



UK Longitudinal Linkage Collaboration

Population Health Sciences

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UK Longitudinal Linkage Collaboration (UK LLC)

DATA ACCESS AND ACCEPTABLE USE POLICY

PUBLIC

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1. PURPOSE

This policy describes the **rules, processes and procedures** involved when:

- 1) Applying to access data in the UK Longitudinal Linkage Collaboration (UK LLC) Trusted Research Environment (TRE).
- 2) Accessing the UK LLC TRE as an approved user.
- 3) Ensuring the reproducibility of research based on data held in the UK LLC TRE.
- 4) Producing outputs based on data held in the UK LLC TRE.

This policy will help to ensure a transparent, consistent and safe approach for using the UK LLC TRE to conduct research that delivers public good.

2. INTRODUCTION TO UK LLC

2.1 Background

UK LLC is the national TRE for longitudinal research. Established in 2020 as part of the COVID-19 Longitudinal Health and Wellbeing National Core Study, UK LLC is led by the Universities of Bristol and Edinburgh, in collaboration with Swansea University, University of Leicester, UCL and many of the UK's most established longitudinal population studies (LPS). The partnership includes a strong public contribution, with members of the public and LPS participants active in decision-making and informing the system's design. The UK LLC TRE contains de-identified data and is based on the [SeRP UK](#) infrastructure.

Initially supported by HM Treasury, UK LLC is now co-funded through a Partnership Grant, by UK Research and Innovation (UKRI), the Medical Research Council (MRC) and the Economic and Social Research Council (ESRC).

Ethical approval for UK LLC was obtained from the NHS Health Research Authority's Haydock Research Ethics Committee (REF: 20/NW/0446, IRAS code: 290946).

UK LLC is ISO 27001 certified (certificate number 21069), completes the annual NHS Data Security and Protection Toolkit (DSPT) audit ([organisation code EE133799-LLC](#)) and has been accredited by the UK Statistics Authority as a [processing environment under the Digital Economy Act \(DEA\)](#).

2.2 Objectives

UK LLC has three main objectives:

- 1) To bring together de-identified data from partner LPS and to systematically link data to their participants' health, administrative (e.g. education, employment, tax and benefits) and environmental records in UK LLC's TRE.
- 2) To permit safe access to the UK LLC TRE to large numbers of UK-based researchers so they can conduct public good research investigations.
- 3) To offer the UK LLC TRE as a long-term solution for data linkage and secure pooled analysis for the longitudinal community, in order to support a broad range of research studies.

The UK LLC TRE is open to applications from any UK-based bona fide researcher conducting research into COVID-19. Pending Research Ethics Committee (REC) approvals, research permitted in the UK LLC TRE will expand beyond COVID-19 to include any public good research.

2.3 Management

The governance structure of UK LLC is shown in figure 1. Membership of the various groups and committees includes the contributing LPS, LPS participants and other members of the public to advise on progress, scientific outputs, communication materials and long-term strategy of UK LLC. The role of the UK LLC Data Access Committee is explained in section 7.

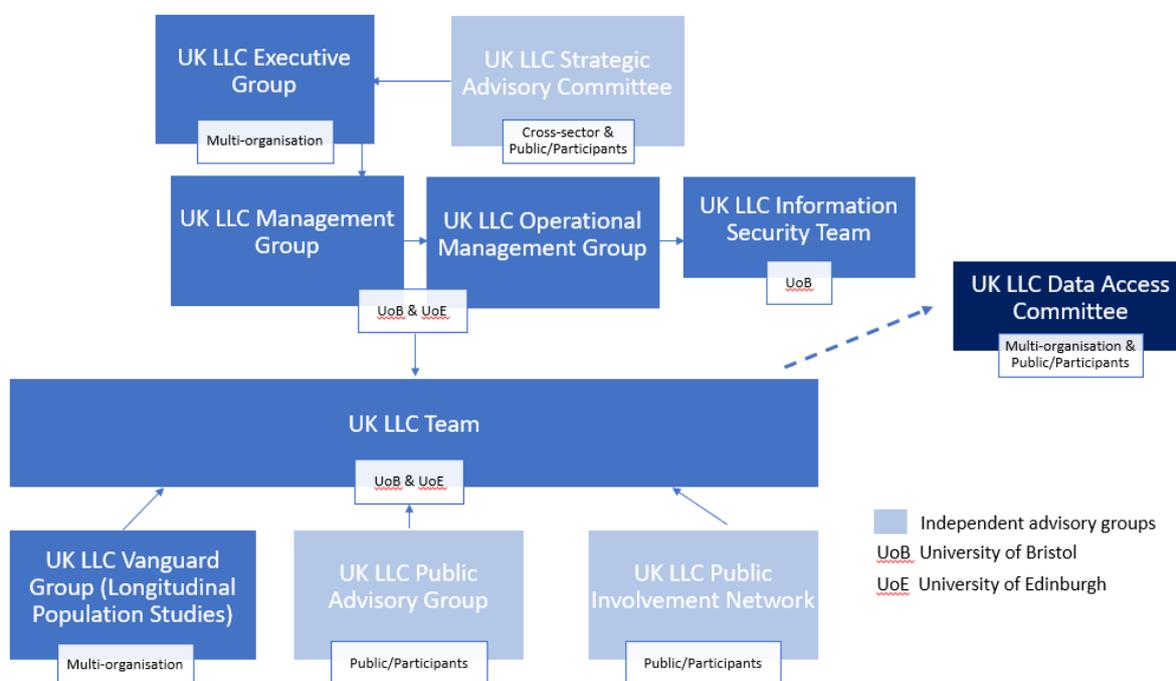


Figure 1 UK LLC’s governance structure, including membership of each committee or group

3. PRINCIPLES

UK LLC is committed to protecting LPS participants’ data, to adhering to data owners’ requirements and to supporting researchers to access de-identified LPS data linked with participants’ routine records, in an efficient, safe and consistent manner to conduct public good research. UK LLC’s principles are based on the [Five Safes Framework](#) that represents best practice in data management – see the [UK LLC Secure Environments Policy](#) and Section 5 for further details.

3.1 Commitment to LPS participants and the wider public

UK LLC and its collaborators have made a series of promises to LPS participants (see [Our Promises to Study Participants](#)). Applications to access the UK LLC TRE must meet these promises. UK LLC runs a Public Involvement programme to ensure that LPS participants and the wider public contribute to the design and operation of the UK LLC TRE. This provides a meaningful way for participants and the public to be part of the decision-making process that determines who can access data and how the data are used.

