York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S18

Risk Assessment

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 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.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	R&D/S18
Version Number:	4.0
Author:	Deborah Phillips
Implementation date of current version:	5th August 2019

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	8th July 2019
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	8th July 2019

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	23rd August 2010	Previously issued as Guidance Document
2.0	14th June 2013	Change of SOP Controller. Removal references to the North and East Yorkshire R&D Alliance.
3.0	21st August 2017	Routine Review. Minor changes to cover multicentre studies
4.0	5th August 2019	Change of author. Change of link to R&D website. Updating of names of related SOPs.

Contents

1 Introduction, Background and Purpose

Under the terms of the UK Policy Framework for Health and Social Care Research the Chief Investigator has responsibility for the design, conduct and reporting of a research study. This also includes ensuring the welfare of study participants, the safety of staff and that the study is conducted according to good clinical practice and legal requirements.

Research studies that are not deemed eligible for proportionate review (see R&D/S82) and require sponsorship by York Teaching Hospital NHS Foundation Trust must have a risk assessment completed (and regularly reviewed) so that foreseeable risks and inconveniences can be weighed against the anticipated benefit for individual participants and the general population as a whole. A study must only be initiated and continued if the anticipated benefits justify the risks.

For research studies requiring sponsorship by York Teaching Hospital NHS Foundation Trust, the R&D Group will may use the completed risk assessment to inform their sponsorship decision.

2 Who Should Use This SOP

This SOP should be used by the Chief Investigator (CI) or Principal Investigator (PI) who is directly responsible for a research study.

3 When this SOP Should be Used

This procedure applies when an investigator seeks sponsorship of research study by the Trust. Studies considered through the Trust's proportionate sponsorship process do not require a risk assessment to be undertaken. The completed Risk Assessment Form (R&D/F15) must accompany an application for sponsorship.

Identification of the risks associated with a research study must be performed at an early enough stage in study development to allow for any necessary modifications to be made to the study design in order to minimise associated risk.

This SOP is also applicable throughout the course of a study because a change that alters the risk:benefit ratio of the study constitutes a substantial amendment. It may therefore be necessary to review and/or repeat the risk assessment when a change to the study is proposed. The frequency will vary depending on the nature of the study but Quarterly Quality Assurance Meetings will maintain oversight of this process for Trust Sponsored studies.

For studies where there is an external sponsor in place there is no need for an investigator to complete this risk assessment unless the R&D Unit deems this to be necessary due to local circumstances.

4 Procedure(s)

In order to identify hazards and assess risk:

- create a list of potential hazards (*anything that could cause harm*) for the study and specify how it is proposed to minimise them.
- assess the risk (*probability that harm will be caused by the hazard*) of each hazard and set out a plan for controlling the risks.

Although the hazards of a study may be defined, the risks to any one individual or organisation will depend on their role(s) and responsibilities in relation to the study, and their ability to control the hazards.

All of the various individuals and organisations involved in a research study need to assess their risks in relation to their responsibilities.

4.1 Completing the Risk Assessment

Complete the Risk Assessment Form (R&D/F15) giving consideration to:

1. the associated risks to the particular study;
2. the potential consequences;
3. reasonable steps to reduce the risks by (i) reducing the probability of the hazard occurring, or (ii) minimising its adverse consequences

Specific consideration should be given to the hazards listed in the table below as <u>*a minimum*</u>. It is recommended that you give consideration to each of these in turn while completing R&D/F15.

Describe the hazards associated with the research study, calculate risk scores for the hazards and then describe the control measures that will be put in place to reduce the risks to the lowest possible level. The risk assessment matrix and risk management key, also included on the form, are there to help you and the R&D Group to judge the level of risk and the action that should be taken. They will also be helpful when completing the 'control measures' column of the table.

4.2 Potential Hazards for consideration

Identify the Potential Hazards for the Trial Participants' Rights	
Hazard	**Points to consider**
Participants entering the clinical trial without fully informed consent (the participant or their legally acceptable representative must always give consent, except in very exceptional circumstances where prior consent is not possible). See also R&D/S10	• the vulnerability of the patient/study group and capacity to give consent, e.g. children, incapacitated adults • consent process, e.g. timing relative to diagnosis, time to consider, signature, witness • participant information provided – clarity, appropriateness, different languages • time allocated for potential participant with the study team for discussion prior to consent • point of contact for potential participant • correct collection, use, storage and disposal of tissue samples • training and experience of those determining

	participant eligibility • training and experience of those providing participant information and obtaining consent
Failing to act on the patient's request to withdraw from the trial	• appropriate communication and recording systems
Failing to protect the privacy of the participants. See also R&D/S17	• appropriate data protection and security systems • anonymisation, pseudo-anonymisation • Provision of non-identifiable data for multicentre studies • Data transfer for multicentre studies

