Informed Consent and the Research Process: Following Rules or Striking Balances?

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Abstract

Gaining informed consent from people being researched is central to ethical research practice. There are, however, several factors that make the issue of informed consent problematic, especially in research involving members of groups that are commonly characterised as 'vulnerable' such as children and people with learning disabilities. This paper reports on a project funded by the UK Economic and Social Research Council (ESRC) which was concerned to identify and disseminate best practice in relation to informed consent in research with six such groups. The context for the study is the increased attention that is being paid to the issue of informed consent in research, not least because of the broad changes taking place in research governance and regulation in the UK. The project involved the analysis of researchers' views and experiences of informed consent. The paper focuses on two particular difficulties inherent in the processes of gaining and maintaining informed consent. The first of these is that there is no consensus amongst researchers concerning what comprises 'informed consent'. The second is that there is no consensus about whether the same sets of principles and procedures are equally applicable to research among different groups and to research conducted within different methodological frameworks. In exploring both these difficulties we draw on our findings to highlight the nature of these issues and some of our participants' responses to them. These issues have relevance to wider debates about the role of guidelines and regulation for ethical practice. We found that study participants were generally less in favour of guidelines that regulate the way research is conducted and more in favour of guidelines that help researchers to strike balances between the conflicting pressures that inevitably occur in research.

Keywords: Informed Consent; Research Ethics; Regulation of Research; Research Governance; Professional Guidelines

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Introduction

1.1 Gaining informed consent from people involved in research is generally regarded as central to ethical research practice in the social sciences. The Social Research Association defines informed consent as: '… A procedure for ensuring that research participants understand what is being done to them, the limits to their participation and awareness of any potential risks they incur' (Social Research Association, 2003:28). This definition is similar to other definitions published by professional associations in the social sciences. The British Sociological Association ethical guidelines, for example, talk of 'a responsibility on the sociologist to explain as fully as possible, and in terms meaningful to participants, what the research is about, who is undertaking and financing it, why it is being undertaken and how it is to be disseminated' (BSA, 2002). Traditionally, as Smyth and Williamson (2004) note, these guidelines have operated primarily on a system of self regulation; membership of these organisations is voluntary and their guidelines are not enforceable. In addition, the guidelines are intentionally vague and leave researchers able to interpret them in ways that fit the needs of the specific research they are undertaking. This point is noted in the BSA statement of ethical practice:

> '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).

1.2 However, the context of social research has been subject to considerable change in the recent period. An increasing concern with issues of research ethics in social research in the UK has been precipitated by concerns with the ethics of bio-medical research following public outcry at medical research scandals where dead children's organs were used for research purposes without parental consent. These events, and a general sense of public concern, prompted the UK Department of Health to develop the Research Governance Framework (RGF) which brings together various guidelines and statutes to provide an ethical context for research in health and social care. The ripples from the RGF have impacted on other areas of research resulting in pressure from research funders for all areas of research, including social research, to be subject to ethical review. Institutional ethics committees have increased in number in recent years (Tinker and Coomber, 2004). Following publication of the ESRCs Research Ethics Framework (ESRC, 2005, see http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf), which from January 2006 make it a condition of funding that all research involving 'human participants' has been subject to ethical review, universities have had to ensure they have ethical committees in place. Ethical review is also a requirement of other funding bodies, such as the Nuffield Foundation. Ethical regulation from research ethics committees may mean that researchers will have less freedom to make decisions about the ways in which informed consent processes are managed and some researchers fear this is likely to mean that more formal procedures of consent will be adopted (e.g., Coomber, 2002). It is, as yet, unclear what the impact of these developments will be on the process of social research.

1.3 Researchers are also subject to legal frameworks and regulation that influence how 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 relation to research with children, the law is complex and relates to the notion of 'competence' (Masson, 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. Consent from parents, guardians or other representatives is generally necessary in relation to research with children and adults who lack the capacity to give consent for themselves. Other legal frameworks such as Article 8 of The Human Rights Act 1998 and the Data Protection Act 1998 have relevance to consent in relation to all research. Researchers working in the area of health generally need to gain ethical approval from NHS Research Ethics Committees.

