Informed Consent in Social Research: A Literature Review

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Abstract:

This paper comprises a literature review outlining the current issues and debates relating to informed consent in social research. Given the rapidly changing nature of the field it draws primarily on literature published between 1998-2004. However, it includes some papers and books published prior to this where these are viewed as having made an important contribution to issues and debates around informed consent. The paper focuses primarily on consent in relation to qualitative research comprising 'traditional' methods of data collection, such as interviews and observation. It does not does not engage with the many complex ethical issues relating to research using visual methods and new digital technologies nor does it engage with the issues of consent in relation to quantitative research both of which, while important, are beyond the scope of this paper. The paper explores issues of informed consent in qualitative social research in general but focuses specifically on research conducted with so called 'vulnerable' groups (to include children, older people and people with a range of physical and mental health problems) in that issues of consent are

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perceived as being particularly pertinent when conducting research with these groups. This review outlines the regulatory, ethical and legal context for consent in social research and the operationalisation of informed consent in practice. This review was conducted as part of a project funded within the ESRC Research Methods Programme 2002-2004.

Contents

1. Introduction

This paper comprises a literature review outlining the current issues and debates relating to informed consent in social research. This topic has gained prominence as a result of the broad changes that are taking place in research governance in the UK and the increasingly regulated frameworks within which social researchers work (Tinker & Coomber, 2004). Given the rapidly changing nature of the field it draws primarily on literature published between 1998-2004. However, it includes some papers and books published prior to this where these are viewed as having made an important contribution to issues and debates around informed consent. The paper focuses primarily on consent in relation to qualitative research comprising 'traditional' methods of data collection, such as interviews and observation. It does not does not engage with the many complex ethical issues relating to research using visual methods and new digital technologies nor does it engage with the issues of consent in relation to quantitative research both of which, while important, are beyond the scope of this paper. The paper explores issues of informed consent in qualitative social research in general but focuses specifically on research conducted with so called 'vulnerable' groups (to include children, older people and people with a range of physical and mental health problems) in that issues of consent are perceived as being particularly pertinent when conducting research with these groups. This review outlines the regulatory, ethical and legal context for consent in social research and the operationalisation of informed consent in practice. This review was conducted as part of a project funded within the ESRC Research Methods Programme 2002-2004. Further information about the project can be found at: http://www.sociologyandsocialpolicy.soton.ac.uk/Proj/Informed_Consent/index.htm

2. Method

The literature review was conducted through searches of bibliographic databases as well as hand-searching of journals and library searches of books. The following databases were searched: BIDS; Ingenta Select; Web of Science; ASSIA; EBSCO; Sociological Abstracts; and, Social Services Abstracts. The initial terms used for the search were: 'informed consent', 'ethics', 'participation rates' and 'confidentiality'. The search was limited to the years 1998-2004. Many of the papers identified using these search terms related to medical studies and these were mostly discarded unless they were felt to have particular relevance to debates in social research. The search strategy was refined by including the term 'social research' to the search categories. The papers identified were checked for relevance. Those included were papers which addressed:

a) general literature relating to research ethics which have relevance to the principles surrounding

consent;

b) general literature on informed consent in social research;

c) papers relating to the six specific areas focused on in the study in relation to informed consent, these included both consent in relation to substantive projects as well as discussions of consent more generally;

d) papers relating to consent to medical research or treatment which have relevance for consent in social research.

The reference lists of key papers identified through this process were also checked for relevant references. Hand searching of key journals in health (Sociology of Health and Illness), youth (Journal of Youth Studies**)** and social research methods (International Journal of Social Research Methodology) was also conducted. Papers or books referred to by researcher-participants in the ESRC project on informed consent were also included in the review. Books on research ethics were identified through library searches and cross referencing papers. These included some of the key texts on this topic published prior to 1998. Research methods textbooks published from 1995 were also checked. We identified 107 references from this search strategy. An annotated bibliography of these references can be found at:
http://www.sociologyandsocialpolicy.soton.ac.uk/Proj/Informed_Consent/index.htm

