**Amendment request form**

Use this template to submit an amendment to an approved application. The completed template will be reviewed by the Confidentiality Advice Team who will then confirm the appropriate action. The Confidentiality Advice Team can be contacted prior to completion to advise on whether the nature of the change requires a formal amendment. Supporting documentation can be used in conjunction with this form.

Please note that support for amendments will not come into effect until a final approval letter is provided.

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| **PIAG/ECC/CAG reference number:** | 21/CAG/0044 |
| **Full application title:** | UK Longitudinal Linkage Collaboration (Study to NHS identifier flow) |
| **Application type: research or non-research** | Research |
| **Amendment date** | 07/10/2024 |

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| 1. Please indicate the nature of the change below. |
| Data flows  Data items  Data sources (see question 4)  Purposes of application  Data controller (please note that an amended application form and supporting documents setting out the new data controller arrangements will be required, you are advised to contact the Confidentiality Advice Team prior to submission)  Data processor (required to have satisfactory security assurances in place - see question 6)  Duration amendment  Other (please specify): Data size |

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| 1. Please summarise the change to the application, specifying how the amendment differs from the detail of the original application: |
| We would like to add the following two NHS England datasets to our CAG application:   1. Maternity Services Data Set (MSDS). 2. Medicines Dispensed in Primary Care NHS Business Services Authority (NHSBSA) dataset (also known as the Primary Care Medicines (PCM) dataset).   Our original CAG application included the following NHS England datasets:   1. **Registration datasets**: Demographics; Civil Registrations of Death; Cancer Registration Data. 2. **Hospital datasets**: Hospital Episode Statistics (HES) Accident and Emergency; HES Critical Care; HES Admitted Patient Care; HES Outpatients; Emergency Care Data Set (ECDS). 3. **Mental health datasets**: Mental Health Services Data Set (MHSDS) and NHS Talking Therapies for Anxiety and Depression dataset (previously the Improving Access to Psychological Therapies (IAPT) dataset). 4. **Community Services Data Set (CSDS)**. 5. **COVID-19 testing, surveillance and outcome datasets**: COVID-19 Second Generation Surveillance System (SGSS); COVID-19 UK Non-hospital Antibody Testing Results (also known as Enzyme-Linked Immunosorbent Assay (IELISA)); COVID-19 UK Non-hospital Antigen Testing Results (also known as National Pathology Exchange (NPEX)); COVID-19 Hospitalisation in England Surveillance System (CHESS – also known as Severe Acute Respiratory Infection (SARI-Watch) surveillance system); COVID-19 General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR). 6. **COVID-19 vaccination datasets**: COVID-19 Vaccination Status (CVS) dataset; COVID-19 Vaccination Adverse Reactions (CVAR) dataset.  * *NHS 111 records to define Covid-19 symptoms and caseness, wider health symptoms (including mental health status) and consider changing patterns in help seeking behaviours and health care interactions;* * *The Shielded patient list to conduct sub-group analysis and to investigate outcomes and behaviours specific to this group and people co-habiting with this group;* |

