Introduction

Informed consent in a changing environment

Introduction

Informed consent has long become the sine qua non of ethical practice in medical research involving human participants (Weindling, 2004). It is a key principle of the Nuremberg Code, perhaps the best known of all codes of ethics, drawn up by judges at the end of the Nuremberg Trials in 1946, and of the subsequent Declaration of Helsinki, drawn up by the World Medical Association in 1964 and regularly updated ever since, most recently in 2000. Informed consent has been incorporated in the national legislation in most industrialised countries, and its influence has spread well beyond research in medicine to reach virtually all areas of research on human participants, appearing in the codes of practice of most professional organisations, funding agencies and institutions engaged with such research. Its central role in research practice is also evident in a vast literature, ranging in focus from moral philosophy to practical training in research methods, the production of which continues apace. The last decade has, however, seen a new and more critical focus, in medicine, social science and in bioethics, on research ethics and on the primacy of informed consent. Paradoxically perhaps, this new critical interest has had the effect of both problematising traditional notions of informed consent and of leading to calls for its tighter regulation.

Developments leading to the problematising of the primacy of informed consent and of narrow conceptions of research ethics review have included changes in medical practice, developments in technologies underpinning biomedical research and a growing interest in the implications of such approaches to research ethics for public health research and epidemiology. Advances in human genetics and genomics, for example, mean that research data provided by one individual, or set of individuals, may have implications for the well-being of other family members or for whole populations, and raise questions about whose consent is required before research can begin. Developments in information technologies, such as grid technology, which have the potential to enable researchers to link datasets involving both biological and social data to create research resources which are so large that it is not feasible to seek informed consent from each individual for each new study, raise further questions about the appropriate ways of protecting the interests of individuals in research. Public health and epidemiological research has also been an area in which informed consent has been seen as particularly problematic, and indeed unethical, by some (British Medical Journal, 2004). This has been most notable in relation to requirements to obtain consent for research on medical records. Finally, developments in the social organisation of medical research, particularly an increasing emphasis on multi-disciplinary research and research which crosses national boundaries, have added another dimension to this critical trend. Where research teams bring together individuals with contrasting perspectives on what is required for ethical practice and where researchers work in communities with diverse social structures and cultural traditions, taken-for-granted assumptions about informed consent inevitably come to be questioned. An example of this is where research is carried out in contexts in which 'valid consent' is considered to require community participation.

At the same time as these developments in the methods and contexts of biomedical research have been opening up new possibilities for the meaning and practice of informed consent, other developments have fuelled a drive in the opposite direction, that is, towards further standardisation and regulation

and towards an even greater emphasis on consent. A perceived decline in trust in 'experts' and 'professionals', characteristic of late modernity, to some extent compounded by new 'scandals' in biomedical research—such as in the UK, the retention of children's organs without their parent's knowledge at Alder Hey Hospital (Redfern, 2001) and in the USA, accusations of poorly regulated medical research among the Yanomami Amazonian Indians (Borofsky, 2005)—have undermined confidence in the governance of clinical research and have led to pressure on governments and professional organisations to provide further protection for the rights and welfare of participants and greater oversight of research practice. This has been manifested in a proliferation of guidelines and other forms of governance and audit (Strathern, 2000; O'Neill, 2002). Such standardisation has also been driven by other structural and economic changes, including the reluctance of the pharmaceutical industry to invest research funds in countries which do not comply with the International Conference on Harmonisation's Guidelines for Good Clinical Practice (ICH GCP, 1996), which have also added significant commercial pressure on the signatory countries—the European Union, USA and Japan—to adopt very strict requirements for informed consent. These changes have been further compounded by political pressure from international organisations like the Council of Europe to harmonise laws across Europe and for member countries to pass legislation to make informed consent a legal requirement in medical research.

These social processes—moves to greater standardisation on the one hand and increasing criticism of such standardisation on the other—are not unrelated. And while much of the critical literature on informed consent requirements has been generated from within biomedicine itself, a great deal of this has also been produced in response to the increasing application of informed consent requirements outwith the scope of biomedical research. One consequence of the strengthening of research governance and of increasing awareness of ethical dimensions of medical research has been to widen the definition of what constitutes research on human participants requiring institutional ethical oversight and consequently to draw social scientists, particularly those working in medicine and health care, under the purview of ethical review procedures associated with medical research. In Canada, for example, the three government funding bodies

