

1. Introduction

This Standard Operating Procedure (SOP) describes the process required to satisfy legislative requirements for Privacy and Data Protection at University Hospitals of Leicester NHS Trust (UHL). It details the steps required to confirm that all research activity hosted by UHL complies with the Data Protection Act 2018 and provides appropriate assurance to the Privacy and Data Governance Committees within the Trust.

2. Scope

This SOP applies to all research activity that is hosted by the University Hospitals of Leicester NHS Trust (UHL).

3. Data Protection & Privacy

The Data Protection Act 2018 sits alongside the General Data Protection Regulations (GDPR) adopted into Europe in 2018. The Act has EIGHT (8) principles:

That data collected is:

- Fair and lawful.
- Specific for its **purpose**.
- Be adequate and only for what is needed.
- Accurate and up to date.
- Not kept longer than needed.
- Take into account people's rights.
- Kept safe and secure.
- Not be transferred outside the EEA.

UHL as an organisation has an obligation to ensure that all data collected, for any purpose adheres to these principles.

4. Data Flows

UHL has a legal obligation to know what data are being collected. Where that data is stored, how long it's being stored for, where it's being stored and if it's stored appropriately. Additionally information is required about whether or not the data is being transferred out of the organisation and if so the method of transfer, the security of the data during transfer and the receiving organisations have appropriate processes and systems to retain it securely.

This SOP deals only with the details for research studies and does not go into detail about the Data Protection Act 2018 or GDPR specifically. When the processes are followed within this SOP, assurance can be provided to Privacy and Information Governance Committees at UHL that all necessary questions have been answered, and all relevant information has been collected for flows of data and issues of data security.

In addition and in most cases, research is subjected to external scrutiny by the Health Research Authority (HRA). Additional guidance is provided <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/>.

5. Data Privacy Impact Assessment (DPIA)

A DPIA has been developed by the UHL Privacy Team. This document must be completed where data is collected. Further guidance on the completion of the document and when it is required is detailed on the INSITE pages. It is important to note that a completion of a DPIA document is not usually required for individual research studies. This is because we've agreed an alternative approach.

5.1 Completing a DPIA for research

Agreement has been reached with the UHL Privacy Team that a separate DPIA document is not required for research. Instead the questions that are relevant to research have been added as a list of attributes in the EDGE Research management database. These attributes are contained within an Entity named 'Data Flows / GDPR'. This Entity has been added to and is being completed for every research study active at UHL from 1st April 2018 onwards. The research teams are asked to complete a Google Form which details all the questions required for the Entity. Once completed the Google Form is sent to Research and Innovation and the data is used to populate the questions listed in the Entity. The process is detailed in a Flow Chart at Appendix 1.

On occasion there is a requirement for data to be transferred from UHL to an external organisation. These external organisations are categorised as 'Third Party'. Following feedback from the research community it was agreed to separate out the information required for ALL research activity from the additional information required where the Third Party transfers were required.

The new Entity lists are to be used with effect from 1st October 2020. They can be identified as:

- Data Flows / GDPR v2 W.E.F 01/10/2020
- External / 3rd Party Data Transfers W.E.F. 01/10/20

5.2 Completing DPIA for third party transfer

Not all research studies require that data is shared with a third party. Where a third party has been identified, additional questions are required and this is represented by a second Google Form and Entity list named 'External / 3rd Party Data Transfers W.E.F 01-10-20'. Once added, the entity must be completed and the UHL Privacy Team notified of the study name and EDGE ID by email. In addition a Workflow named 'Privacy Team Workflow – EXTERNAL DATA FLOWS' must be added to the project on the 'SITE' or 'RED' level. This workflow enacts as confirmation that all Privacy checks have been completed and that the study is ok to start.

6. Reporting to Privacy

A regular report on all data flows is produced by UHL R&I and sent to the UHL Privacy Team.

7. Responsibilities

Responsibility	Undertaken by	Activity	
1	R&I	Research Personnel working study up for Capacity and Capability	Add 'Data / GDPR' attribute and send Google Form link to research team
2	R&I	Research Personnel working study up for Capacity and Capability	Populate 'Data / GDPR' attribute list from Google Form. If Third Party identified, send additional Google Form to research team, add External / 3 rd Party Data Transfers W.E.F. 01/10/20 to the study along with the 'Privacy Team Workflow – EXTERNAL DATA FLOWS' and adding the UHL Privacy Team to both the GREEN and RED levels of EDGE
3	R&I	Research Personnel working study up for Capacity and Capability	Notify UHL Privacy Team of the study by email and that the External / 3 rd Party Data Transfers W.E.F. 01/10/20 is being or has been completed.
4	R&I	Research Personnel working study up for Capacity and Capability	Notify UHL Privacy Team when External / 3 rd Party Data Transfers W.E.F. 01/10/20 has been fully completed
5	UHL Privacy Team	UHL Privacy Team	Review External / 3 rd Party Data Transfers W.E.F. 01/10/20. Complete relevant internal process. Once finalised, complete 'Privacy Team Workflow – EXTERNAL DATA FLOWS' to confirm that all relevant checks have been completed and that UHL Privacy are in agreement for the study to commence.

7. Supporting Documents and Key References

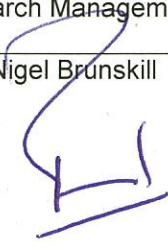
SOP C-2029 - Appendix 1

8. Key Words

Research, Innovation, Volunteers, Participants, Trials, Privacy, GDPR, DPIA, Data Protection Act

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

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