1.4 While at first glance informed consent may appear 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 (Alderson and Goodey, 1998). Social researchers have to balance a number of factors in managing issues of informed consent. Obviously they have to comply with any legal frameworks and regulation as 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'.

1.5 The study described here explored how researchers manage issues of informed consent. The study was funded as part of the ESRC Research Methods Programme. The focus of the study was to explore researchers' views and experiences of managing informed consent with the aim of developing resources for use by the social science community and encouraging debate on the topic (see http://www.sociologyandsocialpolicy.soton.ac.uk/Proj/Informed_Consent/Resources.htm). The context for the study is the increased attention being paid to the issue of informed consent in research, not least because of the broad changes that are taking place in research governance and regulation in the UK, and the increasingly legally-oriented frameworks within which academic and social research organisations have to work (Truman, 2003; Tinker and Coomber, 2004; ESRC, 2005)

Methods

2.1 The project involved collecting data primarily through telephone interviews and focus groups with academic and non-academic researchers and focused specifically, but not exclusively, on researchers who conduct qualitative research on or with children, young people, older people, people receiving palliative care, people with learning disabilities and people with mental health problems. The focus on these particular areas of research was chosen because of the assumed vulnerability of members of these groups within the research process which would enable the issue of informed consent to be exposed with particular clarity.

2.2 The decision to undertake telephone rather than face-to-face interviews was undertaken for primarily practical reasons; academics are busy people and we felt it more likely that they would agree to participate in a telephone interview that could be arranged (and rearranged) at short notice. Furthermore, the wide geographical spread of participants meant that telephone interviews were both more practical and cost

effective. While telephone interviews present some challenges to data collection, such as the absence of body language and cues, we did not find them a barrier to the collection of good quality data. Focus groups were conducted to provide us with a different type of data; that which emerges as a result of interaction and discussion between a group of researchers focusing on a specific topic. These were designed to enable us to identify issues within specific topic areas and across levels of experience.

2.3 In inviting people to participate in this study we adopted fairly formal consent procedures involving information sheets and consent forms sent by email to be signed and returned if people were willing to participate. Our decision to adopt these formal procedures was made partly because several of our participants were working in health related areas where such processes are the norm. Additionally, we felt that conducting research on this topic demanded that we pay careful attention to our own consent procedures and that we made considered plans to ensure we did not exploit our participants; such considerations are heightened when one is researching one's own peer group (see Wiles et al 2006 for a detailed discussion of these issues).

2.4 Individual interviews were conducted (29 by telephone and two face-to-face) with experienced researchers with reputations for work in specific areas (n=24) or in research ethics more broadly (n=7). The two face-to-face interviews were conducted at the specific request of two of the researchers who lived locally. The individual 'experts' were identified through our own knowledge of the area, recommendations from other academics approached to participate, the literature and web searches. A semi structured interview guide was developed for the study which was designed to explore researchers' general views and experiences relating to informed consent, their views on good and bad practice, regulation and the impact of consent processes on methods. The interviews lasted for an average of 40 minutes (range 30-75 minutes).

2.5 The six focus groups were conducted in six academic institutions which had recognised expertise in each of the topic areas. These groups comprised experienced researchers, academics and PhD students working in these broad areas. A total of 35 people participated in these groups, this comprised two groups of seven participants; one group of six participants; and three groups of five participants. The focus groups were facilitated by the Research Fellow and observed by another member of the research team. The groups discussed the same topics to those explored in the interviews although in a less structured way. The observer recorded the order of speech to aid the transcription of these data and also observed the group dynamics and interaction of the group. These were used to inform the analysis of these data.

2.6 To supplement our data, the project website invited interested researchers to email us their views on these issues. In addition, we emailed 33 researchers inviting them to respond by email to these specific issues. The researchers contacted comprised those that we were unable to include in interviews or focus groups but would ideally have wanted to. We had responses from ten of these individuals and a further two unsolicited responses.

2.7 All interviews and focus groups were audio recorded and fully transcribed. Interview and focus group data were analysed separately. A thematic analysis was conducted on each data set using QSR Nvivo for the coding of themes. Data from email responses were used to supplement these data in relation to the specific themes identified.