Identify the Potential Hazards for the Trial Participants' Safety	
Hazard	**Points to consider**
The intervention, e.g. expected adverse effects, unexpected adverse effects, clinical management of adverse effects, clinical management of patients' underlying medical condition See also: R&D/S03 R&D/S05 R&D/S06 R&D/S08 R&D/S24	• The nature of the intervention • The treating clinician's previous experience of the intervention • In a medicinal product trial ○ Phase of trial, previous use in humans, licensing status, indications, clinical experience, pharmacology ○ Pharmacy/drug handling requirements, training and competence ○ Suitability of location proposed for study activity ○ Special requirements such as GM ○ Access to emergency treatment facilities • Staff training • Susceptibility of the population – disease, genetic, age, sex • Systems to monitor, review and report adverse effects • Systems to maintain awareness of and to act on new knowledge • Systems on wards, etc for notifying trial personnel of unexpected admissions of trial subjects • Ability of participants to report adverse events and study outcomes reliably • Data Monitoring Committee requirement • Overview of sites in multicentre studies
The assessment methods	• Increased radiological exposure • Additional invasive tests including screening
Indemnity	• Having non-negligent harm indemnity insurance if the Ethics Committee states it is required • Requesting honorary contracts for non-NHS staff involved in the trial

Risks to Researchers

Hazard	Points to consider
Lack of experience or training to carry out responsibilities delegated within study See also: R&D/S03 R&D/S10 R&D/S25	• Previous experience • Scope of delegated tasks (in particular informed consent) • Mentoring/training/courses • Ability to refuse delegated tasks
Inadequate/outdated or lack of training	• Training received/required • Training records/CV
Contact with abusive individuals	• Trust policy
Trial proceeding without necessary regulations See also: R&D/S02 R&D/S03 R&D/S07 R&D/S09 R&D/S14 R&D/S82 R&D/S83	• Applications required • Responsibility for submission • Responsibility for maintaining • Ongoing trial administration
Researcher time	• Adequate time for study duties
Adequate facilities	• Storage of IMP • Storage of TMF • Laboratory/pharmacy/radiology • Archiving arrangements

Identify the Potential Hazards to the Completion of the Trial in Relation to Recruitment and Follow-up	
Hazard	**Points to consider**
Non-completion of the trial in relation to recruitment and follow-up	• Feasibility, study population, numbers of subjects required • Over utilisation of proposed study population • Recruitment strategies • Time scale of the trial • Researcher time allocated to the trial • Defining roles and responsibilities • Length of follow-up • Frequency of follow-up • Alternative means of follow-up, e.g. GP, relatives, NHS Central Register flagging (ONS) • Engagement of sites in multicentre studies
Competency of partner organisations	• Staff competence and experience at sites
Inadequate Trial management	• Having adequate trial management • Provision of a Trial Manager

Identify the Potential Hazards to the Reliability of the Results	
Hazard	**Points to consider**
Lack of study power	• Plausible treatment effects

	• Patient numbers
Setting the wrong eligibility criteria	• Unduly restrictive/prescriptive eligibility criteria • Appropriate access to clinical trials to patients of both sexes, all ages, ethnic backgrounds, etc
Major violation of eligibility criteria See also R&D/S04	• Importance to trial • Need for checking/procedures to verify eligibility of participants • Unduly restrictive/prescriptive eligibility criteria
Fraud See also R&D/S16	• Potential for fraud • Incentives – financial and non-financial • Consequences – size and severity of threat to trial results and investigator reputation • Options for checking
Randomisation procedure	• Robustness of the procedure • Potential for loss of allocation (unblinding)
Outcome assessment	• Blinding (single, double) • Objectivity of the measure • Standardisation of assessment methods • Potential for independent review • Potential for simple external verification, e.g. death certificate, laboratory investigation result
Data being incomplete and inaccurate See also R&D/S29	• Data type and complexity (CRF design) • Collection method (paper, electronic) • Data entry method • Key data items • Staff training • Need for and options for data verification • Data clarification forms/queries
Non-adherence to the protocol, GCP or SOPs See also R&D/S04	• Complexity • Staff training and trials experience • Barriers to compliance with the intervention (for trial personnel and participants)

Identify the Potential Hazards to the Organisation	
Hazard	**Points to consider**
Research project inaccurately costed	• Costing received and reviewed • Contingency plan
Routine clinical services affected	• Service provision for trial

5 Related SOPs and Documents

R&D/F15	Risk Assessment Form
R&D/S02	Application to the Trust for Sponsorship of a CTIMP
R&D/S03	Delegation of Tasks for Trust Sponsored Research Studies
R&D/S04	Breaches of GCP or the Study Protocol
R&D/S05	Research Related Adverse Event Reporting procedure for CTIMP Studies (including reporting of a pregnancy)
R&D/S06	Reporting Requirements During Research Studies

R&D/S07	Implementing Amendments for Research Studies NOT Sponsored by the Trust
R&D/S08	Monitoring of Trust Sponsored Research Studies
R&D/S09	Set up and Management of Research Studies
R&D/S10	Receiving Informed Consent in Research Studies
R&D/S16	Research Misconduct and Fraud
R&D/S17	Information Governance Review of Research Governance Applications
R&D/S24	Identifying Research Participants in the Medical Records and on CPD
R&D/S25	Providing and Documenting Training for Researchers
R&D/S29	Data Management
R&D/S71	Auditing of Research Studies and Processes
R&D/S82	Application to the Trust for Sponsorship of a Research Study
R&D/S83	Application to the Trust for Sponsorship of a Device Study

ICH Guideline for Good Clinical Practice, The Institute of Clinical Research, Copyright ICH Secretariat