Part 2: Researcher Handbook

Date	Author(s)	Version created	Approval committee	Date of approval	Date next review due	Key changes made to document
24-07-2026	Chantal Chaney, Michael Dahl, Ashley Heinson	1	**Managing Director** Mark Heffernan **IG Lead** Shrayan Banerjee	28/8/26 	28/2/27	Newly created document

This is Part 2 of the researcher handbook and contains information specifically in relation to applying and accessing the Wessex SDE. It is intended for researchers who have identified the data that they require and have completed the 'Initial Feasibility Stage'.

Further information about the pre-application process is available in "Part 1: Explore and Connect". The final part of this Handbook is currently under development and will be: "Part 3: Access and Accelerate."

2. Apply and collaborate

Researcher and Organisation Registration

As part of the NHS Research Secure Data Environment (SDE) Network, the assessment of researchers and organisations is now managed through a national NHS Research SDE Network Registration Service. Before access to data can be approved through the Wessex SDE, both the sponsoring organisation and any researchers requiring access must be registered with this national service.

The Registration Service provides a single, network-wide process for verifying organisations and individuals against the **"Safe People"** requirements of the Five Safes Framework. This means that registration completed once can be recognised across multiple NHS Research SDEs, reducing duplication for researchers working across regions.

Registration is separate from your project application. Researchers should complete registration before, or alongside, submitting a Data Access Request Form (detailed below). Registration confirms that an organisation and researcher are suitable to apply for access, but it does **not** guarantee approval of any specific project or dataset. Project-specific reviews, including public benefit, feasibility, governance and data access approvals, continue to be undertaken through the relevant SDE's data access process.

As part of the registration process, organisations provide assurance regarding their researchers, and individual applicants must demonstrate an appropriate professional affiliation, complete relevant information governance training, and agree to the NHS Research SDE Network terms and conditions.

For detailed guidance, eligibility criteria and application forms, please refer to the NHS Research SDE Network Registration Service:

Registration Process Guidance

Policy on User and Organisation Registration

Researchers are encouraged to begin registration as early as possible, as registration and project review are separate processes that must both be completed before data access can be granted. **Most registration applications are processed within approx. one month, although complex applications may take longer.**

Data Access Request Form (DARF)

The DARF is the key document used by researchers to request access to the Wessex SDE. The DARF uses a national template that is consistent across the SDE Network. A copy of the Wessex DARF including Researcher guidance for completion is provided in Annex 1.

When completing the DARF researchers should provide as much information as possible to ensure that the Wessex Data Access Committee (DAC) is able to fully understand the study and the request being made. The DARF should be completed in Plain English and clearly explain how the study will deliver public benefit to our communities and the NHS.

Note: All DARF forms must be submitted to the DAC by the project PI to ensure that there is a clear line of sight and accountability between the request to access data, the rationale for the approach, and the use of the data.

Tip: When completing the public value sections of the DARF it may be helpful to consider the 'Core Values' of the SDE (provided at the start of this document) which have been set for us by the Wessex public. Showing clear alignment with these values is a key consideration for the DAC evaluation and approval, making it easier for them to approve your project.

Pre-Check

Once your DARF is returned to the SDE it will be undergo an initial pre-check process to:

- Validate completeness
- Ensure that the request is technically possible
- Provide early consideration of additional data, consultancy and/or specialist tools required

The pre-check will also include consideration of:

- Clinical robustness: ensuring that the proposed methodology is in line with local and national best practice for research, uses a robust approach, and does not introduce potential bias or further health inequalities
- Money: project funding and costing
- Ethics: ensuring that the objectives are well defined and deliver public benefit
- Legal: aligned with the SDE's HRA approvals
- Technical: that only the necessary data is being requested to meet the objectives of the study, the availability of the data and any exceptional requests, e.g. sending data outside the SDE to a super computer

Once the pre-check process is completed the SDE Team, via the SDE's Commercial Director or Managing Director, will complete the Data Access Committee (DAC) Pre-Check Report. A blank template showing what is included in the report is provided in Annex 3.

