

Special Conditions

Trusted Research Environment (TRE) Supplemental Terms

NICE TRE ACCESS

1. Introduction

- 1.1. These supplemental terms shall apply as Special Conditions under the relevant DSA to any Recipient and its Personnel accessing and/or otherwise using the TRE Service pursuant to a Contract between NHS Digital and the Recipient.
- 1.2. Unless otherwise set out below, all defined terms used herein are defined in the Contract.

"2FA"	two-factor authentication;
"DARS"	NHS Digital's Data Access Request Service;
"Incident"	an unplanned interruption or reduction in quality of the TRE service;
"NSD"	NHS Digital's National Service Desk;
"Problem"	a cause, or potential cause, of one or more Incidents;
"Service Request"	a request for information, advice, access to a tool, or an amendment to the existing TRE service;
"Severity"	<p>Severity 1: A critical adverse impact on the provision of the TRE or impacting on the core availability of the TRE; a critical loss or corruption of data;</p> <p>Severity 2: A major adverse impact on the provision of the TRE or poor performance of a key component part of the TRE which is causing a major impact; a major adverse impact on the provision of the TRE; a security breach; a significant loss or corruption of data;</p> <p>Severity 3: A moderate adverse impact on the provision of the TRE or poor performance for a key component part of the TRE which is causing a moderate impact; a less than significant loss or corruption of data;</p> <p>Severity 4: A minor adverse impact on the provision of the TRE;</p> <p>Severity 5: A cosmetic flaw affecting only the presentation of the TRE that does not undermine the Personnel's confidence in the service;</p>
"TRE"	a trusted research environment provided by NHS Digital as an enhanced service to the Data Access Environment;
"Working Day"	any day excluding Saturdays, Sundays and other days on which banks are not generally open for a full range of business in London.

2. Services to be Provided

“Day-1” Services

2.1. ‘Safe People’: User Provisioning

- 2.1.1. The DSA specifies the personnel authorised to use the TRE service and which data assets they are permitted access to in line with NHS Digital’s overarching legal/information governance framework.
- 2.1.2. Authorised personnel will be provisioned upon approval of the DSA. This process includes the:
 - a. creation of the authorised personnel’s account;
 - b. creation of a virtual desktop for each authorised personnel;
 - c. creation of a personal storage area;
 - d. installation of the tooling; and
 - e. granting access to the datasets specified in the DSA.
- 2.1.3. In line with NHS Digital’s existing DARS policy and procedures, NHS Digital accredits authorised personnel using organisation-based DSAs. NHS Digital accredits organisations that either have ISO27001 or submit a System Level Security Policy which, following review by NHS Digital’s security team may enable authorised personnel to have access to NHS patient data and systems. DSPT places the requirement on accredited organisations to ensure that authorised personnel hold the appropriate credentials and information governance training, and it falls upon accredited organisations to fulfil this provisioning activity.
- 2.1.4. Where additional authorised personnel need to be added to the TRE, the change to authorised personnel will be recorded on the NHS Digital CRM system.

2.2. ‘Safe Data’: Data provisioning

- 2.2.1. The governance mechanism for gaining access to data sets is the DSA. Authorised personnel will be granted access to data sets only in-line with approved DSAs once the data set is available in the TRE.
- 2.2.2. Where access to additional data sets is required, the Recipient must follow the DARS process to request that access, including undertaking any enhanced review required by the DARS process.

2.3. ‘Safe Setting’: Use of NHSD’s Data Access Environment

- 2.3.1. NHS Digital will provide access to its DAE – a safe setting for the TRE Service.
- 2.3.2. The entire environment sits within a secured environment, with data assets residing behind multiple security layers, and includes encryption on all health

data and encryption key management infrastructure configuration such that only NHS Digital controls the keys.

- 2.3.3. As part of NHS Digital's new strategic data platform, the DAE complies with the NHS Digital cloud security guidance meaning the TRE is compliant with noted safe computing stipulations.

2.4. TRE Access

- 2.4.1. Both parties confirm that they have the required authority and all necessary licences and/or consents to enter into these supplemental terms.
- 2.4.2. The TRE is accessed remotely over the internet, using most modern browsers.
- 2.4.3. Authorised personnel access a 'safe setting' – NHS Digital's DAE.
- 2.4.4. Access by authorised personnel is secured using 2FA. The authorised personnel enters a unique TRE-specific username and an associated (self-selected) password. The second level of authentication is provided by an authenticator application to be installed by the Recipient or the authorised personnel on the authorised personnel's personal or business mobile phone, desktop or laptop.
- 2.4.5. If the authorised personnel forgets its TRE password, the authorised personnel will be able to reset the password using a self-help feature found in the TRE.
- 2.4.6. If the authorised personnel requires any changes to its 2FA application (by way of example, if the authorised personnel acquires a new mobile phone), the authorised personnel must contact the NSD for assistance.
- 2.4.7. To protect the security of the TRE, the authorised personnel will be automatically logged out of the TRE after 30 minutes of inactivity. Any processing activities will continue even after logging out.