3. Ethical Context for Consent in Social Research: Approaches, Regulation and Frameworks

3.1. Approaches to research ethics

There are a number of different approaches to research ethics. Social research ethics are closely aligned to medical research ethics (see Beauchamp & Childress, 2001). Frameworks for ethical medical research developed following the evidence of abuse experienced by human research 'subjects' during the Second World War and were enshrined first in the Nuremberg Code (1947) and later in the Helsinki Declaration (1964). Local Research Ethics Committees (LRECs) were formed in the UK in early 1968 (Institutional review Boards (IRBs) in the USA have a similar function although are backed up by Federal law unlike LRECs) to regulate medical research and to ensure adherence to these frameworks. However, there was evidence that research in both medical and social science contexts continued to be conducted in ways that did not respect individuals' rights (Milgram, 1963; Corrigan, 2003). More recently, the scandal at Alder Hey Hospital in Liverpool, where dead children's organs were retained for research without parental consent, has highlighted the extent of unethical research practice prompting the Department of Health to develop

the Research Governance Framework (Department of Health 2001). The framework brings together various guidelines and statutes to provide a coherent and ethical context for health research.

In medical and health related research, consequentionalist, rights-based approaches or principle-based (or deontological) approaches tend to be used in which ethical decisions are made on the basis of the consequences or outcomes of research participation, on the rights of individuals (see Alderson, 2004) or on the basis of moral principles (Beauchamp & Childress, 2001; Seymour & Skilbeck, 2002). Rights-based approaches involve respect for individuals, protection from harm and participation in research (Alderson, 2004). Principle-based approaches involve adherence to moral principles which can be outlined as follows:

- Autonomy: people must be free to make their own informed decisions about participation in research
- Non-maleficence: research must not inflict harm
- Beneficence: research should benefit others
- Justice: people must be treated equally within the research process.

Some social researchers have argued that these approaches do not necessarily translate well to social research, partly because the ethical dilemmas that arise in social research are context-specific (Punch, 1998; Swain et al, 1998; Small, 2001; Goodwin, et al, 2003). In addition, some social researchers argue that adhering to specific ethical rules in relation to research can affect the very issue that is being studied, such that it becomes impossible to conduct the research (Homan & Bulmer, 1982; Homan, 1991; Punch, 1998). This issue is particularly relevant to psychology experiments but is also relevant to research in sociology and anthropology, particularly ethnographic research. There is widespread debate about the basis for ethical decision making in social research, these include a commitment to participants' rights (e.g., the protection of privacy); a commitment to 'respect' for participants; a commitment to knowledge (or the right for others to know e.g., how specific organisations operate); a commitment to the promotion of respect for social science (i.e., to avoid 'spoiling the field'); and, protecting the researcher (e.g. from litigation) (see Alderson, 2004; Homan, 1991; Homan & Bulmer, 1982). Elements of all these approaches are enshrined in the professional guidelines for social researchers, such as those produced by the Social Research Association (www.the-sra.org.uk/Ethicals.htm), the British Sociological Association (BSA) (www.britsoc.co.uk/library/ethicsguidelines2002.doc), and the British Education Research

Association (www.bera.ac.uk/publications/guides.php)[5]. One would expect social researchers to want to satisfy themselves and their colleagues or supervisors that they are adhering to these ethical guidelines. However, as Smyth and Williamson note (2004: 10), these guidelines operate primarily on a system of self regulation; membership of these organisations is voluntary and the guidelines are not enforceable. In addition, they are intentionally vague and leave researchers able to interpret them in ways that fit the needs of the specific research they are undertaking and their own orientation to research ethics. This allows social researchers to adopt a 'situational relativist' approach in which ethical decisions are made on the basis of the researcher's moral stance and issues applicable to individual research projects (Small, 2001; Goodwin et al, 2003). This point is noted in the BSA statement of ethical practice (2002):

'The Association encourages members to use the statement [of ethical practice] to help educate themselves and their colleagues to behave ethically. … [It] does not, therefore, 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.' (BSA, 2002).

However, following the development of the Research Ethics Framework by the Economic and Social Research Council (ESRC), universities and other research organisations are putting processes in place to ensure that all research with 'human subjects' is subject to formal ethical review and this will inevitably impact on the freedom of researchers to make independent decisions on the ethical issues relating to their research (see www.esrc.ac.uk/esrccontent/ourresearch/research_ethics_framework.asp

This issue is discussed further in the section on regulation and ethical review.

