Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Risk Assessment of Research Studies**		
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* For all University sponsored research recorded as risk category level 4, including IMP studies
\# For all other University sponsored research involving human participants

Revision Log

Previous Version number	Modification Reason	Date of modification	New Version number
Draft v 2.0	Greater SOP control	6 January 2011	Final v 2.0
Draft v 2.0	Changes to Directorate title and Director	6 January 2011	Final v 2.0
Draft v 2.0	Post MHRA inspection paragraphs relating to 3rd party SOPs removed.	6 January 2011	Final v 2.0
Draft v 2.0	Editorial revision to Introduction	6 January 2011	Final v 2.0
Final v 2.0	Periodic Review of SOPs	14 September 2012	Final v 3.0
Final v 3.0	Periodic Review	23 October 2014	Final v 4.0
Final v 4.0	Periodic Review	18 January 2017	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) provides guidance to all researchers for the assessment of risks to an individual study, research participants, researchers and the University.

2. Introduction

The International Conference on Harmonisation Good Clinical Practice guidance requires that "before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks".

The risk in Clinical Trials can be defined as the likelihood of a potential hazard occurring and resulting in harm to the participant and/or an organisation, or to the reliability of the results. It is necessary that the University, when involved in a clinical trial must consider its specific responsibilities/duties with respect to the trial and the level of risk in relation to these.

However, for every trial there is a core set of risks inherent with an individual clinical trial and these risks can be considered with regard to the:

- Research to be undertaken e.g.:
  (i) Lack of experience resulting in poor quality research;
  (ii) Lack of attention to detail to determine feasibility of study;
  (iii) Non-completion of research;
  (iv) Failure to comply with research protocol.
- University and other institutions involved in the research e.g.:
  (i) Reputation;
  (ii) Financial;
  (iii) Failure to comply with the relevant legal and governance frameworks.
- Participants – both research subjects and the researchers e.g.:
  (i) Recruitment without informed consent;
  (ii) Not respecting participants requests during research;
  (iii) Hazard of any proposed interventional technique to research subject;
  (iv) Health and safety hazards to researcher e.g. Human tissue, biological material, lone field workers, CoSHH.
- Completing the research study e.g.:
  (i) Lack of project management to complete on time and within budget;
  (ii) Inadequate recruitment.
- Dissemination of research findings e.g.:
  (i) Failure to publish.

The personal safety of the research participant and other risks related to the design and methodology of the clinical trial, in particular, participant safety, participant's rights and reliability of results remain paramount. During development of the research protocol these risks should be assessed and plans to mitigate against the risk included in the protocol.

Identifying risks at an early point in the research management process allows for necessary remedial actions to be costed as part of the grant application.

Definitions

Hazard: Anything that could cause harm.

Risk: Probability or likelihood that harm will be caused by the Hazard.

Likelihood:	Low	Unlikely to occur but not impossible.
	Medium	Less likely than not to occur.
	High	More likely to occur than not to occur.
	Very high	Very likely though not certain to occur.
Impact:	Minor	Unexpected complications and full recovery made.
	Moderate	Some permanent loss of function or loss of earnings to research participant.
	Significant	Death or disability.

3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are conducting research within or on behalf of the University.

4. Responsibilities

4.1 Chief Investigator

It is the responsibility of the Chief Investigator (CI) to protect the safety and well-being of the research participants, the researchers involved and protect the integrity of the study. The CI, or the appropriate designated person, should identify the potential hazardous aspects of the research and ensure that these are assessed and appropriately managed. Where necessary the CI should involve the expertise of staff involved in managing risk within the University and, if appropriate, the Trust.

The risk assessment matters relating to participant safety and study integrity should be incorporated into the research protocol

Other risks, examples of which are described in 5.1.1 below, should be considered and a separate risk assessment completed in conjunction with the Research Governance Team. The CI is responsible for ensuring that all those involved in the study are aware of the risks and how these are to be managed. Copies of all risk assessments must be retained as part of the Trial Master File.