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| 1. Please confirm the justification for the amendment. This should explicitly include the following:  * the reason why it is in the public interest for the amendment to proceed * the benefits that the amendment will, or is expected to, provide * The time period for which the amendment is expected to be required * The consequences if the amendment did not go ahead |
| **Justification for the amendment**  *Public interest*  UK Longitudinal Linkage Collaboration (UK LLC) is the national Trusted Research Environment (TRE) for the UK’s longitudinal research community. UK LLC has an explicit remit to support longitudinal public good research across the breadth of the sector, including supporting a broad range of both epidemiology and social science research. Examples of research topics include (Note: these are only indicative of the breadth of research that UK LLC can support):   * Long-term consequences of mental health conditions and disparities in care provision across socio-demographic groups * Identifying modifiable risk factors of work-related mental ill-health to inform the Health and Safety Executive’s national interventions * Impact of air pollution on COVID-19 infection/re-infection, and patterns of recovery and wider adverse impacts of air pollution * The role of common infections in neurodegenerative disease, examining the impacts of infections on long-term brain health * Health and social consequences of early adversity as a key driver of adult health inequality * Understanding changes in social mobility across generations * Identifying the biological antecedents of multimorbidity * Intergenerational and family health and socio-genomics research * Understanding how complex and interacting built environment factors influence modifiable risk factors for non-communicable diseases across childhood * Identifying risk factors and patterns of interaction with health services for rare cardiovascular disease in ethnic minority groups * Investigation of health inequalities in different socio-economic and demographic groups, in relation to COVID-19 pandemic and the cost-of-living crisis.   *Benefits that will be provided by the amendment*   1. The NHS England Maternity Services Data Set (MSDS) collects data about all NHS funded maternity care in England. The starting point for inclusion in the dataset is the formal antenatal booking and the end point is when the mother is discharged from maternity services, which is typically 10 days after discharge from hospital. The dataset provides information about the mother’s demographics, booking appointments, admissions and re-admissions, screening tests, labour and delivery, along with the baby’s demographics, admissions, diagnoses and screening tests. **Inclusion of the MSDS in UK LLC’s CAG application will enable researchers to consider the health and outcome of pregnancies for both mother and child.** 2. The Medicines Dispensed in Primary Care NHS Business Services Authority (NHSBSA) dataset comprises prescriptions for medicines that are dispensed or supplied by community pharmacists, appliance contractors and dispensing doctors in England. The dataset contains information about all prescriptions that have been submitted by prescribers to the NHSBSA for reimbursement purposes. **Inclusion of the Medicines Dispensed in Primary Care NHSBSA dataset in UK LLC’s CAG application will enable researchers to consider the safety and effectiveness of a wide range of prescribed medicines.**   *Time period requested by the amendment*  We request that this amendment is aligned with the duration of UK LLC’s current support, which is until June 2028.  *Consequences if amendment not approved*  The UK LLC database will be less able to support research into the health and outcomes of pregnancy for both mother and child, and the safety and effectiveness of prescribed medicines. |

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| 1. If amending the data sources, has the data controller for this agreed in principle for this access to be provided? Please provide evidence of any authorization. |
| University of Bristol (as Data Controller for UK LLC) has a Data Sharing Agreement (DSA) with NHS England. Both the MSDS and Medicines dispensed in Primary Care NHSBSA dataset are included in the DSA – please see Appendix 1. |

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| 1. It is a requirement of the Regulations that an application cannot be inconsistent with the principles of the General Data Protection Regulation and Data Protection Act 2018 (GDPR/DPA). The first principle of the DPA requires that reasonable efforts are made to inform data subjects of the use of their data. The nature of the change may mean that there is a need to update the current information provided to patients. Please confirm whether patient information materials (websites, leaflets, posters etc.) have been updated to reflect the change and detail the changes below.   If no change is intended to be made, please specify the reasons for this decision. |
| No changes required. All supported LPS’ fair processing materials already cover linkage to participants’ NHS England electronic health records. |