3.2. The Legal Context

While social researchers are able to interpret ethical guidelines to meet the needs of their research project, researchers are, nevertheless, subject to legal frameworks and regulation that influence how research ethics, and more specifically issues of informed consent, are managed. This is particularly the case in some areas of research, such as in research with children and in health contexts. In terms of legal frameworks, Article 8 of The Human Rights Act 1998 and the Data Protection Act 1998 have relevance to consent in relation to all research (see Montgomery, 2003). The Human Rights Act protects the right to respect for private and family life and thus supports the need for

[5] A list of guidelines for various professional and research organisations can be found at: http://www.sociologyandsocialpolicy.soton.ac.uk/Proj/Informed_Consent/links.htm

consent to participate in research (Masson, 2004). In relation to the Data Protection Act (DPA), specific issues relating to consent concern the disclosure to researchers of data or information about potential participants, the need to ensure consent to individual's data except in very specific circumstances, the use to which data is put (i.e., that this should be limited to that for which consent has been sought) and the storage of data (see, Masson, 2004; for a detailed discussion of these issues within a health context see Montgomery, 2003). Guidance on the law in relation to the DPA can be found at:
www.informationcommissioner.gov.uk/eventual.aspx?id=34.

In relation to research with children, the law is complex and relates to the notion of 'competence' (see Allmark, 2002; Masson, 2004; Alderson & Morrow, 2004). In England, Wales and Northern Ireland, children under 16 are not *automatically* presumed to be legally competent to give consent. However, if a child can be judged to 'understand' what participation in research will involve (known as 'Gillick competence') then parental consent is not necessary. This is based on the assumption that a child who has 'sufficient understanding' can provide consent and that, under such circumstances, a parent has no right to override their child's wishes. Assessing children's competence is not straightforward; understandings of, and attitudes to, competence vary among researchers and assessments of competence are clearly dependent on the complexity and risks inherent in the research being conducted (see e.g., Ensign, 2003; McCarthy, 1999). Alderson notes that one way round these problems is to assume that school age children are competent and that the onus is then on parents who disagree to prove incompetence (Alderson, 1995**).** Masson (2004) argues that a researcher should not be at risk of legal proceedings brought by parents by involving an under 16 year old in social research without having sought parental permission, although a researcher would be at risk if a claim of harm was made by the child. Alderson and Morrow (2004) note that only a very controversial piece of research would be likely to reach the courts in which case the researcher would have been wise to seek parental consent in the first instance. No such cases have been brought against social researchers. The Children's Act (1989) has some relevance to informed consent in relation to research with children but this relates primarily to the limits of confidentiality if a child is identified as being in danger (see France, 2004). Again, there have been no cases brought against a researcher in relation to this.

Children over the age of 16 are deemed to be competent to give consent for themselves. However, consent from parents, guardians or other representative is generally necessary in relation to research with children and adults who lack the 'capacity' to give consent for themselves (this relates to people with mental health problems or learning disability who do not have the ability to understand

fully what taking part in a specific research project would comprise or what the consequences of their involvement might be). It is noted that the courts have held that people with parental responsibility can consent to research on another individual's behalf as long as it is not against the individual's interests and imposes only a minimal burden (www.doh.gov.uk/consent). However, the lawfulness of research with 'incapacitated' children and adults has not be tested in the English courts and the Department of Health advise that research with these groups should not be considered if it is possible to carry out the research with people with capacity to give consent. The ways in which social researchers have engaged with and managed these issues within the legal context are varied and will be discussed further below.

3.3. Regulation and ethical review

Researchers are subject to regulation from NHS or institutional Research Ethics Committees and these have a significant impact on the procedures researchers are able to adopt in relation to informed consent. All research involving NHS patients or staff or conducted on NHS premises have to be approved by a NHS Ethics Committee (see, www.corec.org.uk). The development of the Research Governance Framework has run parallel with changes in the management and organisation of NHS Research Ethics Committees. These changes have resulted in a more bureaucratic system of ethical approval with procedures that are onerous and time consuming and have been subject to much criticism from social researchers (see, for example, Truman, 2003; Ramcharan & Cutliffe, 2001) and medical researchers (Mayor, 2004; Jamrozik, 2004; Jones & Bamford, 2004). As a result of these criticisms an advisory committee has been formed and is due to report in March 2005 on how the system can be streamlined.