3.2 Commitment to LPS and other data owners

As the ‘onward sharers’ of data, UK LLC is both legally and morally obliged to uphold a number of commitments made to data owners that are documented in the data deposit agreements/data sharing agreements entered into with each contributing data source. The UK LLC commits to:

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- Hold data in the UK LLC TRE and ensure access to data is restricted to approved users for approved purposes.
- Ensure the technical and organisational measures are in place to maintain the confidentiality and integrity of the data in the TRE and to protect against unauthorised use.
- Ensure that relevant governance and security terms and conditions set by data owners in the data deposit agreements/data sharing agreements are also applied to users.

UK LLC works in partnership with all contributing LPS to set the design and operating rules of the TRE. UK LLC supports and provides materials to LPS to help them engage directly with their participants to ensure the transparent use of data in the UK LLC TRE, to provide a route to object and to explain and promote the benefits of TRE-based research. Some LPS have additional specific commitments and agreed ways of working with their participants. UK LLC manages a review process that enables each LPS to decide whether their data can be included in each application.

3.3 Commitment to researchers

UK LLC is committed to:

- Processing applications in a fair, transparent, consistent and timely way.
- Maintaining clear communication channels with researchers throughout the application process.
- Maintaining the integrity of the data and to evaluate this and document our findings.
- Providing clear documentation and guidance to researchers and providing advice when questions arise.
- Ensuring all data and associated code and tools generated through approved projects in the UK LLC TRE are Findable, Accessible, Interoperable and Reusable (FAIR), as detailed in the [FAIR Guiding Principles for scientific data management and stewardship](#).
- Working alongside researchers to facilitate team data science for the aim of public good research.

4. DATA TYPES AND DISCOVERY

UK LLC allows approved users access to the source data in the UK LLC TRE to create anonymous outputs for the purpose of the approved project. The source data comprises: (i) LPS data; (ii) Linked data; (iii) Synthetic data (not yet available in the UK LLC TRE); (iv) Derived data; and (v) Metadata relating to the source data.

UK LLC uses all LPS data and linked data under licence. Neither the recipient organisation nor the researcher gains ownership of these data and will need to comply with any specific requirements or conditions imposed by the original data owner – see Appendix 1 for details.

4.1 LPS data

LPS data are collected by the contributing LPS, directly from, or about, LPS participants and are deposited in the UK LLC TRE by the contributing LPS. All LPS data are provided as de-identified coherent 'logical blocks'. These blocks can relate to a data collection assessment (e.g. a 'wave' of data collected by fieldworkers or through a questionnaire) or a set of measures collected over different timepoints (e.g. mental health assessments collected longitudinally across questionnaires). Where possible, these logical blocks are designed to match the existing datasets used by LPS to share data directly or that are used in other repositories (e.g. UK Data Service).

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The variable names and labels match the LPS' existing format. UK LLC is not seeking to recreate LPS metadata held in existing resources. It will signpost applicants to the relevant LPS resources and existing catalogues (e.g. CLOSER Discovery). All LPS datasets are provided to the user with the same structure as defined by the contributing LPS.

4.2 Linked data

UK LLC systematically links to participants' health and geo-coded environmental data. UK LLC has agreement to link to UK Government administrative records via the Office for National Statistics (ONS) and is now working out the detailed data flows. The extent of the linkage is controlled by each contributing LPS based on LPS and participant permissions. This means that not all LPS are linked to all data sources, or that all participants are linked to their records. The linkages are determined by each data sharing contract, which is subject to change and is subject to any licence conditions imposed by the data owner within the linked datasets.

4.2.1 Linked health data

UK LLC has a data sharing agreement with NHS England (formerly NHS Digital), permitting the sharing of linked English NHS records. UK LLC is negotiating access to linked health records from the NHS in Scotland, Wales and Northern Ireland.

The data sharing agreement with NHS England enables UK LLC to host, process, curate and onwardly share (within the confines of the UK LLC TRE) linked health records. Access to these records is only available for applicants requiring linked LPS data (i.e. for projects only requiring NHS records, please contact the NHS data services directly). UK LLC is required to onwardly assert all conditions and contractual terms imposed by NHS England (see Appendix 1). Applications are assessed against the NHS England conditions by the UK LLC Linked Data Review Panel (see section 7.3). The UK LLC Data Access Agreement (DAA), which must be signed by each organisation hosting approved users prior to them gaining access to the UK LLC TRE, refers to the NHS England terms and conditions.

UK LLC has a responsibility to minimise NHS England data shared through the UK LLC TRE. Not all variables are included, direct identifiers are excluded and potentially identifiable information (such as practice codes or geographical IDs) are masked prior to deposit in the TRE. UK LLC does not have access to the information needed to reverse masking.

UK LLC respects the rights of the public to opt-out of the use of their data for research purposes. The [NHS National Opt Out](#) (England only) is respected unless specific consent is in place.

4.2.2 Linked administrative data

UK LLC has negotiated access to administrative records (e.g. education, employment, tax and benefits) from the following UK Government Departments: Department for Work and Pensions, Department for Education, and HM Revenue & Customs.

4.2.3 Linked geographical and multi-level modelling data

UK LLC is a de-identified resource where inclusion of real-world geographical indicators is kept to an absolute minimum. The only real-world indicators available are LPS participants' UK region and devolved nation of residence. These data are essential for reporting purposes. All other levels of geographical indicator are encrypted. Encrypted identifiers are made available where required for multi-level modelling or other geospatial purposes.

Linked geospatial records and Geographical Information Systems (GIS) approaches

UK LLC has developed a mechanism to geocode LPS participants' addresses using trusted third parties and masking address data to counter confidentiality concerns. Only some contributing LPS participate

in this feature and based on LPS-level governance controls some LPS permit geocoding to property-centroid and some to postcode-centroid.

UK LLC's Data Team (University of Bristol) use this mechanism to add commonly used natural environment and built environment indicators to the UK LLC TRE (e.g. deciles of indices of multiple deprivation, urban/rural indicator). It is possible to add additional geospatial indicators to the UK LLC TRE to meet project needs and to enable GIS approaches (subject to disclosure risk checks and processing). Please contact support@ukllc.ac.uk to discuss options.

Modelled geospatial exposure data

UK LLC has commissioned the University of Leicester's Centre for Environmental Health and Sustainability to model a range of environmental exposure estimates relating to air pollution, noise and green space.

4.3 Synthetic data (not yet available)

Synthetic data are representations of the source data that are artificially generated rather than relating to real individuals. Synthetic data are typically created using statistical techniques, so that while the data are not 'real', they may retain a similar underlying structure and distribution. The University of Bristol retains ownership of the synthetic data and, for the avoidance of confusion or mistakes, the distribution and handling of synthetic data must still use rigorous and secure processes.

