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Good Practice Guide: Informed Consent

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This good practice guide explores the issue of gaining informed consent from people taking part in research or evaluation projects. It provides an overview of what informed consent means, the legal context, and key considerations for ensuring informed consent, including when working with vulnerable groups. It is not a comprehensive guide to all issues, particularly as some are contentious and there is debate within the research community; however it does provide links to further information and resources. The guide has been developed to support the evaluation of the *Fulfilling Lives: Supporting people with multiple needs* initiative.

What is informed consent and why is it important?

Informed consent is a process by which a participant voluntarily confirms his or her willingness to take part in a particular project, after having been informed of all aspects of the project that are relevant to their decision to participate

Market Research Society (2014)

The Social Research Association's (SRA) ethical guidance sets out the obligations of researchers to society, their funders/ employers, colleagues and those taking part in projects. Obligations to participants relate to ensuring that they are protected from possible harm arising as a result of taking part; a key element of this is ensuring informed consent. The requirement for researchers to ensure participation in their activities is based on voluntary informed consent is also the first principle of the Market Research Society's (MRS) revised code of conduct (effective from September 2014). Informed consent is of particular importance in clinical and medical research, and there are many resources available on this subject, but the key principles are also relevant to social research and evaluation.



The settings, contexts, purpose and methods of social research and evaluation vary widely and as such it is difficult to provide hard and fast rules for informed consent. There is disagreement on some points amongst social researchers and a flexible but considered approach is often needed to balance competing pressures and considerations. The SRA (2003) Ethical Guidelines acknowledge that “*no universal rules can be framed*” and the British Sociological Society’s (2002) statement of ethical practice makes clear that “*it does not ... provide a set of recipes for resolving ethical choices or dilemmas, but recognises that it will be necessary to make such choices on the basis of principles and values, and the (often conflicting) interests of those involved.*”¹

However, Wiles et al (2004) set out three key elements of informed consent to participate:

- **Adequate information:** *people should understand what they are agreeing to*
- **Voluntariness:** *people should understand they are not obliged to take part and can withdraw at any time*
- **Competence:** *people are capable of understanding what participation entails and can make a decision.*

This guide explores these key elements in further detail below.

Legal context

The ethical guidance provided by the SRA (and other similar organisations) is a voluntary code. However some aspects of informed consent do fit with wider legal frameworks. In particular the **Human Rights Act 1998** enshrines in law the right to respect for private and family life. This supports the need for informed consent.

The **Mental Capacity Act 2005** applies in England and Wales and sets out legislation pertaining to determining the capacity of individuals to make decisions. Under this Act a person is assumed to have capacity unless it is established otherwise. A person lacks capacity if they are unable to make a decision due to impairment of or disturbance in the function of the mind or brain. The Act makes clear that this cannot be determined by age or appearance. The Act does not apply to under 16s. A person is unable to make a decision for himself if he or she is unable—

- *to understand the information relevant to the decision,*
 - *to retain that information,*
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- *to use or weigh that information as part of the process of making the decision, or*
- *to communicate his/her decision (whether by talking, using sign language or any other means).*

The **Data Protection Act 1998** (DPA) protects personal data and has implications for consent in terms of the storage and processing of data. Processing data fairly means providing or making readily available to data subjects the identity of the organisation processing their data, how their data will be used and any other necessary information to ensure fair processing. Meeting these legal requirements can be achieved through providing a ‘privacy notice’. Detailed and accessible guidance on applying the DPA 1998, including drafting privacy notices, is available from the Information Commissioner’s Office (ICO) (See links at the end of this document).

Consent to data sharing

The ICO has also set out its interpretation of the DPA’s requirements in relation to sharing personal data in a statutory code of practice. Sharing personal data must be legitimate. One of the ways in which this requirement can be met is through consent. If consent is to form the basis for data sharing then individuals must understand what data will be shared and the consequences for them of this. They must also have genuine control over whether data sharing takes place. Consent for sharing sensitive personal data must be explicit.

What information should be provided?

As part of giving informed consent, participants in research or evaluation should understand what is involved in participating and be aware of any potential risks. To be ‘informed’ about all relevant aspects of participation, the MRS suggest the following information needs to be communicated to potential participants:

- *Who has commissioned the research/evaluation*
- *The subject and purpose of the research/evaluation*
- *Whether the data collection will be recorded or observed*
- *Who will have access to the data collected*
- *The length of data collection / participation, and*
- *Any costs that the participant might incur*

To ensure that participation is voluntary, potential participants need to know that that:

- *their participation in the research/evaluation is voluntary, and*
- *they can withdraw from the research/evaluation at any stage without giving a reason and withdraw any data they have supplied.*



Format for information

The information listed above is often provided to potential participants in the form of an information sheet. The amount of information provided will depend on the size and complexity of the project and what participation entails. Wiles et al (2005) set out some of the considerations when providing information and the balancing act required to ensure that potential participants have sufficient information but are not put off participating. Providing written information that can be taken away is a good idea, but it may not always be necessary or appropriate. In some settings or for some participants the formality of a written information sheet is inappropriate; Wiles et al (2005) give the examples of researching illegal activities or research with young people in a club setting. Don't overburden participants with unnecessary information, but you should not withhold crucial information or mislead participants either.

Consider the format of your information and provide information in a way that potential participants will find most accessible. It is of key importance that potential research participants have the ability to understand the information presented to them. Use plain language and avoid technical terms and other jargon. Consider whether information needs to be translated into other languages. The inclusion of pictures may help, particularly for children or people with learning difficulties (see section below on vulnerable people). Consider other formats for providing information such as video or podcasts, for example. As Wiles et al (2005) point out, understanding the target audience's information needs is particularly important when seeking to recruit 'hard to reach' groups. Working closely with a community to understand information needs and engaging with peer researchers may help to ensure information is provided in the most appropriate way.

