York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S17

Information Governance

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all York Foundation Trust R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.northyorksresearch.nhs.uk/sops.html and/or Q-Pulse

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	Signature:	Signed copy held by R&D Unit
	Date:	17th July 2017
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	Signature:	Signed copy held by R&D Unit
	Date:	17th July 2017

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	4th April 2012	
2.0	19th January 2014	Two year review
2.1	17th August 2017	Updated in line with HRA Approval Process

Contents

1 Introduction, Background and Purpose

Information Governance is an over-arching term for processes involving information handling. Compliance with the Data Protection Act, Freedom of Information Act, information security, record retention, confidentiality and consent are areas which must be considered when reviewing information provision and disclosure in relation to research governance applications.

As part of the Health Research Authority (HRA) Approval Process that oversees the approval of research studies conducted within NHS Organisations throughout England, all studies that are granted HRA Approval will have undergone an Information Governance review conducted by the central HRA Assessors who act in the interests of all NHS Trusts in England.

However, the Trust's R&D Department may request additional local Information Governance review should there any be doubts over the IG processes involved and require assurances that the research can adhere to local Trust procedures and facilities.

Local Information Governance reviews will be conducted by reference to the Department of Health's approved IG standards, as set out in the Information Governance Toolkit at https://nww.igt.hscic.gov.uk/

This SOP describes the key criteria that must be satisfied before IG approval can be granted. In particular, under the Data Protection Act 1998 the Trust has a legal obligation to protect the person-identifiable information it holds. IG reviews will ensure that Confirmation & Capability Reviews conform to the eight legally enforceable good practice principles, ensuring that personal information is:

- Fairly and lawfully processed
- Processed only for limited purposes
- Adequate, relevant and not excessive for the purpose
- Accurate and up to date
- Only retained for as long as necessary
- Processed in line with data subjects' rights
- Held and transmitted securely
- Not transferred to other countries without adequate protection.

2 Who Should Use This SOP

Information Governance professionals, with responsibility for reviewing research governance applications.

3 When this SOP Should be Used

This document should be used when an application is received by the R&D Department to support a new study in which the department feels they need additional local IG review and assurance.

The Information Governance team receive R&D applications from both the York Foundation Trust R&D Unit and from the Comprehensive Research Network – Yorkshire and Humber.

4 Procedure(s)

Applications are sent to the Outlook mailbox 'Information Governance R&D Applications' (e-mail infogovrd@york.nhs.uk). Requests are reviewed by the Information Governance Officer based in Park House, under the guidance of the Information Governance Lead. The IG team undertakes to respond to requests for IG approval, within 10 working days of receipt.

It is important that reviewers are supplied with sufficient information on which to base their assessment. For new applications this means, as a minimum, the IRAS form, patient information sheet and consent form. Templates for all routine correspondence should be provided and where patients are to be identified should include provision for the NHS number within them.

Amendments should always be accompanied by the appropriate Notification form and supporting documentation should have Track Changes activated so that the effect of the amendment is clearly identifiable.

The IG review will incorporate each element listed in Appendix A, in order to ensure that legislative requirements have been considered and are being met.

The IG team will raise queries regarding any apparent or suspected non-compliance, with the appropriate R&D unit in the first instance. These will normally be resolved on further contact with the researcher, by provision of further information or clarification.

Unresolved issues amounting to a clear breach will result in IG approval being withheld. IG approval will only be given on proof of satisfactory evidence of compliance, which may require the Sponsor to make a study amendment. Matters of contention may be escalated to the Deputy Director of Healthcare Governance and ultimately to the Medical Director, who, as Caldicott Guardian, oversees arrangements for patient confidentiality.

5 Related SOPs and Documents

R&D/S10 Receiving Informed Consent in Research Studies

R&D/S77 Identification of Potential Research Participants

http://www.hra.nhs.uk/about-the-hra/governance/information-governance/

HRA IG Privacy Charter
(http://www.hra.nhs.uk/documents/2015/12/hra-ig-privacy-charter.pdf)

HRA IG Confidentiality Code of Conduct
(http://www.hra.nhs.uk/documents/2015/12/hra-ig-confidentiality-code-conduct.pdf)

NHS Information Governance Toolkit
(https://www.igt.hscic.gov.uk/)

NHS Confidentiality Code of Practice 2003
(https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice)

Records Management: NHS Code of Practice 2006

Research Governance Framework for Health and Social Care

Appendix A:

IG Criteria for Review of Research Applications

Identifying Potential Research Subjects

The application should state how research subjects will be identified. This may be through the team providing care, through promotional material such as posters in clinical areas or by reference to a research register to which patients have agreed. It should be noted that York Foundation Trust employed research nurses are considered to be part of the team providing care for research purposes (see R&D/S77).