2.5. Tooling & Analysis

- 2.5.1. NHS Digital will provide a suite of tools enabling authorised personnel to undertake research analysis, each with user support. The following tools may be installed and available as required by the Recipient and subject to confirmation by NHS Digital:
 - a. Databricks, with Python and SQL
 - b. RStudio [1] (packages available will be confirmed by NHS Digital subject to a written request by the Recipient).
- 2.5.2. Additional packages associated with the tools listed above can be requested by the Recipient and NHS Digital may provide them at no charge. In time NHS Digital will provide functionality in the TRE for authorised personnel to

acquire additional packages direct from a trusted, whitelisted website, though this will not be offered on day-1 of service.

2.5.3. As new and/or different tools other than those listed above becomes available in the TRE, authorised personnel will be given the option to adopt the new tools. A cost may be associated with this and NHS Digital may factor this cost into the Charges.

2.5.4. If an authorised personnel has a specific tool requirement (including additional R packages) a request may be raised via the NSD. A cost may be associated with this and NHS Digital may factor this cost into the Charges.

2.6. Importing Code

2.6.1. Authorised personnel can import code into their applicable secured environment within the TRE (e.g., Recipient's existing code, sample code, etc.) by pasting into the TRE environment. Note that there is no limit to the number of lines that can be pasted into the TRE.

2.7. Collaboration

2.7.1. All authorised personnel named on a specific DSA will have access to a shared space within the TRE to support collaboration within the safe setting.

2.7.2. Code, scripts, notebooks, etc. can be stored in this shared space, providing a facility for authorised personnel to collaborate. Note that sharing of any code, scripts, notebooks, etc. with users outside of a specific DSA is not permitted.

2.7.3. Results can be shared within the TRE between authorised personnel named on a specific DSA.

2.8. Safe 'Outputs': Research Results Out

2.8.1. The TRE service allows results to be exported via an escrow function provided by NHS Digital. Artefacts are examined by NHS Digital prior to release to the authorised personnel, and any material will only be exported in accordance with NHS Digital's disclosure control output policy.

2.9. 'Safe people': Auditing TRE usage and user activity

2.9.1. The activity of each authorised personnel is timestamped and logged to provide a comprehensive audit trail. If necessary, access to audit information can be requested via the NSD.

Service Wrap

2.10. NHS Digital provide a service wrap for the TRE through the end-to-end service, supporting the Recipient through provisioning and the delivery of live service, including:

2.10.1. Providing a range of guidance for the TRE and its associated tooling and datasets on the NHS Digital website and/or within the authorised personnel's workspace. Resources include:

- a. details of the minimum tech requirements for the computer accessing the TRE;
- b. setting up 2FA and logging onto the TRE;
- c. data dictionaries;
- d. how to use the available tooling; and/or
- e. tutorial / sample workbooks – available in the authorised personnel's workspace.

2.10.2. A welcome email sent to new authorised personnel to use the TRE with links to all documentation and detailing how to get support.

2.10.3. Access to the NSD as set out below.

2.10.4. As necessary, NHS Digital's service management team will send emails to the Recipient and/or authorised personnel informing them of any operational matters, such as planned downtime or new features and facilities.

3. Service Targets

3.1. NHS Digital will aim to meet the following target service levels in its provision of the TRE:

3.1.1. New authorised personnel provisioning: Within 5 Working Days, once authorised via a CRM.

3.1.2. Service availability/operational hours: The TRE is available for use 24x7x365.

3.1.3. Availability (in business support hours): 98% (i.e., Mon-Fri 8am-6pm – available 98% within that time).

3.1.4. Exporting data: 80% of requests within 1 Working Day and 100% within 2 Working Days.

3.1.5. Business Support Hours: Human support is available to the Recipient and authorised personnel via the NSD. Hours of service are 8am - 6pm Mon - Fri (excluding Bank Holidays). The NSD can be contacted on [REDACTED] or by sending an email to [REDACTED]

a. NSD response times:

