

## STANDARD OPERATING PROCEDURE 44

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

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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	<b>N/A new SOP</b>

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

#### 1. Purpose and Scope

This Standard Operating Procedure (SOP) describes the steps required to apply for external research datasets held by NHS England. The SOP also describes procedures to maintain the datasets and comply with the terms of the associated contracts. Although NHS England applications are the focus of this SOP, some of the overarching good practice principles and responsibilities will apply to receipt and handling of datasets from other third parties (e.g. Clinical Practice Research Datasets).

For more information on receipt of data from third parties and the assurances that should be in place, please refer to SOP 15 (part 3) 'Data Sharing'.

This SOP is applicable to any staff working on WCTU managed studies where applications for these datasets are to be made on behalf of the Sponsor. For non-WCTU managed studies, please contact the Sponsor's Office via [sponsorship@warwick.ac.uk](mailto:sponsorship@warwick.ac.uk) for advice regarding applications to NHS England.

#### 2. Definitions

<b>Personal Identifiable Data (PID)</b>	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.
<b>Special Category Data</b>	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.
<b>Confidential Data</b>	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.
<b>Senior Information Risk Owner (SIRO)</b>	Person with overall responsibility for Data Security and Protection. At WCTU, this role is delegated to the WCTU Head of Operations.
<b>Data Sharing Agreement (DSA)</b>	Formal contract that clearly documents which data are being shared, how the data can be used, and for how long.
<b>Information Asset Register (IAR)</b>	List of all information assets in an organisation to help understand and manage the organisation's information assets and the risks to them.
<b>Data Controller</b>	Organisation who determines the purpose and the means of the data processing.
<b>Data Processor</b>	Follow instructions for processing of data on behalf of another organisation but do not determine the purpose or means.
<b>Data Security and Protection Toolkit (DSPT)</b>	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.
<b>Data Protection Impact Assessment (DPIA)</b>	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.

### 3. Background

NHS England is the national provider of health and social care data in England. NHS England hold and maintain several datasets which can be accessed for health research or commissioning purposes. Datasets held include registration data from the Office of National Statistics (ONS) and Hospital Episode Statistics (HES) data along with many other datasets. A full list of their products and services can be found here: [NHS Digital - Products & Services](#). Requests for access to datasets held and maintained by NHS England must be online via the Data Access Request Service (DARS). DARS coordinate the review of all data requests through the Independent Group Advising on the Release of Data (IGARD). Charges for data vary depending on dataset, level and number of linkages required.

Where researchers intend to collect additional data held by NHS England, an application and subsequent review process is undertaken by NHS England before any data can be released. As part of the application process, NHS England will want to be assured of WCTU's compliance with the appropriate parts of UK Law that govern the processing of PID and confidential data. Confidential data and PID often overlap but are governed by two separate parts of the UK law, the Common Law Duty of Confidentiality (for confidential data) and the UK GDPR for PID.

Part of the conditions for processing data received by NHS England is that there are robust data security and protection procedures in place by the processing organisation. The organisation applying for data needs to assure IGARD that applicants can keep these datasets safe and process them within the confines of the UK law governing both PID and confidential data as described above. WCTU supports data request applications by submitting and maintaining a Data Security and Protection Toolkit (DSPT). The DSPT is usually done at an organisational level, however WCTU maintain a DSPT at a quality system level. The WCTU quality system includes additional safeguards which are not generalisable to the whole university. This toolkit can therefore only be used by applicants who are within WCTU.

### 4. Procedure

#### 4.1 Responsibilities

<b>Programming Team Manager</b>	<ul style="list-style-type: none"> <li>Named IG Lead on WCTU DSPT submission.</li> <li>Chair of WCTU IG Working Group</li> </ul>
<b>WCTU Head of Operations</b>	<ul style="list-style-type: none"> <li>Designated Senior Information Risk Officer (SIRO)</li> </ul>
<b>IG Working Group</b>	<ul style="list-style-type: none"> <li>Oversight and submission of WCTU's DSPT</li> </ul>
<b>Chief Investigator (CI)</b>	<ul style="list-style-type: none"> <li>Ensure all relevant approvals and contracts are in place prior to any trial specific activities taking place</li> </ul>
<b>QA Manager</b>	<ul style="list-style-type: none"> <li>Review of applications in line with this SOP and the DSPT</li> </ul>

