

## Beyond “misunderstanding”: Written information and decisions about taking part in a genetic epidemiology study

Mary Dixon-Woods<sup>a,\*</sup>, Richard E. Ashcroft<sup>b</sup>, Clare J. Jackson<sup>a</sup>, Martin D. Tobin<sup>a</sup>, Joelle Kivits<sup>a</sup>, Paul R. Burton<sup>a</sup>, Nilesh J. Samani<sup>a</sup>

<sup>a</sup>University of Leicester, Leicester, UK

<sup>b</sup>Queen Mary, University of London, UK

Available online 29 September 2007

### Abstract

Although the need to obtain “informed” consent is institutionalised as a principle of ethical practice in research, there is persistent evidence that the meanings people attribute to research tend to be substantially at variance with what might be deemed “correct”. One dominant account in the ethics literature has been to treat apparent “misunderstandings” as a technical problem, to be fixed through improving the written information given to research candidates. We aimed to explore theoretically and empirically the role of written information in “informing” participants in research. We conducted a qualitative study involving semi-structured interviews with 29 unpaid healthy volunteers who took part in a genetic epidemiology study in Leicestershire, UK. Data analysis was based on the constant comparative method. We found that people may make sense of information about research, including the content of written information, in complex and unexpected ways. Many participants were unable to identify precisely the aim of the study in which they had participated, saw their participation as deriving from a moral imperative, and had understandings of issues such as feedback of DNA results that were inconsistent with what had been explained in the written information about the study. They had high levels of confidence in the organisations conducting the research, and consequently had few concerns about their participation. These findings, which suggest that some “misunderstanding” may be a persistent and incorrigible feature of people’s participation in research, raise questions about the principle of informed consent and about the role of written information. These questions need to be addressed through engagement and dialogue between the research, research participants, social science, and ethics communities.

© 2007 Elsevier Ltd. All rights reserved.

**Keywords:** UK; Genetic epidemiology; Research participation; Qualitative study; Bioethics; Written information

### Introduction

The apparently unassailable status of informed consent as an ethical principle in medical research can be traced to series of shocks and crises (McNeill & Pfeffer, 2001). These have caused research to occupy a distinctive moral space in which the expert system (Giddens, 1990) of medical research is

\*Corresponding author. Tel.: +44 116 2297262.

*E-mail addresses:* [md11@le.ac.uk](mailto:md11@le.ac.uk) (M. Dixon-Woods), [r.ashcroft@qmul.ac.uk](mailto:r.ashcroft@qmul.ac.uk) (R.E. Ashcroft), [cjj4@le.ac.uk](mailto:cjj4@le.ac.uk) (C.J. Jackson), [mt47@le.ac.uk](mailto:mt47@le.ac.uk) (M.D. Tobin), [joelle\\_kivits@hotmail.com](mailto:joelle_kivits@hotmail.com) (J. Kivits), [pb51@le.ac.uk](mailto:pb51@le.ac.uk) (P.R. Burton), [njs@le.ac.uk](mailto:njs@le.ac.uk) (N.J. Samani).

treated as less trustworthy than that of medicine (Chalmers & Lindley, 2001). Informed consent, by operationalising people's autonomy and ability to make choices about participation, is seen as the last defence against the risks of research, including those associated with the motives and practices of researchers (Ashcroft, 2001). A requirement that written information be provided is now a near universal feature of research ethics committee approval of procedures for obtaining consent.

Expert systems such as research are existentially troubling because ordinary individuals lack the specialist knowledge necessary to make appropriate judgements about them (Misztal, 1996). A major element of the regulation of medical research has therefore focused on controlling what is disclosed to research candidates. Participant information leaflets (PILs) play an important role here in producing consent as an "auditable moment" with its own documentation and visibility to judicial scrutiny (Ashcroft, 2003), and thus in the management of risks to researchers themselves. Perhaps no element of the submission is as carefully scrutinised as the PIL (Kent, 1997). Nonetheless, a body of work has persistently demonstrated that research participants frequently lack full comprehension, and that their ideas about basic elements of research procedure such as randomisation may be substantially at variance with what would be regarded as "correct" (Appelbaum, Roth, Lidz, Benson, & Windsdale, 1987; Snowdon, Garcia, & Elbourne, 1997).

