

STANDARD OPERATING PROCEDURE 44

NHS England: Data Sharing Applications, Receipt of Data & Compliance

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Version 3.0	12 June 2026	Biennial review: minor clarifications to text throughout. Content not changed but significant text changes to ensure readability. Addition of quality control reminder for upload of identifiers.
Version 2.0	04 March 2024	Biennial review: Addition of some DARS usability tips, clarification on how the Data Sharing Framework Agreement works and some general expansion of concepts to improve clarity. Addition of responsibility for SPMs to monitor expiry of agreement via asset register.
Version 1.0	December 2021	N/A new SOP



CONTENTS

1	PURPOSE AND SCOPE	3
2	ACRONYMS.....	3
3	DEFINITIONS	4
4	BACKGROUND.....	4
5	RESPONSIBILITIES	5
6	WHEN	5
7	HOW.....	6
7.1	COMPLETION OF DARS APPLICATION.....	6
7.2	REVIEW OF DRAFT DARS APPLICATION.....	7
7.3	DATA SHARING AGREEMENT & DATA TRANSFER	7
7.4	COMPLIANCE & MAINTENANCE	9
7.5	DELETION OF DATA OR DSA EXTENSION	10
7.6	TRAINING REQUIREMENTS FOR STAFF	10
8	ASSOCIATED TEMPLATES AND DOCUMENTS	10

1 Purpose and Scope

This SOP describes how to apply for external research datasets held by NHS England. It also sets out the requirements for managing these datasets and complying with the relevant contractual, data protection, and governance obligations. Whilst this SOP focuses on applications to NHS England, the principles of good practice described may also apply when receiving datasets from third-party providers. Further information on receiving data from third parties, and the assurances that must be in place, is provided in [SOP 15 Part 3 'Data Sharing'](#).

This SOP is applicable to staff working on WCTU managed studies where applications for external datasets are made on behalf of the Sponsor. For studies not managed by WCTU, advice on application to NHS England should be sought from the Sponsor's Office via sponsorship@warwick.ac.uk.

2 Acronyms

CAG	Confidentiality Advisory Group
CI	Chief Investigator
DAE	Data Access Environment
DARS	Data Access Request Service
DPA	Data Protection Act
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
DSA	Data Sharing Agreement
DSPT	Data Security and Protection Toolkit
GDPR	General Data Protection Regulation
HES	Hospital Episode Statistics
HRA	Health Research Authority
IAR	Information Asset Register
ICNARC	Intensive Care National Audit and Research Centre
IG	Information Governance
IGARD	Independent Group Advising on the Release of Data
NICOR	National Institute for Cardiovascular Outcomes Research
ONS	Office of National Statistics
PID	Personal Identifiable Data
QA	Quality Assurance
ROPA	Record of Processing Activity
R&IS	Research & Impact Services
SEFT	Secure Electronic File Transfer
SIRO	Senior Information Risk Officer
SPM	Senior Project Manager
SOP	Standard Operating Procedure
TM/TC	Trial Manager/Trial Coordinator
UoW	University of Warwick
WCTU	Warwick Clinical Trials Unit

SOP: 44

Title: NHS England: Data Sharing Applications, Receipt of Data & Compliance

Version: 3.0

Effective: 12/06/2026

3 Definitions

Personal Identifiable Data (PID)	Any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
Special Category Data	This is PID related to: Racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, data concerning health or data concerning a person's sex life or sexual orientation.
Confidential Data	Information that is given with the expectation that it is kept confidential. It is not always, but in most cases likely to be related to an identifiable person. Unlike personal data, confidential data are always sensitive and never in the public domain and is applicable to data subjects that are both living or deceased.
Senior Information Risk Owner (SIRO)	Person with overall responsibility for Data Security and Protection. At WCTU, this role is delegated to the WCTU Head of Operations.
Data Sharing Agreement (DSA)	Formal contract documenting which data are being shared, how the data can be used, and for how long.
Information Asset Register (IAR)	List of all information assets in an organisation to help understand and manage the organisation's information assets and the risks to them.
Data Controller	Organisation who determines the purpose and the means of the data processing.
Data Processor	Follow instructions for processing of data on behalf of another organisation but do not determine the purpose or means.
Data Security and Protection Toolkit (DSPT)	An online self-assessment tool that allows organisations to measure their performance against the National Data Guardian's 10 data security standards. All organisations that have access to NHS patient data and systems can use the DSPT to provide assurance that they are practising good data security and that personal information is handled correctly. In WCTU this is maintained on an annual basis by the Information Governance (IG) Working Group.
Data Protection Impact Assessment (DPIA)	A DPIA is a process to help identify and minimise the data protection risks of the project. WCTU maintains a DPIA at a quality system level but where processing is outside of its scope, an individual DPIA may be needed.
Record of Processing Activities (ROPA)	An internal record that contains information on all personal data processing activities carried out by WCTU.