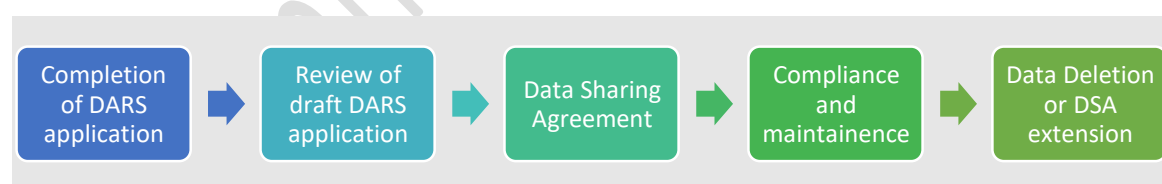
<b>Trial Manager/Trial Coordinator (TM/TC)</b>	<ul style="list-style-type: none"> <li>• Coordination of applications NHS England under supervision of the CI</li> </ul>
<b>Senior Project Manager (SPM)</b>	<ul style="list-style-type: none"> <li>• Review applications and ensure appropriate funding is in place</li> <li>• Maintenance of the Information Asset Register (IAR) inc. contract review and its documentation in the IAR</li> <li>• Ensure all members of the processing team are aware and are adhering to contractual terms.</li> </ul>
<b>Research &amp; Impact Services (R&amp;IS)</b>	<ul style="list-style-type: none"> <li>• Maintenance of the Data Sharing Framework Contract with NHS England (this is required in addition to DSA's where individual record level data is being requested)</li> <li>• Assigning signatory to individual DSAs with NHS England</li> </ul>
<b>Governance Committee</b>	<ul style="list-style-type: none"> <li>• Oversight of compliance with training requirements for Information Security</li> </ul>
<b>Data Protection Officer (DPO)</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• The DPO is responsible for reviewing and approving any Data Protection Impact Assessments (DPIA)</li> </ul>

## 4.2 When?

Applications for data from NHS England or other external organisations should be started well in advance to allow time for review, contract negotiation, and signatories. For example, the application process for NHS England can take up to 12 months from request submission to release of data. Approvals, contracts, and all other necessary data protection processing safeguards must be in place before any data are received and processed. Consideration early in the development of study documentation is key for a smooth application process. Consent and participant information sheets should contain clear information about the intention to obtain data in this way from NHS England.

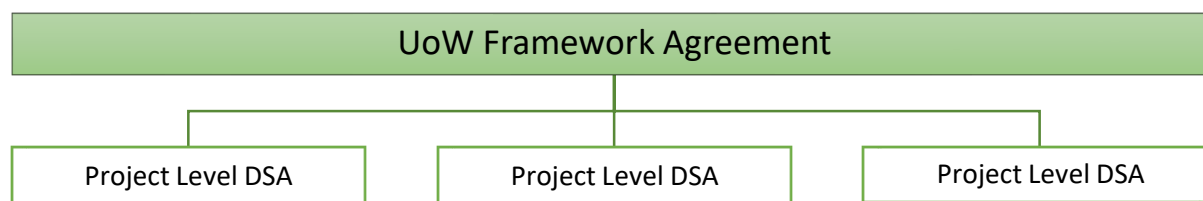
## 4.3 How?

The process for applying for NHS England data is outlined below. Detailed information on each of the required steps are described in subsequent sections.



Applications for datasets held by NHS England need to be completed via the online DARS system by registering for an NHS England Account: [DARS - Register for an account](#). You can then log in and 'Create a NEW application'.

To successfully receive data, you will need two contractual agreements in place. Applicants will need to comply with the terms in both agreements. The scope of these agreements is detailed below:



The UoW Framework agreement is a contract that is maintained annually between NHS England and UoW. This is required to be in place before anyone can apply for data. It contains terms that apply to any data processed such as compliance with UK GDPR and promotes ease of access. Once an application for data is approved, a project level Data Sharing Agreement will be put in place with terms specific to that project dataset.

#### 4.3.1 Completion of DARS Application

NHS England have a pre-application checklist: <https://digital.nhs.uk/services/data-access-request-service-dars/process/data-access-request-service-dars-pre-application-checklist#pre-application-eligibility-criteria>. This should be considered prior to making a full application. There is detailed guidance on the NHS England website on how to proceed with the full application: <https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-process>.

DARS will only share special category or PID to organisations that have a legal basis to do so, that reason has to align with data protection regulations which state only a few reasons where it is permitted. One example is that the sharing will benefit health and social care or the public. This is known as the 'Legal Basis' It is a requirement of the application that the nature and the purpose of holding the data is described in detail. Important details needed for the DARS application including how to establish the correct legal basis are described in guidance document [G32](#). Working on the DARS Application means the completion of a series of tabs, each tab can be saved separately. In general, all the fields in a tab need to be complete before the whole tab can be saved. Beware there is a limit on the number of characters that can be used in each section so it may be best to write the sections in Word first then copy and paste them over. You can continue working on an existing application as often as you like.