Social research in other fields is increasingly being subjected to ethical review from institutional Research Ethics Committees. Such committees have increased in number in recent years with a recent survey indicating that most universities are aware of the need for such Committees and are beginning to put processes in place to ensure the ethical scrutiny of research involving 'human subjects' (see Tinker & Coomber, 2004). It seems likely that such regulation will increase in the future and, while this prospect has been met with resistance by some social scientists (see, for example, Coomber, 2002), others have identified the advantages of regulation and urged social researchers to become involved in the process of their development (Williamson et al 2002; http://www.york.ac.uk/res/ref/index.htm). The ESRC are (at the time of writing) in the process of developing a Research Ethics Framework which will contain guidelines for ethical review (see: http://www.york.ac.uk/res/ref/documents.htm; www.esrc.ac.uk/esrccontent/ourresearch/research_ethics_framework.asp). Ethical review is set to

become a requirement of funding bodies.

The ethical regulation of social research is in a state of flux with change occurring in response to a variety of institutional, legal, political and moral influences that are themselves evolving very rapidly. Researchers are advised to keep themselves updated on requirements for ethical review at their own institutions as well as the requirements set out by funding organisations.

4. Operationalising informed consent

While at first glance informed consent appears a relatively straightforward issue involving the provision of appropriate information to enable people to make informed decisions about participation in a research project, a closer examination of the issues involved reveals that the process is far from straightforward (see Alderson & Goodey, 1998). Authors such as Homan (1991, 1992) argue that the notion of true informed consent, where study participants are given a full explanation and are able to reach a clear understanding of what participation involves, exists more in rhetoric than reality (see also, Domestic Violence Research Groups (DVRG), 2004). Homan notes a number of practical reasons why this might be the case, for example, the difficulties of explaining research fully in a way a participant can understand and the impossibility of knowing all the consequences of participating before a study has commenced. However Homan also argues that, because of the tension between the participant's right to refuse and the motivation of the researcher to achieve a high response rate, researchers use various strategies at their disposal (including providing less than full information and incentives to participate) to encourage participation. Homan's and Punch's (1985, 1998) work on informed consent raises some important issues that researchers can usefully consider when reflecting on their own information (and consent) processes.

Social researchers clearly have to balance a number of factors in managing issues of informed consent. They obviously have to comply with any legal frameworks and regulation (outlined above) but additionally they have to balance a range of sometimes competing interests, such as the aims of the research, what they consider to be the best interests of research participants and the interests of formal or informal gatekeepers. They also have to operationalise and be reflexive about issues of, 'information', 'consent' and 'competence'. The ways these issues can, and have been, managed are discussed below.

4.1. Information provision: written information

Researchers need to negotiate a delicate balance in providing information. They clearly need to provide sufficient information to enable participants to make informed decisions about participation. Indeed, some would argue that information provision should extend to including information about the researcher, their views and the funding of the research (Scraton, 2004; Wilkinson, 2001). However, as Harris and Dyson (2001) and Homan (1991) note, researchers also need to avoid providing information in such a way that it might put people off participating.

Decisions about the styles and means of information provision have an impact on the type of people likely to agree to participate. There is some research from psychology which has illustrated the ways different methods of information provision impact on peoples' understandings (Kent, 1996) which in turn may impact on their willingness to participate (Pokorny et al, 2001; Edwards et al, 1998). Information provision generally comprises written information in conjunction with, or followed by, oral information. The importance of not overwhelming study participants with information and making information sheets friendly and attractive has been noted (Alderson, 2004). This involves researchers paying attention to the layout, colour, size of text, type of language used and the inclusion of graphics. The need to avoid information sheets that look too official has also been noted, although various forms of ethical regulation appear to be constraining researchers' ability to do this, especially in health care settings (Truman, 2003). 'Official' information sheets that labour the point about confidentiality or the possible distress that might arise from participating are viewed as likely to make research participants reluctant to participate or, in medical settings or research with 'dependent' groups, to encourage relatives or care workers to refuse participation on their behalf (Wiles et al, 2004).

For studies wanting to recruit 'hard to reach' or socially excluded groups the style and means of information provision is particularly important and the importance of working closely with the communities from which researchers want to recruit study participants has been identified as crucial (Ensign, 2003; http://www.ccsr.ac.uk/methods/projects/posters/emmel.shtml). This is also an important issue for researchers working with so called 'vulnerable' groups where innovative ways may need to be identified to ensure potential study participants can truly understand what participating in a study might involve. Childhood researchers and researchers working with people with learning disabilities, for example, have demonstrated the importance of keeping written information to a minimum and incorporating pictures and graphics into the information they provide (see e.g., Connors and Stalker, 2003; Alderson, 2004). Researchers have also experimented with a range of ways of providing information to meet these needs including the use of photos, video and computers (Dunn et al, 2001).

