



# MRS Best Practice Guide on Research Participant Vulnerability

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## **MRS Best Practice Guide on Research Participant Vulnerability**

MRS has produced this best practice guide and checklist to help practitioners identify, understand and respond to research participant vulnerabilities effectively and consistently. This will help to ensure that the needs of vulnerable participants are taken into account in product and service development, policymaking and regulatory supervision and enforcement.

**Researchers can use the questions in this best practice guide to assess whether a participant is in a vulnerable position and how to conduct research in such a manner as to reduce the likelihood of causing harm or adverse effects.**

### **LEGAL AND REGULATORY OBLIGATIONS**

The Data Protection Act 1998 establishes an obligation on researchers to ensure that personal data has been “fairly and lawfully” sourced. Under the MRS Code of Conduct 2014 it is important to assure yourself of the provenance and legitimacy of your data source in order to ensure that you have a legitimate ground for processing and using personal details. Breaching these requirements can leave you open to regulatory action by the Information Commissioners Office (ICO) and/or the MRS disciplinary and complaint processes.

Principle 1, Data Protection Act 1998

*“Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless –*

*(a) at least one of the conditions in Schedule 2 is met, and*

*(b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.”*

All data collection exercises where personal data is collected must comply with the Data Protection Act 1998.

Rule 4 of the MRS Code of Conduct:

*“Members must take reasonable steps to ensure that others do not breach or cause a breach of this Code.”*

Rule 6 of the MRS Code of Conduct:

*“Members must take all reasonable precautions to ensure that participants are not harmed or adversely affected by the member’s professional activities.”*

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These rules require researchers to make every reasonable effort to ensure that their research does not cause harm either to those who have directly participated or, more broadly, to anyone affected by it.

This includes members taking reasonable steps to ensure that the people with whom they work (including, for example, other members, non-member practitioners, colleagues, clients, consultants, sub-contractors) are sufficiently familiar with the MRS Code that they are unlikely to breach or cause it to be breached unknowingly or unintentionally

In addition, members with responsibility for implementing processes, procedures and contracts, must take reasonable steps to ensure that they are such that the MRS Code is unlikely to be breached or caused to be breached by others unknowingly or unintentionally.

## **VULNERABILITY CAN AFFECT ANYONE**

Participant vulnerability is a complex, dynamic state that can affect anyone at any time for many different reasons. All participants are different, with a wide range of needs, abilities and personal circumstances. These differences can place some in a position of vulnerability or greater risk of harm.

Some people's ability to participate effectively in the research may be affected by certain individual characteristics. These can be short-term or long-term, might fluctuate over time, and may not be obvious. Participants may be vulnerable because their competence to give informed consent is uncertain, because socially they are in a position where it is difficult for them to give informed consent or their circumstances may affect their decision to consent. Additionally being involved in the research project can also increase participants' potential vulnerability.

It is also important to recognise that not all the risk factors will be relevant all of the time, and the important point is to manage the relevant risks rather than seek to avoid risks involved in researching individuals or populations in vulnerable positions.

### Permanent vulnerabilities

Permanent or long-term characteristics could include, for example: people who have learning disabilities or other permanent or long-term disabilities, those on a low income, people with low literacy levels, or communities which have cultural barriers to participation. These characteristics can affect large numbers of people.

### Fluctuating vulnerabilities

People can be made vulnerable by transitory situations which are not necessarily obvious at first glance. Fluctuating characteristics might include mental health issues, where English is not a first language, health problems, location, lack of internet access, etc.

### Short-term vulnerabilities

Short-term characteristics causing vulnerability could be things related to sudden changes in circumstances like loss of employment or income, bereavement, relationship breakdown, or caring responsibilities.

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The impact of vulnerability on the research will also vary according to the type of research method used in the project, for example:

#### Telephone research

Some participants find it difficult to differentiate between genuine research calls and sugging, frugging, personal protection insurance (PPI), etc. Researchers must realise that calling a telephone number after a firm refusal has been given is in breach of the MRS Code, as it is likely to cause harm and/or adverse effects and damage the reputation of research. This is why MRS requires its members to maintain 'do not call' lists to avoid harassment of individuals.

#### One-to-one interviews, for example in-home

Many participants are understandably wary about inviting interviewers and researchers into their home, particularly the elderly and/or less mobile.

This also applies to the safety of interviewers and researchers when this methodology is used, and, as such, practitioners must be trained on how to alleviate a threatening situation.

#### Group interviews

Care must be taken that all participants are able to contribute to group discussions and are not bullied, intimidated or belittled.

Participants must be told what will be expected of them when they agree to participate. This includes any physical exercise or unusual that may be required.