#### 4.3.2 Review of draft DARS application

Before an application is submitted to NHS England, internal review should be undertaken by creating a PDF of the application using the 'Application Summary' button in the DARS application. The following people should review the application:

- SPM
- CI
- QA Manager
- The member of staff that is named as a data user
- Sponsor

You should also inform the Research Support Manager in R&IS of your data sharing intentions at the time you start the application 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(3) 'Data Sharing' for more information.

### 4.3.3 Data Sharing Agreement

Once DARS have accepted and reviewed the application and any queries have been addressed, a DSA will be initiated by NHS England. This must be electronically signed by an approved signatory in R&IS. Once signed, WCTU will need to provide NHS England with the pre-defined identifiers to enable NHS England to link to the correct data. Following this, the data will be made accessible via the Data Access Environment (DAE) or by Secure File Transfer (SEFT). This involves identification of a named person from the study responsible for accessing the secure link for data download. There is usually a limited time period for data download which will be specified by NHS England in their correspondence. The cost and time will depend on whether there is one or multiple downloads. It is the responsibility of NHS England to apply any NHS National Data Opt Outs prior to sending the data if the data is being processed without consent. If you are unable to get consent from participants then you should have approval for this from the Confidentiality Advisory Committee (CAG) (Section 251 approval) before you apply for the data from NHS England. SOP 43 outlines the process of applying for CAG. More information on compliance with the NHS National Data Opt Out can be found here: [NHS Digital: Compliance with the National Data Opt Out](#).

Before the data are downloaded by one of the approved users of the data, the WCTU Data Sharing Green Light will need to be completed and signed (see SOP 15 (part 3) 'Data Sharing'. IGARD will publish details of any data release approvals here: [DARS - Register of Data Release](#).

### 4.3.4 Compliance & Maintenance

Once downloaded via SEFT or the DAE, the dataset needs to be held and processed in line with the DSA. Compliance with the DSA is subject to audit by NHS England. It is good practice to hold a contract review where all of the contractual terms in the DSA are scrutinised and understood by anyone involved with processing of the data (e.g. Statistician/Health Economist) or day to day management of the research study into which the data flows (e.g. Trial Manager). Any special conditions associated with named staff, processing/sharing restrictions, processing locations and when the DSA expires should be highlighted. This information should in turn be used to update the study Data Flow Map and complete an entry in the WCTU IAR by the academic lead, SPM, or QA Manager (see SOP 37 'Maintenance of the WCTU IAR' and G19 'Information Asset Register Guidance'). 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.

All parties being aware of the contract requirements will reduce the likelihood of any non-compliance with the contract, however if a non-compliance is noted or there is an associated breach of the dataset provided, please refer to SOP 36 'Data Breach and Incident Management Procedure'.

Devices used to process data under a DSA should be assigned to the individual and tracked by the QA Team. If a device changes hands, this should also be tracked and the device re-imaged if required.

### 4.3.5 Deletion of Data or DSA extension

All data must be deleted when the DSA 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. Data also needs to be deleted if the overarching framework agreement expires. For information on secure deletion please see SOP 15 (1) Data Management, as well as following current NHS England guidance which can be found here: [DARS - Data Deletion](#). Completed data deletion certificates should be sent to [Data.Deletions@nhsdigital.co.uk](mailto:Data.Deletions@nhsdigital.co.uk).

If processing of the data is still required, an extension to the DSA will be needed and copies should be present in the TMF. It is important that the application for a DSA extension is started well before the



expiry date so that there are no periods where the University is out of contract. An appropriate review date can be set in the IAR to enable oversight of this. A sample template certificate of deletion can be downloaded here: [DARS - Certificate of Destruction](#). It is the responsibility of the SPM to notify the Trial Manager before this expires. The Information Asset Register should detail the expiry date of any contracts associated with the data sharing with NHS England.

It is good practice when data processing is complete, that any staff processing NHS England data, have their UoW devices re-imaged to ensure any trace of the data is removed.

#### 4.3.6 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.

#### List of abbreviations

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
R&IS	Research & Impact Services
SEFT	Secure 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

#### Associated Templates and Guidance

G32 – NHS England Data Sharing Application Crib Sheet  
G19 - Information Asset Register Guidance