Expectations of Risk Assessment prior to Ethical Approval via UREC or IRAS

The risks inherent in any research project should be identified and assessed, and mitigations put in place to reduce risk of harm to the researcher, research participants and anyone else involved in the research whether directly or indirectly.

Where research involves contact with research participants, the University's Ethics Oversight Committee and Health Research Authority Oversight Committee require that researchers consider the following risks when conducting their risk assessment.

Please note, for guidance on the completion of risk assessments or lone working procedures, researchers should seek support from health and safety colleagues within their respective school.

Research involving travel - including field-based activity

Risks associated with travel should be considered for the researchers themselves but also research participants if they are being expected to travel to take part in the research.

We would expect the following guidance to be utilised when considering the risks of traveling to undertake participant-based research:

1. Travel risk assessment flowchart.
2. Protocols for minimising risk associated with fieldwork

Research involving children or young people

When working with children or young people (those under the age of 18 years), the risk of uncovering safeguarding concerns should be considered and a plan for how to handle such disclosures put in place.

Researchers are expected to familiarise themselves with the University's Child Protection Policy, Guidance and Training and to ensure they are aware of the named Safeguarding Lead to whom they should report any concerns.

Research involving vulnerable individuals

Researchers are expected to consider the potential vulnerability of any individual or group with whom they are interacting as part of a research project. It is important to note that vulnerability is contextually dependent and can vary considerably from one research project to another, even if the same group of participants are approached to take part. To assist researchers with this important consideration, the UREC has developed Guidance on Vulnerability that highlights a number of frequently encountered situations which may lead to participants being classed as potentially vulnerable.

Research involving lone working

If researchers will be conducting in person (face-to-face) research while working alone, off University premises and/or outside of normal working hours, they are considered to be lone working. Please note, if researchers are working from home and performing digital method only (i.e. Zoom interviews), this is **not considered to be lone working**. Researchers should refer to their own School/Division's lone working procedures and the University's Lone working guidance.

As part of their ethics application researchers will need to confirm that they have read and understood the University's Lone Working Policy and detail how they plan on keeping themselves safe for the duration of data collection.

Research involving topics that may cause distress to participants

Researchers are expected to consider the risk of distress, both for themselves as well as their research participants. Where distress is considered possible, researchers are expected to have a distress protocol that outlines the specific steps they will take if they detect any signs of possible distress during their interactions with research participants. These steps should include clear descriptions of what actions will be taken, by whom as well as details of any third parties that may need to become involved if necessary (e.g. family members, friends, GP, emergency services). The distress protocol should include several steps of escalation, should the level of distress increase and previous steps fail to provide appropriate mitigation. A helpful example of a distress protocol for high risk studies can be found here.

Researchers using digital methods of data collection (e.g. Zoom interviews) should carefully consider their strategy for detecting distress across a digital platform, as it varies considerably from how one would detect distress in person. As part of this consideration, they should note if additional data collection may be required (e.g. physical address) in order to ensure appropriate safeguards are in place for potentially vulnerable participants.

Researchers should also consider providing a debrief sheet to research participants with contact details of relevant support services (e.g. charities or other third party organisations that can provide free, unbiased support). In some cases, it may be appropriate to include the researcher's UoM contact details on the debrief sheet, but only if they are appropriately trained to manage possible distress.

Research involving potential disclosures

Researchers should consider the likelihood of a research participant disclosing illegal/potentially harmful information. Researchers are legally required to report any disclosures pertaining to terrorist offenses, treason or child protection. In addition to this, researchers should consider whether there are any professional obligations that would require them to report specific instances of disclosure such as whistle blowing or poor practice. The specific procedure(s) for reporting such instances should be outlined in detail as part of the ethics application process. More information on disclosures can be found in the Research Ethics Handbook.

Research involving physically invasive procedures

Physically invasive procedures are:

- any test in which the skin of the participant is broken or:
- an implement is inserted into any opening of the human body (e.g. eyes, ears, nose, mouth, lungs, stomach, rectum, vagina and urethra) or;
- involves the taking of body samples such as saliva, hair, urine, faeces, sputum, skin, nails, or:
- taking biopsies of any form for any purpose or:
- any form of scanning such as DEXTA scans, Ultrasound scans, MRI, fMRI, CT, or PET scanning.

Researchers should consider any discomfort (physical and non-physical), bruising, scarring etc which can be caused by the invasive procedures being undertaken in the research activities and ensure these are appropriately addressed in their risk assessment.

Where activities are happening at a research site external to the University (NHS, for example) it is appropriate for researchers to follow local risk assessment procedures, this should be referenced in their UoM risk assessment if separately provided.

Research involving the use of study specific equipment

Researchers should consider the risks associated with the use of any study specific equipment used during the study by researchers, participants or site staff. Consideration should be given to loss of equipment (and therefore loss of data, if applicable), calibration, maintenance, technical issues, breakdown of equipment, and ensure risks are appropriately addressed in their risk assessment.

Where activities are happening at a research site external to the University (NHS, for example) it is appropriate for researchers to follow local risk assessment procedures, this should be referenced in their UoM risk assessment if separately provided.

Research Data Issues

Researchers should consider and address the issues around data for their study. This includes but is not limited to, theft/loss of portable devices used for recording data, data corruption, access to personal data, and data protection incidents.

Researchers are expected to comply with the UoM policies and procedures for research data, and follow guidance as provided by the UoM library and UoM Information Governance.