In some areas and types of research (e.g., some youth or criminology research) oral information only may be provided (Coomber, 2002; Ensign, 2003). This occurs in cases when the formality of written information is viewed as inappropriate to a particular group (for example, research relating to illegal activities) or because the setting is not one that is conducive to potential participants reading written information (for example, research with young people taking place in a club setting).

Some researchers have noted that they need to be cautious in relation to minimising the amount of information they give. Study participants are often very keen to take part in research because of an interest in the topic, because they don't want to appear unco-operative by saying 'no' or because they are unaware of any risks that participation might involve (Goodenough et al, 2004). In these cases, study participants often disregard researchers' explanations of what the research will involve or are reluctant to take the time to read information sheets (Wiles et al, 2004).

The important message emerging from work in this area is that it is crucial that researchers understand the information needs of the group that they want to research and that they use this knowledge to provide information in a way that will enable potential study participants to understand what participation will involve. Most social researchers, especially those working in the area of childhood research but also those working with other 'vulnerable' groups, note that such research does not necessarily raise unique methodological and ethical obstacles (Casarett, 2003; Harden et al, 2000; Morrow & Richards, 1999). Most social researchers view it as possible and preferable, where they are not prevented from doing so by gatekeepers, to provide information in appropriate ways that enable potential study participants to understand what participation will involve whatever their level of 'capacity'(Alderson & Morrow, 2004; Alderson, 2004; Cameron, 2004; Goodenough et al, 2004; Fisher, 2003; Christiansen and Prout, 2002; David et al, 2001; Casarett and Karlawish, 2000; Edwards & Alldred, 1999; Rodgers, 1999). These researchers have noted that it is their responsibility to identify ways of enabling people of varying ages and abilities to consent to participate in research by providing information that is appropriate to individuals and checking that such information has been understood. For some researchers this involves developing partnerships with potential participants to ensure that their views are respected (Alderson, 2004; Thomas & O'Kane, 1998). In order to achieve this some researchers have worked closely with peer researchers (children or services users) to help ensure they are providing information in appropriate ways (see Jones, 2004; Tarleton et al, 2004).

4.2. Withholding information

In observational and ethnographic research, information may intentionally or unintentionally not be provided to all study participants (Mulhall, 2003; Punch, 1998). In some observational studies it is not possible to inform all participants that they are being observed, for example, if observation is being conducted in a pub or a street it is not possible to provide information to all people who might enter the area. In other research contexts, such as on a hospital ward or in a residential home, researchers may inform patients or residents and staff that observation is taking place and may put up posters to inform people of this, but other people may enter the research 'field' who have not been made aware of this. Some researchers have argued that it is not always appropriate to provide information (and seek consent) for participation in that once people know they are being observed their behaviour is likely to change (Homan & Bulmer, 1982). Many studies in psychology follow this model, although often researchers provide information about participation but not about the *actual* focus of the research (see, e.g., Millgram, 1963; for a more contemporary example, see Berger et al, 1998).

Some researchers take a more radical stance and have argued that withholding information and consent from participants in some research contexts is appropriate because it is the only way that some areas of social life, institutions or organisations can be exposed and it is in the public interest that such exposure occurs. Typical examples of this type of research are studies of football hooligans, of neo-nazi groups or of corporate activities (Scraton, 2004). There is considerable debate in the social science literature about the ethics of covert research (i.e., research that is conducted among groups where some, or all, participants are not aware they are taking part in a research study). Proponents of covert methods have argued that covert research is not necessarily harmful to participants and that so-called 'open' research often uses procedures based on various levels of deceit (see Homan, 1991). However, the criticisms of covert research are extensive and it is argued that covert methods are generally not necessary in that the same objectives can be achieved by open methods, that the use of covert methods are a betrayal of trust, that it 'spoils the field' for other researchers and brings all social science into disrepute (Herrera, 1999; Punch, 1985; 1998; Homan & Bulmer, 1982; Dingwall, 1980). Increasing levels of research governance severely restrict researchers' ability to conduct covert research or indeed to provide only oral information without signed consent. This is a concern for many researchers (Scraton, 2004; Coomber, 2002).