Much interest to date has focused on responses to information provision in situations where ill people are asked to take part in studies involving some kind of experimental design, especially clinical trials. However, the issues that attend the involvement of healthy volunteers outside of experimental studies have been much neglected (Morris & Balmer, 2006). In this paper, we explore, empirically and theoretically, the role of written information in recruiting healthy unpaid volunteers to research. Our empirical exploration uses accounts from participants in the Genetic Regulation of Arterial Pressure of Humans in the Community (GRAPHIC) study, a genetic epidemiology study. GRAPHIC provides an ideal opportunity to explore the issue of informed consent in a situation where participants were "healthy" volunteers who were not making decisions immediately relevant to their own therapy, and were recruited outside of a clinical setting. If we consider decision-making by healthy volunteers under near-ideal conditions to be nor-

mative for models of informed consent to participation in research, an empirically informed understanding of consent in this context offers important empirical and theoretical insights into strengths and limitations of the available theories and practices of information, understanding and consent. Our example thus has relevance not only to medical research, but to other studies—including social science research—conducted in health settings.

### **"Informed" consent**

A standard account of "informed consent" in bioethics characterises it as meaning that research participants fully understand the nature of scientific rationale and procedure; have insight into a set of risks of various types that might be identified on their behalf by ethicists or regulators; and have motives for participation that are not "false" (National Commission, 1979). Potential research participants are thus produced both as bearers of rights but also bearers of responsibilities: they have entitlements to disclosure, but obligations to assess the information they are given carefully, to understand, to make rational decisions, and to avoid false hopes or expectations. For example, candidates for clinical trials must not believe that research involves individualised treatments selected for the benefit of participants, as to do so would be to engage in the "therapeutic misconception" (Appelbaum et al., 1987), and thus threaten the validity of their consent. On this view, people may participate in research only on grounds that are deemed ethically licensed: it is seen as imperative that potential research participants comprehend but also accept the "scientific" account of research.

As part of our theoretical exploration of this model of informed consent, we begin by outlining a currently dominant approach to explaining the problem of "misunderstanding." We then trace a distinctively sociological tradition of studying lay theories about health and illness, and speculate on what this might offer as an alternative theorisation of what it means to be "informed".

### **The "patient education" model**

Two possible explanations for why misunderstandings occur are prominent in the ethical literature. One is that the information given to potential participants is too incomplete, misleading,

or badly written to allow proper understanding; the second is that potential participants fail or refuse to produce the appropriate response to the information (Moreno, 2003). These explanations are well illustrated in the following excerpt:

if informed consent is to achieve its goals of promoting autonomous and rational decision making [...] But even subjects with [...] capacity [...] may not be able to make decisions in this manner for many reasons (e.g., because the disclosure was inadequate or because of a lapse in attention to the disclosure). (Lidz, Appelbaum, Grisso, & Renaud, 2004, p. 1690)

The “failure” of research participants to understand what is deemed in their interests to understand is frequently blamed on deficiencies in the process of information disclosure or design (Macklin, 1999). The solution to “misunderstanding” and “misconception” is then seen as lying in the more thorough informing of research candidates, of disabusing them of any “false” emotions they might feel about their participation, and, above all, of persuading them of the scientific account:

What is needed ... is not a process of informing subjects, but one of convincing them. (Fried, 2001, p. 337)

A critique of this approach might begin by pointing to the deficiencies in its conceptualisation of communication. It draws on what we have previously (Dixon-Woods, 2001) identified as a “patient education” model of communication, which is based on a stimulus–response sequence. Any failure of the recipient to interpret the message as intended is attributed to “noise” or “interference” in the system, such as poor readability of the printed materials or (reading) incompetence on the part of patients. In expecting that written information will “do” something to patients, it characterises patients as passive. The problem of “misunderstanding” is therefore constructed as a technical one, to be resolved through the application of principles of clear writing, leaflet design, and full disclosure.

Neither theory nor empirical evidence, however, supports the view that it is possible to close down the meanings of texts in such a way as to make only those intended by the authors the only possible ones (Bloor, 2002; Derrida, 1977). As Pearson (1987) notes, to view an individual’s comprehension of a text as an inadequate reproduction of the original

text misses the whole point about the reader’s enormous contribution to the comprehension process. The now abundant literature on the public understanding of science has, from a rather different perspective, also offered a wide-ranging critique of this “deficit model” of communication (Bauer, Allum, & Miller, 2007).

### Being “informed” and lay theories

A second element of a critique of the “patient education” approach to informed consent would have its origins in sociology, and particularly in medical sociology. In sociological terms, the (standard) bioethical position on informed consent is concerned with the degrading or erosion of agency that might result from participation in research on the basis of a false prospectus. An alternative conception, however, is that insisting that people only take part in research on the terms of those conducting the research (and their regulators) is a different form of challenge to agency.

