>2) Date of birth<br>3) Local hospital number (MRN)<br>4) Date of relevant CT scan |
| **Identifiers required for analysis purposes** | 1. Ethnicity<br>2. Unique study ID<br>3. Covid-19 status<br>4. Gender<br>5. Date of death in the following format MM/YYYY.<br>6. Date of birth in the following format MM/YYYY |

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| | This dataset can be considered anonymous as the applicants will not be able to re-identify any patient. |
| **Additional information** | The third party that performed the data linkage will keep linkage files to enable yearly outcome updates for 10 years. |

## 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 the Confidentiality Advice Team.

1. **Please provide REC Favourable Opinion regarding substantial amendment 6.**

The applicant provided the REC Favourable Opinion to the CAG on 07 January 2021.

## 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. Favourable opinion from REC. This application is relevant to substantial amendment 6 - **Favourable Opinion Confirmed 05 January 2021**

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

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

## b. 20/CAG/0113 - Heart Protection Study Long-term Follow-up: A randomised study of the effects on mortality and morbidity of HMG CoA reductase inhibitors and of antioxidant vitamins in a wide range of people at high risk of coronary heart disease.

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Dr Martin Andrew | CAG Member |
| Ms Sophie Brannan | CAG Member |
| Ms Diana Robbins | CAG Member |
| Dr Paul Mills | HRA Confidentiality Advice Service Manager |

### Context

### Purpose of application

This application from the University of Oxford set out the purpose of medical research that seeks to assess the very long-term effects of around 5 years statin treatment and the very long-term effects of around 5 years use of antioxidant vitamin supplements.

The Heart Protection Study (HPS) was a large randomised controlled trial, which ran between 1994 and 1997. 20,536 individuals at increased risk of coronary heart disease were randomised to receive 40mg simvastatin daily versus a matching placebo, and to an anti-oxidant vitamin supplementation with vitamins E, C and beta-carotene versus placebo. Participants took trial medications for an average 5 years scheduled treatment period and the main trial closed in 2001. The aim was to study the overall effects on survival by preventing heart attacks, strokes and other major vascular events. The results of this trial showed that allocation to cholesterol-lowering therapy with simvastatin was associated with

a 20% reduction in the risk of heart attack and stroke, and a reduction in all-cause mortality. Statins are now commonly prescribed to patients.

Annual questionnaires were sent to participants between 2001-2007. This follow-up was supplemented with cause-specific mortality data from HES and ONS, and incident cancers via the national cancer registries. Post-trial follow-up showed that the reductions seen in heart attacks, strokes and vascular death associated with allocation to simvastatin were maintained during this 5-year period. This suggests that longer statin use would result in greater absolute benefits and supports the early initiation and long-term continuation of lipid-lowering therapy in those at increased vascular risk. Concerns about the long-term safety of use of lipid-lowering therapy persist amongst the public. The applicants are now seeking to conduct a long-term follow-up of surviving patients from HPS via central registries and routine health records in order to gather evidence of the long-term safety of lipid-lowering therapy.

Data from participants in HPS will be linked to their electronic health records and other routinely collected health data from NHS Digital and NHS Wales Informatics Service. This will include HES data, mental health data, cancer and mortality data. Data requested will also include fact and cause of death. Other data requested may include deceased participants due to data lag with some datasets e.g. cancers. Data previously collected from deceased participants will be retained. NHS Digital and NHS Wales Informatics Service will return the data in a pseudonymised format, using trial ID number, and all datasets will be linked within Nuffield Department of Population Health (NDPH), University of Oxford.

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

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|---|---|
| **Cohort** | 20,536 patients enrolled in the HPS main trial. The last NHS Digital linkage in 2016 linked 18,715 records. |
| **Data sources** | 1. HPS records held by the University of Oxford<br>2. HES, Admitted Patient Care (APC), Emergency Care Dataset (ECDS), Critical Care (CC), Outpatients (OP), cancer registrations, mental health and death statistics, held by NHS Digital<br>3. Patient Episode Database for Wales (PEDW) held by NHS Wales Informatics Service (NWIS) |

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| **Identifiers required for linkage purposes** | 1. Name<br>2. NHS Number<br>3. Date of birth<br>4. Date of death<br>5. Postcode – district level<br>6. Gender<br>7. Cancer Type<br>8. Cancer Behaviour<br>9. ICD code<br>10. Place of death<br>11. Place of birth<br>12. Occupation<br>Event data |
| **Identifiers required for analysis purposes** | No identifiers 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.