4 Background

<https://digital.nhs.uk/services/data-access-request-service-dars/dars-products-and-services>NHS England is the national provider of health and social care data in England and holds a range of datasets that may be used for health research or commissioning.

Access to NHS England datasets must be requested via the Data Access Request Service (DARS) and is subject to governance review, including advice from the Independent Group Advising on the Release of Data (IGARD). Charges vary depending on the datasets requested and any data linkage requirements.

SOP: 44

Title: NHS England: Data Sharing Applications, Receipt of Data & Compliance

Version: 3.0

Effective: 12/06/2026

NHS England requires assurance that organisations receiving data comply with relevant UK legislation, including the UK GDPR and the Common Law Duty of Confidentiality, and that robust data security measures are in place.

WCTU supports applications by maintaining a Data Security and Protection Toolkit (DSPT) aligned to its quality management system. This DSPT includes safeguards specific to WCTU and may only be used for WCTU managed studies.

5 Responsibilities

Programming Team Manager	<ul style="list-style-type: none"> Named IG Lead on WCTU DSPT submission. Chair of WCTU IG Working Group
WCTU Head of Operations	<ul style="list-style-type: none"> Designated Senior Information Risk Officer (SIRO)
IG Working Group	<ul style="list-style-type: none"> Oversight and submission of WCTU’s DSPT
Chief Investigator (CI)	<ul style="list-style-type: none"> Ensure all relevant approvals and contracts are in place prior to any trial specific activities taking place
QA Manager	<ul style="list-style-type: none"> Review of applications in line with this SOP and the DSPT
TM/TC	<ul style="list-style-type: none"> Coordination of applications NHS England under supervision of the CI
Academic lead	<ul style="list-style-type: none"> Ensure oversight of the terms of the DSA Complete or delegate completion of ROPA records for any NHS England data
SPM	<ul style="list-style-type: none"> Review applications and ensure appropriate funding is in place Maintenance of the Information Asset Register (IAR) inc. contract review and its documentation in the ROPA Ensure all members of the processing team are aware and are adhering to contractual terms.
Statistician or Health Economist	<ul style="list-style-type: none"> Download, processing, analysis and deletion of the data (if named)
Research & Impact Services (R&IS)	<ul style="list-style-type: none"> Maintenance of the Data Sharing Framework Contract with NHS England (this is required in addition to DSAs where individual record level data are being requested) Assigning signatory to individual DSAs with NHS England
Governance Committee	<ul style="list-style-type: none"> Oversight of compliance with training requirements for Information Security
Data Protection Officer (DPO)	<ul style="list-style-type: none"> Responsible for overseeing an organisation’s data protection strategy and its implementation to ensure compliance with GDPR requirements. UoW’s DPO sits in Legal and Compliance Services. The DPO is responsible for reviewing and approving any Data Protection Impact Assessments (DPIA)

6 When

Applications for data from NHS England or other external providers should be initiated at an early stage. This allows time to:

- scope data and linkage requirements;
- complete governance and ethics review;

SOP: 44

Title: NHS England: Data Sharing Applications, Receipt of Data & Compliance

Version: 3.0

Effective: 12/06/2026

- agree contracts and obtain required signatures; and
- put appropriate data protection and security safeguards in place.

Access to NHS England data can take several months from application submission to data availability. No data may be accessed or processed until all approvals and contractual arrangements are finalised.

Data access plans should be considered during study setup. Where relevant, consent documentation and participant information sheets must clearly explain the intention to obtain data from NHS England.