4.4 Derived data

Derived data are individual-level data generated from analyses or functional combinations of the source data in the UK LLC TRE. An example of a derived data variable is body mass index (BMI), it being a function of height and weight. UK LLC produces some derived data products for commonly used information and these are catalogued and made available for request. Approved users must report any data they derive during their research projects and provide the syntax and documentation for these so they can be added to the UK LLC TRE (by the UK LLC Data Team). UK LLC manages the source data of these derived data and the information used to produce the derived variables remains the property of the original data owner.

4.5 Harmonised data

UK LLC produces and maintains a harmonised set of core socio-economic status (SES) and demographic indicators. We welcome applications that involve harmonisation approaches and all documented harmonised datasets will be added to the UK LLC TRE as derived data once completed. Insights from the production of the core SES and demographic indicators are available to all users.

4.6 Metadata

Metadata include variable names and labels, data collection protocols, information about the tools and techniques used to collect the data, the staff involved, the time and place of data collection, details of quality control and error – i.e. the 'provenance' of the data, which allows future users to understand and accurately use these data in a secondary context. The contributing LPS and external third parties provide metadata to support approved users and prospective users and to inform the public about the types of data collected about participants. UK LLC generates additional metadata when processing linked data and will make these accessible in a clear and understandable format.

4.7 Data quality, coverage and completeness

A summary of UK LLC data quality, coverage and completeness:

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- Most data in the UK LLC TRE are accessed and used under licence and are a secondary reuse of datasets owned and/or controlled by other organisations. This means that some data may be removed with limited notice and that some variables may change over time.
- UK LLC cannot guarantee the quality of the underlying data but will provide assessments of completeness and coverage and will make assessments of linkage quality.
- UK LLC cannot guarantee the quality of reusable research outputs, including documentation, syntax and derived data. It is the responsibility of the researcher to check reusable research outputs prior to inclusion in analyses and subsequent interpretation.
- The denominator of the UK LLC TRE (i.e. the sum total of participants across contributing LPS) will change over time. This will be recorded in UK LLC documentation and it will be clear which 'denominator version' is in place for each project's dataset.
- Linked records are refreshed on a regular basis. Each refresh may be based on a different underlying denominator where new LPS and/or participants are added and some participants may be removed.
- Users are provided with a snapshot of data current at the time of project approval; updates (due to data refreshes or amendments) may not include data for all individuals.

4.8 Data discovery

UK LLC is designed to be a discoverable and accessible resource for public good research. A summary catalogue of the data held in the UK LLC TRE is available at the [HDR UK Innovation Gateway](#). An overview of available data can be found on the [UK LLC website](#).

5. ELIGIBILITY AND REQUIREMENTS TO ACCESS DATA

To ensure the appropriate and fair use of LPS participants' information, UK LLC operates a rigorous multi-stage application assessment process (see section 7) that considers the eligibility of applicants and their projects, as well as the requirements of the contributing LPS and owners of linked data.

5.1 Eligibility

UK LLC welcomes applications from any **UK-based bona fide researcher** (including PhD students, on condition that appropriate supervision is in place from an applicant who is a senior researcher) who is conducting a **COVID-19 focused research project** for public good. UK LLC aims to move beyond COVID-19 to encompass any public good research, subject to relevant REC approvals and engagement by LPS with their participants.

A **research project** is defined as a specific research activity addressing a pre-defined purpose. A project may consist of activities investigating a range of hypotheses, but these must all be specified and related to the project theme. The purpose of a project may be to conduct applied research, methodological research or resource enhancements (e.g. the creation of a harmonised dataset or outcome adjudication).

All applicants and their applications are assessed against the '[Five Safes' Framework](#) to determine whether they meet the requirements and commitments agreed with participants of LPS and data owners:

- 1) **Safe people:** UK LLC will determine if the **applicants** (those applying to access the UK LLC TRE, not their wider team) are trained and authorised to use the data safely. It is important that all applicants have the technical skills necessary to use the data effectively and are either already an **Accredited Researcher** under the Digital Economy Act (DEA) or have signed up to an Office

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for National Statistics (ONS) Safe Researcher Training course (training providers include the ONS, Scottish Centre for Administrative Data Research and the UK Data Service).

- **Only Accredited Researchers are permitted access to the UK LLC TRE.**
 - All applicants must provide a short CV demonstrating their ability to conduct the proposed research.
 - All applicants must be part of a research organisation that is capable of high-quality public good research and where research is either the main purpose or a substantial sub-purpose of the organisation.
 - All applicants must sign a UK LLC Data User Responsibilities Agreement (DURA).
- 2) **Safe projects:** applicants need to demonstrate that their proposed research and data request is appropriate, ethical and likely to deliver clear public good that will be disseminated.
- The scope of all applications must be COVID-19 research, either regarding the virus itself and its outcomes, efforts designed to ameliorate the virus, or the wider effects of the pandemic and (all aspects) on health and social wellbeing. The intention is to broaden this scope to any public good research once relevant approvals are in place.
 - Ethical frameworks must be in place for all applications. These are reviewed for each application using the process outlined in the Ethics Decision Tree (Figure 4) and described in more detail in section 7.
 - Applicants must provide relevant information about their protocols, including information about the purpose of their research, the data and methods to be used and the intended outputs and means for effective dissemination.
 - Applicants must commit to publish their workings (syntax, code lists, documentation, protocol) and findings into the public domain as quickly as possible.
 - For all approved projects, the organisation(s) that employs the applicant(s) must sign a Data Access Agreement (DAA) with the University of Bristol (the owner of UK LLC).
 - The UK LLC TRE hosts data under licence, where conditions are defined in data deposit agreements or data sharing agreements. All applications are assessed against these conditions either by UK LLC (where this permission has been delegated) or by the data owner. Successful applicants are bound by the conditions detailed in this policy, in the DAA and in the DURA.
- 3) **Safe data:** all organisations providing data to UK LLC must ensure their data are de-identified. They achieve this by removing names, addresses and any other details that would directly identify a participant. UK LLC performs a series of checks throughout the data processing pipeline to ensure confidentiality. Only the minimum required data are provided to approved applicants.
- 4) **Safe setting:** UK LLC operates a TRE model using infrastructure provided by [SeRP UK](#) (Swansea University). All data in the UK LLC TRE are sensitive. To maintain the confidentiality and security of LPS participants' information, data are only made available *within* the UK LLC TRE. The TRE is a locked down environment for analysis which hosts statistical packages and other software needed for research. See the [UK LLC Secure Environments Policy](#) for further details.
- 5) **Safe outputs:** all outputs (e.g. tables, statistical results) must be population level and not individual level data. All outputs are checked by staff trained in statistical disclosure control prior to release – see the [UK LLC Output Review Policy](#). Once approved, the results are sent to

the researcher, who can then publish or present their analyses, in line with the [UK LLC Publication Policy](#).