**Clarify whether cancer registry data is being requested from NHS Digital or Public Health England.**
The applicants confirmed that the data originates from PHE but is disseminated through NHS Digital. Members were content with this.

**Provide further information on the planned used of the data in the near future, and whether there is any consideration to set up a research database in the future.**
It was clarified that the data will be combined with the existing Heart Protection Study database. The applicants noted that patient cohort is a valuable resource for prospective observational analyses and they may pool data from several studies to allow reliable analyses.

Whilst the sub-committee were content with this, members also remind the applicants that confidential patient information processed under this legal support is for a specific purpose, as outlined in the application. Where there are additional uses (and therefore purposes) of this information the applicants may be required to submit future amendments or new applications. A condition of support has been added to confirm this.

**Provide clarity on the exit strategy for using confidential patient information without consent, as well as an expected end date.**
The applicants confirmed intentions to retain pseudo-anonymised information for 15 years, with the linkage key held by NHS Digital. The applicants anticipate further data will be requested from NSH Digital over this time period.

Members were content with this response.

**Update the privacy notice to make clear, in the opt out section, all methods that participants may contact the study team.**
The privacy notice was updated as requested by the CAG, and no further concerns were raised.

**Update the lay summary notification to:**

a. **Review and make it more user friendly and succinct**

b. **Be clear that the study will collect information on mental health (specifically dementia)**

A revised lay summary has been provided by the applicants. Members agreed that, whilst relatively long, it does clearly cover all key points, and addresses the requests of the CAG. No further concerns were raised.

**Explore the possibility of displaying the lay summary on other websites (for example the British Heart Foundation) and feedback to the CAG where else the notification can be displayed (or justification why it cannot).**
The applicants will approach the British Heart Foundation to enquire about the lay summary being posted on their website, or linking to the study website. The applicants also advised that the other funders websites are less public facing and less appropriate to post the notification on.

Members were content with this approach and no further concerns were raised.

**Prior to using the data for future research undertake project specific patient and public involvement for the future research.**
The applicants confirmed that patient and public involvement will be undertaken prior to using the data for future research

**It is advised that the applicants consider adding further notification on the use of blood samples to their study website**
It was confirmed that the study website is being updated and this will be considered as part of the update.

## 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. A separate application for support should be submitted if the applicants will use this data to set up a research database.
2. Where the confidential patient information collected under this legal support (as outlined in the application) is used for a different purpose, the applicants should consider whether an amendment or new application is necessary.
3. Favourable opinion from REC **Confirmed 19 July 2019**
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 NHS Digital 19/20 DSPT review for NHS Digital and University of Oxford - Medical Sciences Division - Nuffield Department of Population Health was confirmed as 'Standards Met' on the NHS DSPT Tracker (checked 22 October 2020).**
5. **The CPiP for NHS Wales Informatics Service was received and is satisfactory.**

# 2. New Amendments

## a. 14/CAG/1012 – Critical Care Health Informatics Collaborative

| Name | Capacity |
|---|---|
| Dr Patrick Coyle | CAG Vice Chair |
| Ms Caroline Watchurst | HRA Confidentiality Advisor |

### Context

### Amendment request

This study is a research database including clinical, laboratory and demographic data in relation to all patients admitted to Adult Critical Care Units across multiple NHS Trusts. Support is currently in place to allow access to data from hospital systems and for linkage with Hospital Episode Statistics (HES) data held by NHS Digital.

This amendment sought support for the inclusion of a further participating site, Manchester University NHS Foundation Trust. The amendment also sought support to extend the data collection from the beginning of hospital admission to the end, instead of only the critical care admission. This amendment will increase the generalisability of the data and increase the understanding of the antecedents and consequences of critical illness. The target population is unchanged.

The applicant has also provided updated patient notification materials alongside this amendment.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Vice-Chair, who was content to recommend support for this amendment. The justification for including clinical data from before and after the patients enter critical care was accepted. It was commented that as the patient group is the same, this amendment will not make the data any more disclosive and adding data from another hospital from a different area using the same methods will enhance the research possibilities.

