West Midlands Secure Data Environment Data Request Form - Guidance Document

University Hospitals Birmingham (UHB) believes that data is a part of the mission in delivering excellent care today and even better care tomorrow.

At UHB, we understand that data is integral in identifying and responding to the needs of the population we serve. Data is at forefront of how evaluate and improve the treatment and care delivered to the population. To support research that can improve care for people in our local area and beyond, the West Midlands Secure Data Environment has been set up as a secure and ethically approved research platform. It allows approved researchers to access health data safely, helping generate insights that can benefit patients and the wider population.

WMSDE will provide safe access to those clinicians, analysts and researchers who are committed to using this data to improve patient care and the population's health and well-being. The WMSDE will contain data collect from patients who access care, treatment and services delivered by UHB.

In order to submit a request to access WMSDE data, a completed data request from will need to return to WMSDE@uhb.nhs.uk.

WMSDE services are costed per request. After we receive your completed data request form, our team will arrange a suitable time to discuss your request either via face-to-face meeting, via web conferencing or, over the phone. At this meeting we will identify the services you require and begin to ascertain the data that would be required for your study. The team can also work with you to help develop the data request form, to ensure the request meets your requirements.

Each data request received from an applicant external to University Hospitals Birmingham NHS Foundation Trust (UHB) will be subject to the 'Data access request' process detailed within Annex A of this document. The process for applicants substantively employed by UHB will differ slightly and omit the requirement of due diligence. Substantive employees will not be issued a contract; in contrast they will be required to sign a 'letter approval' issued by the Research & Development Governance team.

When completing the Data request form it is important to populate the form under the assumption that all persons assessing the request, will have no prior knowledge in the clinical/ scientific area relating to the project.

The application form will be subject to a review by the Data Access Committee review and will require the lay summary to be completed in plain English. The Data Access Committee is group of people, who are impartial to the Trust and have a primary objective of representing patients and the public. The committee will review all

applications submitted and determine if the project aligns with the 'five safes' framework, WMSDE ethical approvals and identify if the project presents benefit to patients/ public. All projects approved and supported by Pathway, will have the lay summary published within domains accessible the public.

Terminology

Aggregated data	Quantities of data compiled together and presented in a summary format
Data Egress	Transfer of data to an environment external of UHBFT
DRF	Data request form
HRA	Health Research Authority (About us - Health Research Authority (hra.nhs.uk))
ISO27001	An international standard for information security. The ISO27001 accreditation can be obtained by organisations to ensure a best-practice approach and help manage their information security by addressing people, processes and technology.
Machine learning	Machine learning is a branch of artificial intelligence (AI) and computer science which focuses on the use of data and algorithms to imitate the way that humans learn, gradually improving its accuracy.
NHS Data security protection toolkit	An online self-assessment tool that enables organisations to measure and publish their performance against the National Data Guardian's ten data security standards. All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly.
RAS	Research Application Support Team (Research Application Support (RAS) - University Hospitals Birmingham (uhb.nhs.uk)
Substantive employee	An employee that holds a contract for permanent employment within an organisation.
Trusted Research Environment	A highly secure computing environment that provides remote access to health data for approved researchers to use in research. The TRE

	provides researchers an environment that enables them to collaborate, analyse, share code and results within the same research projects.
Real World Data	Data collected from real-life settings outside of traditional clinical trials. This includes information from electronic health records, insurance claims, patient registries, and wearable devices. RWD helps researchers understand how treatments work in everyday practice.
Health Categories	This is the category of the dataset and its contents as determined by the Health Research Classification System. The Health Categories dimension of the HRCS captures the area of health or disease being studied. There are 21 separate categories which encompass all diseases, conditions and areas of health. Each of the Health Categories includes research into both disease and normal function. Should your project have a broader reach, i.e. impact of living in a coastal community then see the further advice and use either the Generic Health Relevance or Disputed Aetiology and Other categories.
Synthetic Data	Artificially generated data that mimics the structure and patterns of real data but does not contain any actual personal information. It is used for testing, training models, or sharing data safely without risking privacy.
Aggregate	Data that has been combined from multiple sources or individuals and summarized to show overall trends or patterns. Aggregate data does not include details that can identify any single person.
Pseudonymised	Data in which personal identifiers (like names or NHS numbers) have been replaced with artificial identifiers or codes. While it reduces the risk of identifying individuals, the data can still potentially be linked back to a person with additional information.
Identifiable	Data that includes personal details that can directly or indirectly reveal an individual's identity, such as name, address, date of birth, or NHS number.

