

## **RESEARCH INVOLVING VULNERABLE PEOPLE**

From the initial research design stage onwards research involving human participants must prioritise how the research process and results are likely to impact upon those who will be directly involved as participants as well as those for whom the research has relevance. This is part of the duty of care owed by the University's staff and students to all people affected by the University's research.

The responsibility for conducting research rigorously, respectfully and responsibly, from start to finish, is magnified when undertaking research with people who are considered to be vulnerable. However, the term vulnerability is open to many interpretations. Certain people or groups of people are potentially more vulnerable than others.

The degree of vulnerability of an individual will depend on a range of factors, some of which can be anticipated and some not. Therefore researchers should take particular care to:

- anticipate and prepare for foreseeable ethical challenges, in order to protect the participant(s) and themselves;
- adhere to recognised research ethical principles and any associated legislative requirements (e.g. consent, confidentiality, etc.); and
- remain pragmatic and flexible in ensuring these principles are applied rigorously.

The type of participants, the research methods employed, and the sensitivity of the subject being researched will all play a part in determining the degree to which participants are vulnerable.

### **1 THE CONCEPT OF VULNERABILITY**

*All* human participants in research may be potentially vulnerable. Some participants may, however, be particularly vulnerable (as described below). Some people may not perceive themselves to be particularly vulnerable. However, there are certain groups that must be considered as vulnerable and appropriate steps taken to account for this.

There are three basic kinds of vulnerability:

- vulnerability to physical harm;
- vulnerability to damage to social standing or reputation; and
- vulnerability to psychological and emotional distress.

These types of vulnerability may occur in combination. People may be vulnerable in different ways and to different degrees at different points in their lives, due to the circumstances in which they find themselves at a particular time. However certain vulnerable individuals may be at more risk of harm when taking part. Accordingly, researchers cannot take it for granted that standard procedures (e.g. for seeking consent) will be appropriate and for some vulnerable groups it is essential that their specific requirements are taken into account and addressed when designing and undertaking research including information sheets.

Among the categories of people who are perceived to be likely to be vulnerable in a research context are:

(a) People whose competence to exercise informed consent is in doubt, such as:

- infants and children under 18 years of age;
- people who lack mental capacity, may be at risk of losing capacity or have fluctuating capacity for example people with learning disabilities, people with dementia or conditions that give rise to cognitive impairments such as stroke;
- people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate; and
- people who may have only a basic or elementary knowledge of the language in which the research is being conducted.

(b) People who may socially not be in a position to exercise unfettered informed consent, such as:

- people who depend on the protection of, or are controlled and influenced by, research gatekeepers (e.g. school pupils, children and young people in care, members of the armed forces, young offenders, prisoners, asylum seekers, organisational employees);
- family members of the researcher(s); and
- in general, people who appear to feel they have no real choice on whether or not to participate.

(c) People whose circumstances may unduly influence decisions to consent, such as:

- people with disabilities;
- people who are frail or in poor health;
- elderly people;
- people who are in care;
- relatives and friends of participants considered to be vulnerable;
- people who feel that participation will result in access to better treatment and/or support for them or others;
- people who anticipate any other perceived benefits of participation; and
- people who, by participating in research, can obtain perceived and/or benefits to which they otherwise would not have access e.g. possibility of a new medication being available, payment for participation.

The above is not intended to be a comprehensive list, it is merely indicative of the range of situations in which questions about the vulnerability of research participants must be addressed.

Vulnerability should not simply be seen as a property or characteristic of individuals or categories of people. The research process may increase the potential vulnerability of participants, of a participant's relatives, friends and others who have a relationship to the participant, and of the researchers themselves. Similarly, research into sensitive topics may also increase a participant's vulnerability to harm or distress.

What is perceived as vulnerability in one research discipline may not be perceived as vulnerability in another; some disciplines and research areas also have specific legal, regulatory and/or governance requirements relating to vulnerable participants which must be met (e.g. for health and social care research). The type of research method and the subject matter of the research also affect the nature and degree of participant vulnerability.