Approaching Potential Research Subjects

The initial approach to patients should be made by the care team or register administrator. Healthy volunteers may come forward in response to an advertisement, have indicated their willingness to participate by means of a register, or respond to an approach by a relative, friend or colleague associated with the study. NHS staff contact details are widely available but the initial approach will often be through a senior professional colleague or peer group.

When the subject is approached, they should be provided with information about the project, the researcher's contact details and asked if their details can be provided to the researcher.

Obtaining Patient Consent to Participate

Consent must be:

- Informed
- Freely given by a competent person
- Evidenced in writing

The Patient Information Sheet (PIS) must detail what person identifiable data (PID) will be collected, what it will be used for, who will have access to it, who it will be shared with, whether it will be transferred abroad and where PID will be stored and for how long.

The consent form should reflect the information on the PIS and should clearly demonstrate that the subject has read and understood how their information will be processed.

Under the DPA a child under 16 years of age may have the capacity to consent for themselves to the processing of their personal data. However, under Clinical Trials regulations a child under 16 would not be able to consent to take part in a CTIMP. In the latter case, or where a child lacks capacity, a parent with parental responsibility can consent on their behalf.

Potential participants must be informed that they can withdraw from the study, including withdrawing permission for access to their personal information, at any time without detriment to their care. For studies where information collected prior to participant withdrawal will still be used for the purpose of the study then this must be detailed in the PIS and in the IRAS application.

Further information is available in the York Foundation Trust SOP on Informed Consent and in the NHS Confidentiality Code of Practice.

Collection of Personal Information

Under the terms of the Data Protection Act 1998, for processing of any personal information to be fair, individuals must be made aware of the purposes for which their information is collected and used. NHS Patients are advised, under the Care Records Guarantee and through local information campaigns, that their medical records may be accessed, by authorised NHS professionals, for limited medical purposes including research. Members of the care team, for example, may access patient notes for screening purposes. York Foundation Trust has produced a separate SOP, setting out an agreed process for the authorisation of Research Nurses acting as part of the clinical care team, to assist with identification of potential research participants (see R&D/S77).

To satisfy the requirements of the DP Act and common law, recruitment into a research study, requiring collection of confidential person-identifiable information, requires the patient's prior knowledge and informed consent.

Exception can be made, under Section 251 of the NHS Act 2006, by formal written application to the National Information Governance Board (NIGB). This exception is available only where the NIGB is satisfied that anonymised data would not serve, and obtaining patient consent is not feasible in all the circumstances of the case.

Recording of Personal Information

With the exception of consent forms, or unless specifically required by the protocol;

- all research data collected and stored in an Investigator Site File (ISF) should be at least pseudonymised;
- source data should be maintained in its original location as specified in the protocol or source data location list and not duplicated in the ISF.

Wherever possible, coded study identifiers should be used to identify research participants. A Participant Identification Code List, matching study identifiers to individual research participants, should be retained by the PI / Research Team at site.

Access to both the ISF and the Participant Identification Code List must be controlled and restricted only to those staff who are authorised to and required to have access.

Storage of Personal Data

The physical storage arrangements for manual/paper records should be secure and accessible only by the research team. Where information will be stored electronically, access should be restricted to authorised personnel by use of folder permissions and password protection, and measures in place to ensure appropriate back-ups are made.

Further checks should be made where information is to be stored on laptops or mobile devices. Encryption should be installed to DoH standards, and

access achieved by secure password or other appropriate means of authentication.

Personal information should never be e-mailed unencrypted across unsecured networks, such as the Internet.

Use of Personal Information

The application must state the how the information will be used and any proposed onward use should be made clear to potential participants. This must also be clear on the consent form and PIS.

Sharing of Personal Information

It should be established whether any disclosures are necessary and justified. Access to medical records must be restricted to the care team or to researchers will the explicit consent of participants.

Any requirement for access by regulatory bodies, and by responsible individuals from the Sponsor and/or host organisation, must be explained to participants in both the consent form and PIS.

Retention of Personal Data

The application should document the retention period for personal data and this should only be for as long as necessary and must be in accordance with the model retention periods documented in the Department of Health Records Management Code of Practice.

Retention periods should be specified and should be reasonable. Secure disposal arrangements and methods should also be documented.

Overseas Transfers

Multinational corporations must have “Binding Corporate Rules” or “Safe Harbor Agreements” in place if information is to be transferred outside the EEA.

Where overseas transfers are to take place, this should be made explicit in the PIS and consent form.