5. Procedure

5.1 Identify the hazard

In order to assess the potential risks, you must first identify the hazards. These can be potential hazards to the research study, the research participants, and the organisation(s) involved. For each study the potential hazards faced by the researcher, the research participants, and the organisation(s) involved should be identified and the level of risk of harm assessed.

In the tables below are the potential hazards for a research study, as taken from the Clinical Trials Toolkit "notes on Good Practice for Research Organisations in the Management of a Portfolio of Trials 2: Assessment of Risk". This is not a comprehensive list.

It is recommended that each of these hazards is considered in addition to others identified by the CI and the research team. Where either the likelihood of the risk occurring is medium or above, or the impact moderate or significant the University's risk assessment form, attached as Appendix 1, should be completed.

Table 5.1.1: Hazards to the Research Study

Generic Hazard	Examples/Points for consideration	Management Strategies
Organisational complexity	Multi-centre studies Multi-disciplinary studies Complex series of events / stringent timings required Non-standardised methods Complex data collection requirements Poor data quality and integrity	Trial Management Protocol Trial Steering Committee Trial Co-ordinator posts Multi-disciplinary project teams Standardised data collection forms, electronic processing, back-ups Regular data quality checks Audit-source data verification
Study power	Plausibility of treatment effect Patient numbers	Statistical input to design and power
Recruitment	Poor fit with clinical pathway Insufficient patient pool Unduly restrictive/prescriptive eligibility criteria Restricted access to patients Large referral base Competing trials Patient health/compliance/ability to travel Patient travel costs Patient preferences Length and frequency of follow-up Ineffective communication with patient (before and after study)	Multidisciplinary project teams Input from service Realistic recruitment schedules Pilot studies Adequate resources External communication and trial promotion

Generic Hazard	Examples/Points for consideration	Management Strategies
Consent	Failure to record consent	Training in consent process
Data	Incomplete and/or inaccurate Non-adherence to protocol	Staff training Key data items Collection methods
Study Results	Violation of inclusion/exclusion criteria Financial / non-financial incentives Randomisation procedure Blinding / anonymisation arrangements Source data availability for verification Results not disseminated / implemented	Trial Management Protocol Independent randomisation Statistical input to data Monitoring and audit Interim reports Literature updates Annual progress report
Staff competence and experience	Standardisation of methods Quality of data collection Communication with research subject Administrative support Staff recruitment	Training Appropriate level of resources Project team meetings Research Manager support Job descriptions

Table 5.1.2 Hazards to the Research Participant

Generic Hazard	Examples/Points for consideration	Management Strategies
Novel or unproven interventions	Novel drugs, devices, surgical procedures, potential for unexpected adverse events Unproven effectiveness Use for new indication Increased susceptibility of patient population Novel handling requirements e.g. drugs, tissue Equipment safety	Regulatory (MHRA) and ethical (REC) approvals Data Monitoring and Ethics Committee Adverse event reporting systems Quality control checks on equipment
Inexperienced clinical team	New clinicians Unfamiliar with underlying condition Unfamiliar with expected adverse events	Project team with experienced support Training
Assessment methods	Increased radiological exposure Additional invasive tests (e.g. venipuncture, endoscopy, amniocentises, catheterisation)	IRMER / ARSAC Data Monitoring and Ethics Committee Adverse event reporting systems

Generic Hazard	Examples/Points for consideration	Management Strategies
Consent – uniformed, absent, pressured	Time to consider Information provided –clarity, appropriate, language Experience and knowledge of person taking consent Timing relative to diagnosis Capacity to give consent Participation in multiple trials Failure to act on withdrawal of consent Consent not recorded and/or filed Incorrect use or storage of tissue samples	REC approval for information and process Training and awareness Panel of people equipped to act as legal representative Communication systems e.g. alert stickers in patient notes, contact details Human Tissue database Audit of consent procedures including verification of signed consent forms
Protecting privacy of participant	Anonymisation Data protection requirements and security of systems Breach of confidentiality	Local Standard Operating Procedures: Passwords / encryption policies Training

