

METHODS BRIEFING 2

Informed Consent and the Research Process

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A series of methods briefings from projects funded by ESRC as part of the Research Methods Programme.

The Programme aims to develop qualitative and quantitative methods within the context of substantive research. It also aims to encourage effective dissemination of good practice.

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Background and aims of the research

There is increasing concern over issues of informed consent in research, partly as a result of the broad changes that are taking place in research governance and regulation in the UK. This project focused on processes of gaining informed consent from study participants in qualitative social research, primarily carried out within the broad areas of health, education and youth research. However, the study has implications for consent in social research more generally.

We aimed to identify best practice in the management of informed consent. The specific aims of the project were to identify:

- how issues of informed consent are dealt with by researchers
- what factors influence the ways in which informed consent is managed
- what influence 'gatekeepers' have on consent
- what impact methods of informed consent have on the research process
- best practice in relation to these issues and to disseminate this to the research community and other user groups

The study comprised three elements: a literature review; telephone interviews with 31 expert researchers and a series of 6 focus groups with 35 researchers.

Key findings

Researchers' orientations to consent

Informed consent is commonly understood as providing sufficient information to study participants to enable them to know what participating in research will entail. However, in practice this is not straightforward and involves researchers making judgements according to the specific contexts in which they work, the groups they work with, their disciplinary backgrounds and research approaches. In each of the study areas we found that approaches to consent were, to some degree, specific to the research area (see Figure 1).

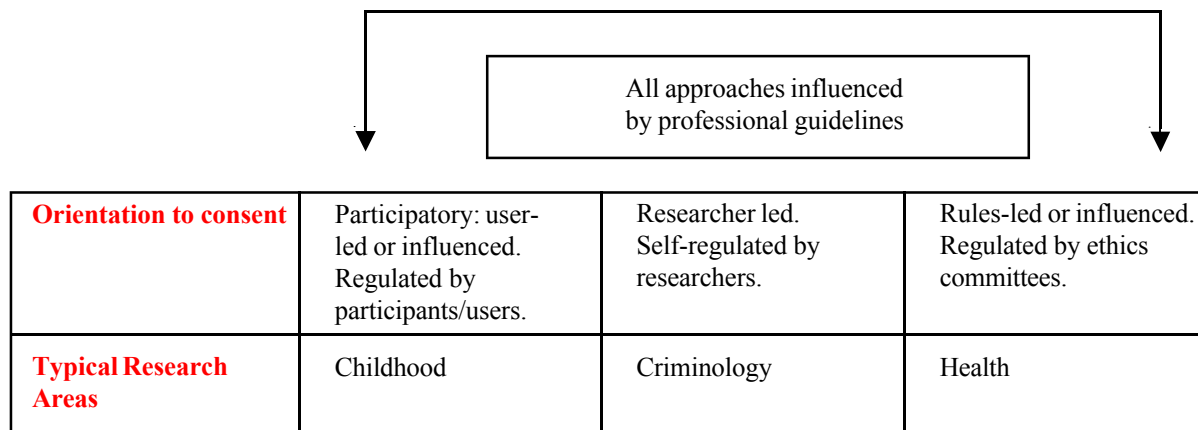


Figure 1: Researchers' Orientations to Consent

Guidance and regulation

Most researchers viewed informed consent as necessary (i.e. were against the notion of covert research). However, many researchers are concerned that the increasing regulation of research through NHS and University Ethics Committees (which is occurring partly as a result of pressure from statutory bodies, universities and funders) may impose methods of gaining consent that, it is feared, may be in

conflict with researchers' area- or disciplinary-specific research orientations. Particular tensions exist for those using participatory approaches and ethnographic approaches. Figure 2 illustrates researchers' perception of how increasing dominance of formal regulation may threaten their own ability to regulate research.

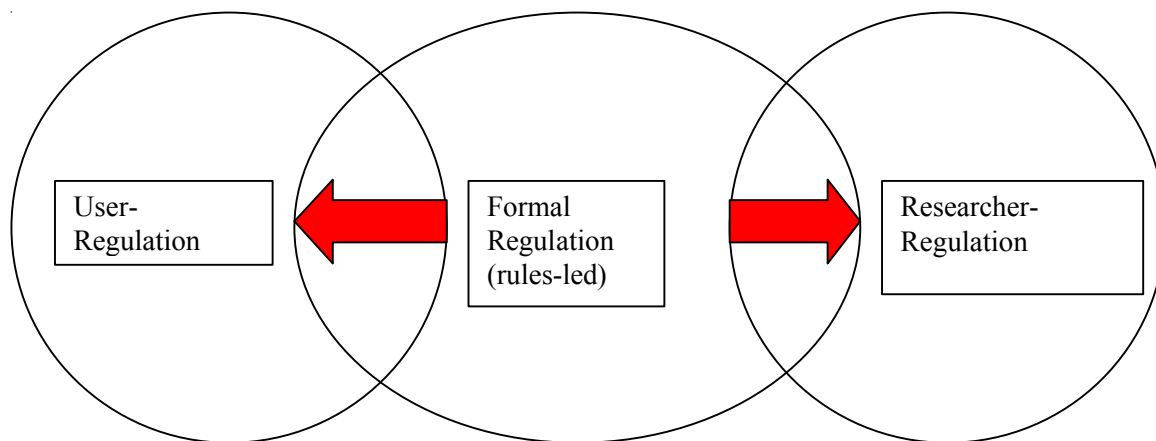


Figure 2: Tensions in the Increasing Regulation of Research Ethics

Managing information provision: what, when, how?

