

## STANDARD OPERATING PROCEDURE 37

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

#### Information Asset Register (IAR)

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<b>Revision Chronology:</b>	<b>Effective date:</b>	<b>Reason for change:</b>
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 the WCTU IAR up to date.

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

##### 2. Definitions

<b>Personal Identifiable Data</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>Information Asset</b>	An information asset is a body of information, defined and managed as a single unit so it can be understood, shared, protected and exploited efficiently. Information assets have recognisable and manageable value, risk, content and lifecycles. In WCTU an asset usually relates to a clinical trial dataset. Datasets that are shared with WCTU from external sources are considered to be separated assets.
<b>Information Asset Register (IAR)</b>	List of all information assets in an organisation to help understand and manage your organisation's information assets and the risks to them.
<b>Information Asset Owner (IAO)</b>	Person who is responsible for the data contained within an asset and the associated risks.
<b>Information Asset Administrator (IAA)</b>	Person who is delegated to work on a day-to-day basis with the information within an asset.
<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.

##### 3. Background

The UK General Data Protection Regulation (UK GDPR) 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. The introduction of the UK GDPR reinforced 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. Keeping a record of all personal data assets and their associated processing purposes is referred to as an 'Information Asset Register'. The UK GDPR also states that records must be kept up to date to accurately reflect current processing activity.

Not only does creation and maintenance of the IAR help an organisation to comply with the accountability principle of the UK GDPR but it aids the general understanding of the data an organisation processes to aid risk management and improve information governance (IG). The IAR captures information assets that originate from WCTU or have been shared with us for processing by a third party organisation. The IAR also contains provision for recording and oversight of data that flows out of any WCTU asset to a third party. For all data sharing activity in or out of WCTU there should be a fully executed DSA.

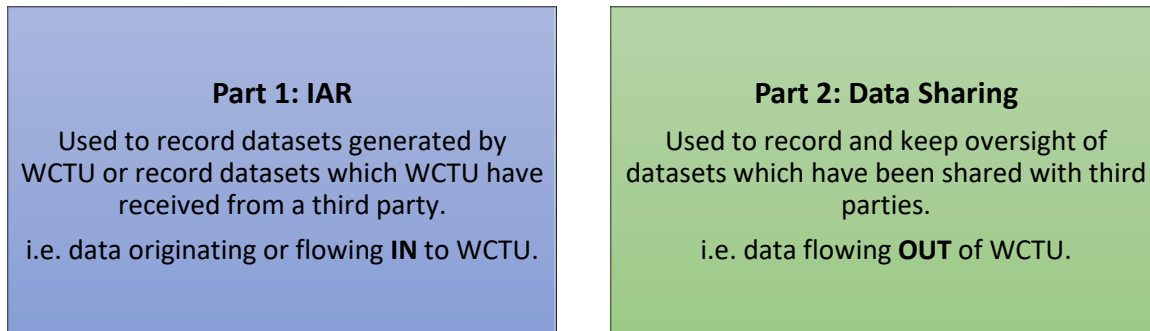
#### 4. Procedure

##### 4.1 Responsibilities

<b>Senior Project Manager (SPM)</b>	<ul style="list-style-type: none"> <li>• Addition, review and maintenance of Information Assets within their portfolio.</li> <li>• Addition, review and maintenance of incidences where data flows to third parties from an asset within their portfolio.</li> </ul>
<b>Chief Investigator/Academic lead</b>	<ul style="list-style-type: none"> <li>• Addition, review and maintenance of Information Assets for which they are the academic lead and the project sits outside of the active WCTU portfolio overseen by the SPMs.</li> <li>• Addition, review and maintenance of incidences where data flows to third parties from an asset for which they are the academic lead and the data sits outside of the current active portfolio.</li> <li>• Named IAO</li> </ul>
<b>Trial Manager/Coordinator or equivalent role</b>	<ul style="list-style-type: none"> <li>• Named IAA</li> </ul>
<b>Governance Committee</b>	<ul style="list-style-type: none"> <li>• Oversight of compliance with IAR</li> </ul>
<b>WCTU Programming Team</b>	<ul style="list-style-type: none"> <li>• Hosting the IAR, providing ongoing functionality and maintaining appropriate access rights.</li> </ul>

## 4.2 When?

The WCTU IAR has two parts which are used at different times:



The person responsible should add new datasets or new data flows to the main IAR or data sharing section of the register as soon as possible but ideally no later than at the point that data collection/collection or sharing event starts. The IAR and its associated sections should be updated regularly if there are new data assets or changes to any existing assets or data flows. As a minimum the IAR and its associated sections must be reviewed and updated every 12 months.

## 4.3 How?

All parts of the IAR are hosted on Microsoft SharePoint and are administered by the WCTU programming team who grant and revoke access as appropriate. The IAR can be accessed by pasting the following link into the internet browser: <https://livewarwickac.sharepoint.com/sites/wms-wctu-pt/trials>

### 4.3.1 Addition of new information data assets

All WCTU information assets and data shared with WCTU must be entered on the IAR. Data that is shared with WCTU will be considered as a separate information asset and should be entered as a new asset on the IAR. If it is related to the delivery of an existing asset, this should be reflected on the data flow map. Any associated data sharing restrictions and DSA expiry information should be added to relevant fields in the asset so that compliance with the terms of the DSA can be monitored. Guidance on completion of each of the fields in the IAR can be found in Guidance document **G19** which can be found [here](#).

### 4.3.2 Recording and oversight of data sharing activity on the IAR

For all executed DSAs where data will flow out of a WCTU asset, information should be added to 'Data Sharing' part of the IAR. Guidance is available on the information required (**G19**)

### 4.3.3 Review and update

Any updates to the IAR should be documented in the relevant fields. Where no update is required, the review and the date of the review should be documented. Review should be annually at a minimum but more frequently as required. The named asset lead as per section 4.1 of this SOP should initiate and complete the review.

Examples of occasions where an asset may require updating prior to the scheduled annual review:

- New data sets are acquired for data linkage with existing assets
- Data is being shared from an asset to an external recipient
- Additional data will be collected
- Changes to the purpose of processing
- A data set is archived or disposed
- Data Sharing Agreement for data shared with a third party has expired and requires confirmation of appropriate destruction.

### List of abbreviations

DPIA	Data Protection Impact Assessment
DSA	Data Sharing Agreement
GDPR	General Data Protection Regulation
IAR	Information Asset Register
ICO	Information Commissioners Office
IG	Information Governance
QA	Quality Assurance
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
SPM	Senior Project Manager
WCTU	Warwick Clinical Trials Unit

### Associated Templates and Guidance

G19