Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Data Protection

Objectives	The objective of this SOP is to outline the procedure for handling data for patients involved in research within Dorset HealthCare.
Scope	Applies to all research study staff.
Responsibility	It is the responsibility of all research study staff.
Related Document	None.

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain the actions required when handling data regarding patients involved in any part of the research process at Dorset HealthCare University NHS Foundation Trust. This includes patients who are considered for, but not entered into research.

2 Introduction

The Data Protection Act of 2018 listed 8 principles of data protection. The act came into force in May 2018 and has implications for research centres and employees.

The eight principles are:

- Personal data shall be processed fairly and lawfully.
- Personal data shall be obtained only for one or more specified and lawful purpose(s) and shall not be further processed in any manner incompatible with that purpose or those purposes.
- Personal data shall be adequate, relevant and not excessive in relation to the purpose(s) for which they are processed.
- Personal data shall be accurate and where necessary kept up to date.
- Personal data processed for any purpose shall not be kept for longer than is necessary for that purpose.
- Personal data shall be processed in accordance with the rights of data subjects under the Act.
- Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction.
- Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection

for the rights and freedoms of data subjects in relation to the processing of personal data.

The purpose of this SOP is to ensure that data relating to research subjects is handled and maintained, in such a way as to satisfy the requirements of the 2018 Data Protection Act.

3 Training

New users must read and understand this SOP before participating in clinical trials. Existing users must read and understand the Revisions Section.

4 Revisions

This is the first version of this SOP.

5 Procedure

5.1 This SOP is applicable at all times when dealing with patient/participant data of any kind (i.e. electronic records, paper notes, etc.).

5.2 All study patient data should be stored in a secure room.

5.3 All study patient data must be locked away if unattended.

5.4 No-one should access study patient data unless authorised via study delegation logs or by formal association with the Sponsor (e.g. a Sponsor's representative).

5.5 Patient confidentiality should be maintained by use of initials and/or study specific ID numbers only on research material.

5.6 Best practice is to password protect databases or software containing patient identifiable information. Spreadsheets or word documents do not require this protection providing they are held securely.

5.7 Personal data that has the potential to identify research subjects should be kept in a secure place, separate from the study files and case report forms (CRFs), with the exception of essential study documents required to be kept as part of the study file e.g., signed consent forms.

5.8 Some documents are retained in the case report forms to facilitate trial management. It is agreed that this will be kept to a minimum, and that all such documents will be removed prior to archiving unless specifically directed by the study office.

5.9 All staff should be familiar with the local NHS Trust data protection policies and have completed mandatory training in Information Governance.

5.10 Medical notes should be stored in accordance with Trust policy.

6 Appendices

There are no appendices to this SOP.

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7 Responsibilities

Every individual involved in the retrieval, handling and storing of patient/subject data should practice in accordance with this SOP.

Extra responsibility for data protection issues lies with the Trust's data protection officer (also known as Caldicott Guardian).

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/19 Date of next review: 12/04/21

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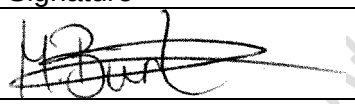
Hazel Burt		12/04/19
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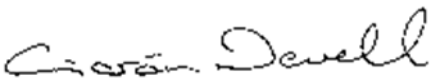
Dr Ciarán Newell		12/04/19
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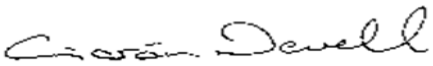
Dr Ciarán Newell		12/04/19