(MRC, NSERC and SSHRC) together produced a single Tri-Council Policy Statement (1998) describing standards and procedures for governing the ethical conduct of all research involving human participants, which is framed within the biomedical paradigm. In the UK, the Department of Health published its Research Governance Framework (Department of Health, 2001, revised 2003), compliance with which is required for all research involving patients, carers and health service personnel broadly within the NHS, and which 'is intended to apply to the full range of research types, contexts and methods' (2003, p. ii). This proliferation of oversight, and the growing emphasis on ethics in social science has not only been driven from outside but has at least in part been the result of a growing awareness of the ethical dimensions of social research among social scientists themselves. Nevertheless, while this closer scrutiny of health-related social research has been welcomed by many, the biomedical research paradigm that underpins it has raised widespread complaint as the discussion of the role of consent has moved beyond the medical arena. Expectations around informed consent and the procedures for documenting it, though by no means the only problems, have been central to the objections raised. In responding to what are seen by many as inappropriate and ill-considered bureaucratic requirements and by others as undermining of that which they are intended to promote, social science researchers have in recent years begun to elaborate their own positions on the meaning and practice of informed consent, and of models of ethical research practice more broadly conceived, which are grounded in the particular concerns, methods and social relations of social science research.

As an example of this, this Special Issue of *Social Science & Medicine* brings together eight papers which address the issues raised for the meaning and practice of informed consent for social scientists by the changing research and regulatory environment in which health and medical research is conducted. It has its origins in an international symposium on informed consent organised by Mary Boulton at Oxford Brookes University and Ray Fitzpatrick, Tony Hope and Michael Parker at the University of Oxford, and funded by the Economic & Social Research Council and the Wellcome Trust. The papers included in the Special Issue were written in the light of the discussions and debate over the course of the conference. In this Introductory paper,

we provide some background to these papers by giving a brief account of the role of informed consent, the justifications offered for it and the key requirements for implementing it as they have been presented in biomedical research, and then outline the main objections raised by researchers working in a different research paradigm. We conclude by providing a brief summary of each of the papers, drawing out their main themes and arguments, before reflecting on the implications of the Special Issue as a whole for what might be appropriate ways of approaching ethics in the context of social research and related methods of enquiry.

Consent in context: meaning, role and requirements

We begin with a consideration of consent. Within biomedicine, informed consent is generally regarded as the main mechanism for providing protection for the rights and welfare of the individual. The concept itself is rooted in the 18th century Enlightenment tradition of the social contract and the principle that freely given consent lends moral legitimacy to actions which would otherwise be regarded as unacceptable (Manson & O'Neill, 2007). Interestingly, while the conceptualisation of consent as a requirement for action that would not otherwise be acceptable in everyday life suggests the possibility of a rich and socially informed approach to consent, in practice the concept has tended to be interpreted rather narrowly and largely in terms of respect for autonomy (particularly in the context of challenges to paternalism in medical practice) and/or respect for individual human rights (particularly in the context of legal challenges by patients or research subjects). In relation to biomedical research, the concept of informed consent first came to widespread international prominence through the Nuremberg Code, drawn up following the Nazi war crimes tribunals in 1946, where it formed the first of ten principles to govern ethical research. These principles reflected the moral values of researchers at the time, and shared concerns about the importance of protecting research participants and their interests from the power of medical research and the interests of society. The Code was widely accepted in principle if not always adhered to in practice (Beecher, 1966; Papworth, 1967). It is worth noting that the progressive tightening of research governance and the closer specification of research ethics, including consent, have regularly followed the exposure of abuses of medical power.

This is at least in part a reflection of the fact that, whatever the practical realities, the impulse for the introduction of informed consent as a principle of research ethics and the institutionalisation of processes of research ethics review have been grounded, at least in part, in attempts to protect research participants from technological and other imperatives, and the power, of medical research.

Most models of consent in the biomedical ethics literature, and in the regulation and guidelines, identify three key criteria by which the validity of consent might be assessed. The first of these is that consent is valid only where potential research participants have been provided with all information likely to be relevant to their decision whether or not to participate, and where such information has in fact been understood. The second criterion for valid consent is that the decision to participate has been made voluntarily, i.e. that it has been free of explicit or implicit coercion. The third criterion is that to be considered valid such consent has to be given by a person who is competent to do so. It is clear from this that the concept of 'valid consent' is rather more broad and more inclusive than that of 'informed consent': there is more to valid consent than information. Over the last 60 years, what each of these elements of valid consent actually entails has been the subject of widespread discussion and debate. What information, at what level of detail, is material to a participants' willingness to participate? When and how should it be provided? Who should judge an individual's capacity to make a reasoned decision and what criteria should be used? What constitutes undue pressure or coercion and are decisions ever freely made? Attempts to reach agreement about the answers to questions such as these, both at national and international levels (see, for example, the various versions of the Declaration of Helsinki, the development of the Council for International Organizations of Medical Sciences (CIOMS) guidelines on international research, and so on), have led to the elaboration of ever more detailed and exacting standards, governance arrangements and guidelines.