Different research methods present different risks to participants; these may be risks that increase the vulnerability of the participants. Researchers should put in place measures to manage and to mitigate foreseeable risks. This may include, for example, research which involves in depth qualitative enquiry and/ or requires the participant to use or recall experiences or incidents that may cause distress. The sensitivity of the subject matter being researched is also significant in this respect. For example, a research project focusing on any of the following subjects may increase the vulnerability of participants:

- 'race' or ethnicity;
- political opinion;
- trade union membership;
- religious, spiritual or other beliefs;
- physical or mental health conditions;
- sex life, sexuality and/or gender identity;
- identity of an individual resulting from processing of genetic or biometric data;
- abuse (child, adult);
- nudity and the body;
- criminal or illegal activities;
- political asylum;
- conflict situations;
- personal violence;
- terrorism or violent extremism; and
- personal finances

Conducting research ethically is not, however, a matter of avoiding potentially high-risk research. It is, rather, about preparing for and managing risks; it is a matter of being risk aware, not risk averse.

## **2 SOME IMPLICATIONS FOR RESEARCH**

All research should be conducted as skilfully and as carefully as possible. Researchers must ensure that they themselves, and any collaborators or members of a research team or students under their supervision, comply with legal requirements in relation to working with infants or children or vulnerable adults.

The principles that govern all research involving human participants should be adhered to with even greater diligence when research involves vulnerable participants. When designing the research, including the informed consent process, and when conducting, communicating and publishing research the researcher should consider the perspectives of actual or prospective participant(s). Depending on the nature of the research, the researcher should also give consideration to how to manage the relationships with participants post-research, for example by offering to send them a summary of the results.

Researchers who collect information about the characteristics and behaviours of individuals and groups should where possible avoid using classifications or designations that give rise to unreasonable generalisations, resulting in the stigmatisation of, or prejudice towards, the group(s) in question.

### **3 THE IMPORTANCE OF CONTEXT**

It is important to be *aware* that prospective participants *may* be vulnerable, but not to *assume* that they *are* particularly vulnerable. Each person is unique with a distinct personality. Therefore, it is worth reflecting that within groups defined as vulnerable there may be significant variation in degrees of vulnerability.

Context is an important factor in influencing vulnerability, such as, for example, the location in which the research is undertaken, the social-economic background of the participants, or the culture and living conditions of the participants. The combination of the research context and the particular research design has the potential to increase the vulnerability of participants.

### **4 GENERIC PRINCIPLES FOR CONDUCTING RESEARCH INVOLVING VULNERABLE PEOPLE**

The following are useful generic principles that should be taken into account when doing research that involves vulnerable people:

- Be perpetually reflective about one's research actions and research decisions.
- Be aware that the particular characteristics of a research project can affect the nature and degree of participant vulnerability.
- In designing the research seek to minimise the potential risks to prospective participants.
- Be aware of the possible need to support participants on completion of the research, and prepare for this accordingly (not least with respect to an exit strategy).
- Where appropriate offer prospective participants as many choices and options as possible.
- Be aware of the risks to researchers themselves, as well as to participants, and minimise the potential risks in the research design.
- Show respect for the potential diversity of prospective participants in designing and undertaking the research.
- Pay attention to communication and prepare to meet support requirements in this respect, if necessary.
- Consider consent as an ongoing process.
- Be aware of power relationships in research (e.g. when undertaking research with people in care).
- Listen to participants and do not make assumptions about what participants want.

For further discussion of related issues, see Research Ethics Policy Notes nos. 2 (Principles of Consent), 3, (Participant Safety and Well-being), and 4 (Principles of Anonymity, Confidentiality and Data Protection), and the following Specialist Research Ethics Guidance Papers:

- Doing research with people with learning disabilities;

- Research involving adult participants who lack the capacity to consent;
- Ethical considerations in research with children and young people; and
- Ethical considerations in research involving older people.