Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Risk Assessment of Research Studies**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

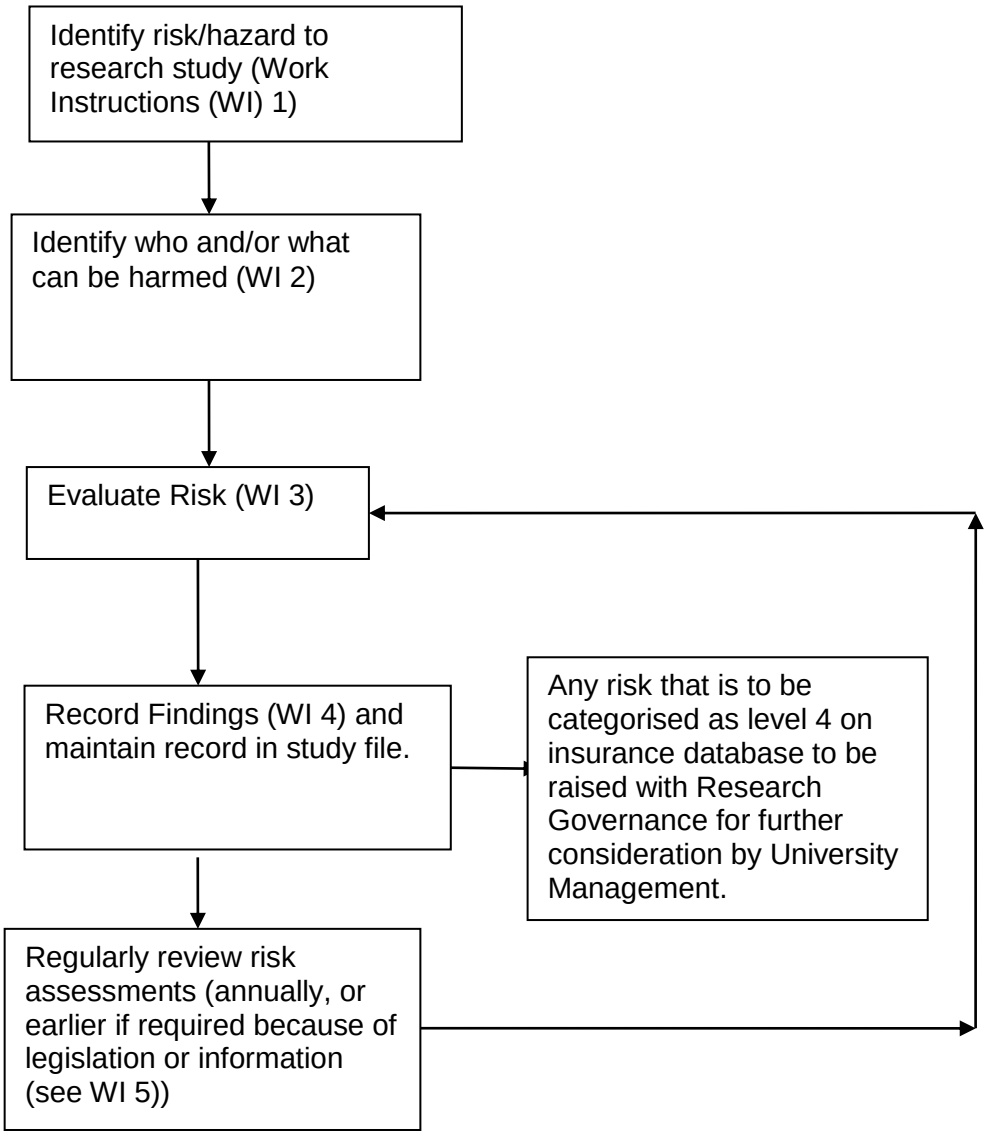
1. Purpose

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

2. 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.