The elaboration of practical requirements for consent since Helsinki has been reinforced by a parallel development of research ethics committees, designed to oversee the ethical standards of research involving human participants including the establishment of whether procedures for informed consent are adequate. These committees developed in remarkably similar ways across Western industrialised

nations so that, by the turn of the 21st century, recognised structures with responsibility for reviewing proposals for research involving human participants (e.g. institutional review boards (IRBs) in the USA, research ethics boards (REBs) in Canada and research ethics committees (RECs) in the UK) had been established in most countries. IRBs are increasingly (if patchily) seen in developing country settings as well. Consequently, an emphasis on informed consent combined with obligatory review by a research ethics committee has now become widely recognised to be the twin procedural mechanisms for ensuring both that potential risks to participants are minimised and that the interests and welfare of research participants are protected.

The biomedical paradigm and social science research

The origins of research ethics committees in the requirements of medical research combined with the growth of biomedical research as a major international industry has meant, perhaps not surprisingly, that the values, concerns and traditions of biomedicine have come to dominate research ethics committees, wherever they are located, in terms of their membership, operating procedures and the framework within which they review proposals. And it is this dominance of the biomedical paradigm, and the poor understanding of social science research among members of research ethics committees, that have tended to be the focus of criticism among social scientists. In Canada, for example, dismay among social scientists with the Tri-Council Policy Statement (1998) was such that a Social Sciences and Humanities Research Ethics Special Working Committee (SSHRESWC) was established to review and revise it in relation to social science research. In its Report (SSHRESWC, 2004), the Working Committee observed that 'No single statement is in need of rethinking more than that on informed consent' (2004, p. 27). In the UK, the publication of the Department of Health's Research Governance Framework (Department of Health, 2001, 2003) evoked a similar response and provided the impetus for the Economic & Social Research Council (ESRC) to develop its own research ethics framework for social science research (ESRC, 2006; Webster, Lewis, Brown, & Boulton, 2004). These responses are just recent manifestations in a long tradition among social scientists of resistance to the extension of the regulation of biomedical research to include social science research which began in the

USA in the mid-1970s with the extension of the Common Rule to cover social science research (Beauchamp, Faden, Wallace, & Walters, 1982).

In arguing against the imposition of a model of informed consent rooted in the biomedical research paradigm, social scientists have often pointed to the distinctiveness of their own research paradigms and the ethical concerns generated by them. In appealing to these differences, social scientists have challenged the appropriateness and feasibility of the biomedical model of informed consent for their own research, while recognising that their own work has important ethical implications, and begun to explore and characterise alternative ways of taking seriously the vulnerabilities and responsibilities of all those engaged in research.

The feature of social science research which is most commonly claimed by social scientists to be different from research in biomedicine is the lower order of risks involved: social research may be intrusive but it is not invasive and does not tend to involve the risk of direct physical harm, injury or death. The social and psychological risks associated with social research, it is argued, are generally no more than those encountered in everyday life, and are risks which we must all accept as the cost of life in a free society: they do not warrant the same kinds and levels of protection as is required for the management of physical risk in medical research. Against this background, formal consent procedures or even review by a research ethics committee are seen as excessive and heavy handed and as posing a risk to 'academic freedom' (Kent, Williamson, Goodenough, & Ashcroft, 2002; Pattullo, 1982; Whittaker, 2005).

A second emerging theme is that differences exist in the nature of the research process in social science and biomedicine, which mean that 'anticipatory' or 'predictive' informed consent as it is conventionally required at the beginning of a medical research project is not always possible or even desirable within social science research (Strathern, 2000). The open-ended and uncertain nature of qualitative research, for example, means that in many cases neither the researcher nor participants can anticipate how the research will develop or what issues may arise, making it impossible to identify the risks involved in participation in advance of the study (Miller & Bell, 2002). In some ethnographic or observational studies, it may not even be possible to identify who the participants are until the data have been collected.