### **KEY POINTS**

#### ➤ Informed Consent

- Researchers must seek the informed consent of all those they wish to participate in their study.
- In the case of children (those under 16), this must include the child as well as the responsible adult. Those involved should be allowed to make a decision based upon a full appreciation of what the research is about and what is expected of them.
- Technique for getting consent – make sure it is tailored to the individual concerned i.e. approach to those with learning difficulties may be different in terms of format/ style of language used etc.; consider using a layered approach to gaining consent

#### ➤ Confidentiality

- Ensure that assurances of confidentiality and anonymity are upheld, especially concerning the collection of sensitive data. Sensitive personal data means personal data consisting of information as to -

(a) Racial or ethnic origin of the data subject,

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- (b) Political opinions,
  - (c) Religious beliefs or other beliefs of a similar nature,
  - (d) Membership of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),
  - (e) Physical or mental health or condition,
  - (f) Sexual life,
  - (g) The commission or alleged commission of any offence, or
  - (h) Any proceedings for any offence committed or alleged to have been committed, the disposal of such proceedings or the sentence of any court in such proceedings.
- Using Identifiable data
    - Researchers must gain additional consent from participants for the use of identifiable participant data and if the data collection is to be recorded and/or observed.
    - In seeking consent researchers must also clearly explain what they intend to do with any identifiable data collected.
  
  - Respecting the Right to decline
    - When approaching individuals to request consent to participate in a study, researchers must ensure that they are free to decline and do not, in any way, feel either pressurised or obliged to participate.
  
  - Notifying of the Right to withdraw
    - It should be made clear to participants that they have the right at any time to withdraw from any research, either temporarily or permanently, without the need to provide a reason.
    - This also includes requests from participants to destroy any data that has been collected from participants.
  
  - Accessibility options to consider
    - Large print questionnaires/instructions etc
    - Braille
    - Foreign language translation
    - Offering the survey in various formats
    - Interviewing via an interpreter
  
  - Researching Sensitive topics
    - Researchers intending to conduct research on sensitive subjects with individuals who may have experienced traumatic events should be very

clear about the precise focus of their research and the information they require.

- Consider sending invites to participants, where appropriate, explaining the research subject matter.
- Any probing of participants' personal experiences should be done with extreme care and sensitivity.
- The details of any relevant support groups may be provided during or at the end of the data collection (NB material left behind cannot also double as seeking donations).

➤ Being aware of the context

- Researchers need to be aware that participants may be vulnerable without making general assumptions on their vulnerability or making a decision on behalf of an entire group or community that they are not capable of participating in research.
- Ensuring that the research is mindful of this and tailored to possible needs is an important part of designing and undertaking the research.

## QUESTIONS TO ASK

In order to recognise a vulnerable person and their needs, researchers developing proposals and conducting research should ask the following questions at an early stage:

- Do members of the research team know how to recognise vulnerability and deal with vulnerable participants?
  - Is supporting guidance and/or training on good practices available?
  - Are staff periodically assessed on their understanding of the guidance?
- If the research is on a sensitive topic, and/or it is known/likely that some or all of the participants are potentially vulnerable:
  - Have members of the research staff involved received specific training ahead of the project?
  - Are staff aware that support materials/helpline numbers may be provided to participants?
  - Has a relevant support group/charity been contacted for their advice on any specific areas? (if this is permitted)
- Have staff been briefed on how to react if any abuse/serious crime is revealed during the data collection process?
- Can participants contact the agency conducting the research without difficulty?
- Are participants at risk because of their individual circumstances?
- Is the informed consent process tailored for the participants involved?
- Has the impact of the research project on participants been assessed?

## HOW TO AVOID MISTAKES

**Scenario 1: Visiting participants in a sheltered housing block under warden control.**

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DO NOT - ignore any signs or information stating that the warden or similar must be contacted before admittance.

DO - be aware that many of the residents may feel threatened by the presence of strangers in and around their home and act accordingly, i.e. have ID (ideally photo ID) and an explanation of the purpose of the research to hand ready for inspection.

DO NOT - automatically assume that participants want to take part, even in circumstances when a warden or similar has given permission to enter premises.

DO - be alert to any signs that participants are becoming anxious or are having difficulties following and/or responding to questions. If there is any concern that participants are becoming distressed and/or confused then interviews and/or any other research should be terminated at an appropriate point.

**Scenario 2: Talking to victims of crime to gain insight into how these individuals judged the process when the matter was reported to the Police.**

DO NOT - hide the true purpose of the project - be clear about the focus of the research and what information will be required from participants.

DO - ensure that participants' personal experiences are treated with extreme care and sensitivity.

DO NOT - assume that any member of research staff can be involved in the project without specific training in the areas to be covered.

DO - consider having some support materials to hand to pass onto participants, such as helpline numbers, particularly when it is known that victims of serious crime are likely to be interviewed.

**USEFUL INFORMATION SOURCES**

[MRS Code of Conduct 2014](#)

[The Care Quality Commission \(CQC\)](#)

[Equality Act](#)