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Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Data Protection Act and Research

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Standard Operating Procedure
Data Protection Act and Research

This SOP has been produced in accordance with the Data Protection Act (DPA) 1998. This SOP will outline the procedure for ensuring research is conducted within the regulations of the DPA.

Definition
Sheffield Teaching Hospitals NHS Foundation Trust holds and processes information in relation to research. In order to comply with the Data Protection Act 1998 information must be collected and used fairly, stored safely and not disclosed to any unauthorised person. This applies to both manual and electronically held data.
The Trust must comply with the eight principles set out in the 1998 Act:

- Personal data shall be processed fairly and lawfully
- Personal data shall be obtained for one or more specified and lawful purposes
- Personal data shall be adequate, relevant and not excessive for the purpose of processing
- Personal data shall be accurate and up to date
- Personal data shall not to be kept longer than is necessary
- Personal data shall be processed in accordance with the rights of the data subject
- Personal data shall be kept secure
- Personal data shall not be transferred to countries without adequate protection

If data collected for research purposes is anonymised it does not fall within the scope of the Data Protection Act, however notification of the data flow to the Department of Information Governance, Caldicott & SIRO Support (IGCS) is still required using Appendix B of the notification form. .

Special provisions for research (Research Exemption):

- Data must be used exclusively for research purposes
- Data must not be used to support measures or decisions relating to any identifiable living individual
- Data must not be used in a way that will cause, or be likely to cause, substantial damage or distress to any data subject
- The results of research or resulting statistics must not be made available in a form that identifies any data subject.

The Data Protection Officer (DPO) for STH is Mr Peter Wilson, Information Governance Caldicott & SIRO Support Manager.

Procedure for STH Chief Investigator (CI)

1. The Chief Investigator (CI) ensures that data is to be collected (prospectively or retrospectively) with consent given by the data subject.
2. The CI documents in the protocol what data is to be collected and how it will be analysed.
3. The CI ensures that data will not be used for anything additional to what is specified at the time of consent.
4. The CI ensures appropriate security arrangements for both electronic (back up/ password protection) and paper (locked cupboard) files.
5. The CI assesses if any data will be sent externally by post or electronically.
   5.1. The CI assess the safety of the data transfer (ensures adequate data protection regulations).
6. The CI assesses if the data is anonymised, if the data is not anonymised:
   6.1. The CI obtains explicit consent from the data subject using a REC approved Informed Consent Form.
   6.2. The CI contacts the Data Protection Officer (DPO) if explicit consent is not possible, to discuss the next step.
7. The CI determines the method of data storage and takes appropriate action.
8. In all cases the CI completes the STH Notification form and sends this to the R&D Co-ordinator and ensures a copy of the protocol, patient information sheet and informed consent form are available in Alfresco

9. The R&D Co-ordinator uploads the details from the STH Notification Form to RMS via the data protection tab, checks the associated documents are available in Alfresco and starts the Information Governance Task on the Tasks tab of RMS.
10. The R&D Co-ordinator ensures compliance with Data Protection Act is documented in the Clinical Trial Agreement (Contract) in the event of commercial involvement.
11. The DPO reviews the information provided and when satisfied the data collection is compliant with the Data Protection Act, completes and electronically signs off the Information Governance task in RMS, which registers the date of completion.
12. In the event that a request is received for release of data under the Freedom of Information Act 2000 , or a Subject Access Request under the Data Protection Act 1998the CI must contact the DPO and/or the Department of Information Governance, Caldicott & SIRO Support within three working days to agree appropriate arrangements for possible data release.

Procedure for STH Principal Investigator (PI)

1. The Chief Investigator (CI) ensures that data is to be collected (prospectively or retrospectively) with consent given by the data subject.
2. The CI documents in the protocol what data is to be collected and how it will be analysed.
3. The CI ensures that data will not be used for anything additional to what is specified at the time of consent.
4. The CI ensures appropriate security arrangements for both electronic (back up/ password protection) and paper (locked cupboard) files.
5. The PI assesses if any data will be sent externally by post or electronically.
   5.1. The PI assess the safety of the data transfer (ensures adequate data protection regulations).
6. The PI assesses if the data is anonymised, if the data is not anonymised:
   6.1. The PI obtains explicit consent from the data subject, using a REC approved Informed Consent Form
   6.2. The PI contacts the Data Protection Officer (DPO) if explicit consent is not possible, to discuss the next step.
7. The PI determines the method of data storage and takes appropriate action.
8. In all cases the PI completes the STH Notification form and sends this to the R&D Co-ordinator and ensures a copy of the protocol, patient information sheet and informed consent form are available on Alfresco.
9. The R&D Co-ordinator uploads the details from the STH Notification Form to RMS via the data protection tab, checks the associated documents are available in Alfresco and starts the Information Governance task on the task tab in RMS.
10. The R&D Co-ordinator ensures compliance with Data Protection Regulations is documented in the Clinical Trial Agreement (Contract) in the event of commercial involvement.
11. The DPO reviews the information provided and when satisfied the data collection is compliant with the Data Protection Act, completes and electronically signs off the Information Governance task in RMS which registers the date of completion..
12. In the event that a request is received for release of data under the Freedom of Information Act 2000 , or a Subject Access Request under the Data Protection Act 1998 the PI must contact the DPO and/or the Department of Information Governance, Caldicott & SIRO Support within three working days to agree appropriate arrangements for possible data release.

Appendix 1
Associated Documents

	Document	Research Department network drive	Website	Database	Created by
1	Data Protection Principles	Directory\Research Governance\Data Protection\Guidance\DPO- STH	NO	NA	AI/PW
2	STH DPA Notification Form	Directory\Research Governance\Data Protection\application forms	Yes	NA	PW
4	STH Data Protection Flow chart	Directory\Research Governance\Data Protection\Guidance\STH- website	Yes	NA	AL
5.	STH FAQ	Directory\Research Governance\Data Protection\Guidance\STH- website	Yes	NA	AL