A third emerging theme is that social relations in social science research differ from those in biome-

dical research. In contrast to much medical research, where participants' willingness to take part in research may be influenced by the institutional context and affiliation of researchers, social science researchers are generally, especially when researching the powerful, faced with busy and sceptical individuals and must establish their credibility and trustworthiness on their own merit. Research relationships in social sciences are also in many cases more enduring, negotiated and equal, affording participants a greater degree of agency and requiring researchers to reflect continuously on ethical dimensions of their activities. Consent in this context is seen by many social scientists as an open-ended process which is continually negotiated, rather than as a formal procedure that is completed at the start of a study (Ramcharan & Cutliffe, 2001; Riessman, 2005). In research where trust between researcher and participants is earned incrementally in the context of a developing relationship with participants, the requirement for signed consent forms, which constructs the relationship in a legalistic way, is inappropriate and may in fact disrupt the development of trust between researcher and participant.

At a more fundamental level, a fourth critical theme concerns the ways in which social scientists and many working in bioethics are increasingly challenging the dominance of the rights-and-justice-based model of ethics underpinning the concept of informed consent in biomedical research. Feminist researchers working within an ethics of care, for example, and advocates of communitarian and virtue-based approaches to bioethics, reject the emphasis given to individuals, universalism and distance as an appropriate basis for the research relationship and pose instead an ethical relationship based on particularism, collective rights and active engagement (Denzin, 1997; Edwards & Mauthner, 2002). Formal informed consent procedures, it is argued, become highly problematic in this context, where attention is often shifted from identifying and eliminating potential risks in advance of the study to engaging actively with the moral dilemmas as they arise throughout the course of the study and from individualistic approaches to those which are more relational.

Taking the arguments forward: papers in this Special Issue

None of these criticisms of informed consent nor the associated attempts to distance social science research from research in biomedicine is in itself unproblematic; in particular, the claim that there is a morally significant difference between social and physical harms in research and the downplaying of the importance of power relations in social science research can be questioned. This special issue of *Social Science & Medicine* critically examines the way researchers from a range of disciplines theorise the meaning and practice of informed consent in relation to social science research in the health and medical fields. Between them, the papers address the range of issues reviewed above and others, investigate the strengths and limitations of conventional approaches to informed consent, suggest possible new avenues for development which would be more appropriate to the social sciences and problematise not only research ethics as conceptualised in biomedicine but also the critique of informed consent itself.

In the first paper, Miller and Boulton (2007) look at the ways in which the meaning and practice of informed consent are embedded in, and change along with, their social context. They argue that current pressures towards standardisation are ill suited to the increasingly fluid and uncertain circumstances of late/post-modern society in general and the emergent and negotiated nature of qualitative research practices in particular. Drawing upon examples from their own research careers, they examine the way social changes in the direction of late/post/reflective modernity, the growth of feminist methodologies and the proliferation of electronic communication technologies have changed the meaning and practice of informed consent over the last 35 years. Miller and Boulton's analysis calls for a more sociologically informed approach to informed consent, which takes account of its socially constructed, changing and multi-layered nature. They argue, furthermore, that ethical research practice in social science depends critically on finding ways of establishing relationships of trust among researchers, participants and ethics committees. They propose a shift from what they see as a predominantly static audit and accountability model of ethics review to a more democratic, process-sensitive and supportive approach involving the establishment of forums, real or virtual, to facilitate communication among all stakeholders and to provide the opportunity to raise and discuss ethical issues including informed consent throughout the course of the study, an idea also considered in Harper's paper (2007).

In the second paper in this collection, Dixon-Woods et al. (2007), argue that there is a mismatch between the assumptions of the biomedical model of informed consent and how people actually make decisions about whether to participate in research. In so doing, they problematise the concept of informed consent not only in social science research but also within biomedicine. Their paper challenges the notion that participation in research can or should be based on an understanding and acceptance of the scientific account of the research as presented in information sheets and consent forms. Individuals make sense of the information they are given in terms of their own lay meanings, expectations and experience, and such understandings can be complex and surprising. Meaning is always constructed through the interaction of the written text and the background experience that the reader brings to it, and this should not be seen as a technical problem that can be solved by technical improvements in the way information is provided. In making decisions about whether or not to participate, participants in Dixon-Woods et al.'s study placed emphasis on a moral imperative to take part in research, and on the view that they might have access to services that would not otherwise be open to them, and based their decision more on their confidence in institutions sponsoring the research than on personal rights and autonomy. Dixon-Woods et al. suggest that participants exercise agency in ways other than those imagined by the biomedical model and argue that ethical research requires such agency to be respected. This is not to suggest, however, that decisions to participate are uninfluenced by consent procedures. Participants may see consent procedures as providing important signals of regard and of respect for autonomy and as providing evidence of good governance, which contribute to their confidence in the institution and trust in the researchers—their sense of security about the study. In the light of their analysis, Dixon-Woods et al. call for dialogue between social sciences, ethics and research communities to address the question of whether the current standard required for participation—that participants understand and accept the scientific account of research—is necessary or appropriate.