5.2 Application governance (legal documentation)

The UK LLC TRE hosts sensitive de-identified data from many contributing data owners. Whilst all use of the data occurs within the TRE, there is an expectation from data owners that those accessing the TRE will maintain adequate levels of security whilst doing so. Once an application is approved, there are several governance steps that must be completed prior to data being accessible to approved users in the UK LLC TRE (figure 2).

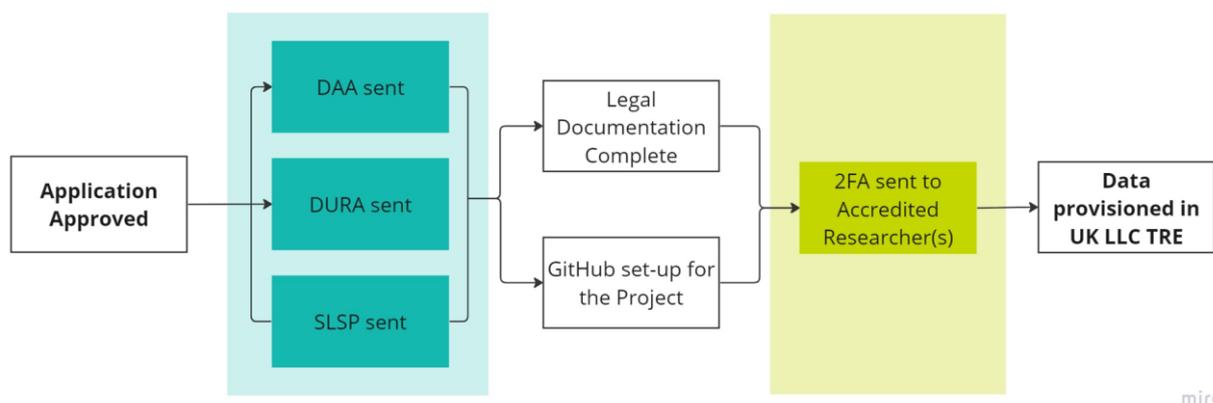


Figure 2 Once an application is approved, application governance steps (legal documentation) must be completed to ensure LPS participant data are protected – only then are data provisioned to approved users in the UK LLC TRE via two factor authentication (2FA). See below for explanations of Data Access Agreement (DAA), Data User Responsibilities Agreement (DURA) and System Level Security Policy (SLSP).

5.2.1 Data Access Agreement (DAA)

The UK LLC DAA defines the terms and conditions for accessing and using data within the UK LLC TRE. These terms and conditions are non-negotiable and signing a DAA is a pre-condition to gaining access to the UK LLC TRE.

For each approved application, there must be a DAA in place with every organisation involved, i.e. the organisations employing the approved users of the UK LLC TRE (individuals involved in the research who will not access the data do not need to be covered by a DAA). Where an individual is employed by multiple organisations, the DAA needs to be in place with the organisation sponsoring the research and taking accountability for it.

5.2.2 Data User Responsibilities Agreement (DURA)

Each approved user of data in the UK LLC TRE must complete a DURA for each application they are named on. The purpose of this document is to make clear to each user the responsibilities they hold. The terms and conditions of the DURA are non-negotiable and signing a DURA is a pre-condition to gaining access to the UK LLC TRE.

5.2.3 System Level Security Policy (SLSP)

Approved users need to demonstrate sufficient levels of security policy and practice at their host organisation to assure UK LLC that they are compliant with expectations. This can be achieved through providing evidence that their research activity falls either within the scope of their organisation’s: (i) ISO 27001 certification; or (ii) NHS England Data Security and Protection Toolkit (DSPT) audit. Where a researcher is not able to provide this assurance to UK LLC, they must complete the UK LLC System

Level Security Policy (SLSP) form – this form contains guidance to help applicants complete it efficiently.

The scope of the SLSP is limited to only the equipment used by the approved users, the setting in which they work and the network they use. It does not extend to the UK LLC TRE itself or their wider organisation. Typical contemporary University IT or Departmental Policy and Practice with adequate user training and awareness are likely to meet the requirements of the UK LLC SLSP.

5.3 Requirements

The following requirements need to be taken into account when applying to access the UK LLC TRE.

5.3.1 Intellectual property

The University of Bristol owns UK LLC and is Data Controller for the TRE, managing the rights to, or owning itself, all rights to the **source data** (see section 4). The majority of source data held within the UK LLC TRE is accessed under DAAs and typically the owners of the data retain all intellectual property rights – **no user will gain any intellectual property over data or participant-level research outputs** (e.g. derived variables) as a result of their project (given the data are accessed under licence, this is a **non-negotiable feature of using the UK LLC TRE**).

Approved users are granted a non-exclusive, revocable, non-transferable, licence to use the source data for their approved project, until the end of their approved access period, so long as the University of Bristol maintains a relevant data sharing agreement with the third-party data owner and retains the rights to sub-license the source data.

Analytical outputs (research findings and tools including syntax, documentation and codelists) are owned by the approved user's organisation, as detailed in the DAA. UK LLC (University of Bristol) is granted an irrevocable, perpetual, worldwide transferrable royalty-free licence to use all user results and tools for research, teaching and other non-commercial purposes.

5.3.2 Transparency and a community of researchers

UK LLC is committed to maximise the benefits of transparent team data science¹ through the following requirements:

- A publicly accessible [Data Use Register](#) of all applications to access the UK LLC TRE and their outcomes is maintained to ensure participants of contributing LPS and the wider public are aware of how data within the UK LLC TRE are being used and the results and impact. This information is also fed back to contributing data owners (LPS and other organisations providing data).
- Users are strongly encouraged to make use of research notebooks such as Jupyter notebook or R Markdown to document their syntax and workings (both systems are provided within the UK LLC TRE).
- Users are required to make their syntax, code lists, protocols and methods accessible and understandable to future users via creative commons licence (or similar) and to deposit any derived data, along with relevant and adequate documentation, for incorporation into the UK LLC TRE – see section 8.7 and the [UK LLC Reproducible and Reusable Research Policy](#).