This conception could be located theoretically within a corpus of work that has documented the existence of lay theories (referred to also as lay “knowledge”, or, in earlier formulations, “lay beliefs”) of health and illness. Mostly using qualitative methods, this work has shown that the lay populace may deploy ideas about health and illness in a logical framework that may differ quite markedly from medical orthodoxy (Stainton Rogers, 1991). Rather than deeming lay theories “wrong”, a dominant approach within medical sociology has focused on creating patients as active, critical and reflexive in the generation of their theories about health and illness (e.g. Blaxter, 1983; Calnan, 1987; Davison, Davey Smith, & Frankel, 1991); has emphasised the internal coherence and “validity” of lay ideas (Stacey, 1994); and has asserted a kind of equivalence between the status of “lay” theories and “expert” theories (Williams & Popay, 1994).

This approach has been prominent in encouraging a rethinking of traditional conceptualisations doctor–patient relationships, in particular through a recognition of the expertise of patients and the recasting of the consultation as a partnership or a “meeting between experts” (Tuckett, Boulton, Olson, & Williams, 1985). The emphasis on valuing patients’ own views of their condition and the appropriate way to manage is most vividly illustrated in debates over compliance. Explanations

for non-compliance located in a model of “disobedience” (Stimson, 1974), irrationality, or ignorance, have given way to models based on “concordance”. Concordance is seen by Weiss and Britten (2003) as an approach that acknowledges patients’ expertise in their bodies, stresses a shared approach to decision-making rather than paternalism, and advocates a sharing of power in professional–patient interaction.

This work on lay theories does two important things. First, it demonstrates the existence of distinct (though overlapping) systems of medical and “lay” belief and knowledge. Second, it creates a moral warrant for a form of decision-making that accords validity and status to lay theories and accepts that the meanings that people choose to give to their health and their behaviours may not be consistent with medical orthodoxy. It allows that patients may make decisions about their health on grounds that are not necessarily authorised within a medical model.

Though some work has begun to suggest that research participants’ accounts of study participation may be seen as alternative rationalisations rather than simply as “misunderstandings” (e.g. Featherstone & Donovan, 2002), the important challenges that this approach poses for the standard bioethical model of informed consent have not yet been fully addressed. It could be argued that the insistence that people make decisions about research participation only on the terms prescribed for them, and that they accept in full the “scientific” account of research, is identical to the insistence that people must believe and comply with medication advice (or other medical instructions). On this account, potential research participants are seen as highly fallible decision-makers who need to be protected from the inherent defects in their capacity to make decisions. Admission to research is seen, in the standard bioethical account, to require that patients demonstrate perfect understanding and acceptance of an account of the research prescribed by others; but patients being admitted to treatment need to do no more than demonstrate that they are happy with the decision made about their treatment, regardless of the basis of that decision. There is thus a tension between the two accounts of agency and decision-making: in research, the participant is a fragile and fallible agent whose choices need to be constrained, while in medical care the participant is a fully autonomous agent whose choices must be respected. We offer a critical

account of this approach using data from the GRAPHIC study.

### The GRAPHIC study

The GRAPHIC study aimed to develop a phenotyped resource of nuclear families (two parents and two adult children) to assess the impact on blood pressure of candidate gene polymorphisms and environmental factors. All participants in GRAPHIC were recruited as (apparently) “healthy” volunteers outside of a clinical situation, and their first contact with the study was by letter.

Women aged 40–59 years registered with participating general practitioners (GPs) in Leicestershire, UK were contacted by mail using an introductory letter from their GP and an invitation from the GRAPHIC study team for women and their families to participate. Recipients indicated whether they met the inclusion criteria and whether they would like further information using a reply slip. Those who expressed interest were sent Participant Information Leaflets (PILs) to distribute to family members. The PIL explained that people would be recruited regardless of blood pressure status, with the aim of including people with blood pressure values in the “normal” range. A research nurse contacted the families to ensure they met the inclusion criteria, check that each eligible family member wished to participate, answer any questions, and arrange appointments.

From July 2002 to November 2004, 7683 invitations were issued, and 4326 responses received (response rate 56.4%). Of these 273 families (1092 participants) who met the inclusion criteria took part in GRAPHIC. Participants were asked during interview to respond to a questionnaire about medical history and exposure to various risk factors. Skin-fold thickness, weight and height were assessed. Participants also underwent 24-h ambulatory blood pressure monitoring, collected urine over 24 h, and provided a blood sample for analysis, including DNA analysis.

### Methods

We conducted a qualitative study of people who had participated in GRAPHIC, aiming to explore views and experiences, with the approval of Leicestershire Research Ethics Committee. GRAPHIC participants who had previously agreed to be contacted about further studies were approached by letter. No more than one participant from any one

family was selected, and purposive sampling was used to select participants based on: position within the family (parent/offspring), gender, and willingness to be involved in different types of further studies.

