MRC Guidance on managing risk in public health research

The following table outlines considerations and mechanisms to minimise risk in each study. This is an ongoing process, which should be revisited during the study.

Potential Risks	Suggested management and monitoring strategies
To Participants Stress, discomfort, emotional or physical harm caused to participant, consider: • Content of questionnaire • Risks of any other intervention • Emotional stability of participants • Novel study design or intervention • Inexperienced research team	• Sympathetic design and wording of any questionnaire. • Understanding the study population, and being able to anticipate likely reactions. • Arrangements with counselling agencies. • Novel study designs or interventions have been suitably piloted. • Appropriate training and supervision of research staff. • Review points in the study to assess feedback from field workers – can improvements be made to minimise any perceived discomfort, stress etc? • An appropriate Research Ethics Committee has reviewed the study and given it a favourable opinion.

Consent is uninformed, pressurised or not taken, consider:
• Vulnerability of study population
  ○ Children
  ○ Unable to give consent
  ○ Disabilities
  ○ English not a first language
• Induced participation through an incentive
	• The consent material and the consent process is appropriate for the study population, and meets ethical requirements.
	• Potential participants (or their representatives) have sufficient time to discuss the study or consider whether to take part.
	• An appropriate Research Ethics Committee has reviewed the study and given it a favourable opinion.
	• Training, supervision and monitoring of researchers/fieldworkers on the consent process.
	• There is a record of consent, which is retained for monitoring purposes e.g. random 10% check.
	• Understand the study population in order to judge what any proposed incentive may mean to them, to ensure that it is not set at a level that could be an unacceptable inducement to participate.

Breaches in confidentiality	• Follow *MRC Guidance Personal Information In Medical Research* • Identifiable information is accessible on a need-to-know basis • Where appropriate, anonymisation and coding of data occurs at the earliest opportunity • Effective security – password protection of electronic data; paper records in locked filing cabinets with restricted access, measures in field taken to prevent unwanted access. • All staff are aware that any breach in confidentiality could incur disciplinary action as stated in MRC code of Practice - all staff requiring access to identifiable data could sign a confidentiality statement.
Failure to act on a request to withdraw	• Appropriate communication and recording systems. • All members of the research team know the process to follow, i.e. who to inform and how it should be flagged that a participant has withdrawn.

Failure to learn from mistakes or amend the study in light of relevant developments	• Systems are in place to minimise the recurrence of mistakes. • Review of study processes, to determine if improvements be made in light of experience or any recent relevant developments, e.g. increased scientific knowledge, and where relevant resubmission of amendments to REC for favourable opinion.
To Fieldworkers Stress, discomfort, emotional or physical harm caused to fieldworker, consider: • Experience of field team • Study population • Research location • Time of day	• Follow guidance in *MRC Health and Safety A practical guide for research involving the public 2004* • Adequate training and supervision • Clear systems and procedures to follow in event of an incident • Adequate resources, e.g. sufficient staff, transport, mobile phones, personal alarms. • Regularly monitor and review all procedures • Respect organisational policies and procedures, e.g. schools
To Study Completeness and reliability of results, consider: • Study uses appropriate methodologies and adequate sample size • Complexity • Unrealistic recruitment targets • Inaccurate/incomplete data • Objectivity of assessment methods • Inexperienced staff • Fraud	• Independent scientific peer review of all projects • Where possible conduct pilot or feasibility study (inform likely recruitment rates) • Simplification of study design and procedures, and early notification of study personnel to ensure adequate training • Monitor that recruitment is according to eligibility criteria, and that fieldwork conducted according to study procedures • Adequate resources available for data collection, entering and analysis • Data monitoring/verification and quality assurance methods employed • Study oversight/advisory committee is in place and meets as appropriate • Consider potential for fraud, the incentives, and consequences. For suspected cases, follow *MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct*
Inadequate funds/resources, consider: • Fieldwork • Staff training • Use of external services • Meeting legal, good practice and ethical requirements	• Realistic planning of required resources, early notification of centralised services, where applicable • Realistic justification of resources in funding application • Where possible standardised operating procedures to reduce inefficiencies and duplication of process • Cost-effective, risk-based approach to implementing systems to meet legal, good practice and ethical requirements

To Researcher and Unit Reputation • Indemnity arrangements not in place • Publication rights or IP not clearly defined or agreed • Roles and responsibilities not identified • Inability to deal with complaints • Risks within the research are not managed appropriately • Fraud	• Indemnity arrangements in place, in particular for close collaborators that do not qualify for MRC indemnity. • Clearly documented roles and responsibilities of all those working on the study • Appropriate agreements, contracts, sub-contracts for involvement of external organisations • Agreement and documentation of publication rights and Intellectual Property for collaborative studies • Retention of key documents, e.g. ethical approval, study proposal/protocol, training records (informal and formal), for audit purposes • Centralised record of all studies taking place that involve unit personnel, and monitoring of studies to ensure that risks are managed in an appropriate way • Systems in place to ensure that complaints can be efficiently handled (appropriate training available), any lessons are learned, and the necessary changes to procedures are made • Consider incentives and consequences for fraud, adherence to *MRC Policy and Procedure for Inquiring into Allegations of Scientific Misconduct*