2.8 It should be noted that the data collected for this study provided us with researchers' opinions about informed consent and their accounts of how they managed the issues that it presents in the context of their own research. A more comprehensive view of consent should also include participants' views but this was beyond the remit of this study. Other research has however considered this issue (see Smyth and Williamson, 2004).

2.9 We cannot consider here all of the issues raised by this study, but seek to concentrate our attention on two particular difficulties inherent in the processes of gaining and maintaining informed consent. The first of these is that there is no consensus amongst researchers concerning how to know when enough has been done to achieve informed consent, and when the point of doing too much has been reached. The second difficulty is that there is no consensus about whether the same sets of principles and procedures are equally applicable to research among different groups and to research conducted within different methodological frameworks. In exploring both these difficulties we will draw on our findings to highlight the nature of these difficulties and some of our participants' responses to them. These issues have relevance to wider debates about the role of guidelines and regulation for ethical practice in research, and we conclude with some comments on this.

Gaining informed consent

Informed consent: how much information to give

3.1 The provision of information about a project is an important part of ensuring that prospective participants in research are informed enough to know what participation in a research project will entail while, at the same time, avoiding providing information in such a way that it would put people off participating. However, researchers cannot always be confident that the information that has been provided is sufficient for this purpose. One problem is that people may quite understandably wish to know more than it is possible for researchers to provide, because the outcomes of research are not entirely predictable at the outset of a study. The experience of being involved in research was therefore seen as difficult to convey:

> 'As researchers…. do we always know what's going to happen with that piece of research?… it's quite difficult to explain to people that, "well I don't know quite where this is going to end up or whether it will have a purposeful end or not"' (Focus Group 2).

> 'I'm not sure that it is possible to outline exactly what it's going to be like for somebody before they've entered into the experience, especially if they've not been a participant in research previously' (Interviewee 11).

3.2 Even leaving aside how best to deal with unknowables such as the outcomes of research, there may still be a sense of having too much information to convey. Researchers in specific contexts, such as researchers conducting research with children, older people or people with health problems, spoke of managing this by attempting to ensure that they do not overwhelm their potential participants with information. Limitation of the information given to prospective participants was sometimes justified in terms of the need to avoid pointing out the obvious. One interviewee, for example, felt that it was patronising to warn study participants that discussing certain topics such as bereavement may be distressing. However, in health care settings the ability of researchers to minimise the amount of information they gave to study participants was limited due to the requirements of ethics committees. One researcher working in palliative care commented:

> 'I was required to provide a lot of information, which actually in practice, for some people, proved too much for them to read, but was required by the Ethics Committee to be given out because of questions of data protection' (Focus Group 1).

3.3 However, in contexts where it was possible to minimise the amount of information given, some researchers noted the need for caution in this regard. Study participants are often very keen to take part in research because of an interest in the topic, because they do not want to appear unco-operative by saying 'no' or because they are unaware of any risks that participation might involve. In these cases, study participants often disregard researchers' explanations of what the research will involve or are reluctant to take the time needed to read information sheets properly.

3.4 In the context of research with children and young people, two study participants noted:

> 'one of the problems was that…. people would cut us off and say "yes I'm happy to participate" before we had chance to finish [reading out the introductory information]…. people often love to participate in research, specifically I think when they are being asked about their drug use, drug users can often be very keen to talk about their drug use' (Interviewee 5).

> 'we do what we can just to hold back young people's enthusiasm for taking part because on the whole most young people are very keen to take part and to be listened to…. we as researchers can be sort of overwhelmed by young people's enthusiasm and just think "yeah they understand, fine let's get on"…. "that's informed consent" and I, you know, I don't think it is…. they just think "oh great, this sounds fun"' (Interviewee 6).

3.5 A researcher working in a palliative care setting similarly noted:

> 'They were very, very keen and they said "Oh we trust you, it's fine, you don't need to explain all that" (Focus Group 1).

3.6 One clear difference of view relates to how much of themselves researchers reveal in the information they provide. Researchers working in participatory frameworks in which participants were viewed as partners in the research process were keen to avoid participants feeling that they were being used to promote researchers' self-interest. One of the ways they addressed this was providing information about themselves to research participants and maintaining contact with participants up to the publication of results, and sometimes beyond. Others were more circumspect about their relationships with participants and what they revealed about themselves fearing that this might adversely affect the project's response rate. So, for example, one researcher noted:

> ‘when I did my PhD it was, it took, supposedly a feminist piece of research but I didn’t tell the other women that my theoretical underpinning to my research was feminist…. I’m sure it would have influenced some of them about whether they spoke with me, if they thought I was a feminist’ (Focus Group 2).