An interview prompt guide, developed following literature review and discussions within the project team, was used to structure the interviews, but was used flexibly in response to the direction in which participants wanted to take the interview. It was modified (modestly) over the course of the project in response to emerging themes. The interviews were conducted by CJ, who maintained a reflexive diary. Interviews were transcribed verbatim. A systematic and iterative method of analysis based on the constant comparative method (Glaser & Strauss, 1967) was employed. Initially, “open codes” were generated, representing the significance of sections of text. These were then incrementally grouped into organising categories or themes. Categories were modified and checked constantly in order to develop a coding frame with explicit specifications. The coding frame was programmed into QSR N6 software and was used by CJ to process the dataset systematically. Assignment of data to categories was independently checked by MDW.

## Results

Twenty-nine GRAPHIC participants agreed to take part in this qualitative study (16 men and 13 women) of 84 invited. Theoretical saturation was reached, with no new themes emerging after the 11th interview. The parents (18) were between 47 and 61 years of age and the offspring (11) were between 23 and 35 years old. Participants’ occupational backgrounds were varied. All participants were of “white” ethnicity, reflecting the GRAPHIC population.

Participants’ accounts suggested that the invitation to take part was met by many with an almost automatic acceptance; the decision was often made quickly without a great deal of thought (13 participants) and participation was not considered to be a “big deal” (16). The decision appeared to be based on four main factors: a positive attitude towards medical research; a desire to do good; a possibility of some (modest) personal gain in the form of a health check; and less directly, confidence in the research process and its governance, and a perception of low risk.

## Positive orientation towards medical research

Participants generally indicated that they considered medical/genetic research to be a good thing (28). For some, the potential for medical research was unspecified, but for most included references to improving knowledge/medical science, prevention and treatment of disease, finding cures for diseases, saving/lengthening lives and the prevention of suffering. Genetic research was seen as being especially rich in potential for medical advancement:

I have opinions about it, that it’s hugely important, that genetic research offers all sorts of possibilities of avoidance or prevention of major diseases in the future and also that genetics offers possibilities of cures and that sort of thing in the future, which you know, we could well do with, should be progressed. (Participant 7)

Having established in their accounts that medical research *per se* was a good thing, almost half of the participants (13) appeared to suggest that the precise nature of the GRAPHIC study aims was unimportant to them, as long as the research appeared generally worthwhile and to be well-run:

Well I just felt that there was enough there, you don’t need all the details of what they are going to do if you agree to do it and you know they’re ok, and that was quite enough for me (Participant 3)

When asked to explain the aim of the study, participants’ accounts were varied, with substantial imprecision evident in many accounts:

I guess in my naiveté I didn’t know but I guess it would be to get an average view of people’s, not fitness but health in general and collate it and use it in some way, I don’t know, people want to use stats. (Participant 9)

## Excerpt 1: GRAPHIC participant information leaflet

What is the purpose of the study?  
High blood pressure is an important risk factor for strokes and heart attacks. Evidence suggests that the lower a person’s blood pressure, the lower the risk of strokes and coronary heart disease. In order to properly understand the genes

that control blood pressure, it is important to study a sample of the whole population containing individuals with low, average and high blood pressure. Such research is best done in a family setting so we can assess the contribution of genes as well as the environment. Scientists define the environment as including diet, lifestyle, physical activity and medication as well as the broader environment. Our study aims to identify which genes are responsible for controlling blood pressure and how they are affected by the environment.

Excerpt 1 shows the explanation of the aims of the study offered by the GRAPHIC PIL. Our analysis suggests how people appropriate meaning about the aim of the study cannot be taken for granted: the meanings given to written information cannot be understood by looking at the structure and content of the messages alone.

Most participants (20), when asked to describe the aims of the GRAPHIC study, mentioned the role of genes in disease, but these accounts were supplemented with notions of heritability that had not been evident in the PIL account. Many accounts, for example, located their interest in the study within a personal family narrative:

we were just quite happy to provide the information that was requested in the hope that it would, you know, help you know, future generations and maybe you know stop another family going through the tragedy we had all those years ago you know, that was a sad thing for us, so. (Participant 15)

Most (22) knew that the aims of GRAPHIC were related to cardiovascular problems including blood pressure (22), but only five accounts referred to the role of environmental factors:

to be honest I wasn't totally sure. I knew there were certain things they would be testing, sort of cholesterol, blood pressure and sort things like that and taking blood test and so I ... To be honest I didn't know that much about it but I was happy for to go along with whatever was needed to be done so .... (Participant 10)

Thus, the content of messages in the PIL did not fix and permanently stabilise the meaning: it was the readers themselves who constructed the meaning

given to text, a contextualised and creative process of interpretation in which individuals drew on the resources available to them (Thompson, 1994). For GRAPHIC participants, these resources often included a generalised commitment to “do good” and to be motivated by a community ethic, rather than a detailed understanding of the specificities of the individual study.