Frequently Asked Questions

1. Writing a plain language executive (lay) summary (A6)

As part of the WMSDE Data Request form and for transparency of how UHB data is being used within WMSDE, we ask for applicants to include a plain language summary (Lay Summary) of their project. This executive summary will be present to the Data Access Committee as part of the review process and will be included on the online public facing WMSDE Data Use Register.

Here are some general principles to follow to write a good plain language summary of your research for a general audience:

- Be accurate, clear and concise
- Do not assume any prior knowledge
- Use words that are appropriate for the reader
- Use short sentences (up to 20 words) and short paragraphs (up to 3 sentences)
- Use neutral language
- We would recommend involving patients, patient representatives, or members of the public in the development and/or review of your summary/feedback plans
- If possible: Involving professionals with experience of writing in plain language for the public such as medical writers can also help.

We recommend that Lay Summaries are broken down with the following elements:

- Stating the aims
- Background, including a lay overview of disease area
- Scientific rationale for research
- Broad description of the data required
- What is the public health or patient benefit.
- If it was felt beneficial, please include a glossary of terms
- If you felt providing images/ flow process would help review, please include these as attachments and highlight these within the lay summary.

Please be advised that this information will be published on our Data Use Register.

For further guidance:

- Writing a plain language (lay) summary of your research findings - Health Research Authority (hra.nhs.uk)
- HRA perspective on Research Transparency involving AI in healthcare - AI and Digital Regulations Service for health and social care (innovation.nhs.uk)

2. **Is Patient and Public involvement required? (A11)**

Yes. Public involvement makes sure research is relevant and meaningful to those it aims to serve, and the HRA recommends Researchers requesting access to data will be required to provide evidence that their project has involved patient or public consultation.

Evidence can be in the form of a 'letter of support' or 'minutes' from a Patient and Public Involvement meeting. If you need to explore providing evidence in an alternative format, please email WMSDE@uhb.nhs.uk

PPIE is an important part of the Governance and our Data Access Committee members review, we recommend that applicants breakdown Patient and Public involvement within their data request form on:

1. Patient and Public Involvement to date
2. Planned Patient and Public Involvement during the project
3. Planned Patient and Public Involvement during dissemination of project outcomes

There are several ways to have PPIE within your project including:

- If applicant is a healthcare professional, discussing the project design and reasoning with the patient cohort or staff to gather feedback
- Approaching disease or area specific charities or groups to explain the project and ask for feedback
- Having a patient or member of the public involved in the project development as a Lay member of the project team
- Asking a Patient or member of the public to review or be involved in the development of the project lay summary
- Where the project is part of a funded grant, many funders expect to see clear PPIE which can be documented in this section on what involvement there has been.

For further guidance:

- Public Involvement - Health Research Authority (hra.nhs.uk)
- The importance of public involvement in research - AI and Digital Regulations Service for health and social care (innovation.nhs.uk)

3. **Data Egress Vs Trusted Research Environment (TRE) (B)**

- All research data hubs at UHB will provide approved researchers access to data in the Trusted Research Environment (TRE). The TRE is UHBs default position for providing researchers access to data, as it enables secure access and fulfils the 'safe setting' principle of the 'five safes' framework.
- There may be scenarios in which the approved researcher will be unable to conduct their research within the TRE. In these exceptional circumstances, we can consider data egress of the approved dataset. The project will need to satisfy the 'five safes' framework and we will conduct an extensive assessment of the intended environment**.** There will be an agreement between the UHB and the lead researcher's organisation stipulating the terms of use, duration of utilising the data and appropriate destruction of the data.