In their paper, Murphy and Dingwall (2007), explore the role of informed consent in the context of ethnographic research. They criticise the broad identification of research ethics with bureaucratic approaches to informed consent and with the biomedical paradigm of the randomised controlled trial (RCT). In so doing, they identify a number of ways in which ethnographic research differs from biomedical research and which make such bureaucratic procedures inappropriate. They are critical in particular of the application of 'anticipatory' consent to ethnographic research within which the methods, research questions and even the identification of the research participants will often be emergent and only manifested as the research progresses. Within this context, they argue that anticipatory forms of consent, which are often the paradigm for research ethics review, will simply not be up to the task of ensuring ethical research. For Murphy and Dingwall, consent in ethnographic research is inevitably a relational and sequential process, and cannot be established as a contractual agreement prior to research. Consent is based on trust, is renegotiated throughout the period of research and is a matter over which the hosts exercise on-going judgement. Power relations will in most cases be very different from those in biomedical research. Murphy and Dingwall also argue that the imposition of biomedical models of informed consent on ethnographic research is unethical and potentially detrimental to society because it may prevent researchers from undertaking research with the potential to make a significant contribution to health care. They call for an alternative approach to research ethics and the development of good ethical practice based on strengthening 'professional' models of regulation, education and training in ethics, mutual accountability and self-regulation, and a greater emphasis on personal integrity.

In the fourth paper, Harper (2007) draws upon his experience both as an anthropologist and as a doctor in Nepal, to consider the ethical review of anthropological research. Acknowledging that the rise of concern about ethics in anthropology has its origins both in the widening application of the medical model and in concerns within anthropology itself, Harper explores the ways in which anthropological research has influenced the debate on informed consent in clinical trials and how biomedical research has influenced the debate on ethics and informed consent in anthropology. He draws upon his own research experience on practices of public health and medicine in Nepal—on how public health initiatives were transformed during the process of implementation of a new programme for tuberculosis control—to explore the question of

what informed consent means at the boundaries of anthropology and public health. In so doing, Harper presents a complex picture of the ethical realities of anthropological research using examples of moral conflicts with which he has himself been confronted in his research involving difficult decisions about how to balance the ethical issue of the primary responsibility of acting in the interests of the research subjects (in his case health workers) and the consequences of his actions for the health of the population more generally (through altering access to life-saving drugs). Like Murphy and Dingwall, Harper suggests that the range of ethical issues arising in such research cannot be resolved through the use of anticipatory approaches to consent. In fact, Harper argues that routinised approaches to informed consent have the potential to deny moral agency to both the researcher and the researched, and thereby to rule out the possibility of potential solutions to ethical problems (a point also raised in Parker's paper (2007)). Acknowledging the importance of the wider international political context as it frames both medical interventions and the focus of medical research in poorer non-industrialised countries—and giving examples of how engaged community action or 'engaged consent' changed the parameters of international research outsourced to Nepal—Harper calls for a greater critical role for research populations in identifying research priorities. As part of his new multi-disciplinary research study in Nepal into the practices of the pharmaceutical industry, for example, the team have run initiation workshops for a range of stakeholders (including company representatives, government officials and donor agencies, NGOs and patient groups). More broadly, Harper endorses a systematic commitment to openness and disclosure as part of the process of commitment to the 'spirit' of informed consent without this being over-determined by the bureaucratic processes

In his paper, Parker (2007) situates the discussion of informed consent against the background of a broader theoretical and methodological debate about the relationship between ethics and method in ethnographic research and about the relationships between research methods and their objects. He does this by juxtaposing an analysis of discussion within anthropology about the ethics of ethnography—and in particular discussion of the role of anticipatory consent—and calls by social scientists for more empirically informed and richer approaches to bioethics. In both cases Parker argues

that it is not possible to separate ethics and method and goes on to call for approaches to ethical research which involve a more explicit and reflexive engagement with the enactment of ethics in research practice and those which take 'ethics' as their research object. On the other hand, like Harper, and Murphy and Dingwall, adopting a critical position in relation to the role of anticipatory consent, Parker goes on to problematise 'negotiational' approaches to informed consent preferred by many anthropologists, arguing that the concept of negotiation, rather than offering a solution to the problem of consent, is itself ethically complex and in need of analysis. What, for example, marks out the difference between negotiation and coercion in research in diverse settings? Parker argues that, in the context of ethnographic research, the possibility of negotiational forms of consent depends on engagement, between researchers and researched, with unavoidably 'ethical' concepts such as 're-spect', 'recognition', 'dignity', 'justice' and so on. Parker calls for the development of new ethico-ethnographic methods of research which take the enactment of ethics in research by researcher and researched as its object.

