

## STANDARD OPERATING PROCEDURE 37

### Maintenance of the Warwick Clinical Trials Unit (WCTU)

### Information Asset Register (IAR) & Record of Processing Activities (ROPA)

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<b>Revision Chronology:</b>	<b>Effective date:</b>	<b>Reason for change:</b>
Version 3.0	13 May 2024	Biennial review: Significant re-write to change the scope of the IAR and to introduce the ROPA. Updated definitions list – clarity between DSA and DPA.
Version 2.0	15 March 2022	Updated to reflect changes to UoW Information Management Policy. Minor clarifications throughout.
Version 1.1	20 February 2020	Addition of a definitions section. NHS digital audit identified the need to define 'Information asset' in the SOP. Update to new format.
Version 1.0	25 July 2019	New document

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##### 1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to detail procedures to follow for keeping WCTU Records of Processing Activity (ROPA) and WCTU Hardware and Software Information Asset Registers (IARs) up to date. This is relevant for any member of staff working with within WCTU or on WCTU systems.

The procedures for managing data more generally are covered in SOP 15 (Information Handling) and all its associated parts. This SOP contains reference to sharing data and therefore part 3 of SOP 15 'Sharing Data' may need to be read in conjunction with this SOP.

##### 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>Processing</b> <i>(in relation to data)</i>	Activities taken in relation to data including: collection, recording, organising, storing, altering, disclosure by transmission, erasure and destruction.
<b>Hardware Asset</b>	A tangible, physical technology asset that includes computer equipment and data storage media.
<b>Software Asset</b>	Asset that includes applications, systems, databases and cloud-based services.
<b>Information Asset Register (IAR)</b>	Collective register of hardware and software assets
<b>Information Asset Owner (IAO)</b> <i>(in relation to the IAR)</i>	Person who is responsible for the data contained within a software asset and the associated risks. Responsible for updating the software assets where they are named as IAO
<b>Information Asset Administrator (IAA)</b> <i>(in relation to the IAR)</i>	Person who is delegated to work on a day-to-day basis with the information within an asset.
<b>Data Custodian</b>	The person who will be responsible for the use, security and management of all data generated by a study. This role is delegated to the study Chief Investigator (CI)
<b>Record of Processing Activity (ROPA)</b>	An internal record that contains information on all personal data processing activities carried out by WCTU. The scope of a single

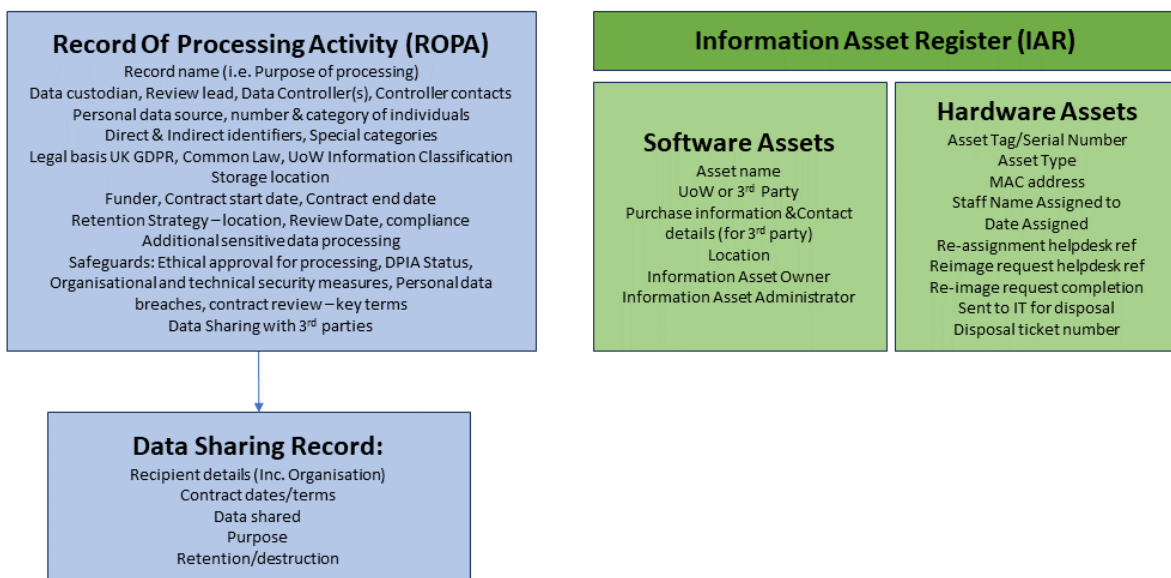
	processing activity is usually determined by the terms of the agreement that covers the processing.
<b>Data Sharing Agreement (DSA)</b>	Formal agreements, usually between two data controllers. Good practice when valuable, high volume or sensitive data will be shared. Used where the data controllers will each have interests in the data.
<b>Data Processing Agreement (DPA)</b>	Formal agreements, usually between a data controller and a data processor. A DPA is a requirement under article 28 of UK GDPR where a data processor or 'supplier' will process data on the controller's behalf.

### 3. Background

The UK General Data Protection Regulation (UK GDPR), Article 30 contains explicit provisions about the documentation of an organisations personal data processing activities. It is a legal requirement that organisations must maintain records on personal data processing which include the purposes of the processing, data sharing and retention requirements. UK GDPR reinforces the principle of accountability for processing and an organisation may have to make records on processing available to the Information Commissioners Office (ICO) on request. The UK GDPR also states that records must be kept up to date to accurately reflect current processing activity.