4. What are the data security standards?

The 'Data security standards' section of the data request form intends to identify appropriate mechanisms that will provide assurance on the requesting organisations technical/ security measures. This section will only be applicable for projects that intend to egress the data. The requestor will need to liaise with their organisation to obtain the relevant evidence and complete the 'data egress' checklist.

5. What is small number suppression?

In the instances where a data field requested presents less than 10, small number suppression will be applied. Small number suppression is a disclosure limitation method which involves removing data (e.g., from a cell or a row in a table) to prevent the identification of individuals in small groups or those with unique characteristics.

6. Ethical approvals

Pathway data hub holds NHS ethical approvals. The hubs ethical approval can be utilised by researchers, where the research projects falls within the scope of Pathways ethics. If you are unsure if your project will fit within the hubs ethical approvals, please email WMSDE@uhb.nhs.uk for further guidance.

Researchers, who have obtained independent ethical approvals from a NHS research ethics committee, can also submit a data request to Pathway. Please provide a copy of your ethical approval, upon submission of the completed data request form.

7. Cost model

operates a cost recovery model for all data requests to keep the service sustainable and accessible for everyone. Our services are costed using a standard service framework and take into account the following areas:

- Complexity of data required - This is broken down into the volume of data, the number of datasets required, whether any cross-linking is required, image datasets.
- Reoccurrence of data - Is the request a one-off or recurrent?
- Nature of services - Is the request just for data access or will additional services be required, such as access to our staff for consulting?
- Type of Environment required for data analysis – Does the request require specific infrastructure or tools for data analysis.

WMSDE can signpost applicants to the Research application support (RAS) team to discuss potential funding avenues that may be available for example open grant calls or future calls as required.

8. What Statistical analysis tools are available?

The following statistical analysis tools are available to approved researchers, within the trusted research environment (TRE):

- R
- Python
- Stata
- MS programs

If your project requires specific statistical tools or involves machine learning or AI additional discussions will take place with the technical team on the ability to onboard these to support data analysis

9. Data licencing

Data access will be licensed. This means that researchers can only use the data for the purpose on the license, and not any other project. It also means that data cannot be shared beyond the licensed agreement. Only the data required to answer the research question is accessed.

10. How will I identify the contract lead within my organisation?

It is important that you identify the contract lead within your organisation prior to submitting the data request form. We will need to liaise with the contract lead at your organisation, in order to agree the contract which will enable you access to the data. The contract lead is likely to be a person within the research governance or information governance team at your organisation.

Recommended reading

The National Data Guardian (NDG) Standards for Healthcare data: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/823491/NDG_progress_report_2018-19_v1.0_FINAL__002_.pdf

The Data Security Standard Overall Guide - (DSP) Toolkit: https://www.dsptoolkit.nhs.uk/help/attachment/24

The NDG review: Review of Data Security, Consent and Opt-Out assets: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review.PDF

Training Requirements

Provide a valid certificate of completion of Data Security and Awareness Level 1 Training offered by e-Learning for Healthcare: https://portal.e-lfh.org.uk/Component/Details/473458

AND

MRCs Confidentiality and Data Protection in Health Research. We will accept a certificate of completion for the accompanying quiz accessible here https://bygsystems.net/mrcrsc-lms/enrol/index.php?id=95

All training certifications must be dated within the last 12 months

Data Requirements

If you are providing your own data for integration, please provide the following details:

- Type of Data: Describe the type of data you will provide (e.g., experimental results, user data).
- Format of Data: Specify the format in which your data is available (e.g., CSV, Excel, JSON, SQL database).
- Volume of Data: Indicate the size or volume of the data (e.g., 10,000 records, 500 MB).
- Whether this data will be anonymised or linked to the SDE data sets.

Ensure that your data complies with relevant regulations and standards. The WMSDE is not responsible for the compliance of externally generated datasets.

Annex A – Data Access Request Process

NHS
University Hospitals Birmingham
NHS Foundation Trust