4.3. When to provide information

A further difficulty for researchers concerns when to give information (and when to seek consent). One of the central difficulties in relation to the provision of information is that, in qualitative

research, the specific focus and outcomes of a research study and perhaps even the specific phases of data collection, are often not known at the start of a study. So, at the outset of a study, a general research focus and research question or set of research questions will generally have been designed but the number of study participants, the number of interviews to be carried out with each individual and the specific direction the research will take is often dependent on the data collected and the emerging analysis. This is particularly the case for ethnographic research. To provide information and gain consent from people to participate at the beginning of a study is viewed as inappropriate because people can not know to what they are consenting.

These issues have been outlined at some length by Lawton (2001) in relation to her ethnographic research in a hospice. Lawton (2001) found that, due to changes in patients' conditions, they were not always able to state whether they still wanted to participate or not. Others had problems remembering that she was a researcher. She had to strike a balance between informing the patients but at the same time respecting that they did not need to be pestered regarding the project. It was for this reason that overt participant observation was used because it was deemed to be the less intrusive way of gathering the data. Grinyer (2001) also points out that the boundaries between overt and covert research can sometimes become blurred. These difficulties have led researchers such as Lawton (see also Goodenough et al, 2004; Cameron et al, 2004; Cutliffe & Ramcharan, 2002; Miller & Bell, 2002; Reid et al, 2001; Smythe & Murray, 2000) to argue for information provision (and consent) to be seen as a process rather than a one-off event. It has been argued that researchers should provide information and seek consent each time they collect data from a study participant to ensure that they are aware that data are being collected and that they are willing to continue participating in the study. However, the process whereby this can be achieved may be difficult and it has been noted that participants may get fed up with being repeatedly asked if they want to continue to participate (Lawton, 2001). This again reiterates the importance of researchers balancing the need to provide adequate information in an appropriate way but at the same time ensuring the information provided does not put people off participating.

4.4. The use of 'incentives'

Some researchers (and research organisations) offer financial or material 'rewards' to study participants who take part in their studies (see e.g., Wright, Waters & Nicholls, 2004; Tarleton et al, 2004) and where this occurs such information is generally included in the information provided to study participants. These might be seen as incentives or inducements and to comprise a form of coercion that impacts on the voluntary nature of research participation (see Homan, 1991). There is little consensus about the appropriateness of payments or other rewards being offered to research

participants. Some researchers view it as important that all people should be paid for their time and effort while others consider that this might encourage potentially vulnerable people to participate for the wrong reasons (Wright et al, 2004; Ensign, 2003). The situation is particularly difficult when participants are people from impoverished groups or where participation might mean participants were 'out of pocket' in some way (Smyth, 2004; Ensign, 2003). One way some researchers manage this is by not informing people that they will be paid and to give payment as a thank you after the individual has participated in the research. Of course, the difficulty with this is that it is not possible to keep this a surprise for long as word soon gets round, especially in specific communities. Incentives aren't necessarily confined to money or gifts and some research projects may provide other incentives, rewards or compensations for time and effort, such as food (Smyth, 2004). One might argue that focus group research that typically provides lunch or refreshments on attendance is using a form of inducement (Truman, 2003).

4.5. Consent: to sign or not to sign?

The provision of information links closely to the gaining consent from study participants. There are several issues that researchers have to address in ensuring people have had the opportunity to consider whether or not they want to participate in a study. Giving people sufficient time to consider whether or not they want to participate is viewed as important. This issue has been raised particularly by researchers working in NHS and social care settings where such procedures are part of everyday clinical and research practice. Indeed NHS ethics committees generally expect people to be given at least 24 hours to consider whether or not they want to take part in a research study (see, www.corec.org.uk).

Views about the importance of gaining a signature as evidence of consent are varied. There is an increasing expectation that researchers will gain *signed* consent from research participants and many researchers view it as important that study participants actively 'opt in' to research studies by signing consent forms. The advantages of using signed consent forms are seen to be that they increase the likelihood that participants understand what participation will involve and what their rights are in relation to participation and issues of confidentiality and anonymity. Furthermore, signed consent forms are seen to protect the researcher from later accusations from study participants (see Coomber, 2002 for a discussion of these issues).