¹Ford E, Boyd A, Bowles JK, Havard A, Aldridge RW, Curcin V, Greiver M, Harron K, Katikireddi V, Rodgers SE, Sperrin M. Our data, our society, our health: A vision for inclusive and transparent health data science in the United Kingdom and beyond. Learning health systems. 2019 Jul;3(3):e10191.

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5.3.3 LPS requirements

Each contributing LPS sets out conditions in the data deposit agreement regarding data use in the UK LLC TRE. Many LPS reserve the right for their Data Access Committees (DACs) to assess applications against their LPS-specific application review frameworks. Users are provided with a list of project-specific LPS conditions when their application is approved.

5.3.4 NHS England requirements

The linked health records in England are accessed under a data sharing agreement and data sharing framework contract with NHS England. These impose conditions as to how UK LLC may use NHS data and, through our application review and governance process, UK LLC 'onwardly share' these conditions to users.

To use NHS England data users must demonstrate:

- How their proposed research clearly articulates 'benefits to healthcare provision, adult social care and/or the promotion of health' (this is a legal requirement and condition of access).
- A realistic and comprehensive plan for how their findings will be disseminated to relevant stakeholders to achieve the stated benefits.
- That the use of NHS data is relevant to the stated purpose. Within this, the applicant must justify how their application requires NHS data linked to LPS data – and why their purpose cannot be satisfied through using either source alone.
- Each and all of the requested data are relevant to the stated purpose, i.e. a justification at an item level, where item relates to the broad datasets requested – e.g. primary care records, mortality register records – or to a range of data defined by a code list (e.g. a list of respiratory health codes).

The full list of NHS England's general requirements can be found in **Appendix 1**.

Applicants must clearly and specifically answer each of these points. Applications which do not achieve this cannot be processed.

Users are also provided with a list of project-specific NHS England conditions when their application is approved.

5.4 Penalties for misuse

Users must adhere to the terms of the DAA and DURA at all times. The DAA is a legally binding contract. Current and future access is at risk for you, your team and your organisation if you do not abide by the terms of these agreements. Serious breaches of these terms may be subject to prosecution to the full extent of civic or criminal law.

6. CHARGES TO ACCESS DATA

UK LLC is jointly funded by UK Research and Innovation (UKRI), the Medical Research Council (MRC) and the Economic and Social Research Council (ESRC). At present, there is **no charge for data access and provision**. For researchers planning a fellowship or small grant proposal, we advise requesting £3,000 for the first researcher with a further £2,000 for each additional researcher named on the application. This is a contingency for data access in the scenarios that (i) UK LLC implements a cost-recovery scheme; and (ii) your application to access the UK LLC TRE is not successful and you therefore have to access data via other means. Please allow for more (using the same costing model) if you are applying to access data in the UK LLC TRE for more than one research project.

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If UK LLC adopts a cost-recovery scheme UK LLC will endeavour to give the longitudinal research community as much notice as possible.

7. MAKING AN APPLICATION

The process to apply to access the UK LLC TRE is currently comprised of three stages (figure 3). Researchers with multiple applications must submit multiple forms; one per application. Once administrative data have been incorporated into the UK LLC TRE under the Digital Economy Act (DEA), applications that include these data will also be reviewed by the UK Statistics Authority’s Research Accreditation Panel, following stage three.

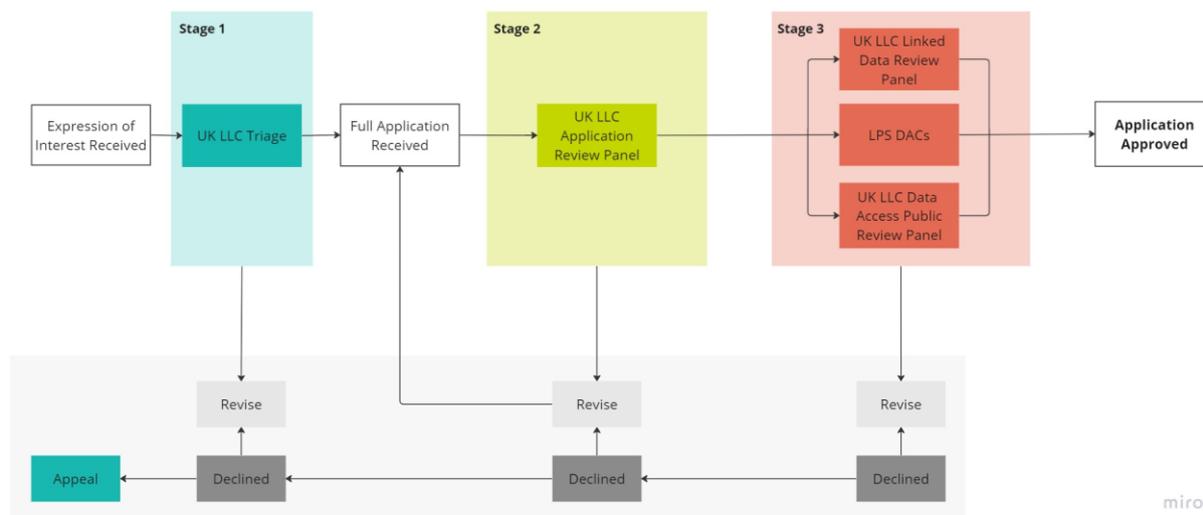


Figure 3 A summary of the three-stage process to apply to access data in the UK LLC TRE. Once an application is approved, the applicant completes paperwork (see section 5) and then moves to the data provisioning stage of the process (see section 8)

7.1 Stage 1

Expressions of Interest (EoIs) must be submitted through the UK LLC enquiry form on the [HDR UK Innovation Gateway](#). EoIs are triaged by the UK LLC Applications Team (University of Edinburgh). Incomplete or insufficiently justified EoIs are returned to applicants, who have the opportunity to revise and resubmit. UK LLC informs applicants of the ethics requirements for accessing different types of data and applicants are directed to the [UK LLC Data Use Register](#) where they can check if a similar application has already been approved. UK LLC permits different research groups to apply to conduct related research investigations and does not monitor potential overlap. Applicants whose EoIs are approved are invited to submit a full application and data request form.

7.2 Stage 2

An initial assessment of full applications and data request forms is conducted in stage 2 by the internal UK LLC Application Review Panel. This review assesses each application against the Five Safes Framework detailed in section 5 and checks that all requested fields are filled out appropriately. In particular, applications are reviewed to ensure that the data being requested are appropriate for the research question, that public involvement plans have been detailed and that a lay summary has been provided. UK LLC assesses whether ethical requirements have been met (figure 4). If not, applicants are referred to the [UK Statistics Authority’s Ethics Self-Assessment Tool](#). Any questions or concerns are sent back to the applicant(s) and resubmitted applications are re-reviewed by the UK LLC Application Review Panel. Applications that are declined are permitted to go through the appeal process outlined in section 7.4.