3.7 Several researchers noted that however extensive the information provided about a study is, there is still scope for misunderstanding. Researchers commonly reported that participants misunderstood the research even though they had gone to considerable lengths to explain it. Thus, one recalled that

> ‘despite having a written information sheet that explained the study really carefully to people…. it was clear they thought I was a social worker or some sort of an appliance officer…. however much time and attention that you explain what research is, people interpret what you do in a number of different ways. And some people see it as a form of therapy, even if you don’t intend that to be the case’ (Focus Group 1).

3.8 Much depends, clearly, not only on what information is conveyed but also on how this is done.

Information: how to give it

3.9 Bearing in mind the potential for information to be misunderstood, several participants emphasised the importance of information being presented in a user-friendly way. The importance of making information sheets friendly and attractive was noted. This involved 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 was also noted, although various forms of ethical regulation were seen as constraining researchers’ ability to do this, especially in health care settings. ‘Official’ information sheets that labour the point about confidentiality or the possible distress that might arise from participating are viewed as likely to make potential 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. As one researcher commented:

> ‘about 90% of people came back and said “oh I’ve spoken to my daughter and she said I mustn’t touch this because this is far too formal”…. they felt it was very threatening, the way it was written’ (Focus Group 1).

3.10 For researchers working with so called ‘vulnerable’ groups, innovative ways often 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, demonstrated the importance of keeping written information to a minimum and incorporating pictures and other graphics into the information they provide. Researchers have also experimented with a range of ways of providing information to meet these needs including the use of photos, video and computers. Typical comments were:

> ‘It’s very simple information in a sort of accessible style and format with pictures from the picture bank’ (Interviewee 8).

> ‘Normally up to about a side of A4…. a side of A4 which just tells young people what’s going on. Often we do them quite graphically as well so that it doesn’t just look like a huge side of text’ (Interviewee 6).

3.11 The important message emerging from participants was 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 enables 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, are confident that it is possible to provide information in appropriate ways that enable potential study participants, whatever their level of ‘competence’, to understand what participation will involve. As one researcher commented:

> ‘there are huge issues around children with disabilities … for instance children with learning disabilities … there is an awful lot of assumptions that those children can’t have good informed consent because they can’t think it through well enough … we would dispute that’ (Interviewee 3).

Researchers in this area went on to elaborate on a variety of instances that confirmed the possibility of gaining consent even in apparently difficult circumstances.

Information: when and how often to give it

3.12 Good practice is seen by many of the researchers to whom we spoke as building in a time gap between when the information about the project is conveyed and when consent is gained or confirmed to allow potential participants time to think through whether or not they want to participate. A researcher reported how she herself had been made to feel manipulated by being pressurised to take part in an interview, but was conscious of how allowing a period of time to pass between information provision and consent and again before data collection increases the opportunity for respondents to decline to take part.

3.13 The significance of informed consent as a process has been highlighted in the literature (Goodenough et al, 2004; Cameron et al, 2004; Cutliffe and Ramcharan, 2002; Miller and Bell, 2002;Lawton, 2001; Reid et al, 2001; Smythe and Murray, 2000) and our informants echoed this. A central difficulty 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 outset. 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 cannot know to what they are consenting.

3.14 These difficulties have led researchers to argue for information provision (and consent) to be given and sought 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. This 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. As our research participants noted:

> ‘there does come a point at which people forget that’s what you’re doing [research] and then that’s another issue for informed consent…. you can…. go into the “Do you remember I’m a researcher?” [mode, but]…. that changes it…. You’re working, I think, in grey territory at that point’ (Focus Group 1).

> ‘I sometimes felt that they, they kind of forgot that this was, you know, this was research and I, I made a point of saying “is it ok for me to speak to you to-day?”…. and people were getting irritated with “well yes, you asked me that before” ’ (Focus Group 2).