Once all paperwork is ready The SDE team works with the DAC Chair to prepare agendas for studies to be considered at an upcoming DAC meeting.

Data Access Committee (DAC)

The Wessex SDE's DAC meets monthly and includes both professional and public members. This is the primary group for approving your study request.

The DAC is an advisory and decision-making body that reviews applications to access data in the SDE and provide formal recommendations regarding their suitability in line with the Wessex SDE's overarching governance structure and section 251 approval.

The DAC decision making focuses primarily on:

- Public benefit
- Ethical alignment with permissions, Wessex SDE Core Values and public acceptability
- Alignment with the Wessex SDE Strategic Research Priorities as set out on our website

Note: studies are presented at the DAC by the Wessex SDE's Technical Team not the researcher making the application. As standard, any clarification or requests for further information about the application are resolved during the pre-check process.

Following the DAC the PI for the study will be notified about the outcome via the SDE Team.

Note: Any projects that are approved by the Wessex DAC will be added to the Wessex Data Use Register hosted on the SDE website and on the HDR Gateway. This is a mandated requirement from NHS England for all studies using the SDE

Network and will be completed by the SDE Team using the information provided in your DARF. Should you have any concerns with regards to your project being added to these registers please raise this with our team in advance of the DAC meeting including your reasons for wanting to keep specific information confidential.

DARF Amendments

From time to time, it may be necessary to amend the information provided in an approved DARF to reflect changes relating to:

- The data required
- The methodology and/or processes used to analyse the data
- The planned outcomes and/or public and patient benefit

How to submit an amendment

All amendments must be recorded in the Amendment Section at the start of the DARF. This section must clearly:

- Identify the specific information being changed
- Explain the rationale for the change

Note: Text from the originally approved DARF must not be altered or deleted. The amended DARF should clearly distinguish between the originally approved content and the proposed changes.

This approach ensures that reviewers can understand the basis on which the original DAC approval was granted and assess whether the proposed amendments constitute a “substantive change” requiring further DAC consideration.

Substantive Changes

Substantive changes are those that the Wessex SDE Technical Team considers may have a potential impact on one or more of the following:

- Size, scope of the research impacting on data requirements and time/cost of the SDE resources required to enable and support the study
- Public benefit
- Ethical alignment with approvals and permissions
- Alignment with Wessex SDE Core Values and public acceptability

Where a proposed amendment is deemed substantive, the researcher will be notified that the study must be re-reviewed by the Data Access Committee (DAC). The SDE will confirm when the review is scheduled to take place.

Substantive changes will only be implemented following DAC approval.

Non-Substantive Changes

Non-substantive changes are considered minor amendments that do not affect public benefit or ethical acceptability and relate only to:

- Clinical methodology
- Financial arrangements
- Technical implementation

(as defined in the Pre-Check process)

Where changes are assessed as non-substantive, they do not require DAC re-review and may be approved by the Wessex SDE Technical Team (and, where appropriate, the Operations Director).

However, researchers should note that multiple non-substantive changes over time may, in combination, be considered to materially alter the study. In such cases, the accumulated changes may be reclassified as 'substantive' and referred back to the DAC for review.

Challenging a DAC decision

Applicants may appeal Committee decisions within **30 days**, providing justification. Appeals are jointly reviewed by the Chair and Wessex SDE Senior Responsible Owner (SRO), who may uphold refusal or remit the decision back to the Committee. Final outcomes are communicated within **30 days**.

Services and tools

Once the study has been approved at DAC our team will start to work up a detailed 'Schedule of Work'. This will be the key document which sets out the detail of the work to be undertaken by the SDE team and will be developed in partnership with the lead researcher, or delegated officer.

For a 'simple' project, using existing SDE data, tools and services, this usually takes **1 calendar month.**

For more complex studies, for example requiring new data that currently sits outside of the SDE, timelines will be discussed and agreed with the study team.

For all approved research projects, we provide a secure and fully supported workspace within the Wessex SDE. Below is a list of all the standard and optional tools that are available to researchers. These can be discussed with the Wessex SDE team and will be captured within your Data Access Request Form and Data Access Agreement/Contract.