### 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: University College London – School of Life and Medical Sciences has confirmed 'Standards Met' assurance on DSPT 2019/20 (**by check of NHS Digital DSPT Tracker on 16 December 2020)

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed 16 December 2020**

# b. 20/CAG/0145 – 2020 Children and Young People's Patient Experience Survey

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

### Context

## Amendment request

The applicants have existing support to undertake the Children and Young People's Patient Experience Survey 2020. In the original application, the sampling period was described as including people aged between 15 days and 15 years who were admitted as inpatients, day-cases and emergencies to an acute hospital and discharged between 1st November and 31st December 2020.

The applicants are seeking to revise the sampling period to People aged between 15 days and 15 years who were admitted as inpatients, day-cases and emergencies to an acute hospital and discharged between 1st November 2020 and 31st January 2021.

The applicants had determined that this extension was required as, after carrying out extensive analysis and modelling of the reduction in children and young people's hospital admissions due to COVID-19 in November 2020 and the expected reduction in admissions in December 2020, it was anticipated that that far fewer trusts are likely to be able to draw full samples of 1250 than for the previous survey of this kind in 2018 and nearly five times as many trusts will not be able to draw the minimum number of 400. The applicants hoped that extending the sampling period would help to mitigate against the impact of reduced admissions to hospital.

The applicants also sought to include each sampled patient's 'month of birth' in the sample file, as well as 'year of birth' as specified in the original application. The sample file is used to link demographic data to the survey responses, to aid analysis and to enable checks to be carried out for any errors in how the sample was drawn. The month of birth data will be used to aid trusts, contractors and the Survey Co-ordination Centre for Existing Methods in determining whether patients are eligible for inclusion when drawing the sample and which age specific questionnaire should be sent to each patient.

### Confidentiality Advisory Group advice

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

### Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAT agreed that the minimum criteria under the Regulations appeared to have been met for this amendment, and therefore advised recommending support to the Secretary of State for Health and Social Care.

## Specific conditions of support

The following sets out the specific conditions of support.

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

- **Confirmed – Picker Institute Europe has a confirmed 'Standards Met' grades on DSPT 2019/20 (by NHS Digital email dated 31 December 2020).**

- **Confirmed – Patient Perspective has a confirmed 'Standards Met' grades on DSPT 2019/20 (by check of the NHS Digital DSPT tracker on 06 January 2021).**
- **Confirmed - Quality Health has a confirmed 'Standards Met' grades on DSPT 2019/20 (by NHS Digital email dated 11 January 2021).**

## c. 18/CAG/0159– Housing, family and environmental risk factors for hospital admissions in children

| Name | Capacity |
|---|---|
| Dr Tony Calland MBE | CAG Chair |
| Ms Kathleen Cassidy | HRA Confidentiality Advisor |

### Context

### Amendment request

The applicants are seeking support to revise the data flows involved in the linkage of the existing mother-baby birth cohort to longitudinal environmental data. It had been planned that University College London would provide the longitudinal environmental exposure data to NHS Digital who would link them to postcode histories in the PDS. The flow had been changed following discussions with NHS Digital and ONS.

The linkage will now be conducted as follows:

- ONS will extract the identifiers (NHS number, baby sex, date of birth, postcode at birth/delivery) and Study ID from the birth cohort identifier file.
- ONS will securely transfer these identifiers for mothers and babies in the birth cohort to NHS Digital.
- NHS Digital will link the mother & baby identifiers to PDS and extract longitudinal postcode histories and time stamps (date of change of address on PDS). NHS Digital will also extract some further variables, including whether a mother or baby has deregistered from PDS (and if so when – these are required for accurate follow up calculation).
- NHS Digital will return cohort Study ID, postcode histories and the other PDS variables to ONS, who will put the data in the ONS Secure Research Service (SRS).
- UCL will upload the postcode level data on environmental exposures (air pollution, building characteristics and tobacco expenditure) to ONS SRS.
- UCL will link the Mother-baby postcode histories to the postcode-level environmental exposure data in the SRS.

- Following linkage, UCL will delete the actual postcode histories for mothers and babies. Only Study IDs, longitudinal air pollution, tobacco expenditure and building exposure histories, and time stamps, plus the additional PDS variables (these are dates of deregistration from the PDS) will be retained and linked to the main mother baby cohort using the study ID.
- UCL proposes that the postcode histories are deleted as soon as possible after linkage to environmental data has been completed and checked. The applicants expect this process to take around 3 months.