Rather than seeing informed consent as the primary ethical principle, in the sixth paper, Martin and Marker (2007), argue that it should be seen as just one of several ethical considerations which need to be taken into account in the process of ethical review. Against that background, their paper, which explores the role of consent in survey research, considers how the requirements of individual informed consent might be balanced against the ethical importance of the pursuit of research in the interests of the public. The paper begins by making the case for the need for good information (high-quality statistics) to inform good government and outlines what is required for a good social survey, contrasting this with what is required for a good randomised control trial (RCT). These contrasts include the fact that, while the main requirement of an RCT is that those who start the study go on to finish it—hence initial efforts to recruit only those with commitment to see it through—social survey research requires a representative sample and hence places a great deal of emphasis on initial efforts to recruit all those identified by scientific sampling methods. This means that while in RCTs any willing individual will do as long as they meet the selection criteria, for social surveys, only the individuals identified by the sampling procedures can form the

sample. This in turn requires recruitment methods to include persuasion, incentives and efforts to convert initial refusals into consents such as appeals to altruism and contribution to the common good. This suggests the possibility of ethical tension between voluntariness of participation on the one hand and the promotion of research in the public interest on the other. Furthermore, in general population surveys, the boundaries between recruitment and data collection are blurred as the identification and recruitment of a sample takes place in stages: since there is no list of all individuals in a country, addresses are used as the sampling frame and the individual participant selected only after contact has been made with the household. While survey research involves few risks to participants, it is important to remember that confidential information disclosed may have consequences for the individual, that questions may be stressful or embarrassing, and that tests may reveal results for which participants are not prepared. Martin and Marker's paper shows that survey research can present important ethical challenges to the primacy of informed consent in ethical research.

In her contribution, Alderson (2007), looks at a range of controversies around the treatment of children and their involvement in research. The paper reviews historical changes in the way children's competence to consent has been constructed and assessed and contrasts the position on health care treatment, in which treatment may be enforced on a resisting child if it is considered in the child's best interest, with that on health care research where children have higher status and researchers must seek their views and take seriously a child's refusal or resistance to take part. She criticises the presumption of incapacity in children in much medical research practice and argues that this means that children are thereby doubly disadvantaged as it is hard for them to challenge the strong views of relatively more powerful/confident adults and hence harder still to demonstrate competence. She goes on to consider the particular aspects of risk and uncertainties of medical treatment and research with children, arguing that there are sometimes extra risks in research with children; that children are more vulnerable than adults to being damaged in the short or long term by interventions; that they are often less able to question, resist or refuse researcher's proposals; and that they can be vulnerable to adult's decision-making and control. These issues are compounded for Alderson by the fact that

parents may be susceptible to the therapeutic misconception and may enter children into trials which are extremely gruelling, or see research for benefit of future families and children as a way of making meaningful their child's suffering. In therapeutic research, parents may find it difficult to refuse or withdraw their children from medical research for fear of harming the child. She also suggests that the significance of social risks may be underestimated in relation to children as it is difficult to assess the risk of intrusion, humiliation, embarrassment and misrepresentation when questioning children and difficult to assess the consequences of research reports which may further stigmatise disadvantaged groups such as children with mental health problems. Alderson goes on to provide examples of how overly rigid bureaucratic and universalistic definitions of competence can be challenged and more flexible, particularistic criteria adopted, making possible respectful and flexible consideration of the individual child's competencies and decision-making through negotiation. Much depends on the skills and abilities of professionals and researchers in supporting children and parents to make informed decisions: that is, their ability to understand relevant information, to explain issues and resolve misunderstandings, to assist children and parents in making reasoned decisions and to respect the decisions made by children and parents.

