

PARTICIPANT AND RESEARCHER SAFETY AND WELL-BEING

Researchers have a generic responsibility to protect participants from any harm arising from research. As a general rule, people participating in research should not be exposed to risks that are greater than, or additional to, those that they encounter as part of their normal lifestyles.

Researchers should ensure that they are aware of the potential risks to the safety and well-being of participants, and should consider carefully how these risks can be managed; such considerations should be set out fully as part of their ethics application. Potential risks to participants' safety and well-being should be discussed openly as part of the informed consent process. This may include asking participants about any factors, such as pre-existing medical conditions, that might create risks to them if they were to participate in a given research project. Participants must be advised of any special action they should take to avoid risk. Researchers also need to be prepared to respond appropriately to participants should issues arise (e.g. through offering advice, or referral to appropriate agencies/services).

Before participating, people should be informed of how to contact the lead researcher, or the Head of Department, who will be able to escalate their concern, within a reasonable time period, if, following participation, they experience stress, harm or have any other concerns about the research.

If during research a researcher obtains evidence of physical or psychological problems the researcher has a responsibility to inform the participant if s/he believes that by not doing so the participant's future well-being may be compromised or diminished. If the issue is serious and the researcher is not qualified to offer assistance, then an appropriate source of professional advice should be recommended to the participant. For some types of research the giving of advice will be appropriate, intrinsic to the research, and will have been agreed prior to the person's participation as part of the consent process.

In the case of clinical trials, research should only take place where the foreseeable potential risks and inconveniences to the prospective participants (i.e. trial subjects and/or patients) are deemed likely to be outweighed by the potential benefits for them and for future patients. In certain cases a patient may explicitly support a research project and support invasive treatment that may be very harmful if, due to the particular circumstances (for example, if s/he is terminally ill), s/he feels that it is worth taking a significant, potentially life-threatening risk. This example represents the point at which participants may feel they have a right to participate as well as a right to withdraw, a right to be harmed, in exceptional circumstances, as well a right to be protected from harm.

In the case of non-invasive research methods such as interviews and questionnaires, the content and line of questioning may be sensitive, may raise confidential personal issues, and may intrude, or be perceived to intrude, upon a participant's comfort and privacy (for example a seemingly simple question asking for a person's gender may cause distress as not everyone will identify themselves as 'male' or 'female'; such information should only be sought if relevant to the research question, and an appropriate range of options should be included – further guidance on this issue can be found on the Equality and Human Rights Commission's website: <https://www.equalityhumanrights.com/en/publication-download/research-report->

75-monitoring-equality-developing-gender-identity-question). The initial judgment about whether or not questions are sensitive and likely to cause harm or discomfort rests with the lead researcher. For advice in such cases, the lead researcher should initially consult their departmental Ethics Administrator.

Researchers should give appropriate consideration to the potential risks to themselves and to others who may be involved with, or affected by, the research. Appropriate steps should be undertaken to mitigate these risks (e.g. undergoing a risk assessment process, implementing a lone work policy – further guidance may be found on the University's Health and Safety webpages, and departments may have their own policies and procedures in place).

Finally, it should be noted that it may not be possible for researchers to identify every eventuality that may arise in the course of a research project, and that this Policy is not designed to cover all possible situations. Unexpected incidents affecting the safety or well-being of those involved, and/or presenting a potential reputational risk to the University, may arise even in a project that has been well-considered and thoroughly ethically reviewed. Should such an incident arise, the researcher should take appropriate steps to manage the immediate situation in line with the University's Health and Safety procedures. At the earliest opportunity they should make their supervisor or line manager aware of the situation. Where there are potential implications relating to research ethics (e.g. if the terms of ethics approval have been breached), the UREC's Secretary should be contacted for advice.