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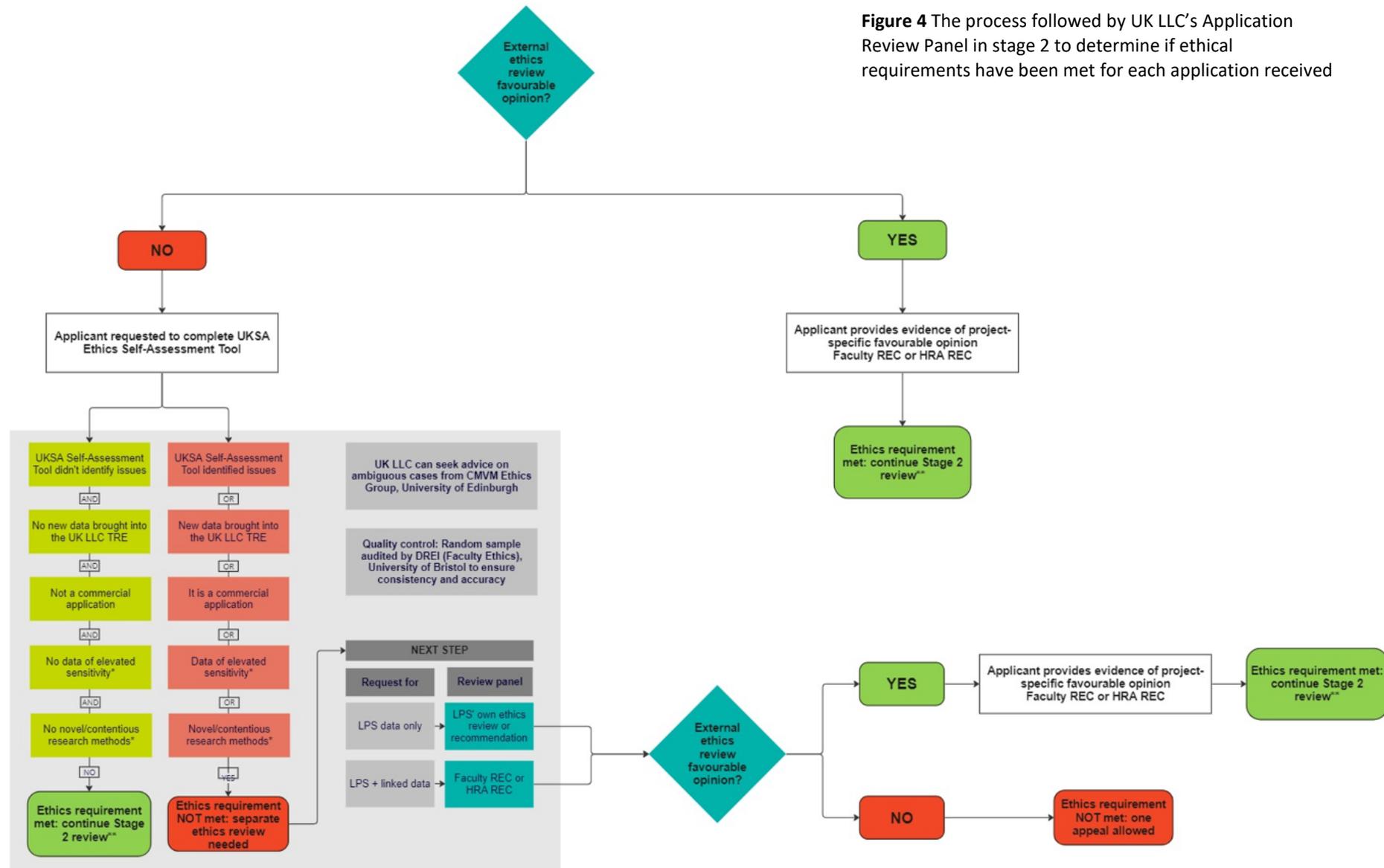


Figure 4 The process followed by UK LLC's Application Review Panel in stage 2 to determine if ethical requirements have been met for each application received

*UK LLC is consulting with UK LLC public contributors to define data of elevated sensitivity and contentious research methods

**ALL requests that include socio-economic data will also undergo ethical review by UK Statistics Authority's Research Accreditation Panel at Stage 4

CMVM - College of Medicine and Veterinary Medicine; DREI - Division of Research, Enterprise and Innovation; HRA - Health Research Authority; LPS - Longitudinal Population Study; REC - Research Ethics Committee; TRE - Trusted Research Environment; UK LLC - UK Longitudinal Linkage Collaboration; UKSA - UK Statistics Authority

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7.3 Stage 3

Approved applications proceed to stage 3. Applicants must minimise their data request to only include data that are relevant to their project. They must specifically justify the inclusion of data of 'elevated sensitivity' such as socially sensitive data (e.g. mental and sexual health data) and demographically sensitive data (e.g. ethnicity). Categories of data that fall under 'elevated sensitivity' are currently under review by UK LLC public contributors.

The majority of applications are from researchers wishing to access LPS data linked with health (or other) data. However, a small number of researchers apply to access only LPS data. The review process at stage 3 differs slightly for LPS only data, versus LPS and linked data.

Applications for **LPS data alone** are reviewed by:

- 1) The individual **LPS DACs** – each LPS DAC is responsible for reviewing the application against their LPS-specific application review framework. UK LLC collates and records the LPS' responses and shares this information, plus any stated conditions, with the applicant.
- 2) The **UK LLC Data Access Public Review Panel** – the panel focuses on the lay summary, public good and public involvement sections of the application. Applicants have a five minute slot to present their research to the panel at an online meeting, with a short Q&A session thereafter.

Applications for **LPS data linked with health (or other) data** are reviewed by:

- 1) The individual **LPS DACs** (see above).
- 2) The **UK LLC Data Access Public Review Panel** (see above).
- 3) The **UK LLC Linked Data Review Panel** – the panel focuses on reviewing the application against the linked data owners' requirements (see Appendix 1).

Once the necessary legal documentation detailed in section 5.2 is completed, the UK LLC Data Team (University of Bristol) sets up approved users in the UK LLC TRE, provisions their approved data and manages their ongoing access.

7.4 Appeal process

Declined applications may go through the appeal process once. Applicants must address all comments, questions and criticisms fully for the appeal to be considered, with all changes to the application highlighted. Amended applications are then submitted for stage 2 approval, and, if successful, progress to stage 3 approval.