Researchers identified the need to balance the provision of sufficient information without deterring people from participating in the research. Specific dilemmas included: the amount and format of information; whether information should be a one-off process or whether it should be provided at each stage of

data collection or as the focus of a study changes; and whether incentives to research participation (which are not necessarily confined to financial rewards) are exploitative or simply recognise the value of someone's time and effort. See Table 1 for an outline of these dilemmas.

Issue	On the one hand...	On the other
How much information should be given and in what format?	Need to provide comprehensive information about study participation to ensure informed consent	Too much formal information is off-putting and encourages people to decline to participate
Should on-going consent from research participants be sought?	Ensures people know to what they are consenting as the focus and direction of a study changes. Addresses participants' tendency to disregard the information about participation that they are given	One-off consent is adequate; seeking on-going consent irritates participants and encourages them to withdraw from participation
Should financial reward for participation be offered?	Recognises the time and effort of study participants	May encourage potentially vulnerable people to participate for the wrong reasons

Table 1: Managing information provision: Dilemmas

Assessing consent: competence, autonomy and gatekeepers

It is also difficult to assess whether consent is 'really' informed. Dilemmas include: the value of signed consent forms; how to assess the ability (or 'competence') of individuals to give informed consent, especially for groups characterised as 'vulnerable'; how to recognise that people want to withdraw from

their involvement in a research study; how to avoid gatekeepers denying consent for people to participate or including people who have not truly consented; and whether consent should be restricted to data collection or include the ways that data are interpreted and presented. See Table 2 for an outline of these dilemmas.

Issue	On the one hand....	On the other
Should signed consent forms be used?	Ensures that participants know their rights; protects the researcher from later accusations from study participants	May discourage people from participating. Signed consent is meaningless for some groups. In some areas of research, signed consent may make participants and researchers vulnerable to investigation and prosecution
Should consent be obtained from parents/guardians/care-workers in the case of 'vulnerable' participants, and assent from participants?	The law is unclear. To protect researchers from legal proceedings, consent should be obtained from parents/guardians /care-workers as well as participants	This approach denies people's agency. The onus is on researchers to identify ways to gain informed consent from participants and to allow participation even if other parties dispute this.
Who do data belong to? Should participants give consent to the ways that data are interpreted and used	Research participants should be able to consent to how 'their' data are to be used (including the use of pseudonyms) and stored	This limits the freedom of the researcher and curtails the critical nature of the discipline

Table 2: Assessing consent: Dilemmas

Management of issues

Researchers used a range of ways of ensuring consent and enabling people of varying ages and abilities to participate in research. For example, potential participants can be asked to repeat back information provided to them to check their understanding; or the consent procedure can be carried out *after* the data have been collected so that the participant will know whether or not they want their data to be used. A range of ways to check on-going consent were also identified including the use of 'stop' cards to indicate a wish not to answer a question or not to continue to participate in a study. Innovative ways to manage consent in institutional settings were also identified, particularly where consent is given by gatekeepers rather than the individuals themselves. There are many ways in which researchers manage issues of informed consent and there is much to be learned from current practices as they are developed in response to a variety of institutional, legal, political and moral influences that are themselves evolving very rapidly.

There is a need to promote further discussion of these issues, and dissemination of good practice, (not least through inclusion in research training) in order to increase understanding of the link between ethical procedures and more practical considerations. We are developing a typology from our data of the actual risks posed by social research and the contexts within which such risks take place in order to inform debates on regulation.

Selected Papers

The following conference papers are available from the project website (see below):

Heath, S., Charles, V., Crow, G. & Wiles, R. 'Informed Consent, gatekeepers and go-betweens' Paper presented at the International Sociological Association Sixth International Conference on Social Science Methodology, Amsterdam, August 2004.

Wiles, R., Charles, V., Crow, G. & Heath, S. 'Researching researchers: lessons for research ethics' Paper presented to the BSA Medical Sociology Conference, University of York, September 2004.

Web Site and Resources

A project website has been developed containing the following resources:

- An annotated bibliography on informed consent
- Teaching resources
- A summary of some of the central issues and debates relating to informed consent
- A 'top tips' page outlining some of the ways that issues of consent can be managed
- Copies of conference papers
- Links to guidelines and regulation relating to consent and other relevant websites

Further details are available from:

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http://www.sociologyandsocialpolicy.soton.ac.uk/Proj/Informed_Consent/index.htm