### Confidentiality Advisory Group advice

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

### Confidentiality Advisory Group advice conclusion

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** the Office for National Statistics has confirmed 'Standards Met' grade on DSPT submission 2019/20 (by check of the NHS Digital DSPT tracker on 16 December 2020), University College London – School of Life and Medical Sciences has confirmed the equivalent of 'Standards Met' grade on DSPT submission 2019/20 (by check of the NHS Digital DSPT tracker on 16 December 2020), and NHS Digital has confirmed the equivalent of 'Standards Met' grade on DSPT submission 2019/20 (by check of the NHS Digital DSPT tracker on 16 December 2020).

2. Confirmation of a favourable opinion from a Research Ethics Committee. **Confirmed 21 January 2021**

## d. 20/CAG/0155 – Community Mental Health Survey 2021

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

## Context

### Amendment request

This non-research application from Picker, on behalf of the Care Quality Commission, set out the purpose of administering the 2021 Community Mental Health Survey. Support is currently in place to include as part of the sample patients who have had a telephone call as a contact. However, Trusts were given instructions not to include service users who would have only ever had telephone appointments regardless of the COVID-19 pandemic**.**

This amendment sought support to include in the sample all service users who received care and treatment by telephone, regardless of whether this was a replacement for face to face contact. The decision to amend the sampling criteria for the 2021 survey resulted from feedback raised by Community Mental Health Trusts. The amendment will enable Trusts to be able to draw their sample correctly without overburdening staff, and also ensure that the survey is able to provide longitudinal data moving forwards, given that the current changes to service provision are likely to remain in place for the foreseeable future; Feedback from Trusts shows that due to the success of implementing telephone and video calls as a usual contact method, it is likely that these methods of contact are to remain in place.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. The application had been recently reviewed by the CAG members and supported, and the sample size is not increased. The CAT team 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 Secretary of State for Health and Social Care.

## Specific conditions of support

The following sets out the specific conditions of support.

1. 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.

   **Confirmed:** The NHS Digital **2019/20** DSPT submission for **Patient Perspective, Quality Health and Picker Institute Europe** were confirmed as '**Standards Met'** by NHS Digital (by check of DSPT tracker and emails to CAG inbox 08 January 2021)

## e. 17/CAG/0174 – UTMoST Study

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

### Context

### Amendment request

This project from Big Health Data Group at Oxford University, funded by the NIHR with a Health Technology Assessment Programme Grant, aims to improve information available on the choice between Unicompartmental Knee Replacement (UKR) or Total Knee Replacement (TKR). Support is currently in place to allow disclosure of data from the National Joint Registry (NJR) via Northgate Public Services to NHS Digital to enable linkage with HES-PROMS data before returning a pseudonymised dataset to Oxford University.

This amendment sought support to extend the duration of support until 28th February 2022, to enable the project to be completed.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advice Team. There were no issues raised.

### 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 of suitable security arrangements via IG Toolkit submission.

   **Confirmed:**
   **Northgate Public Services (on behalf of the National Joint Registry)** and **NHS Digital**, have confirmed **'standards met'** on the 19/20 DSPT submission.

# f. 18/CAG/0159 - Housing, family and environmental risk factors for hospital admissions in children

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

### Context

## Amendment request

The applicants are seeking support to revise the data flows involved in the linkage of the existing mother-baby birth cohort to longitudinal environmental data. It had been planned that University College London would provide the longitudinal environmental exposure data to NHS Digital who would link them to postcode histories in the PDS. The flow had been changed following discussions with NHS Digital and ONS.

The linkage will now be conducted as follows:

- ONS will extract the identifiers (NHS number, baby sex, date of birth, postcode at birth/delivery) and Study ID from the birth cohort identifier file.
- ONS will securely transfer these identifiers for mothers and babies in the birth cohort to NHS Digital.
- NHS Digital will link the mother & baby identifiers to PDS and extract longitudinal postcode histories and time stamps (date of change of address on

PDS). NHS Digital will also extract some further variables, including whether a mother or baby has deregistered from PDS (and if so when – these are required for accurate follow up calculation).

- NHS Digital will return cohort Study ID, postcode histories and the other PDS variables to ONS, who will put the data in the ONS Secure Research Service (SRS).
- UCL will upload the postcode level data on environmental exposures (air pollution, building characteristics and tobacco expenditure) to ONS SRS.
- UCL will link the Mother-baby postcode histories to the postcode-level environmental exposure data in the SRS.
- Following linkage, UCL will delete the actual postcode histories for mothers and babies. Only Study IDs, longitudinal air pollution, tobacco expenditure and building exposure histories, and time stamps, plus the additional PDS variables (these are dates of deregistration from the PDS) will be retained and linked to the main mother baby cohort using the study ID.
- UCL proposes that the postcode histories are deleted as soon as possible after linkage to environmental data has been completed and checked. The applicants expect this process to take around 3 months.