Informed consent: how to gain it

3.15 Views about the importance of gaining a signature as evidence of consent were 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 perceived advantages of using signed consent forms are 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. Typical comments on this point were:

> ‘I don’t think you should have somebody as a research subject who hasn’t got, where there is no document that shows that they are consenting to participate in the research’ (Interviewee 9).

> ‘And that consent form is witnessed as well … it doesn’t have to be a signature, it can be a mark on the consent form. But we do, we prefer to get something even if it’s, you know, a scribble on the page’ (Interviewee 8).

3.16 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. 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 issue for research with people with learning disability and here researchers have developed a range of ways of obtaining consent without the use of signatures, such as the use of tape recorded consent or holding up green or red cards to indicate yes or no.

> ‘A lot of people I’m spending time with can’t write their names so actually, you know, any

signature for me is kind of meaningless … we've had to look at more creative ways of getting people to consent' (Focus Group 2).

3.17 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 could 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). One researcher commented:

'it's usually verbal consent that we get rather than written consent…. very rarely do I try and go for written consent…. When you're researching sort of very excluded groups…. it's very threatening to ask someone to sign a form. Like the young refugee project…. it would just be incredibly threatening and it would be counter-productive' (Interviewee 4).

3.18 Some researchers (and research organisations) offer financial or material 'rewards' to study participants who take part in their studies (e.g., Wright et al, 2004; Tarleton et al, 2004). These might be seen as incentives or inducements and to comprise a form of coercion that impacts on the voluntary nature of research participation. 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:

'I just think it's good practice to recompense people for their time' (Interviewee 9).

'I do think that payments should never be used as an inducement to take part in research…. [if a small token is given] good practice should dictate that it is given at the end as a complete surprise to them, the person taking part in the research' (Interviewee 8).

3.19 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). 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). Researchers researching drug taking in clubs provided participants in their study with what was in effect a chill-out area:

'And they really liked it. We often found that…. we were often asked for cigarettes as well…. it seemed fair [to have cigarettes to give to them] although, looking back on it, providing people with, you know, cancer causing agents isn't probably the best thing to do' (Interviewee 5).

3.20 Thus, while applying ethical procedures for obtaining consent from participants to participate in research were viewed as important, participants did note that this could at times be in conflict with the pressure to recruit people to their study:

'there's masses of stuff out there where people are thinking, you know, "if we don't get this kind of seventy-five by whenever then my contract is up the chute"…. And then you go and cry in the toilet because you're not going to get it' (Focus Group 1).

3.21 Additionally, examples were given of where the consent procedures that researchers wanted to be adopted were circumvented in various ways by others. A researcher whose fieldwork included school settings noted that some organisations give out questionnaires to pupils without going through the process of consent. Understandably unhappy with this, she developed ways of moderating the impact of pupils being dragooned in this way:

'we have had that quite often where a group of pupils have turned up in a room and, and have absolutely no idea, they haven't been given the information sheets that, that we asked to be given out and haven't been told what they're there for…. I think they have a right at that stage just to go "well I didn't realise that's what it was" and they can head off, although actually that's quite tricky in a school because we've also often been told to keep the group together, you know, can't have pupils wandering around the school…. a researcher has to manage that and what we've done sometimes is just literally sort of divided a group up in class, in a

classroom or the room that we're in and those who don't want to take part are over there and those who do are here and we take some wordsearch things for them to do, you know, that they can do so that they're not wandering around the school…. it doesn't always work but we try as hard as we can to do it' (Interviewee 6).

3.22 Part of informed consent concerns giving people the right to withdraw from 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 reluctant to state they do not want to continue being involved with a project. 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 do not 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. Researchers noted that they needed to be vigilant to participants' unspoken expressions of reluctance to continue to participate during data collection, such as an apparent lack of interest or irritation with the data collection. In research with children and people with limited communication, researchers have used 'stop' cards that participants can hold up if they do not want to answer a particular question or no longer want to participate, as the following quotes illustrate:

> 'with one child…. her level of understanding was quite high although she was non-verbal, we had a stop sign and we practised at the beginning and we made it really fun so I was going "ok, go on, tell me to stop, tell me to stop" and she put it up and she loved it and she just thought it was really funny. And at one point in the interview she did do it and she just said she wanted something to drink and she was just tired and, but then she let me know when she wanted to start again' (Interviewee 4).