Table 5.1.3 Hazards to the University

Generic Hazard	Examples/Points for consideration	Management Strategies
Liability	Breach of primary contract / sub-contracts Legal obligations under: UK Clinical Trials Regulations	Input from Research Support Office / Knowledge Exploitation Unit Monitoring of collaborating

	Human Tissue Act Clarity of liability information in patient information sheet e.g. arrangements for non-negligent harm.	sites Systems in placed and followed for reporting obligations for medicinal trials Archive/Storage/Consent for human tissue samples Clear identification of research governance sponsor
Intellectual property	Overlooked opportunities Lost opportunity due to disclosure	Knowledge Exploitation Unit
Duty of Care under health and safety	Use of potentially dangerous harmful equipment Use of potentially dangerous / harmful substances/organisms Lone Workers Long periods working with computers	Relevant health and safety risk assessments Health and Safety Policy Training
Fraud	Incentives – financial and non-financial Consequences to the research	Financial management systems
Reputation	Hazard resulting in serious harm and/or death of research participant/researcher	Systems and procedures Risk assessment process

5.2 Identify who can be harmed and how

Each hazard should be considered in terms of who can be harmed e.g. the researcher, the research participant, the University and how this might happen. For example, a researcher working alone interviewing participants in their own home, a participant wrongly recruited to a trial, or the University's reputation is damaged through poor compliance with legislation.

5.3 Evaluate Risks

In keeping with Good Clinical Practice (GCP) guidance it is necessary to weigh the perceived risks against the anticipated benefit for the individual research participant and society as a whole. It is through this evaluative process that the CI determines whether the anticipated benefits justify the risks. In addition, it is necessary to determine what procedures and precautions are required in order to minimise the risk within a study. For example, ensuring that researchers are adequately trained, a lone worker SOP is prepared and invoked, equipment appropriately maintained, or sufficient time is allocated to complete the research etc.

5.4 Record findings

It is necessary to ensure that all staff involved in the research study are aware of the potential risks faced and how these can be minimised. In order to assist with the communication of these risks, findings should be recorded on the risk assessment form and discussed with the research team. A record of the risk assessment and discussions should be retained in the Trial Master File in order that the risks can be reviewed and updated accordingly, as necessary.

For University sponsored research recorded as risk category level 4 copies of initial and review risk assessments should be forwarded to the Research Governance Team. The risk assessment of CT-IMPs will be undertaken in conjunction with the relevant member of the Research Governance Team. These risk assessments will inform the monitoring arrangements for individual research studies.

5.5 Regular Review

Risk Assessments should be reviewed annually, or whenever there is a change in legislation or information that may impact on your research study. Any amendments/updates should be recorded and shared with members of the research team. A copy of the new risk assessment should be filed in the Trial Master File, along with the previous version(s). Where applicable (as outlined in 5.4) a copy of the review should also be forwarded to the Research Governance Team

6. References

International Conference on harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice EF (R1) (last accessed 18 January 2017) http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

Belfast Health and Social Care Trust Policy and Procedural Arrangements Relating to the Management of Risk Assessment in Research Projects. (Reviewed August 2008).

NHS R&D Forum. Notes on Good Practice for Research Organisations in the Management of a Portfolio of Trials 2; Assessment of risk. 4 June 2004. (Reviewed August 2008)

Clinical Trials Toolkit "Notes on Good Practice for Research Organisations in the Management of a Portfolio of Trials 2: Assessment of Risk" (last accessed January 2017) http://www.ct-toolkit.ac.uk/routemap/trial-planning-and-design

7. Appendix

Appendix 1: Risk Assessment Form.

University Risk Assessment Form
Copy as required

Description of Risk	Impact 1. Minor 2. Moderate 3. Significant		Likelihood 1. Low 2. Moderate 3. High 4. Very High		Impact * Likelihood		Action to reduce risk	Responsibility
	Gross	Net	Gross	Net	Gross	Net		