Keeping a record of all processing activity and maintenance of information assets is also a key part of the maintenance of the Data Security and Protection Toolkit (DSPT). The DSPT is the mechanism by which WCTU provide assurance of our information governance (IG) and security arrangements to the NHS for WCTU to process any data incoming from health and social care sources.

Maintenance of such records helps an organisation to comply with the accountability principle of the UK GDPR and it also aids the general understanding of the data an organisation processes to assist with risk management. The content of the ROPA and IARs are detailed in the image below and have been informed by UK GDPR article 30 and associated good practice guidance:



## 4. Procedure

### 4.1 Responsibilities

<b>Senior Project Manager (SPM)</b>	<ul style="list-style-type: none"> <li>Addition, review and maintenance of ROPA within their portfolio, including any data sharing events occurring prior to publication of the main study results.</li> <li>This can be delegated to appropriately informed and trained staff if appropriate.</li> </ul>
<b>CI/Academic lead</b> <i>(where no SPM is allocated)</i>	<ul style="list-style-type: none"> <li>Addition, review, and maintenance of ROPA where processing is outside of the portfolio overseen by the SPMs.</li> <li>This can be delegated to appropriately informed and trained staff if appropriate.</li> </ul>
<b>Governance Committee</b>	<ul style="list-style-type: none"> <li>Oversight of compliance with this SOP</li> </ul>
<b>Information Governance Working Group</b>	<ul style="list-style-type: none"> <li>Escalating issues related to the ROPA or IAR to the Governance Committee</li> <li>Delegating an IAO to each software asset</li> </ul>
<b>QA Team</b>	<ul style="list-style-type: none"> <li>Hosting the ROPA and Asset Registers</li> <li>Providing ongoing functionality and maintaining appropriate access rights.</li> </ul>
<b>Data Sharing Committee (DSC)</b>	<ul style="list-style-type: none"> <li>Addition of data sharing activity to ROPA where requests are made and executed post study publication and have gone through Data Sharing Committee Approval.</li> <li>Oversight of data sharing agreement compliance</li> </ul>

### 4.2 When?

	<b>When to add new</b>	<b>When to review or update</b>
<b>ROPA</b>	Prior to or at the point of processing activity starting	Timely manner in line with any processing changes but should be reviewed annually at a minimum
<b>Software Assets</b>	Prior to or at the point of processing activity starting using the asset	Annually
<b>Hardware Assets</b>	If a new laptop is allocated to an existing staff member (new or existing).	If computers or hardware are reallocated to different staff members

### 4.3 How?

The ROPA and IARs are hosted on Microsoft SharePoint and are administered by the WCTU QA team who grant and revoke access as appropriate. The ROPA and IAR can be accessed through this or via the 'ROPA & Asset Management' MS Team where there are applications that can be used to update the records in the SharePoint site. There is an instructional video within the MS Teams site.

### 4.3.1 Addition of a new ROPA

The scope of a processing activity is usually determined by the terms of the agreement that covers the processing. Only one record of processing activity is required for delivery of a clinical trial as this is governed by the funding contract. For additional processing covered by other contracts a separate ROPA should be considered. E.g. Where we receive a supplementary dataset for data linkage and it is governed by a separate DSA.

If we will share data with external organisations we should indicate this within the ROPA record to which it relates.

### 4.3.2 Review and update of the ROPA

At a minimum, the named review lead should review or nominate a delegate to review ROPAs on an annual basis but ideally as and when the processing changes or the retention review date is reached. Oversight of compliance with this will occur via the WCTU IG Working Group and Governance Committee. Automatic reminders can be set for review leads. Any updates to a ROPA should be documented in the relevant fields and the review date updated. Where no update is required, the review date of the review should still be documented to demonstrate compliance with annual review.

Examples of occasions where a ROPA may require updating prior to the scheduled annual review:

- There will be new data sharing activity with a third party
- Additional data will be collected
- Changes to the purpose of processing
- Change to the status of the processing
- Review date for review of the retention schedule is due.

### 4.3.2 Information Asset Register

The purpose of the software asset register is to help understand and manage software assets and any risks to them. The hardware asset register allows all hardware assets which may be used to process personal data to be tracked through to destruction to demonstrate compliance with retention and data security principles.

#### 4.3.2.1 Software Assets

Software Assets records are maintained by the IAO who will be assigned by the IG Working Group. Assets should be reviewed on an annual basis.

#### 4.3.2.2 Hardware Assets

Hardware Assets should be maintained by Line managers as part of staff onboarding and leaving process. This is essential for ensuring we are able to track all hardware assets from assignment through to destruction. This is a key part of our accountability responsibilities regarding appropriate use of personal data. Where personal data has been processed using a hardware asset, there is a possibility for temporary files to be stored locally and remain even after deletion of data, therefore it is important to track them to destruction or track the change in use so a decision can be made about the level of processing and whether a re-image of an asset would be appropriate prior to giving the new staff member the asset.

### List of abbreviations

CI	Chief Investigator
DPA	Data Processing Agreement
DSA	Data Sharing Agreement
DSC	Data Sharing Committee
DSPT	Data Security and Protection Toolkit
GDPR	General Data Protection Regulation
IAA	Information Asset Administrator
IAR	Information Asset Register
IAO	Information Asset Owner
ICO	Information Commissioners Office
IG	Information Governance
PID	Personal Identifiable Data
QA	Quality Assurance
R&IS	Research & Impact Services
ROPA	Record of Processing Activities
SOP	Standard Operating Procedure
SPM	Senior Project Manager
WCTU	Warwick Clinical Trials Unit

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