i. Severity 1

- 1. Incident: 15 minutes
- 2. Service request: 30 minutes
- 3. Problem: 9 hours

ii. Severity 2

- 1. Incident: 15 minutes

- 2. Service request: 30 minutes
 - 3. Problem 9 hours
- iii. Severity 3
 - 1. Incident: 30 minutes
 - 2. Service request: 30 minutes
 - 3. Problem: 9 hours
- iv. Severity 4
 - 1. Incident: 30 minutes
 - 2. Service request: 30 minutes
 - 3. Problem: 9 hours
- v. Severity 5
 - 1. Incident: 30 minutes
 - 2. Service request: 30 minutes
 - 3. Problem: 9 hours

b. Incident resolution times (in business support hours) are:

- i. Severity 1 issues: 8 hours.
- ii. Severity 2 issues: 16 hours.
- iii. Severity 3 issues: 40 hours.
- iv. Severity 4 issues: 120 hours.
- v. Severity 5 issues: 240 hours.

c. Problem fix times are:

- i. Severity 1 issues: 30 Working Days or an agreed release.
- ii. Severity 2 issues: 60 Working Days or an agreed release.
- iii. Severity 3 issues: 120 Working Days or an agreed release.
- iv. Severity 4 issues: 240 Working Days or an agreed release.
- v. Severity 5 issues: 360 Working Days or an agreed release.

d. In the event of a catastrophic failure:

- i. Lose no more than 24 hours of change. The recovery point objective is 24 hours.
- ii. NHS Digital will use reasonable endeavours to reinstate the service as soon as possible. There is no target recovery time, and the recovery time objective is reasonable endeavours.

3.2. If at any time NHS Digital fails to achieve any or all of the service levels (or has reasonable grounds to believe that it will not be able to achieve a service level) then it shall provide the Recipient with a service improvement plan (the Service Improvement Plan) within five (5) Working Days (or such other period as the parties agree in writing) and in doing so NHS Digital will use its best endeavours to:

- a. appoint a service improvement manager to own the Service Improvement Plan;

- b. set out in the Service Improvement Plan the action that it will take to:
(i) rectify or prevent the service level failure; or (ii) prevent the service level failure from recurring;
- c. obtain the Recipient's approval of such Service Improvement Plan;
and
- d. carry out the Service Improvement Plan approved under this clause 3.2 in accordance with its terms until such time that NHS Digital is achieving the relevant service level(s).

4. Service objectives and Service Charges

4.1. The Recipients requirements and quote are based on the following summary:

Project name:	Replacement of existing HES DAE access with a TRE solution to include HES and other linked datasets.
Project objectives:	<ul style="list-style-type: none"> 1) Replicate existing DAE access to HES using the TRE and providing access to additional tools (initially Databricks) 2) Provide linked access to additional datasets (likely require ONS deaths data and ePACT2).
NHS Digital quote reference:	[REDACTED]
Quote criteria:	<ul style="list-style-type: none"> a) 6 users b) 8 datasets ([REDACTED]) c) Includes HES HES-Civil Reg bridge file d) low compute (1000 monthly DBU) e) 12-month DSA. f) Databricks & R Studio (Server Pro + Connect) licences
Exclusions	a) The Recipient has elected not to order Data Wrangler services (as per paragraph 4.2.2)

4.2. The costs and charges associated with using the TRE to access the Data for NICE TRE Access, to be payable by the Recipient as a part of the Charges, are as follows:

Charges

4.2.1. The forecast Charges for the original scope of work under this service (subject to the provisions of this section 4) are:

Service description*	Unit Price	Frequency	Charge
Data Minimisation & Set Up	██████	██████	██████
Platform, Run and Third Party	██████	██████	██████
Compute	██████	██████	██████
User Costs	██████	██████	██████
Sub total			£40,658
VAT (20%)			£8.132
Total			£48,790

* Charges subject to change as set out in these Special Conditions, and in accordance with the Contract.

4.2.2. Optional addition(s), to be included in the Charges if the addition is selected by the Recipient:

Addition	Description	Annual Cost (ex VAT)
N/A		
* Charges subject to change as set out in these Special Conditions, and in accordance with the Contract.		

4.2.3. Assumptions

DSA Estimated authorised personnel	As per table at paragraph 4.1
DSA Estimated Datasets	As per table at paragraph 4.1

4.3. Charges will only be applied for the periods in which access to the Data is permitted and shall be invoiced by NHS Digital quarterly in arrears.

4.4. The Charges are stated exclusive of VAT, which shall be added at the prevailing rate as applicable and paid by the Recipient following delivery of a valid VAT invoice.