However, while a signature may be viewed as important to safeguard participants and researchers, on the other hand asking for a signature might be problematic in research in some contexts, particularly in relation to research that relates to socially unacceptable or deviant behaviour or

where participants need protection (see Ensign, 2003). Additionally the need to obtain a signature in other contexts might be problematic in that it makes the process a formal one and it is feared that this might be seen as offputting for some people and there are the additional problems of how to manage signed consent with people who are illiterate or have language or communication problems (The Domestic Violence Research Group (DVRG), 2004). This is a particular issues for researchers working with people with learning disability and researchers have developed a range of ways of obtaining consent without the use of signatures (Rodgers, 1999), such as the use of tape recorded consent, providing marks on a consent form or holding up red or green cards to indicate yes or no.

Researchers such as Coomber (2002) and the DVRG (2004) have noted that the use of signed consent forms may compromise issues of confidentiality and anonymity which are important issues where participants are in need of protection. Participants may fear that signed consent forms may make the information they provide traceable to them which may put them at risk of physical harm (in the context of research topics such as domestic violence) or vulnerable to potential investigation and prosecution by the criminal justice system (in the case of illegal activities). Coomber (2002) has noted that individuals may want to protect their identities from the researcher and expecting them to divulge it runs counter to other ethical principles. He notes that individuals involved in illegal activities who are asked to sign consent forms are unlikely to want to participate in research and, if they do so, they are likely to give a false name, thereby making the process meaningless. Furthermore, that signed consent forms are not in the interests of researchers as they may force them to be complicit in the prosecution of research participants which would contravene researchers' responsibility to their participants.

4.6. Proxy consent

Proxy consent is sometimes used in research with 'vulnerable' groups who are viewed as lacking the capability or 'competence' to understand what participating in a study will involve and so are unable to provide informed consent for themselves. Studies where proxy consent has been used involve research with young children, with mental health service-users, with people with learning disabilities and with older, infirm people (see, Cameron et al, 2004; Goodenough et al, 2004). People providing proxy consent are generally relatives or caregivers of the individual. Consent from proxies may be used to examine an individual's records, for observation or, perhaps less usually, for interviews. Many researchers view proxy consent as inappropriate and to be avoided wherever possible. Certainly, ethical review committees would want a strong justification for the use of proxy consent. As noted above, many researchers hold the view that it is generally possible to explain a study in ways that someone can understand whatever (within reason) their level of

'competence'. If this is not possible, including an individual in a study raises significant ethical concerns and needs a strong justification.

4.7. Wider consent

Consent is not necessarily confined to consent to data collection at the time which this takes place. Some researchers, particularly those working in participatory paradigms view it as appropriate to send transcripts to study participants so that they can check that they are happy for what they said in the interview to be included in the study (Smyth, 2004). Researchers working in this style are generally happy for participants to amend transcripts. Others object to this approach and view the transcript generated from research as belonging to the researcher who has collected the data and that once the data collection has been completed that the interviewee should have no say over how these data are used (Wiles et al, 2005). Some researchers also feel consent should extend to consent for the ways that the data collected are used, by for example, asking study participants' agreement for the way their data are presented in reports, publications or presentations (Smyth, 2004). The assumption that participants always want to be anonymised has also been questioned (Grinyer, 2002). Researchers conducting research with children and in palliative care contexts have found that participants often want their own names to be used and it has been noted that this is an issue that should be clarified at the consent stage. Similar issues have been identified in relation to the use of visual data, such as photographs (Heath & Cleaver, 2004). A further issue concerns consent to the archiving and re-use of data. The Qualidata archive provides a resource for archiving and re-using qualitative data sets[6], however, specific signed consent from study participants must be obtained for this (see Thompson, 2003; Corti et al, 1995). Such consent should ideally be obtained after data collection so that the individual knows what their data will comprise and the issue of anonymity of participants needs to be agreed (Thompson, 2003).

4.8. Right to withdraw from research participation

Part of informed consent concerns giving people the right to withdraw from their participation in a study at any point. This implies the need for researchers to ensure that they have people's ongoing consent to participate in a study (as discussed above) and that they are sensitive to recognising participants' expressions of desire to opt out of a study. It is generally expected that information sheets and consent forms would state that participants have the right to withdraw from a study at any stage. However, researchers have noted that it is common, particularly for some groups, to be

[6] See: www.esds.ac.uk

reluctant to state they don't want to continue being involved with a project (Alderson, 2004). So, for example, children might find it difficult to tell an adult that they no longer want to participate in a study or that they don't want to answer a particular question. The same issue can apply to people in a range of contexts because of the power relations that can exist between the researcher and the researched or simply a lack of awareness that they can say no to something they have previously agreed to. It is noted that researchers need to be vigilant to participants' unspoken expressions of a reluctance to continue to participate during data collection, such as an apparent lack of interest or irritation with the data collection (Langston et al, 2004; Rodgers, 1999). In research with children and people with limited communication, some researchers have used 'stop' cards that participants can hold up if they don't want to answer a particular question or no longer want to participate (Wiles et al, 2004). If this type of method is to be used it is important that participants practice using it before the data collection proper commences.

