Appendix 2: Risk assessment matrix

Appendix 2: Risk assessment matrix

NOTES: The assessment of risk may be one of those areas where some degree of overlap between research governance and independent ethics review might occur. Institutions might themselves allocate a clear division of labour between governance and ethics, and indicate areas where some assessment in both spheres of activity should be allowed. For example, an ethics review of a research proposal would be remiss if clear risks to researchers might be anticipated, or seen as potentially arising, and the REC made no observations or comment about it.

The decision to take such risks must lie with the researchers and the employing institution – hence while the REC might state an opinion about such risks, thereby assisting the researchers' risk-taking decisions. It must remain up to the employer to approve the research going ahead – after all they hold the 'duty of care' for the researcher and, presumably, their insurance indemnity cover. In a similar vein, staffing issues (health and safety, working space, resources) are clearly of governance concern, but if a REC review finds something that concerns them, they should be in a position to state an opinion about it and its relevance to the project. Hence the following risk matrix does separate ethics and governance – the line of accountability has to be decided at an institutional level.

Appendix 2: Risk assessment matrix

Project Title:		Proposer/ proposers:	Principal Investigator (PI) and collaborator/Research Associate (RA) – list names	Date:	...of completion of this risk assessment form
Reference No.:					

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Participants	Harms – physical, emotional or social Stressors Inconvenience and discomfort Invasions of privacy/ breaches of confidentiality Incidental disclosures raising concerns such as safeguarding Incidental findings impacting on the physical or mental health of the individual Personal expense – out of pocket expenses such as travel Unfair/discriminatory inclusion/exclusion					

Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Financial	**Funder/ commissioner problems:** Funder insolvency? Failure to deliver promised funds? Last minute budget changes – under-funding? Matched funding not available? No infrastructural support? Funding delays in monies being delivered? Funder linking funding to deliverables. Change in funder contact persons Dispute re adequacy of deliverables	**Estimate:** High Medium or Low	**Estimate impact:** High Medium or Low	Information from any source accounting for risk	Outline proposal already submitted and approved Clear criteria for deliverables Cautionary notes minuted and recorded Regular meetings with funders/ advisors Regular progress meetings with project team Progress reporting to funder Audited oversight of institutional financial management	Named person with responsibility

Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Financial	**Project budget overspend**			Regular (monthly) finance reports Regular reporting mechanisms to funder and institutional finance department Project management systems to control project stages	Designated budget holders (for all partner organisations) Monthly finance reports Budget projection modelling Sanctions for overspends Expenditure monitoring Finance procedures for each partner organisation followed Clear contingencies allowances indicated in budget	Named person with responsibility
	Specific project-related sources of income generation			Market research of potential income sources and likely returns Monitoring of income sources Evaluations of income generation proposals	Provide information to help assess potential Network with appropriate individuals/organisations Develop effective marketing strategy Pilot any proposed income generation	Named person with responsibility
	Any partner organisations or individuals unable to meet deliverables due to financial difficulties			Annual finance audits Yearly business plans Formal reporting mechanisms	Check partner organisations individual finance procedures Monitor partners' management meetings	Named person with responsibility

Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Legal/ Contractual	Lack of appropriate working space for research project staff Inadequate infrastructure support Damage/costs to larger institution			Formal health and safety risk assessment undertaken Project staff feedback Disputes with staff unions, or need to address concerns of public representative bodies	Health and safety risk assessment action plan Office space planned for and commissioned Information Communications Technology (ICT) requirements implemented Public relations and normal negotiating procedures in place	Named person or persons with responsibility
	Poor communication between research collaborators and/or partner organisations			Clear project meeting minutes – circulated reviewed Independent advisors on project board Stage reviews and authorisations to continue	Non-disclosure agreement signed by partner organisations Project management system followed to check off project deliverables and ensure each stage signed off by key partners/ stakeholders Standard reporting mechanisms in place ensuring external review of project processes Regular internal project team meetings Written agreement between partner organisations setting out terms and conditions for joint working accountabilities Official research governance framework followed	Named person or persons with responsibility

Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Reputation, delays and grievances	Any potential for adverse publicity for the project			Stakeholder meeting minutes Related local and national media stories	Proactive engagement with stakeholders & media throughout project Establish and maintain strong formal and informal links with partner organisations Develop effective marketing plan for any project products or outputs Develop a project communication and dissemination strategy for project duration Monitor live issues in public spaces related to project areas of interest	Named person or persons with responsibility
	Lack of commitment from any related professional/ service user/client organisations or groups			Summary project meeting minutes made available (Who collects? Who edits?) Feedback from professional/ service user/client organisations or groups	Involve key stakeholders from the start of the project Set up a stakeholder group with input, evaluation (and control?) over aspects of the project Develop a project communication and dissemination strategy for project duration	Named person or persons with responsibility

Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Reputation, delays and grievances	Loss of subject/respondent or participant information Inappropriate disclosure of subject/respondent or participant information Respondents/subjects expressed dissatisfaction			Research ethics committee Database monitoring arrangements Feedback from respondents and/or research team member or members Complaints made by respondents	Comply with data protection legislation If 'anonymity' required: ensure personal data is non-identifiable to subject/respondent – code questionnaire immediately All subject data stored electronically is password protected Double-key encrypt sensitive data All other subject data stored in a lockable file Follow research governance guidance on the protection of subject information Implement any appropriate recommendations from the relevant research ethics committee or committees Research data regularly backed-up Clear specification of levels of data access for staff Two copies of research database stored securely Clear grievance route – indicated to subjects If 'non-anonymised' – clarify mutual expectations between researchers and participants	Named person or persons with responsibility

Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Methodological limitations	Project rejected/ subjected to amendment by research ethics committee			Feedback sought from research ethics committee Feedback from stakeholders and advisors	Input from ethics advisor sought prior to submitting project proposal Independent ethics advisor or advisory group if ethics issues warrant Advice and input from institutional research director and research sponsor Implement recommendations from ethics committee and resubmit if required Stakeholder group approves project proposal	Named person or persons with responsibility
	Poor uptake of project outputs or deliverables (if appropriate)			Feedback from stakeholder steering group Feedback from user panel Monitoring of outputs and uptake Feedback from any pilot phases	Develop project communication and dissemination strategy Full involvement of stakeholder group and user groups throughout project Marketing strategy developed for each project output Evaluate pilot phases of project products and implement changes	Named person or persons with responsibility
	Project overruns planned timeframe			Project board meetings Feedback from PI at key project stages Evaluation against original project schedule	Project management systems used to manage project time frames GANTT chart developed and updated regularly to monitor timeframes involved for each task Project supervision undertaken by project board Timely updates to sponsor/funder	Named person or persons with responsibility

Appendix 2: Risk assessment matrix

	Potential Risk Factors	Probability of Risk Arising (H/M/L)	Impact (H/M/L)	Risk Indicators	Control Mechanisms	Named Risk Lead
Resource	Changes in key project staff			Recruitment processes Appraisal process Adequate staffing	Develop succession plan Ensure handover mechanism in place Involve other key members in partner organisations in project processes Ensure 'cover' arrangements for illness etc. Allow for contingencies in initial staffing needs appraisal	Named person or persons with responsibility
	Appropriately qualified and experienced PI and other staff recruited to undertake project			Recruitment process Appraisal process Liaison meetings with any partners sharing recruitment	Clear and appropriate training plan for researchers developed & implemented All human resources processes in place to manage the recruitment process Regular specified supervision undertaken, and as required, from project sponsor	Named person or persons with responsibility
	Project overruns planned timeframe			Project board meetings Feedback from PI at key project stages Evaluation against original project schedule	Project management systems used to manage project time frames GANTT chart developed and updated regularly to monitor timeframes involved for each task Project supervision undertaken by project board Timely updates to sponsor/funder	Named person or persons with responsibility