### **A desire to do good**

There was no indication that the participants felt under any pressure from the research team to take part GRAPHIC. Instead, accounts contained two principal motivations for taking part. The first, given by all participants (29), was to help others, with the theme of good citizenship highly prominent:

as much as we didn't have a reason not to take part I suppose, just to be helpful and you know and anything that encourages medical progress you know I think has got to be advantageous to people. (Participant 24)

Eleven participants provided other examples of how they helped others, including donating blood and bone marrow, carrying an organ donation card, and engaging in charitable work. Many saw themselves as fortunate, having a moral or religious obligation (12) to help others:

We've, all of us as a family have always not necessarily thought about ourselves first but thought about others, we realise that actually we've got all our health and everything, we're lucky and other people haven't. (Participant 6)

### **Possibility of some form of personal gain**

The second motivation for participation was the possibility of some form of (modest) personal gain, either directly through the medical tests conducted as part of GRAPHIC (12) or less directly through the possibility of the research findings benefiting themselves or their family in the future (12). For many participants cardiovascular disease (18) or genetic problems (11) were particularly salient, often because of family history:

I embraced it, I thought it was a wonderful opportunity for my family to have a health check so it would benefit both the research programme and my family [...] I couldn't wait to do it, I was

so, I just thought this was like manna from heaven, this was just what I had been looking for, for my family. (Participant 26)

In line with current advice, however, the GRAPHIC study does not provide individualised feedback on genetic analysis to participants (Excerpt 2).

#### Excerpt 2: GRAPHIC participant information sheet

We emphasise that the information on genes (which we will get from your blood sample) is obtained for research purposes only. At the present time, the significance of the results is unknown and may remain unknown for some time. The study we are doing aims to add to our knowledge of how genes and other factors affect health and blood pressure. We are gathering this knowledge by studying groups of people, and the genetic research is not meant to test your personal medical status. For these reasons, we will not give you the results of our genetic research on your sample. However, the newsletter will tell you in general about the research we are doing. This does not affect your legal rights to request your information.

Despite the message in Excerpt 2, eight participants nonetheless believed that genetic information from the study would be shared with them, though they did not imply that feedback about genetic findings formed any part of their motivation for their participation in GRAPHIC:

I think that if they did find anything, they'd let you know. I'm sure they would. Sure they would. (Participant 12)

Such findings again suggest that we cannot take people's appropriation of meaning for granted; people may customise the information to fit with pre-existing notions, may resist the explanation offered by the text altogether, or may make use of the information in unanticipated ways.

#### Confidence in research process and perception of low risk

Even though not all GRAPHIC participants attributed meaning in the way that was intended, it would be a mistake to assume that the texts of leaflets are empty of meaning or had no value for participants. As Prior (2003b) argues, documents function in many ways, not all of them directly related to their content. For GRAPHIC participants, the PILs were the primary source of information at the time when they were making the decision about whether to take part. PILs appeared to play the role of the visible face of the expert system (Giddens, 1990), and providing insights into the nature of the tasks and risks that participants are expected to take on.

Almost all participants (27) indicated that they had no concerns about taking part in GRAPHIC and most had difficulty in identifying any risks that might be involved. When pressed, participants pointed to the possibilities of data being shared inappropriately, of the potential for family secrets to be unveiled, for DNA donated as part of the study to be used by the police or by insurance companies, or something negative about their health being revealed:

It would bother me if it ended up in some database with the police or stuff like that [...] But no I mean, apart from that it wouldn't bother me no. (Participant 15)

you might find out that you're about to fluff it or you might find out that there's something seriously wrong with you, but then it's probably better to know that, but as far as negatives go, generally, no, none. (Participant 27)

More than half of the accounts (15) made explicit reference to the credibility of those conducting the research. Confidence was reported in the NHS (8), the University of Leicester (5), the British Heart Foundation (5), and the hospital setting (5). These judgements appeared to be based on displays of credentials such as logo, the general quality and appearance of the study leaflets and other documentation and the professionalism of the study staff:

I think so, I think that I knew it was affiliated to the hospital, I can't remember now, it was the university wasn't it? As well as the hospital and so it, you know that it's a pukka organisation, as

opposed to any research organisation that you haven't heard of. (Participant 3)

There was a generalised faith that some form of regulation must safeguard the interests of people involved in research, though few had heard of or understood the role of a research ethics committee:

it's like a trust sort of thing, you don't tend to look into it too much because you know they're looked into anyway the way they sort of conduct themselves and the things that they do. You know they're overseen so it doesn't hugely bother me what ... I know it sounds daft but I do read the letters and I do take it all on board but you can skim over it and you know you're safe. [...] like I say if [NHS] wasn't on the top of the letters then I'd be a little bit worried about taking part and that's when I start asking around, going on the internet to find out exactly who the people were that were doing it. (Participant 2)