7.5 Amendment process

Researchers should make every effort to reduce the number of amendments to a project by ensuring that all known project requirements are included within their original application. Amendments to approved projects are considered by the UK LLC Application Review Panel. For further details see the [UK LLC Project Amendment Policy](#). To submit an amendment contact access@ukllc.ac.uk.

7.6 Application timescales

For the parts of the process under UK LLC control we set the following timescales:

- **Stage 1.** We aim to review EoIs within one week of receipt.

Following receipt of a full application and associated paperwork:

- **Stage 2.** We aim to review applications within two weeks.
- **Stage 3.** We aim to review applications within four weeks.

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On completion of required legal documentation (DAA and DURA, and SLSP where needed):

- We aim to provision data within two weeks.

When seeking funding please enquire at the earliest opportunity (access@ukllc.ac.uk). You must make clear that any access to data in the UK LLC TRE is subject to approval.

8. WORKING IN THE UK LLC TRE

An application is referred to as a project at the point data are prepared for provisioning within the UK LLC TRE. The [UK LLC TRE User Guide](#) is available on the UK LLC website. It explains how to set up and log into the UK LLC TRE; how to access and work with your approved datasets, including the various software packages available; how to interpret standard UK LLC datasets; how to bring files in and out of the TRE, including data output guidance; how to request an amendment to your project; how to close down your project, including how to use the UK LLC Git repositories; and how to publish or present your analyses. Key information from the guide is summarised below.

8.1 Two factor authentication (2FA)

Once the legal documentation is completed, each approved user will be set up with 2FA to protect access to the TRE.

8.2 User support

UK LLC aims to help researchers begin their analyses in the TRE as quickly as possible. The UK LLC Data Team maintains a library of self-service user help tools in multiple formats, including the [UK LLC TRE User Guide](#), [YouTube videos](#) and helper syntax. In addition, all active users are invited to join the monthly UK LLC Analyst Group meetings and the UK LLC Google Groups Data User Forum.

If users are unable to find the help they require, the UK LLC Data Team can be contacted at support@ukllc.ac.uk. If users experience issues with the software or the SeRP environment they should contact helpdesk@chi.swan.ac.uk in the first instance.

8.3 Permitted access period

The permitted access period runs from the date the DAA is signed until the end date stated on the application. If approved users wish to extend their access period, they can submit an amendment (see section 7) and, if approved, the access period will be adjusted accordingly.

All users in the TRE must have **current ONS Accredited Researcher status** – this is carefully recorded and audited by UK LLC (see section 8.6). If accreditation expires before the end of the agreed access period, access to the TRE for that user will be automatically terminated. It is the responsibility of the user to maintain their ONS Accredited Researcher status and to communicate successful renewals to the UK LLC in good time (access@ukllc.ac.uk), so that their access to the TRE is not interrupted.

8.4 Reproducible and reusable research

Researchers must make their **project workings** (syntax, code lists, protocols, methods) and **derived variables accessible and understandable to future users**. Users should add cleaned and documented project workings to their dedicated GitLab project space *within* the UK LLC TRE. Following output review (see section 8.5) users should add these files to their project-specific repository on the [UK LLC GitHub](#), thereby making them publicly accessible.

It is not possible for derived data to leave the UK LLC TRE; however, it is legitimate for researchers to claim derivations as an output which are then discoverable and accessible to future users. Following a disclosure risk assessment, data files returned are written as a database table to the UK LLC database

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and are available to requests by other research projects. If the derived data come from linked data that were sourced from NHS England, then NHS England retain the right to determine whether derived data are derived data or manipulated data. Manipulated data are defined as information created by the approved users using NHS England source data that can be identified as originally from NHS England and must be returned by the project access end date.

See the [UK LLC Reproducible and Reusable Research Policy](#) for further details.

8.5 File-outs

It is a critical principle of the UK LLC TRE that only anonymous population level aggregate data can be released. No individual level data are permitted to leave the TRE. The Statistical Disclosure Control (SDC) threshold is 10 data subjects, i.e. counts ranging from zero to nine, inclusive, are not permitted.

In order to export tables, graphs, syntax and documentation from the TRE, users must submit a file-out request through the [SeRP Portal](#). Before any output is released from the UK LLC TRE it must be **manually inspected** to ensure:

- 1) It is within the **scope** of the approved project.
- 2) It conforms to the **terms and conditions** set by **data owners**.
- 3) It is **not disclosive**, i.e. it does not reveal information about a known individual.

All **analytical or statistical outputs** are reviewed independently by two members of the SAIL SDC Team based at Swansea University. This process can take several days depending upon the complexity of the output.

See the [UK LLC Output Review Policy](#) for further details – **failure to adhere to the conditions in this policy may result in sanctions, such as users being required to undergo renewed training or suspension from access to the UK LLC TRE.**

8.6 Audit of users and their projects

All users must agree to being audited and must provide full co-operation to internal UK LLC audit processes or audits being conducted by external organisations. Audits include scope checks of approved projects and checks of ONS Accredited Researcher status. All auditors commit to the confidentiality of the research project. See the [UK LLC Audit Policy](#) for further details.

9. PUBLISHING OR PRESENTING RESEARCH

9.1 Publications and presentations

The [UK LLC Publication Policy](#) describes the requirements for researchers when publishing **papers and similar outputs** based on data accessed in the UK LLC TRE. All such outputs must be submitted to UK LLC (access@ukllc.ac.uk) for review prior to submission.

UK LLC does not require to see **presentations** before they are delivered, but researchers must acknowledge the use and funding of the UK LLC resource and the collaborative contribution of the LPS and other data owners and partners – for logos and other useful materials see the [UK LLC GitHub](#) repository.

9.2 Media communications

Where possible, press releases and other media communications should be developed in conjunction with the UK LLC Communications Team. UK LLC reserves the right to publish press releases on certain articles and expects the lead author of the article to agree to the press release with the UK LLC

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Communications Team and to be available to deal with media enquiries and interviews. UK LLC may also ask authors to prepare a précis of important papers and/or lay summaries to include in reports to funders and future applications for core UK LLC funding.

10. CONFIDENTIALITY AND DATA SECURITY

Users must adhere to the requirements listed below. These include, but are not limited to, rules regarding the maintenance of confidentiality, IT equipment and reporting breaches or risks.