Getting signed consent

In some circumstances researchers ask for signed consent from participants. This provides confirmation of consent and thus some protection for researchers but can also compromise anonymity and it may not always be appropriate to gain written consent. Coomber (2002) explores some of the problems of insisting on signed informed consent from participants engaged in illegal activities. Individuals committing acts of illegality asked to sign consent forms are unlikely to take part in research; if they do sign it may open them up to the potential of investigation and prosecution by the criminal justice system; those who do sign often use a false name, making the process worthless.

Gaining consent from vulnerable participants

Some participants may be considered to lack the necessary capability to give their informed consent. Such 'vulnerable' participants may include children, those with learning disabilities, and those with mental health problems. Extra care is needed in these cases to protect the rights of participants and to ensure that they are taking part in research or evaluation freely.



However, as Wiles et al (2004) point out, researchers also have a responsibility to ensure the voices of people of different ages and abilities are heard.

Proxy consent is sometimes used with vulnerable groups, with consent sought from a parent, relative or other caregiver. The Market Research Society (2014) Code of Conduct states that before children (defined as anyone under the age of 16) can participate in research, permission must be gained from a responsible adult. A responsible adult is an individual who has personal accountability for the well-being of a child, for example, a parent, guardian, teacher, nanny or grandparent. The Code goes on to state that children should also be given the opportunity to decline to take part, even if an adult has given permission for their participation.

Some researchers consider proxy consent inappropriate and best avoided. It is often possible to find ways to explain research in such a way that it can be understood by people regardless of their 'competence' (Wiles et al 2005). Nind (2008) highlights positive steps that researchers can take to increase capacity to consent, for example, simplifying information, using visual imagery and allowing time for potential participants to absorb information. More accessible information can be provided, for example on DVD or by using pictures that people can take away to look at before deciding whether to take part (University of Sheffield). CHANGE, a human rights organisation led by disabled people, produces a guide to making information accessible using easy words and pictures: <http://www.changepeople.org/free-resources/>

Use of 'incentives'

Use of 'incentives' in recruiting research participants (for example, providing small amounts of money, vouchers or other gifts to participants) is hotly contested amongst social researchers. Some argue that this constitutes a form of coercion to participate. Others are uncomfortable at asking participants to give up their time to get involved without compensation. A possible answer suggested by Wiles et al (2005) is to not publicise the incentive but provide it as a 'thank you' after participation.

References and further information

Research ethics

British Sociological Society (2002) *British Sociological Society Statement of Ethical Practice*
<http://www.britsoc.co.uk/about/equality/statement-of-ethical-practice.aspx>

Market Research Society (2014) *Code of Conduct*
https://www.mrs.org.uk/standards/code_of_conduct/



Economic and Social Research Council, Researcher Development Initiative and Institute of Education (no date) *The Research Ethics Guidebook: a resource for social scientists*
<http://ethicsguidebook.ac.uk/>

Social Research Association (2003) *Ethical Guidelines* <http://the-sra.org.uk/wp-content/uploads/ethics03.pdf>

The University of Sheffield (2014) *Research Ethics and Integrity*
<http://www.shef.ac.uk/ris/other/gov-ethics/ethicspolicy>

Informed consent

Coomber, R. (2002) *Signing your life away? Why Research Ethics Committees (REC) shouldn't always require written confirmation that participants in research have been informed of the aims of a study and their rights – the case of criminal populations*
Sociological research online vol 7, 1. <http://www.socresonline.org.uk/7/1/coomber.html>

ESRC Research Methods Programme and University of Southampton (no date) *Informed consent and the research process*
http://www.sociology.soton.ac.uk/Proj/Informed_Consent/index.htm

Wiles, R. Charles, V. Crow and Heath, S. (2004) *Informed Consent and the Research Process*
Paper presented at the ESRC Research Methods Festival, University of Oxford Available from:
http://www.sociology.soton.ac.uk/Proj/Informed_Consent/Resources.htm

Wiles, R. Heath, S. Crow, G. and Charles, V. (2005) *Informed Consent in Social Research: A Literature Review* NCRM Methods Review Papers NCRM/001 ESRC National Centre for Research Methods <http://eprints.ncrm.ac.uk/85/1/MethodsReviewPaperNCRM-001.pdf>

Research with vulnerable groups

CHANGE (no date) *How to make information accessible – a guide to producing easy read documents* <http://www.changepeople.org/free-resources/>

Nind, M. (2008) *Conducting qualitative research with people with learning, communication and other difficulties: methodological challenges* National Centre for Research Methods <http://eprints.ncrm.ac.uk/491/1/MethodsReviewPaperNCRM-012.pdf>

University of Sheffield (No date) *Doing research with people with learning disabilities – Specialist Research Ethics Guidance Paper*
http://www.shef.ac.uk/polopoly_fs/1.165642!/file/SREGP-Learning-Disabilities.pdf



Data protection

Information Commissioners Office: http://ico.org.uk/for_organisations

Information Commissioners Officer: Privacy notices code of practice
http://ico.org.uk/for_organisations/data_protection/topic_guides/privacy_notices

Data Sharing Code of Practice
http://ico.org.uk/for_organisations/data_protection/topic_guides/data_sharing

Legislation

Data Protection Act 1998 <http://www.legislation.gov.uk/ukpga/1998/29/contents>

Human Rights Act 1998 <http://www.legislation.gov.uk/ukpga/1998/42/contents>

Mental Capacity Act 2005 <http://www.legislation.gov.uk/ukpga/2005/9/contents>