Finally, in his paper, Burgess (2007), provides an overview, from the perspective of an ethicist engaged in qualitative social science research, of many of the themes which run through this Special Issue. His central argument is that, while it is true that the institutional role of informed consent and the goal of voluntary and informed participation require greater flexibility in their application to social science research, there is no justification for abdicating either in principle: both have the potential to play modest but important roles in health and social research. Burgess argues that IRB review should be maintained but made more sensitive to social research and, while highlighting the limits of bureaucratic forms of consent (following Faden and Beauchamp, 1986), which can make social research impossible, he nevertheless emphasizes the importance of informed consent as a counterbalance to power and paternalism and as the basis of agreement to build respectful research relationships. Burgess argues that the problem with informed consent as currently interpreted, and the bureaucratic procedures which surround it, is that

they are increasingly expected to do all the work of protecting the interests and welfare of research participants and that this is more than they are either intended to do or capable of doing. He argues that good social and ethical research is needed "to build on the limited success of informed consent to design other institutional and cultural practices to protect and promote the notion of voluntary and knowledgeable participation. It is collaboration between ethics and social scientists that holds greatest promise." Such collaborative research is required to devise appropriate modifications of consent procedures which show respect for individuals in the context of the particular nature of social science studies. These approaches might include: dialogue with individual participants which responds to their individual understandings, values, priorities and concerns; participatory design where research is directed by the group and supported by the researcher; advance notice of observation through the likes of announcements, notices and posters; emails with those individuals identified as important as the study becomes informed of the details of the study and consent obtained at that time; and group-based permission.

Conclusions

The papers in this Special Issue address matters of practical as well as theoretical relevance to researchers in the health and medical field. Their analyses of the role of informed consent and formal ethics review in social science research will be of interest to a wide range of readers of *Social Science & Medicine*, including those who plan and conduct research, those who review and approve research proposals and those concerned with theoretical developments and debates about informed consent and research ethics generally. Taken together, the papers in this Special Issue critically examine the way researchers from a range of disciplines theorise the meaning and practice of informed consent in relation to social science research in the health and medical fields. Between them, they provide a rich and diverse analysis of the strengths and limitations of conventional approaches to informed consent and suggest possible new avenues for development which would be more appropriate to the social sciences. Importantly, these papers not only problematise the growing influence of research ethics as conceptualised in biomedicine across the range of social science methods but also reflect critically on

the growing critical reaction to such influence and to the proliferation of research ethics review.

The papers individually and collectively have the potential to enrich the debate in social science about research ethics and identify a number of key critical themes. Perhaps the most fundamental of these themes is the importance for any account of research ethics to take account of the *situatedness* of informed consent practices. The contributors all argue that the processes of informed consent are unavoidably socially constructed and embedded in social relationships, values, expectations and understandings which inevitably change as society changes (Miller & Boulton, 2007). Consent practices developed in the mid-20th century, for example, do not have same meaning in the early 21st century and do not perform the same 'work'. Similarly, consent practices developed for individualistic Western societies may be culturally inappropriate and incomprehensible in other societies (Harper, 2007). 'Understanding' as the basis of a knowledgeable decision cannot simply be 'transferred' from researcher to participants, but is produced in the interaction between them (Dixon-Woods et al., 2007), and explicit engagement with these process can lead to creation of more appropriate approaches to ethical research (Parker, 2007, Harper, 2007, Burgess, 2007). Contributors also question and reject the equation of informed consent with a particular set of bureaucratic procedures adopted within biomedicine, espousing instead a model of consent as relational, based on trust and continually negotiated throughout the course of a study (Miller & Boulton, 2007; Murphy and Dingwall, 2007). This is just as valid for large-scale social survey research as for small-scale qualitative studies (Martin & Marker, 2007). These studies point to the need to rethink what we expect of informed consent and what practices might be more appropriate for doing the work that has been expected of informed consent in the context of late modern, globalised and multi-cultural society (Burgess, 2007).

A second key theme arising in these papers is a critique of the *emphasis on informed consent above other ethical principles*. Many of the authors call for recognition of the need for the respect for rights of the individual to be 'balanced' against, or understood and analysed in the context of, other ethical concerns such as public interest and the responsibility of citizenship (Murphy and Dingwall, 2007, Martin and Maker, 2007). A key question presented

by this critique concerns the extent to which such recognition of, or engagement with, other principles warrants compromises around informed consent such as identifying and persuading (randomly) selected individuals to take part in a study rather than calling for volunteers (Martin & Marker, 2007), observing people covertly in public or semi-public places (Murphy and Dingwall, 2007) or carrying out research on patient records without consent.