3. Procedure



4. References

Clinical Trials Toolkit “Notes on Good Practice for Research Organisations in the Management of a Portfolio of Trials 2: Assessment of Risk” (last accessed October 2021)
http://www.ct-toolkit.ac.uk/routemap/trial-planning-and-design

5. Appendices

Work Instruction 1 – Identify the Hazard
Work Instructions 2 - Identify who can be harmed and how
Work Instructions 3 – Evaluate the Risk
Work Instructions 4 – Record Findings
Work Instructions 5 – Regular Review

Appendix 1: Examples of Risks to Research Studies
Appendix 2: Risk Assessment Form

Work Instructions 1 - Identify the hazard

1. Potential hazards (anything that could cause harm) to a research study can include: the risk/hazard to the participants, the organisation(s) involved, location of research and/or delivery of actual research. For each study the potential hazards faced by the researcher should be identified and the level of risk (probability or likelihood) of harm assessed. The Chief Investigator should work with the research team to consider the hazards that may impact on the planned research.
2. Core risks are:
    a. Lack of experience resulting in poor quality research;
    b. Lack of attention to detail to determine feasibility of study;
    c. Non-completion of research;
    d. Failure to comply with research protocol;
    e. Failure to comply with relevant legal and governance frameworks;
    f. Reputation – researcher/collaborator/University or Financial – loss/non-completion penalty etc;
    g. Recruitment – lack of consent, non-compliance with criteria;
    h. Participant's requests not being respected;
    i. Hazard of any proposed intervention to the research participant;
    j. Health and Safety hazards to researcher (and research participant);
    k. Completion of research study (inadequate recruitment/lack of project management to complete research on time and within budget);
    l. Dissemination of research findings (failure to publish).
3. Appendix 1 provides further examples of potential hazards for a research study - this is not a comprehensive document.
4. Where either the likelihood of the risk occurring is categorised as medium or above, or the impact moderate or significant, the University's risk assessment form, attached as Appendix 2 should be completed.

Work Instructions 2 - Identify who can be harmed and how

1. Consider each risk in terms of who can be harmed – e.g. the researcher, the research participant; the University; the host organisation etc.
2. Identify for each how this might happen e.g. – researcher working alone, participant wrongly recruited to a study, risk to the University because of poor compliance with the legislation bringing about reputational damage; the host organisation because they don't get paid appropriately for their involvement.

Work Instructions 3 - Evaluate Risks

1. Each risk should be considered in terms of how likely it might occur and what the impact of the event would be:

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.

2. For clinical research the research team should 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.
3. A determination should be made as to 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.

Work Instructions 4 - Record findings

1. Record the potential risks to facilitate communication within a research team. Risks should be recorded on the Risk Assessment Form, exampled in Appendix 2.
2. A record of the risk assessment and discussions should be retained in the Study/Trial Master File in order that the risks can be reviewed and updated accordingly, as necessary.
3. University sponsored research recorded as risk category level 4 (as per insurance database) must be escalated to the Research Governance and a determination made regarding whether onward consideration is required by University Executive Board.

Work Instruction 5 - Regular Review

1. Review all risk annually to ensure actions to reduce risk remain effective.
2. In the event of legislation changing or other information that may impact on the research risks should be reviewed to determine any impact on your research study.
3. Any amendments/updates should be recorded and shared with members of the research team.
4. New risk assessment paperwork should be filed in the Study/Trial Master File, along with the previous version(s). Where applicable (as outlined in WI 4) a copy of the review should also be forwarded to the Research Governance Team.

Examples of risks to research studies to support Work Instruction 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 /	Trial Management Protocol Independent randomisation Statistical input to data Monitoring and audit Interim reports Literature updates Annual progress report

	implemented	
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

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. venepuncture, endoscopy, amniocenteses, 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

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 Human Tissue Act Clarity of liability information in patient information sheet e.g. arrangements for non-negligent harm.	Input from Research Contracts / IP and Innovation Team Monitoring of collaborating sites Systems in place 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	IP and Innovation Team
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

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		