4.9. Consenting 'vulnerable' people: the role of gatekeepers

The ability of people, particularly children, young people and people with mental health or learning disabilities, to give informed consent is a widely debated issue and has been discussed above in the section on the legal context of consent and in the section on the provision of information. It has been noted that, where researchers have the freedom to provide information to potential 'vulnerable' study participants (primarily children and 'incapacitated' children or adults), they need to work closely with them in order to provide information in ways that they can understand. However, researchers frequently are not able to approach potential participants directly but have to negotiate access through a range of gatekeepers. In various areas of research where people are accessed through organisational settings, such as schools, the NHS and social care settings, access has to be negotiated through individuals or groups who manage these institutions and agreements that are reached through this process of negotiation determine the way that potential research participants will be approached and invited to participate (see Masson, 2004; Morrow, 1999; Stalker, 1998). There are various levels of gatekeepers in these contexts. They include professionals who run organisations through which people are accessed as well as service providers, care-givers, parents, relatives or guardians. These gatekeepers have no legal rights in respect of the person's decision to participate in research but generally control the places where people are accessed from and they may, in addition, have legal responsibility for an individual's well being in that setting (Masson, 2004). This means that they have the power to refuse permission for a researcher to recruit participants in a specific setting. Additionally, where approval is given, they have the power to determine the ways in which potential participants are informed about a study and the process of consent, which may influence potential participants' willingness to participate

Two specific problems have been identified in relation to gatekeepers and the consent of study participants. The first concerns an over-protectiveness of gatekeepers which may result in people being denied the opportunity to participate in research (Heath et al, 2005). The second concerns a failure of gatekeepers to provide opportunities for potential participants to exercise choice in participating in research (Miller and Bell, 2002). In relation to the first of these issues, some gatekeepers may deny access to researchers for a range of reasons, one of which may be an assumed lack of competency on the part of the potential research participant. Even where access is agreed the gatekeeper may seek consent from relatives alongside the consent of the individual concerned (especially in the case of children). This often means that even if the person wants to participate their wishes may be overridden by refusal from a relative (Heath et al, 2005). The issue of seeking parental consent in relation to research focusing on sensitive issues such as drug use and sexual behaviour is particularly problematic (Allen, 2002; Valentine et al, 2001). In most cases researchers are not in a position to influence an organisation's decision to deny access or to seek additional consent from relatives.

The second problem, that of a failure to allow potential study participants to exercise choice, often occurs in institutional settings, particularly, but not exclusively, in schools (Heath et al, 2005). In the school context, young people may be told they are participating by teaching staff and the research activity may become, or be perceived as part of overall class work (see David et al, 2001; Morrow, 1999) or researchers may not be given sufficient time to fully explain the study and give children the opportunity to decide whether or not they want to participate. It has been noted that in a range of institutional settings refusal to participate in any case can be a difficult thing to do (Miller and Bell, 2002). A variety of ways to manage the issue of 'assumed' consent have been identified in ways that do not reveal to gatekeepers that individuals are not actually participating in the research. These include respecting the rights of participants to remain silent in discussion groups, allowing participants to discuss what they want to in interviews and allowing them to not complete questionnaires (France, 2004; Edwards and Alldred, 1999).

5. Conclusion

Gaining informed consent from potential study participants is far from being a straightforward process. Researchers need to consider a broad range of issues in providing information to study participants and in obtaining consent. These include the format, style and timing of information provision and the form of consent that is appropriate. Consideration also needs to be given to the

level of consent and whether this should comprise something more than consent to data collection only. The context in which the research takes place and researchers' ethical orientation inevitably influences the approach researchers have to these issues. However, decisions about informed consent are increasingly driven by the legal, ethical and regulatory frameworks in which social research takes place. The rapid changes taking place in the ethical regulation of social research, which are occurring in response to a range of institutional, legal, political and moral influences, mean that this issue is likely to be subject to further change in the coming months and years.

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