## Discussion

This study of participants in a genetic epidemiology study explored the meanings given by healthy volunteers to the PIL that was the primary source of their information about the study. Healthy unpaid volunteers being recruited outside of a clinical situation are arguably best placed to read PILs and make decisions under ideal conditions, without experiencing the stress, pressures or conflicts that may attend participation in clinical research involving ill people. Our analysis suggests that people may make sense of information about medical research, including the content of written information, in complex and unexpected ways. Following one currently dominant approach in the ethics literature, it could be argued that apparent "failure" of many GRAPHIC participants to understand more precisely the study aims or that they would not be given feedback on their DNA would be attributable to some fault in the written information itself—complexity, poor explanation, poor writing style, and so on. However, if we abandon (at least partly or temporarily) the search for an explanation located in the text, "readability", or layout of the leaflet, we are left with an explanation that suggests that the process of meaning creation occurs when the text interacts with people's own meaning systems.

Our analysis of the meanings given by research participants to research is consistent with the

medical sociology literature on lay theories, suggesting that, as for their relations with information about medicines, people's relationships with research are not defined by what leaflets tell them. As in other areas of health and illness, people are emphatic in their need to tell their own story (Frank, 1997). "Misunderstanding" is therefore likely to be an incorrigible and persistent feature of people's reading of PILs; no "technical fix" would reliably ensure that all people would be able to reproduce and believe in any single authorised "scientific" account of any research project, whether medical, social science, or other.

A critical dilemma for the standard bioethical account of medical research then results. Should it continue to insist that people only participate in research on grounds that are deemed to be ethically licensed—they understand and accept the scientific account of research, and have emotionally pure motives—and refuse to enrol those who appear to have "misconceptions" or "improper" motives? Or should it, like the "partnership" approach in medical treatment, treat the meanings people give to phenomena as a form of moral warrant, to be valued as the basis for engagement on the patient's terms rather than the researcher's? Dialogue between the social sciences, ethics, and research communities is required to address this.

Our findings identify that people's meaning-making in relation to GRAPHIC meant that they sometimes agreed to take part in the research for reasons that were not technically authorised within the bioethical model—they often "misunderstood" the purpose of the research and various features of the study. Theories of participant misunderstanding based on "patient education" or "deficit" models might see these individuals as making mistakes of fact that need either to be corrected, or argue that these individuals should be excluded from participation until they can demonstrate full understanding and proper motive. However, in emphasising individual autonomy and formal rationality, this approach may neglect other values such as solidarity and informal reasoning about trust, participation and relationships.

Our evidence suggests that far from participating on the basis of a false prospectus, people may simply participate in research for different reasons, or with different values in view, to the ones that researchers or ethics committees prioritise. In particular, healthy volunteers such as those in GRAPHIC may value a community ethic or moral



imperative as a motivation for participation, be untroubled by the risks and burdens described in the PIL (perhaps reasonably enough in the case of GRAPHIC), see the need to understand in detail the precise design and aim of the study as irrelevant, but be more concerned with whether taking part will be useful and promote the common good. They thus exercise agency in a way that is not identical to that imagined by the standard bioethical approach to research, but they have nonetheless exercised agency legitimately. Looking at participation and decision-making in this way would be consistent with a long-standing tradition in social thought, and more recent critical work in bioethics (Ashcroft, 2004; Ashcroft, Jones, & Campbell, 2000; O'Neill, 2002), as well as sharing some features of the “partnership” approach to medical decision-making.

It is of course important not to take this argument too far: we do not intend to imply that understanding never matters, only that it is possible for legitimate decisions to be made that do not require full understanding and acceptance of the scientific account of a research study. Agency based on legitimate motivations in situations where good understanding of the scientific account may be of relatively little consequence should not be confused with those situations where the exercise of agency requires people to have a reasonable understanding if they are to ensure that they arrive at decisions consistent with their values (Dworkin, 1998), and to avoid making decisions that they would not stand by if their mistaken belief were pointed out. However, the same argument could be applied to decisions about medical care, suggesting that a more critical approach to some currently influential approaches within medical sociology is required, perhaps particularly to those that align themselves politically with “the patient”, and celebrate the rationality and coherence of lay theories and treat these as welcome evidence of resistance to a hegemonic and oppressive politico-medical establishment (Prior, 2003a). Thus, while it is not always necessary for participants’ accounts of their reasons and understanding to be identical to the scientific/ethical account in order for them to make a legitimate decision about participation, it is important to identify where a mistaken belief would threaten legitimacy. An important conclusion is that even if researchers cannot guarantee that PILs will be read as intended, they must operate under aspirations towards clarity and honesty, and aim

for the potential for people to be deceived or misled to be minimised.