> 'I felt quite delighted when the first person said to me "I don't want to do this, I'm going now". The next day he came and found me and said "I do want to be interviewed today" so…. he'd understood the information and he was using it as he wanted to which was good' (Focus Group 2).

> 'it's not just what people say, it's how they are, whether they're agitated, whether they were kind of not wanting to sit down, wanting to go out, so there's all those sort of levels of consent and assent' (Focus Group 2).

Do some people or some research areas warrant different treatment?

Potential vulnerability: Do some groups of people need special treatment?

4.1 People in receipt of services are a good example of a group that may be particularly vulnerable to experiencing as coercive requests to take part in research. Researchers working in areas of health and social care commented that patients might imagine that they may not receive the best treatment if they refused to participate. The same point was made in relation to people within the penal system:

> 'I was kind of troubled on occasion about their motives for consent…. one left after two minutes, he said "I don't want to do this any more but I was told it would affect my parole". Now, you know, I'd been very clear in all the literature I'd sent out that [it would not] but clearly it's, you know, whoever was in charge of him had, had said that and that was disappointing' (Focus Group 2).

4.2 This issue links closely with the role of gatekeepers. In research with children, young people and people in a range of institutional settings, the issue of negotiating access through gatekeepers is one that has been widely discussed (Morrow and Richards, 1996). Gatekeepers determine the way that potential research participants are approached and invited to participate. It is abundantly clear that service providers in educational, medical and penal establishments do not always convey information about informed consent as researchers would like it to be conveyed. This influence can work both ways, sometimes providing academics with 'research fodder', and sometimes denying access to prospective research participants who show indications of preparedness to participate but are denied the opportunity by paternalistic gatekeepers:

> 'the whole philosophy behind informed consent is that people make rational choices and they make them on their own…. I've had that experience two or three times where actually a respondent has indicated that they might like to take part and then they've been overruled either by a care-worker or by a spouse' (Focus Group 1).

> ‘working through social workers, there’s many reasons why it can be hard to get the children sometimes…. they can be very paternalistic and very protective of the children…. much more so than the child would want them to be’ (Interviewee 3).

> ‘we’re insisting that people with dementia have got a right to decide for themselves whether they take part or not but in a couple of cases where they have agreed to be interviewed then relatives have stepped in and prevented access’ (Focus Group 2).

4.3 How such problems arise can be readily appreciated in the contexts of particular groups. The difficulties of ensuring informed consent from people with mental health problems or learning disability are considerable and these difficulties increase when researching people who are critically ill:

> ‘some people are more or less capable than other people but still it’s, it’s at least a minefield…. how does one determine the capacity of somebody who consents?’ (Focus Group 2).

> ‘people with dementia, can you be sure that they really understand what you are doing? … and there’s the issue of continued consent, because obviously they might forget later’ (Focus Group 2).

> ‘When I was working in intensive care…. clearly I couldn’t get consent from the patient because they were unconscious…. I got a surrogate consent, or proxy consent’ (Focus Group 1).

4.4 Nevertheless, most researchers held the view (as noted above) that it was important to identify ways for participants, whatever their level of capacity, to have the opportunity to take part in research and, ideally, to be able to provide that consent themselves. This view has been widely expressed by childhood researchers who note that research with children does not necessarily raise unique methodological and ethical obstacles (Christiansen and Prout, 2002; David et al, 2001). Casarett and Karlawish (2000) have made a similar argument in relation to palliative care research. The following quotes illustrate these issues:

> ‘doing research with children is not in theory different than doing it with adults because it’s all about respect whoever it is…. there’s no point in talking to adults in language they don’t understand either’ (Interviewee 3).

> ‘I can’t see how we can do research into young people’s rights…. and then say, you know, if they’re seventeen they can choose to participate, if they’re sixteen they can’t’ (Interviewee 6).

Do some research areas need different treatment?