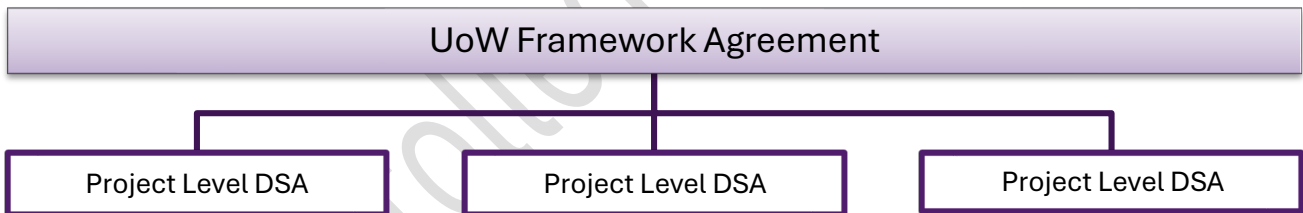
7 How

The process for applying for NHS England data is described below with further detail provided in subsequent sections. Project specific arrangements should be documented in the Data Management Plan and Data Flow Map.



Applications for datasets held by NHS England must be submitted via the online DARS system. Applicants must:

- register for an NHS England Account: [DARS - Register for an account.](#)
- log in to 'Create a submit a new application.



Access to NHS England data requires two contractual agreements:

- An organisational Framework Agreement
- A project specific DSA

The UoW Framework agreement is maintained annually between NHS England and UoW and must be in place before any data application can be submitted. It sets out organisation level information governance and legal requirements. Following approval of an application, a project level DSA is issued with terms specific to the approved dataset. Applicants do not need to take action regarding the Framework Agreement, but must comply with its terms. Audits of project level DSAs may also assess compliance with the Framework Agreement. Copies are available from R&IS on request.

7.1 Completion of DARS Application

Before starting a full application:

- Review the NHS England pre-application checklist to confirm eligibility: <https://digital.nhs.uk/services/data-access-request-service-dars/process/data-access-request-service-dars-pre-application-checklist#pre-application-eligibility-criteria>.
- Refer to NHS England guidance on completing a DARS application: <https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-processDARS: how to make an application - NHS England Digital>

DARS will only release special category or PID where a lawful basis for processing exists. The legal basis must comply with UK GDPR and align with the stated purpose of the data use. Important details needed for the DARS application including how to establish the correct legal basis are described in guidance document **G32**. The DARS application is completed via multiple online tabs:

- Each tab can be saved separately
- You can continue working on an existing application as often as you like
- Character limits apply so drafting responses offline before entering is recommended.

7.2 Review of draft DARS application

Before an application is submitted to NHS England, internal review should be completed. A PDF copy of the application can be generated using the 'Application Summary' function within the DARS application. The following people should be included in the review:

- SPM
- CI
- QA Manager
- Anyone named as a data user
- Sponsor
- Statistician
- Health Economist

Reviewers should pay particular attention to the identifiers requested, as these cannot be changed once the application has been approved. The SPM or their delegate should inform the Research Support Manager in R&IS of the intention to apply so that they can be involved in contract negotiation and signatories upon the agreement from NHS England to share the data. Please see [SOP 15 Part 3 'Data Sharing'](#) for more information.

7.3 Data Sharing Agreement & Data Transfer

DARS Approval

- Once the DARS application has been reviewed and approved by NHS England, and all queries resolved, NHS England will initiate a DSA.

Signature of the DSA

- The DSA must be electronically signed by an approved signatory in R&IS.
- Transfer of identifiers and data must not proceed until the signed DSA is in place

Provision of Identifiers

SOP: 44
Title: NHS England: Data Sharing Applications, Receipt of Data & Compliance
Version: 3.0
Effective: 12/06/2026

- After the DSA is signed, WCTU must provide NHS England with the pre-agreed, pre-defined identifiers required for the data linkage.
- The person preparing the identifiers must ensure:
 - No identifiers are included for participant who have withdrawn consent for this activity
 - No identifiers are included where there is no legal basis for the data sharing.

Quality control

- A second individual should independently check the identifier file to confirm it contains only the expected participants and fields.
- Any discrepancies must be resolved before submission to NHS England.

Information governance

- Creation, storage, transfer, and download of identifier lists must comply with the university's information classification and handling procedures: <https://warwick.ac.uk/services/secretarytocouncil/info-security/im-policy-framework/>

Data access

- NHS England will provide access to the data either:
 - Via the Data Access Environment (DAE), or
 - Through Secure Electronic File Transfer (SEFT)
- A named individual from the study team must be identified as responsible for accessing and/or downloading the data.