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| 1. All applicants processing confidential patient information under the Regulations are required to provide evidence of suitable security arrangements via agreed routes. This must be in place before any support can come into effect, must be maintained for the duration of the support and is expected to be up to date and (in England) reviewed by NHS England at each annual review.   Security assurance is required in relation to ALL organisations involved in processing confidential patient information. Please carefully assess where the processing is taking place, and provide security assurance based upon the jurisdiction and organisation where the information is being processed. Applicants may need to provide more than one security assurance depending on the jurisdiction information is processed, or if processing of identifiable information is taking place in more than one organisation.   |  |  |  |  | | --- | --- | --- | --- | | **Processing takes place in:** | **England** | **Wales** | **Scotland** | | **Security assurance provided by:** | Data Security and Protection Toolkit (DSPT) – by organisation or specific function | Caldicott Principles into Practice (CPiP) report/or Welsh Information Governance Toolikit – by organisation | Review by the Public Benefit and Privacy Panel for Health & Social Care | | **Applicant should contact:** | [Exeter.Helpdesk@nhs.net](mailto:Exeter.Helpdesk@nhs.net) | The Confidentiality Advice Team (CAT) [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk) | Public Benefit and Privacy Panel (PBPP) for Health & Social Care | | **How assurance is provided to CAG** | 1. Organisational self-assessed completion of relevant DSPT. 2. Applicant contacts Exeter Helpdesk to request NHS England to review the relevant DSPT self-assessed submissions 3. NHS England review the DSPT submission and confirm to CAG when ‘Standards Met’ | Relevant CPIP out-turn report/Welsh IG toolkit provided directly by DHCW to CAG | An approval letter from PBPP, where processing is taking place in Scotland, is accepted as evidence of adequate security assurance. | |
| **For applicant completion:**  Please list all organisations physically processing relevant information without consent for which security assurance is required. Security assurance is provided through NHS England DSPT team reviewing the self-assessed submission. Please ensure you have contacted NHS England and asked them to review your submission. The annual review will not be valid until NHS England has reviewed the submission and confirmed its status as ‘standards met’.  If confidential patient information is being processed by NHS England (previously NHS Digital), please select this box:  *Security assurance has already been provided for NHS England (previously NHS Digital) so please do not complete any details below for NHS England (previously Digital).*   |  |  |  |  | | --- | --- | --- | --- | | **Organisation (Full name)** | **ODS Code** | **Date self-assessment submitted to NHS England** | **Date NHS England confirmed assessment reached ‘Standards Met** | | NHS Digital Health & Care Wales | W00 | Not published | Not published | | UK Longitudinal Linkage Collaboration | EE133799-LLC | 12/04/2024 | 12/04/2024 | | University of Cambridge (School of Clinical Medicine) (EPIC-N) | 8F331 | 26/06/2024 | 26/06/2024 | | King’s College London – Dept of Twin Research (TEDS & TWINS UK) | EE133874-DTR | 07/05/2024 | 07/05/2024 | | ALSPAC | 8J370 | 27/06/2024 | 27/06/2024 | | University College London – Data Safe Haven (NSHD46) | EE133902-SLMS | 26/06/2024 | 26/06/2024 |   Is any processing of identifiable information taking place in Wales? **Yes – via NHS Digital Health & Care Wales for data linkage**  Is there any processing of identifiable information taking place in Scotland? **No – although this is intended as a future development of UK LLC**  If processing of confidential patient information is taking place in Wales or Scotland, please contact the Confidentiality Advice Team for advice on next steps. |

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| 7. If a research application, has an amendment to a Research Ethics Committee been submitted? Please provide supporting documentation/date to be reviewed/favourable ethical opinion. |
| N/A – UK LLC’s REC Protocol V2.0 already includes the MSDS and Medicines Dispensed in Primary Care NHSBSA dataset. |

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| 8. Confirmation of contact details  Please confirm contact details for the purpose of our publicly available register of approved applications. |
| Applying organisation: UK Longitudinal Linkage Collaboration, University of Bristol  Contact Name and role: Katharine Evans, Senior Data Manager (Governance & Users)  Full address: University of Bristol, Canynge Hall, 39 Whatley Road, Bristol, BS8 2PS  Telephone:  Email:katharine.evans@bristol.ac.uk |

Information Guardian/Chief Investigator Name: Andy Boyd

Signed:  Date:

This form should be submitted, in conjunction with any relevant supporting documentation, to [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk). If you require any assistance in completing this form you are advised to contact the Confidentiality Advice Team on [cag@hra.nhs.uk](mailto:cag@hra.nhs.uk).

Once submitted the form will be reviewed by the Confidentiality Advice Team in the first instance who will confirm whether the amendment is valid or if further information is required