Our findings identified a further important role for PILs that has been little examined in the literature that has focused on “misunderstandings” and the disclosure of content. GRAPHIC participants’ accounts suggested that the leaflets appeared to function for research participants not only as carriers of content, but also as evidence of reliability, or warrants of trust (Giddens, 1990), through their origins in expert systems such as the NHS and academia in which people have high levels of trust. They therefore functioned as one of the “symbolic tokens” (mechanisms that can store and transmit value, enabling it to be conveyed across time and space) that form the basis of faith in such systems (Giddens, 1991). This might be seen as the form of trust that Giddens (1990) refers to depending on a “faceless commitment”—trust achieved without interacting with another person, since GRAPHIC participants received the invitation to participate through the mail. Provision of PILs may therefore function as a means of signalling respect for autonomy and commitment to good governance, and may well interact powerfully with other aspects of the recruitment process. Moreover, participants’ accounts explicitly referred to their confidence in systems of (ethical) oversight and regulation of research that contributed to their feeling of security about the study, suggesting that there may be some congruence between the expectations of the lay population and regulatory bioethics. Forms of governance must therefore aim to ensure that people’s expectations of research governance are not disappointed: if people believe that researchers are regulated, that projects are approved by competent authorities, and that there is oversight of the system, then efforts should be made not to do violence to this trust.

This study of healthy unpaid volunteers has implications for understanding the role of PILs in other studies, including social science research. Our identification of the role of PILs in generating trust, for example, will require empirical exploration in the context of social science studies, where it has been argued that PILs can potentially disturb and disrupt relationships with both candidates and participants in research (Wiles, Crow, Heath, & Charles, 2005). An understanding of how far people believe that similar arrangements are in place to govern and oversee “non-medical” forms of research, such as health-related social

science research, will be an important focus for future work.

## Conclusions

“Informed” consent to research participation, and the role of PILs in achieving “informed” consent, is not simply a technical problem. A more sophisticated approach to understanding the ways in which meaning is attributed to research participation is required, as is a more thorough theorisation of the implications of those meanings for the ethical practice of research, and of the more diverse functions of leaflets. This is likely to require dialogue between the social science, ethics, and research communities. This suggests the need for an approach to understanding PILs that goes beyond seeing provision of information as a technical problem, or one solely of disclosure.

## Acknowledgements

Thanks to the GRAPHIC participants and GRAPHIC staff who gave up their time to help with this study. GRAPHIC was funded by the British Heart Foundation (BHF). This qualitative project was funded by the Healthcare Epidemiology (Leicester) research fund and drew on theorisations developed as part of the ESRC’s Science in Society Programme (Project number RES-151-25-0026). Nilesh J Samani holds a BHF Personal Chair. Joelle Kivits was funded by ESRC post doctoral fellowship PTA-026-27-0403. Thanks to Nuala Sheehan for helpful input at the early stages of the study.

