SHORE-C Departmental Procedure

General Data Protection Regulation

Introduction

This document indicates how SHORE-C has implemented the General Data Protection Regulation (GDPR), in accordance with the University's Code of Practice on handling Personal Information and other applicable regulations/guidelines *(e.g. Good Clinical Practice, Research Governance, Health Research Authority Guidance).*

SHORE-C collects and processes research data, including personally identifiable data. These data are collected according to study protocols which describe the research basis for collecting and processing data, including how it will be analysed. All study protocols have been reviewed by an ethics committee to ensure subjects' rights are protected and data collected are the minimum required to conduct the research.

SHORE-C conducts its own research (SHORE-C led research) and also collects patient reported outcome data for clinical trials and studies coordinated and sponsored externally (externally led research).

At the time of the introduction of GDPR, SHORE-C activity included the collection of patient reported outcome data for externally led studies. SHORE-C did not have ownership of study documents such as patient information leaflets and consent forms. This document describes how SHORE-C implemented GDPR within these studies and also indicates how it will be implemented in future new studies.

Information held at SHORE-C

SHORE-C maintains an Information Asset Register which documents personal data held for all studies conducted in the department. It outlines the following:

- how the data are stored and what security is in place
- whether participants have been made aware of the reasons for processing their data
- whether participants have been made aware of their rights
- any intentions to share data within the study team or with a third party
- date of data destruction

Information included in the Information Asset Register will be supplied to the University of Sussex Asset Register. *November 2018 – SHORE-C is awaiting further instructions from the University regarding this.*

All personally identifiable data are held securely and confidentially, as listed in the Information Asset Register and are accessible only by authorised personnel. Personal data are held separately to study data.

Consent

Participants are able to join SHORE-C and externally led research following completion of a detailed study consent form. This is composed of a number of study specific statements accompanied by a box to be initialled by the participant to confirm their agreement and/or consent to each statement. It also contains one or more statements enabling the participant to confirm that they understand the reason why SHORE-C will hold their data and if applicable, their agreement for SHORE-C to hold their name and contact details for the purpose of collecting patient reported data. Participants may also be invited to give permission for anonymised interview quotes or photographs to be used for illustrative purposes.

In the case of online questionnaires or surveys, participants are directed to an online Participant Information document. They are able to continue only after checking a tick box to give their consent after reading it.

Where data are collected at more than one time point for SHORE-C led research, participants are asked to confirm that they are happy to continue in the study at each time point.

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Communicating Privacy information and individuals' rights

Patient information leaflets for SHORE-C and externally led research are submitted for ethics committee approval prior to study recruitment. They are written in plain English and indicate the scientific rationale for the study and reasons for collecting personal data. Details on how personal data are kept confidential are provided. Participants are informed of their right to withdraw from a study and what will happen to the data already collected.

Participants are provided with the name and contact details of their SHORE-C researcher via study information packs, study documents or compliments slips accompanying study documents.

The **SHORE-C Data Privacy Statement** is available on the SHORE-C website *http://shore-c.sussex.ac.uk/dataprotection.html*. It invites patients with any queries regarding their data to contact their SHORE-C study coordinator in the first instance. At the time of GDPR implementation, a statement informing study participants how to access it was added to a suitable study document routinely sent to all active participants in open studies, e.g. patient questionnaire instructions sheet.

In future, this information will also be included in SHORE-C led research patient information leaflets or other study documents.

Data transfer for inclusion in progress reports and analysis

Data collected and held at SHORE-C may be transferred to an external statistician for inclusion in study progress reports and analysis. Data may also be transferred at the end of a study to an external sponsor or trials unit. These pre-planned data transfers will usually be included in study contracts with the sponsor/funder. *Ad hoc requests for data transfer are addressed in the **Data Transfer SOP***

SHORE-C will provide data in the format required by the statistician but personally identifiable data will not be included. Details of transfers to external people or organisations are kept in the SHORE-C Transfer Log.

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This information is currently included in the SHORE-C Data Privacy Statement.

In future, this information will also be included in SHORE-C led research patient information leaflets or other study documents.

Lawful basis for processing personal data

This is currently included in the SHORE-C Data Privacy Statement.

In future, it will be included in all SHORE-C led research patient information leaflets.

Data archiving

SHORE-C will archive SHORE-C owned data. Arrangements for archiving or transferring data collected for externally led studies will be determined during study design and may be written into a protocol or contract.

SHORE-C owned personal data will be destroyed when no longer required. Contact details for patients wanting copies of published study results will be held until the publication is available. Data collected for externally led studies will be transferred for archiving after personally identifiable data have been removed.

A general statement regarding archiving is currently available on the SHORE-C Data Privacy Statement.

In future, SHORE-C led research patient information leaflets will contain study specific archiving information.

Externally led research

Where SHORE-C collects data for externally led research, the main patient facing study documents e.g. consent form, patient information leaflet, will not be owned by SHORE-C. SHORE-C will make every effort to ensure that all GDPR information relevant to the data collected, held

and processed within the unit is included in these documents but it is recognised that the document owners will have final responsibility for their content. The SHORE-C data privacy statement contains detailed information regarding how the unit processes participant identifiable data. Information about how to access the statement or request a hardcopy will be provided to every SHORE-C research participant.

SHORE-C will usually not be provided with copies of consent forms for participants taking part in externally led research.