Access window and costs

- NHS England will specify the time period which the data can be accessed or downloaded.
- Costs and timelines may vary depending on whether one or multiple downloads are required.

NHS National Data Opt-Out

- Where data are processed without consent, NHS England is responsible for applying the NHS National Data Opt-Out before releasing data.
- If consent cannot be obtained, Section 251 (CAG) approval must be in place before applying to NHS England.
- The process for obtaining CAG approval is described in [SOP 43](#)
- Further guidance is available here: <https://digital.nhs.uk/services/national-data-opt-out/compliance-with-the-national-data-opt-out>

WCTU Data Sharing Green Light

- Before identifiers are uploaded to the linkage platform, the WCTU Data Sharing Green Light must be completed (**T04**).

Publication of the release

- Details of approved data releases are published by IGARD and can be viewed via the DARs Register of Data Release: <https://digital.nhs.uk/services/data-access-request-service-dars/register-of-approved-data-releases>.

7.4 <https://digital.nhs.uk/services/national-data-opt-out/compliance-with-the-national-data-opt-out>
<https://warwick.ac.uk/fac/sci/med/research/ctu/ctuintranet/qa/sop/https://digital.nhs.uk/services/data-access-request-service-dars/register-of-approved-data-releases>
Compliance & Maintenance

Use and storage of data

- Once the dataset has been accessed or downloaded it must be stored, accessed, and processed strictly in line with the DSA.
- NHS England may audit compliance at any time.

Contract review

- It is good practice to hold a contract review once the data have been received
- This review should include all staff involved in:
 - Processing and analysing the data (e.g. Statistician/Health Economist), and/or
 - Day to day management of the study (e.g. Trial Manager).
- The purpose of the review is to ensure all relevant staff understand the contractual requirements.

Key contractual terms

- During the contract review, the following must be clearly identified and recorded:
 - Named staff with permission to access the data
 - Restrictions on processing, sharing, or onward disclosure
 - Approved processing locations
 - The DSA end data and data retention requirements
 - Any special conditions

Records and documentation

Information from the SSA and contract review must be used to:

- Update the study Data Flow Map
- Complete a separate entry in the WCTU ROPA.

See [SOP 37](#) ‘Maintenance of the WCTU ROPA’.

<https://warwick.ac.uk/fac/sci/med/research/ctu/ctuintranet/qa/templates/Receipt> of a dataset from NHS England should constitute a separate entry on the ROPA and should indicate clearly the end of contract. This way, if staff leave, oversight remains of when data must be deleted. If staff change, considerations should be made for amendments to the agreement and/or additional contract reviews to ensure new staff are aware of the contractual terms.

Non-compliance and breaches

- If a non-compliance with the DSA or framework agreement is noted or there is an associated breach of the dataset, this should be managed in accordance with, [SOP 36](#) ‘Data Breach and Incident Management Procedure’.

Computer devices used for data processing

- Computer devices used to process data under a DSA must be:
 - Allocated to a named individual
 - Tracked using the process in [SOP 46](#) ‘Device Allocation & Lifecycle Management Procedure’.

- If a device is reallocated to another individual, this must be recorded and the device re-imaged.

7.5 Deletion of Data or DSA extension

Deletion at DSA Expiry

- All data received under the DSA must be deleted securely when the DSA expires or the overarching framework expires.
- Confirmation of data deletion involves parties completing and signing a certificate of deletion. This certificate must be returned to NHS England once data are deleted. For information on secure deletion please see SOP 15 Part 1 Data Management, as well as following current NHS England guidance which can be found here: <https://digital.nhs.uk/services/data-access-request-service-dars/process#deletion-of-data>.

DSA Extensions

- If continued processing of the data is required beyond the DSA expiry date, an extension to the DSA must be obtained.
- Applications for DSA extensions must be initiated well in advance of the expiry date, to avoid any period of processing without a valid contract.

An appropriate review date should be recorded in the ROPA to ensure prompt consideration of deletion or extension.

7.6 Training requirements for staff

All staff should ensure that their Information Governance and Information Security training is up to date. This can be checked using the competency tab inside your Personal Development Log. Up to date training is a key part of the DSPT security assurance.

8 Associated Templates and Documents

G32	NHS England Data Sharing Application Guidance
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