4.5 Running alongside debates about whether some categories of people need special treatment in relation to consenting to involvement in research, are debates about whether some research areas need to be approached differently. Where possible, researchers make judgements about appropriate consent procedures according to the specific contexts in which they work, the groups they research, their disciplinary background and their research approaches. In some areas and types of research (e.g., some youth or criminology research) it is preferred that oral information and consent only is provided and sought (Coomber, 2002). 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 and signing consent forms (for example research with young people taking place in a club setting). A similar case may be made by those working in participatory paradigms for whom formal consent procedures may be viewed as inappropriate. 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 a hospital ward or 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 be made aware of this. Some researchers have also argued that it is not always appropriate to provide information (and seek consent) for participation because once people know they are being observed their behaviour changes. As one researcher noted:

> ‘in certain methodologies…. requiring written informed consent seriously damages the method that you’re going to pursue…. Any recording or observation that requires spontaneously occurring behaviours or speech, and I’m thinking particularly things like conversation analysis and ethnography…. both of those are highly problematic.’ (Focus

Group 1).

4.6 Some researchers take a more radical stance and argue that withholding information and consent from participants in some research contexts is appropriate because only in this way can some areas of social life, institutions or organisations 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. Proponents of covert methods have argued that it is not necessarily harmful to participants and that so-called 'open' research in practice often uses procedures based on various levels of deceit (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. Further, it is argued 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, 1986; 1998; Homan and 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. Participants in our study were almost universally critical of covert methods, for example:

> 'maybe some research just can't be done…. If you can't get informed consent then there's maybe a good case for saying it can't be done…. I can't think of a piece of covert research I'd be happy to [do]' (Focus Group 2).

Conclusion: Guidance or regulation?

5.1 The focus in this study was primarily on researchers working with groups that are commonly characterised as 'vulnerable' because, as we noted above, it is in these contexts that issues of informed consent are exposed with particular clarity. However, we view the issues identified as having relevance to social research more broadly. The increasing regulation of research ethics, and consequently informed consent, will impact on all researchers. The ways in which this is played out in particular research projects is dependent on the context of each study but nevertheless issues of how and when to provide information and the ways in which consent can be most appropriately obtained are common features of all research. These are issues that all researchers need to engage with reflexively in reaching decisions about how to conduct their research.

5.2 These various issues have relevance to wider debates about the role of guidelines for, and regulation of, ethical practice in research. Many social researchers have argued that adhering to standardised ethical rules is not appropriate in social research, partly because the ethical dilemmas that arise in social research are context-specific (Punch, 1998; Small, 2001; Goodwin et al, 2003). There is a preference to work to the more vague professional guidelines which leave researchers able to interpret them in ways that fit the needs of the specific research they are undertaking. This allows social researchers to adopt a 'situational relativist' approach in which ethical decisions are made on the basis of issues applicable to individual research projects (Small, 2001; Goodwin et al, 2003).

5.3 Their long association with procedures requiring the approval of medical research ethics committees means that social scientists working in the area of health and illness are particularly familiar with research governance as it relates to formalised procedures of gaining informed consent. Participants working in other areas are aware of the restrictions that NHS research ethics committees impose and many fear the consequences of such procedures being adopted in university-based ethics committees. It is feared that greater regulation may impose methods of gaining consent that are in conflict with researchers' area- or disciplinary-specific research orientations. Particular tensions exist for those researchers using participatory or ethnographic approaches.

5.4 For some researchers this sense of increasing regulation raised concerns about the remit of ethics committees. Some researchers were concerned that standardised procedures would make some issues unresearchable. Other researchers drawing on the difficulties that they had experienced in having their qualitative studies reviewed by NHS Research Ethics Committees noted that ethics committees for social research would need to have members with broad ranging methodological skills.

5.5 These comments suggest that the area is likely to see significant further developments as debates about the balance between consistency and flexibility in guidelines and regulation are worked through. Researchers held the view that however far research governance extends, regulation cannot fully determine what happens in the research process because the issues that emerge are invariably more complex than can be addressed in guidelines or regulation. Flexibility was viewed as important but it was seen as important to distinguish this from an 'anything goes' philosophy. The dilemma of what guidelines and regulation should comprise was summed up by the focus group member who said:

> ‘often the problem with guidelines is in their interpretation, if they’re too flexible then they become valueless, if they’re too rigid they can interfere badly’ (Focus Group 2).

5.6 Thus, our study participants were generally less in favour of guidelines that regulate the way research is conducted and more in favour of guidelines that help researchers to strike balances between the conflicting pressures that inevitably occur in research.

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