A third key theme concerns the question of whether the *differences in the nature risks in biomedical and social research* warrant a more relaxed approach to informed consent or a different level and degree of scrutiny in social science research from that appropriate to biomedical research (Murphy and Dingwall, 2007; Martin & Marker, 2007). While this has been a position adopted by many social scientists in their critique of the application of models of research ethics review from biomedicine to social research, it is not an unproblematic position to hold. While the risks of physical harm may be lower in many, if not most, cases, it is important not to discount the psycho-social risks—e.g. intrusion, embarrassment, humiliation—of such research. Social scientists of medicine have long argued that the social consequences of illness and medical interventions are as important as the physical, and this is no less the case for the consequences of participating in research (Burgess, 2007). Estimating the psycho-social risks of research is also difficult and uncertain, particularly when research involves those embedded in a culture or occupying a social position different from that of the researchers, such as children (Alderson, 2007).

A fourth theme emerging from these contributions concerns the question of whether it is important, given the diversity of study designs in social research, to allow a *more flexible approach to recruitment and to ways of establishing a respectful relationship* with participants than is the case in biomedicine. This theme emerges most powerfully in the context of ethnographic research, but similar issues arise in relation to social surveys and other social research methods (Harper, 2007; Martin & Marker, 2007; Miller & Boulton, 2007; Murphy and Dingwall, 2007; Parker, 2007). In the context of qualitative research methods, many of the contributors reject the application of formalised processes of consent in favour of trusting relationships and mutuality (Murphy and Dingwall, 2007), in which consent is negotiated at each stage as a trusting relationship is formed and evolves. Like the other

critiques of research ethics review and informed consent, this theme and the associated call for a central role for trust and emergent models of consent is not unproblematic, particularly in the potential of asymmetries of trust in the context of complex power relations between researchers and researched. While consent procedures may have their limitations, they may serve as a useful function in some cases as signals of regard and evidence of good governance and contribute to confidence in the institution and trust in the researchers (Burgess, 2007; Dixon-Woods et al., 2007).

A fifth and related theme has been an argument that *the more equal, democratic and negotiated relationships in social science research reduce the need for legalistic protections for participants*. In research based on negotiation, mutuality and reciprocal responsibilities, a progressive deepening of trust over time also allows participants' control over the extent of their consent and the possibility of withdrawing co-operation at any time. This negotiated, trusting, mutual relationship, it is argued, provides its own protections for participants and negates the need for formal consent procedures which may even be counter-productive in raising anxieties and disrupting trust. Furthermore, bureaucratic and formulaic models of consent have the potential to undermine the creativity of social relations and the moral agency of researchers and researched (Murphy & Dingwall, 2007, Harper, 2007). Here too, many contributors, while supporting the general thrust of this argument, call for critical reflection on its implications. Burgess (2007) points out that researchers are not disinterested parties to research, and Alderson (2007) argues that in some cases children are in particular need of protection as they are less able to question, resist or refuse researcher's proposals and are more vulnerable to adult's decision-making and control. Social scientists must consider the effect of the 'authoritative context' in which they conduct research—the status of the institution confers legitimacy and authority, which shapes the research relationship (cf. Miller & Boulton, 2007; Dixon-Woods et al., 2007). Finally, while negotiation and developmental relationships between researchers and researched may give the appearance of solutions to the problem of ethics in research, the concept of 'negotiation' is itself ethically problematic, complex and in need of both empirical research and ethical analysis (Parker, 2007).

We began this introduction with the claim that informed consent and formal research ethics review

have increasingly become the sine qua non of ethical research in biomedicine and increasingly of research on human participants outside the sphere of biomedicine and adopting methods radically different from those in medicine. Like researchers in virtually all areas of research, whether on humans or not, social scientists have been progressively more concerned with the ethical dimensions of their practice and with the need to think critically about what it means to carry out ethical research and to be an ethical researcher. Most of these developments in social science towards a greater ethical sensitivity and awareness have arisen out of a combination of social scientists' own reflections on their practice, sometimes in the light of scandals such as the Yanomami Amazonian Indians affair (Borofsky, 2005), but more often from a concern to carry out high-quality ethical research. Some of these reflections have also been generated by critical reaction to the application of models of research ethics review and in particular of informed consent more appropriate to medicine. In this Special Issue, the contributors have engaged with the problem of what is to constitute ethical social science research and what kind of ethical review might be appropriate to its regulation, and have identified both a number of ways in which research ethics review might be developed and a number of key areas for further research and debate.

Acknowledgements

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