Standard secure workspace

Includes:

- User-friendly interfaces for essential data exploration, analytics, and cohort dashboarding.
- Advanced analytical environments (Jupyter Notebook, Nextflow).
- Base computing resources suitable for most clinical analytical needs.

- Expanded infrastructure available on request (GPUs, additional storage for imaging or genomic data).

Expert consultancy services

The Wessex SDE offers a suite of specialised consultancy services to strengthen and streamline your research project:

- AI and Machine Learning solutions and strategic advice
- Clinical expertise and support
- Contracting, legal, and data governance assistance
- Data access application guidance
- Dedicated specialist support (Data Analysts, Data Scientists)
- Epidemiological analyses
- Detailed feasibility assessments
- Health economics analyses
- Project management and oversight
- Real-World Data (RWD) monitoring aligned to FDA guidance
- Retrospective studies (please enquire for prospective research needs)

Analytical tools

Included Tools (standard access):

- Azure BLOB Storage
- Azure Fileshare
- Azure Virtual Desktop
- Cohort Builder
- Jupyter Notebook
- Python, R
- R Studio
- Libra office

Additional platform services

- “Bring your own tool”: flexibility to securely integrate external analytical tools into your workspace.
- “Bring your own code”: securely import and run your own analytical code.
- "Bring your own data": securely import your data, with the ability to also view and link your data with SDE held data
- Custom computing power configurations available to suit project needs.
- Secure workspace lifecycle management (setup, maintenance, decommissioning).
- Long-term secure data storage to support regulatory submissions.

To discuss how Wessex SDE can support your specific research requirements, please contact us at: WessexSDE@uhs.nhs.uk.

Contracting

Once the Schedule of Work has been completed with the study team, this will be passed to our Commercial Director to support the completion of the contracting phase and finalise pricing. Agreements will be captured in a detailed Data Access Agreement (DAA) and shared with the lead researcher to complete relevant highlighted sections. The SoW will be included as Appendix [2] to the DAA.

There is a pre-existing 'heads of terms' which governs the relationship between the Wessex SDE, UHS as the SDE Host and University of Southampton. For studies led by researchers working for either of these organisations, the lead researcher must involve their organisation's Research and Development (R&D) team, or the appropriate contracting or governance contact, as early as possible.

The researcher should not sign the Data Access Agreement personally; it must be reviewed and signed by an authorised representative of the organisation employing or sponsoring the researcher. For smaller organisations, this may be another designated contact responsible for contracts rather than a dedicated R&D team. Early notification will help avoid delays during contracting and confirmation of capacity and capability.

Workspace setup

In line with the Wessex SDE Platform's ISO 27001 accreditation and information governance requirements, researcher workspaces can only be permissioned once approved study data has been prepared and made available for researcher access.

The preparation of study data is a multi-stage process which may include:

- Onboarding and validation of new datasets, where approved and required
- Data curation and quality assurance
- Data linkage, where explicitly approved and agreed
- Data minimisation in accordance with the approved study requirements
- Application of local, national and Type 1 Opt-Outs, where applicable
- Pseudonymisation and other privacy-enhancing controls

The activities required for each study will vary depending on the approved data requirements and the datasets involved.

Data Linkage

Researchers should not assume that dataset linkage will be available for all studies. Data linkage activities require specialist resource and are subject to technical feasibility, governance approvals, and available capacity within the Wessex SDE team.

Where data linkage is required, this must be clearly described and justified within the Data Access Request Form (DARF) and subsequently agreed during the Data Access Committee (DAC) approval and Contracting stages. Only linkage activities

that have been explicitly approved and scoped as part of the study will be undertaken.

The Wessex SDE team may support linkage of datasets that are already available within the SDE, subject to feasibility and capacity. However, the Wessex SDE does not routinely undertake the acquisition, onboarding and linkage of new external datasets on a study-specific basis. Researchers wishing to use additional datasets not currently available within the SDE should discuss requirements with the Wessex SDE team as early as possible, as this may affect study timelines, feasibility and costs.