UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 37

Maintenance of the Warwick Clinical Trials Unit (WCTU) Record of Processing Activities (ROPA)

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Revision Chronology:	Effective date:	Reason for change:
Version 4.0	22 July 2026	Biennial review: Moderate change – removal of IARs, SOP now solely covers the ROPA. Moved to new template. Minor amends to text to make more succinct.
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

To detail procedures to follow for keeping the WCTU ROPA up to date. This is relevant for any member of staff working within WCTU. For information on the management of Information Assets (Hardware & Software), see SOP 46 'WCTU Device Allocation & Lifecycle Management Procedure'.

Procedures for managing data are detailed in in SOP 15 (1) 'Information Handling' and its associated parts. As this SOP includes references to data sharing, please read SOP 15 (3) 'Sharing Data' alongside it.

2 Acronyms

CI	Chief Investigator
DPA	Data Processing Agreement
DSA	Data Sharing Agreement
DSC	Data Sharing Committee
DSPT	Data Security and Protection Toolkit
GC	Governance Committee
GDPR	General Data Protection Regulation
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

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.
Processing *(in relation to data)*	Activities taken in relation to data including: collection, recording, organising, storing, altering, disclosure by transmission, erasure and destruction.
Data Custodian	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 CI
Record of Processing Activity (ROPA)	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.
Data Sharing Agreement (DSA)	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.

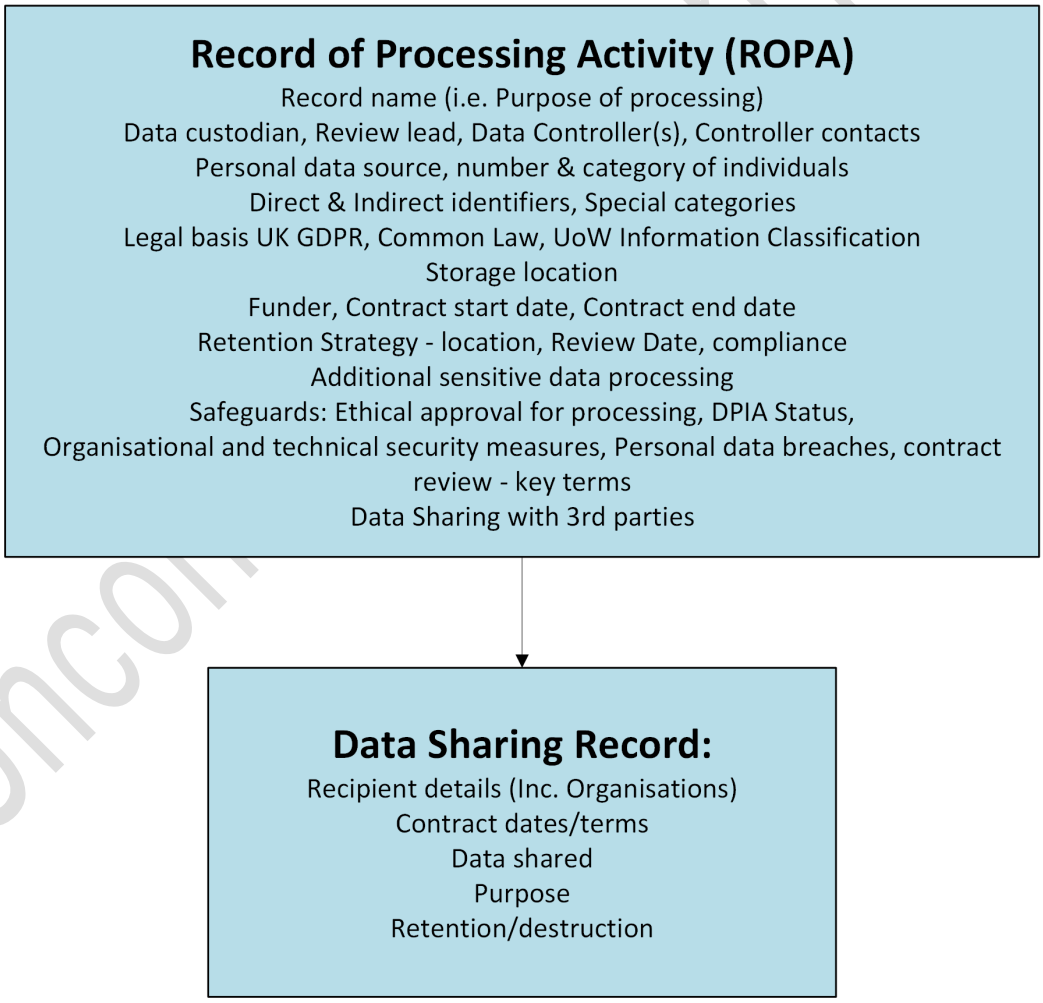
Data Processing Agreement (DPA)	Formal agreements, usually between a data controller and a data processor. A DPA is a requirement under article 28 of UK GDPR where a data processor or 'supplier' will process data on the controller's behalf.

4 Background

Article 30 of the UK GDPR requires organisations to document their personal data processing activities. This includes recording the purposes of processing, data sharing, and retention. Organisations must keep these records up to date and make them available to the ICO on request. Maintaining such records is a legal requirement, supports accountability and helps organisations understand their data use and manage associated risks.

Keeping a record of all processing activity is also a key part of the maintenance of the DSPT, a 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.

The content of the ROPA detailed in the image below is informed by UK GDPR article 30 and associated good practice guidance:



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5 Responsibilities

SPM	• Addition, review and maintenance of ROPA within their portfolio, including any data sharing events occurring prior to publication of the main study results. • This can be delegated to appropriately informed and trained staff if appropriate.
CI/Academic lead *(where no SPM is allocated)*	• Addition, review, and maintenance of ROPA where processing is outside of the portfolio overseen by the SPMs (inc. archived projects) • This can be delegated to appropriately informed and trained staff if appropriate.
GC	• Oversight of compliance with this SOP
Information Governance Working Group	• Escalating issues related to the ROPA to the GC
QA Team	• Hosting the ROPA • Providing ongoing functionality and maintaining appropriate access rights.
DSC	• Addition of data sharing activity to ROPA where requests are made and executed post study publication and have gone through DSC Approval. • Oversight of data sharing agreement compliance

6 When

Studies should create a new record on the ROPA prior to or at the point of processing activity starting.

Reviews and updates to a record should be performed in a timely manner in line with any processing changes but should be reviewed annually at a minimum.

7 How

The ROPA is hosted on Microsoft SharePoint and administered by the WCTU QA team who grant and revoke access as appropriate. The ROPA 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 stored in the SharePoint site. There is an instructional video within the MS Teams site.

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

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.

7.2 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 date the review was performed should still be documented to demonstrate compliance with annual review.

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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.

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