4.5. Subject to the relevant provisions of this schedule, the Recipient shall make payment to NHSD within 30 days of receipt of a valid invoice.

4.6. Unless the Parties agree otherwise in writing, all invoices shall be paid in sterling by electronic transfer of funds to the bank account that NHSD has specified on its invoice.

4.7. Should the Recipient fail to make payment of a valid invoice NHSD reserves the right to terminate the Data Sharing Agreement. In such an event, the recipient shall

have 10 days from receipt of notification from NHSD to remedy the non-payment. Failure to remedy within such timeframe shall entitle NHSD to terminate the DSA with immediate effect.

4.8. Charges may be subject to change:

4.8.1. Should additional licences be required, NHS Digital will endeavour to provide updated pricing to the Recipient within 5 Working Days of the Recipient's request.

4.8.2. If additional costs and Charges are incurred by NHS Digital in relation to:

- a. the Recipient's election to use an optional addition in accordance with section 4.2.2 of these Special Conditions;
- b. a specific project of the Recipient;
- c. the Recipient's use exceeding anticipated volumes in relation to the assumptions set out at section 4.2.3 of these Special Conditions or the authorised Recipient's usage of the Third-Party Tools; and/or
- d. providing bespoke add-ons or services to the Recipient or authorised personnel (by way of example only, in relation to the provision of analytical resource and landing project specific datasets);

4.8.3. NHS Digital will endeavour to provide the Recipient with at least 5 Working Days' notice of changes to the Charges before those changes take effect (this may not be possible in relation to usage of authorised third party licences).

4.8.4. in accordance with the DARS process, if additional datasets are requested by the Recipient (an additional DARS Application is required);

4.8.5. the overall charging mechanism for the TRE, DAE, and/or DARS process changes (on an annual basis, in accordance with the Contract).

5. Procedure for agreeing, adding and funding toolsets to the TRE:

5.1. If the Recipient requires any of the following, the process laid out at clause 5.2 and 5.3 shall apply:

- a. Additional Datasets
- b. Additional Users
- c. Additional Services

5.2. The Recipient shall submit details of the requested change to NHS Digital in writing. NHS Digital shall, within a reasonable time following such a request, provide a written estimate to the Recipient of:

- a. the likely time required to implement the change;
- b. any necessary variations to the Charges arising from the change; and
- c. any other impact of the change on these supplemental terms.

5.3. If the Recipient wishes to proceed with the change, NHS Digital has no obligation to do so unless and until the parties have agreed the necessary variations to its Charges and/or the services.

5.4. Notwithstanding any clause to the contrary in these supplemental terms or any appendix to it, NHS Digital may, from time to time and without notice, change the services in order to comply with any applicable statutory requirements, provided that such changes do not materially affect the nature, scope of, or the Charges for the services. If NHS Digital requests a change to the scope of the services for any other reason, the Recipient shall not unreasonably withhold or delay consent to it.

6. Recipient Activity and Responsibilities:

6.1. Recipient shall:

- a. Provide details of organisation and analytical users;
- b. Provide details of any required changes to the number of authorised personnel, the Datasets required and the type of usage;
- c. Ensure analytical users use login details / access to TRE and its outputs responsibly;
- d. Promptly inform NHS Digital on becoming aware of any issues with the TRE;
- e. as fully as reasonably practicable, respond to all reasonable communications of NHS Digital relating to the TRE; and
- f. Submit payment of invoices within 30 days of receipt of the relevant invoice.

7. Governance and Reporting:

7.1. The TRE service will be supported by a quarterly review process.

7.2. Each quarter, the parties shall meet in good faith to review the following:

7.2.1. Performance of the service in accordance with the service levels at clause 3.1.5

7.2.2. Usage of the TRE (to support invoicing purposes) including:

7.2.2.1. number of authorised personnel for the preceding quarter;





7.2.2.2. number of Datasets available within the TRE; and

7.2.2.3. analytical usage volume within the TRE.

7.3. NHS Digital shall use reasonable endeavours to provide a report on the actual usage of the TRE versus the estimates set out at clause 4.

7.4. NHS Digital shall produce a monthly service report detailing performance against the above service targets.

These Supplemental Terms have been entered into on the date of last signature as set out below:

For and on behalf of NHS Digital		For and on behalf of National Institute for Health and Care Excellence	
Signature:		Signature:	
Name:		Name:	
Title:	Commercial Specialist	Title:	Programme Director Data and RWE
Date:	04/04/2022	Date:	28 Apr 2022



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