### Confidentiality Advisory Group advice

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

### Confidentiality Advisory Group advice conclusion

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

## Specific conditions of support

The following sets out the specific conditions of support.

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

   **Confirmed:** the Office for National Statistics has confirmed 'Standards Met' grade on DSPT submission 2019/20 (by check of the NHS Digital DSPT tracker on 16 December 2020), University College London – School of Life and Medical Sciences has confirmed the equivalent of 'Standards Met' grade on DSPT submission 2019/20 (by check of the NHS Digital DSPT tracker on 16 December 2020), and NHS Digital has confirmed the equivalent of 'Standards Met' grade on DSPT submission 2019/20 (by check of the NHS Digital DSPT tracker on 16 December 2020).

2. Confirmation of a favourable opinion from a Research Ethics Committee.
   **Confirmed 21 January 2021**

## g. ECC 2-03(c)/2012 - National Paediatric Diabetes Audit (NPDA)

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

### Context

### Amendment request

The applicants are seeking support to add UKFast as a data processor. The NPDA team at the Royal College of Paediatric & Child Health have been commissioned by HQIP to deliver a one-off spotlight audit of Type 2 diabetes diagnosis and management in children and young people in England and Wales.

The items of confidential patient information that will be collected are the same as those collected for the core audit, under the existing s251 support. These data items are:

- NHS number
- Date of birth
- Postcode

However, other, non-sensitive, data items required for the spotlight audit, but which are not collected for the core audit, will be collected via the UKFast server for a four-month period. The CaseCapture software used for this new data collection is not hosted on Rackspace, which is the data capture system for the core audit, but will instead be hosted on a UKFast server. This is a one-off collection and the NPDA team will then delete the data from the UKFast server. In total, the data could sit on the UKFast server for up to 12 months.

The CaseCapture software was developed by Netsolving specifically to collect identifiable patient level data for national audits. The applicants have opted to use this software as the alternative would require the applicants to commission Netsolving to create a bespoke data capture platform, hosted by Rackspace. This would delay implementation of the spotlight audit and be a significant cost to the applicants.

### Confidentiality Advisory Group advice

The amendment requested was considered by the Confidentiality Advisory Group. The CAG 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 Royal College of Paediatrics and Child Health and UKFast have confirmed 'Standards Met' grade on DSPT submission 2019/20 by check of the NHS Digital DSPT tracker on 06 January 2021.**

## 3. Annual Review Approvals

| CAG Reference | Application Title |
|---|---|
| 18/CAG/0166 | National Clinical Audit for Specialist Rehabilitation following major Injury (NCASRI) – Transfer of Controllership Arrangements to TARN |
| 18/CAG/0002 | Trajectories of diabetes related health measures (from linked lab data) and subsequent health and educational outcomes |
| 14/CAG/1043 | SOCCER (Symptoms of Colorectal Cancer Evaluation Research) |
| 19/CAG/0226 | The SAFER Trial: Screening for Atrial Fibrillation with ECG to Reduce stroke – a randomised controlled trial |
| 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 | Multicentre randomised controlled trial of 'once only' flexible sigmoidoscopy in prevention of colorectal cancer morbidity and mortality |
| 18/CAG/0105 | The incidence, management and early outcome of congenital ichthyosis |
| 19/CAG/0127 | CRIS Linkage with the HIV and AIDS Reporting System |
| 20/CAG/0003 | Study of cancer risks in ataxia telangiectasia heterozygotes |
| 19/CAG/0137 | National Cancer Patient Experience Survey 2019 |
| 18/CAG/0159 | Housing, family and environmental risk factors for hospital admissions in children |
| 20/CAG/0148 | Evaluating alternative protocols for identifying and managing patients with FH: cost effectiveness analysis with qualitative study |
| 19/CAG/0189 | Barts Gynae Tissue Bank |
| 17/CAG/0055 | CRIS Linkage with DWP Employment and Benefits Data |
| CR10/2014 | UKAEA & AWE Epidemiology Studies in the SHIELD database |

| Signed – Chair | Date |
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| Signed – Confidentiality Advice Team | Date |
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