## References

- Appelbaum, P. S., Roth, L. H., Lidz, C. W., Benson, P., & Windsdale, W. (1987). False hopes and best data: Consent to research and the therapeutic misconception. *Hastings Center Report*, 17, 20–24.
- Ashcroft, R. E. (2001). Ethical aspects of experiments. In N. J. Smelser, & P. B. Baltes (Eds.), *International encyclopedia of social and behavioural sciences* (pp. 9512–9515). Oxford: Pergamon.
- Ashcroft, R. E. (2003). The ethics and governance of medical research: What does regulation have to do with morality? *New Review of Bioethics*, 1, 41–58.
- Ashcroft, R. E. (2004). The public interest. *Cambridge Quarterly of Healthcare Ethics*, 13, 20–27.
- Ashcroft, R. E., Jones, S., & Campbell, A. V. (2000). Solidarity in the UK welfare state reforms. *Health Care Analysis*, 8, 377–394.
- Bauer, M. W., Allum, N., & Miller, S. (2007). What can we learn from 25 years of PUS survey research? Liberating and expanding the agenda. *Public Understanding of Science*, 16, 79–95.
- Blaxter, M. (1983). The causes of disease: Women talking. *Social Science & Medicine*, 17, 59–69.
- Bloor, D. (2002). *Wittgenstein, rules and institutions*. London: Routledge.
- Calnan, M. (1987). *Health and illness: The lay perspective*. London: Tavistock.
- Chalmers, I., & Lindley, R. I. (2001). Double standards on informed consent to treatment. In L. Doyal, & J. S. Tobias (Eds.), *Informed consent in medical research* (pp. 266–275). London: BMJ Books.
- Davison, C., Davey Smith, G., & Frankel, S. (1991). Lay epidemiology and the prevention paradox: The implications of coronary candidacy for health education. *Sociology of Health and Illness*, 13, 1–19.
- Derrida, J. (1977). *Of grammatology*. Baltimore: Johns Hopkins University Press.
- Dixon-Woods, M. (2001). Writing wrongs? An analysis of published discourses about the use of patient information leaflets. *Social Science & Medicine*, 52, 1417–1432.
- Dworkin, G. (1988). *The theory and practice of autonomy*. Cambridge: Cambridge University Press.
- Featherstone, K., & Donovan, J. L. (2002). “Why don’t they just tell me straight, why allocate it?” The struggle to make sense of participating in a randomised controlled trial. *Social Science & Medicine*, 55, 709–719.
- Frank, A. (1997). *The wounded story teller: Body, illness and ethics*. Chicago: University of Chicago Press.
- Fried, E. (2001). The therapeutic misconception, beneficence, and respect. *Accountability in Research*, 8, 331–348.
- Giddens, A. (1990). *The consequences of modernity*. Cambridge: Polity.
- Giddens, A. (1991). *Modernity and self identity*. Cambridge: Polity.
- Glaser, B., & Strauss, A. (1967). *The discovery of grounded theory*. Chicago: Aldine.
- Kent, G. (1997). The views of members of Local Research Ethics Committees, researchers and members of the public towards the roles and functions of LRECs. *Journal of Medical Ethics*, 23, 186–190.
- Lidz, C. W., Appelbaum, P. S., Grisso, T., & Renaud, M. (2004). Therapeutic misconception and the appreciation of risks in clinical trials. *Social Science & Medicine*, 58, 1689–1697.
- Macklin, R. (1999). Understanding informed consent. *Acta Oncologica*, 38, 83–87.
- McNeill, P., & Pfeffer, N. (2001). Learning from unethical research. In L. Doyal, & J. S. Tobias (Eds.), *Informed consent in medical research* (pp. 49–60). London: BMJ Books.
- Misztal, B. A. (1996). *Trust in modern societies*. Cambridge: Polity.
- Moreno, J. D. (2003). Abandon all hope: The therapeutic misconception and informed consent. *Cancer Investigation*, 21, 481–482.
- Morris, N., & Balmer, B. (2006). Volunteer human subjects’ understanding of their participation in a biomedical research experiment. *Social Science & Medicine*, 62, 998–1008.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). The Belmont report: Ethical principles and guidelines for the protection of

- human subjects of research. Reprinted. In A. R. Jonsen, R. M. Veatch, & L. Walters (Eds.), *Source book in bioethics: A documentary history* (pp. 22–28). Washington, DC: Georgetown University Press 1998.
- O'Neill, O. (2002). *Autonomy and trust in bioethics*. Cambridge: Cambridge University Press.
- Pearson, P. D. (1987). The comprehension revolution: A twenty-year history of process related to reading comprehension. In B. M. Mayor, & A. K. Pugh (Eds.), *Language, communication and education*. London: Croom Helm.
- Prior, L. (2003a). *Using documents in social research*. London: Sage.
- Prior, L. (2003b). Belief, knowledge and expertise: The emergence of the lay expert in medical sociology. *Sociology of Health and Illness*, 25, 41–57.
- Snowdon, C., Garcia, J., & Elbourne, D. (1997). Making sense of randomization; responses of parents of critically ill babies to random allocation of treatment in a clinical trial. *Social Science & Medicine*, 45, 1337–1355.
- Stacey, M. (1994). The power of lay knowledge: A personal view. In J. Popay, & G. Williams (Eds.), *Researching the people's health*. London: Routledge.
- Stainton Rogers, W. (1991). *Explaining health and illness: An exploration of diversity*. Hemel Hempstead: Harvester Wheatsheaf.
- Stimson, G. V. (1974). Obeying the doctor's orders: A view from the other side. *Social Science & Medicine*, 8, 97–104.
- Thompson, J. B. (1994). Social theory and the media. In D. Crowley, & D. Mitchell (Eds.), *Communication theory today*. London: Polity Press.
- Tuckett, D., Boulton, M., Olson, C., & Williams, A. (1985). *Meetings between experts: An approach to sharing ideas in medical consultations*. London: Tavistock.
- Weiss, M., & Britten, N. (2003). What is concordance? *Pharmaceutical Journal*, 271, 493.
- Wiles, R., Crow, G., Heath, S., & Charles, V. (2005). Research ethics and regulation in the UK: The case of informed consent. *Paper presented at the 1st International Congress of Qualitative Inquiry*. University of Illinois at Urbana-Champaign.
- Williams, G., & Popay, J. (1994). Lay knowledge and the privilege of experience. In J. Gabe, D. Kelleher, & G. Williams (Eds.), *Challenging medicine* (pp. 118–139). London: Routledge.