10.1 User security requirements

All UK LLC users must:

- Only access the UK LLC TRE using organisation owned/approved machines, which are automatically maintained so that they are fully patched and up to date with relevant virus protection.
- Only access the UK LLC TRE from the UK and via a secure private or corporate network. Where using a private network, the user must make all reasonable efforts to ensure this is maintained and the equipment is secure (strong password) and kept patched and up to date.
- Keep their UK LLC user access password private and their 2FA secure and not share these with anyone else.
- Comply with the data security requirements set out in the DAA, DURA and this policy.
- Maintain the confidentiality of the UK LLC held data.
- Report any breaches of data security to UK LLC – see examples below.

10.2 Reporting breaches and risks

It is vital that all users report any breach of the UK LLC TRE as soon as possible (support@ukllc.ac.uk). Examples include, but are not limited to:

- The loss or theft of the computer used to access the UK LLC TRE.
- Any unauthorised person gaining access to the UK LLC TRE (i.e. a person who is not approved and has not signed a DURA).
- Any sharing of login details or devices that permit access to the UK LLC TRE.

UK LLC is committed to continuous improvement of its systems. We ask that all users notify UK LLC about risks and any weaknesses they identify in UK LLC systems, policies and procedures (support@ukllc.ac.uk).

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11. APPENDICES – DATA OWNERS’ CONDITIONS AND REQUIREMENTS

11.1 Appendix 1: NHS England

Project-specific conditions are shared with users when their application is approved. Below are the general sub-licensing conditions and assessment process for applications that include NHS England data.

11.1.1 Sub-licensing conditions for host organisations

Where the Recipient Institute is accessing NHS Linked Data, the following additional conditions will apply:

- 1) The University [of Bristol] reserves the right to enter any of the premises where the data are accessed at its own discretion and when required by an NHS Contributor.
- 2) The NHS Contributors shall benefit from and can enforce the terms of the Licence directly in accordance with the Contracts (Rights of Third Parties) Act 1999 (without the involvement or consent of the University) against the Recipient Institute.
- 3) The NHS Contributors shall have the right at any time and at their own discretion to perform an audit of the Recipient Institute, provided that the Recipient Institute is given seven (7) days’ notice where permissible and practicable.
- 4) The NHS Contributors shall have the right to suspend, in whole or in part, the Licence in relation to all or part of the Data where:
 - i. The agreement between the University and the NHS Contributor is suspended in whole or in part; or
 - ii. The Recipient Institute has not complied, or is not complying with any of its obligations under the Licence, until the breach is resolved to the NHS Contributor's reasonable satisfaction.
- 5) The Recipient Institute shall have no rights in or to the NHS Linked Data other than the right to use the NHS Linked Data in accordance with the express terms of the Licence, which shall not exceed the Sub-licence permitted under the Data Sharing Agreement signed between the University and the NHS Contributor.
- 6) The Recipient Institute shall prospectively assign any and all future Intellectual Property Rights in any NHS Contributor Manipulated Data to the relevant NHS Contributor, from creation and shall execute or procure the execution of any document, or shall perform, or procure the performance of any acts as may be required to give this effect.
- 7) Where the Recipient Institute does not maintain a registration under the NHS Data Security and Protection Toolkit, the Recipient Institute warrants that the Data Security Policies outlined in the Systems Level Security Policy (available upon request) provide an equivalent level of protection of any Personal Data accessed by the Recipient Institute.
- 8) The Recipient Institute shall not have the right to assign, novate, transfer, charge, dispose of or deal in any other manner with the Licence, or any of its rights or beneficial interests under it, or purport to do the same, nor sub-contract any or all of its obligations under the Licence without the prior written consent of both the NHS Contributor and the University.

11.1.2 Application assessment process

The points listed below summarise the process followed by the UK LLC Data Access Committee when assessing applications to access NHS England data.

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- 1) To consider and define criteria by which application subject matter/data content is determined to have an 'elevated sensitivity' and thus requires additional review steps.
- 2) To assess applications against the following criteria:
 - i. Has the applicant demonstrated how their research outputs will lead to public good?
 - a. Are there clearly articulated scientific and wider societal impacts of the proposed research?
 - b. Are there clearly articulated benefits to healthcare provision, adult social care or the promotion of health?
 - c. Is the applicant committing to publish the findings of the research into the free-to-access public domain?
 - d. Has the applicant provided a realistic and comprehensive plan for how their findings will be disseminated to relevant stakeholders to achieve the stated benefits?
 - ii. Is the data request proportionate?
 - a. Is the data request minimised sufficiently so that all requested data are justified by the stated purpose?
 - b. Is there a clear and specific justification for the use of data of particular sensitivity?
 - c. Is the request to use linked data justified as being necessary to realise the intended benefits of the application?
 - d. Has any request to use linked data demonstrated how the intended purpose is only achievable by using NHS data linked to non-NHS data within the UK LLC (i.e. that the request could not be fulfilled by the NHS directly)?
 - iii. Does the application generate any additional or unacceptable risks of disclosure of participant identity?
 - iv. Does the proposed research have the potential to bring the UK LLC or the owners of the data deposited in the UK LLC TRE into disrepute?
 - v. Does the applicant demonstrate adequate levels of data security at their institution?
 - a. Is there organisational security assurance for applicants requesting linked NHS data?
 - vi. Is there a clear legal basis for this use of UK LLC data?
 - a. Is there a clear legal basis for any processing of linked NHS data?
 - vii. Has the applicant committed that their proposed data use will not be for profit-making purposes?
 - viii. Where the applicant is a student/PhD student, has the applicant demonstrated how their use of the data will be adequately supervised?
- 3) To consider any emerging risks, issues and/or data access policy issues and to refer these to the UK LLC Executive Group and UK LLC Strategic Advisory Committee for advice.
- 4) To, where appropriate, take advice of third-party specialist knowledge to inform decision-making and the evolution of the UK LLC access request process.
- 5) To provide regular updates to the UK LLC Executive Group and UK LLC Strategic Advisory Committee, including a summary of applications made, decisions taken, performance metrics and any arising risks, issues or landscape changes that members of the UK LLC Data Access Committee wish to report.

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- 6) For each onward sharing of the linked NHS data, to publish information about the dissemination on the NHS England release register. This should include the name of the organisation(s) accessing the data, the purpose (summary of the project) and details of the data released.
- 7) To provide regular updates to the contributing LPS summarising the applications made, decisions taken, performance metrics and an overview of projects and project outcomes.
- 8) To publish information into the public domain about applications made, the decisions relating to these and the name of the organisation(s) accessing the data, the purpose (summary of the project) and details of the data released.
- 9) To ensure a clear and reproducible process for decision making is established and made clear to members, applicants, key stakeholders and the public through a 'Standard Operating Procedure' and through set Service Standards (quantifiable metrics for service delivery).