Chapter 2

Consent

Consent

Introduction

2.1 The importance of obtaining informed consent from individuals who take part in research has been widely recognised. Individuals giving consent must be informed of the potential risks and benefits of participating in research. If they take part, they must do so voluntarily. In the case of research involving minors or individuals without the mental capacity to consent, consent can be given by a person authorised to do so on their behalf. When externally sponsored research is conducted in developing countries, a range of additional issues may arise when consent is sought from potential participants. For example, in some communities it is customary for male members of the family to make decisions on behalf of wives and children. There will often be a tension between the duty of the researcher to be sensitive to cultural differences, and the duty to ensure that each individual has consented to participate in research.

2.2 The way in which information on the potential risks and benefits of research is provided is particularly important when participants are from developing countries. Those approached to participate may lack familiarity with basic practices of medical research, such as the use of clinical trials to test new treatments. Views about the causation of illness may differ from the 'western' medical model. Researchers must do their best to communicate information accurately and in an intelligible and appropriate way, taking account of local knowledge and beliefs. There are also questions about the type of documentation that is suitable for use in communities where many lack literacy. In such situations, it may be inappropriate to ask participants to sign consent forms. Witnessed verbal consent might be used instead.

2.3 Participants in research are likely to have a range of motivations for taking part. In developing countries some may agree to participate because they believe it may be their only means of receiving improved healthcare or other benefits. There is a potential conflict between the dual roles of healthcare practitioners who simultaneously provide healthcare and recruit research participants. The process of gaining informed consent must therefore be carefully designed.[1]

2.4 In the Workshop, four issues were considered:

- who should give consent?
- provision of information;
- recording consent; and
- inducements to take part in research.

Who should give consent?

Guidance

2.5 There is general consensus in the guidance that, in the majority of cases, informed consent must be obtained from potential research participants.[2] In addition to individual consent, some guidance (CIOMS 2002, EGE 2003 and NCOB 2002) also requires investigators to respect cultural traditions by consulting the community or 'senior family members' when

1 For further information about consent and the ethics of healthcare-related research see NCOB 2002, Chapter 6.

2 Exceptions to the general requirement for informed consent include epidemiological research activities that entail monitoring for public health by using, for example, surplus human tissue.

appropriate[3] (see Appendix A, Table 1). Such 'community consent' may be crucial in specific cases, although the guidance is unanimous that it must be in addition to, rather than instead of, properly informed individual consent.

Workshop discussion

2.6 During discussion, delegates reaffirmed that where community consent was sought, it should be in addition to genuine, voluntary consent by individuals (see Box 2.1).[4] Community consent could have several purposes. It could be used as a form of consultation with the community before individuals are approached, as a method of obtaining 'permission' from leaders, and as an additional means of providing information. Indeed, consultation with the community as a complementary activity was often likely to be crucial. Understanding the social and cultural context in which research was being conducted was essential, and involving the community demonstrated respect for local traditions. In addition, it was suggested that, on many occasions, informing and consulting with the community had been proved to be the most effective means of aiding understanding and helping to ensure that consent was genuine. (See paragraphs 2.9–2.16 for further discussion about the provision of information for informed consent.)

Box 2.1: **Genuine consent**

The concept of 'genuine consent' was introduced by the Council in 1995 in the Report *Human tissue: ethical and legal issues*. In this Report, the Council concluded that 'the ethically significant requirement is not that consent be complete, but that it be genuine' (paragraph 6.20). This concept was further discussed in NCOB 2002 (paragraphs 6.4–6.8). Since description can never be fully exhaustive, consent will always be an action that is incompletely described; moreover the descriptions given may often be incompletely understood. This incompleteness cannot be remedied by devising more elaborate consent forms. Fully informed consent is therefore an unattainable ideal. Obtaining genuine consent requires medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about procedures and risks, and to react to the limits of their understanding, and of their capacities to deal with difficult information. If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent. Ensuring that consent is genuine requires care in detecting and eliminating lack of consent. The apparent genuineness of consent can be defeated by a number of circumstances, including coercion, deception, manipulation, deliberate misdescription of what is proposed, lack of disclosure of material facts or conflicts of interest.

2.7 However, it was observed that in practice, obtaining consent was often not straightforward. Researchers had experienced a range of problems which could not be resolved by recourse to current guidance. One such example involved a clinical trial of anti-malarial treatment in Malawi (see Box 2.2). Treatment of patients with acute disease in a hospital-based trial had raised particular difficulties. The need for immediate treatment meant that there was often little opportunity to discuss research with potential participants and to give them adequate time for reflection before seeking consent. The patient or guardian might also be very distressed. It was suggested that in these circumstances, consent forms must be particularly clear and brief, and that it might be helpful to continue to provide information after emergency care had been initiated. It was suggested that provision of information before a trial started would enable the community to be involved, and allow potential participants to consider the issues in

3 CIOMS 2002, Commentary on Guideline 4; EGE 2003, paragraph 2.7; NCOB, paragraph 6.22.

4 See also NCOB 2002, p77 Box 6.4.

advance (see paragraph 2.14). However, it was often difficult to consult with the relevant community, which might include the entire catchment area of a hospital. This approach would involve contacting large numbers of villages in an area near a hospital, which would be impractical and require significant resources that were unlikely to be available.

Box 2.2: **Difficulties in obtaining consent in emergency situations – clinical trial of antimalarial treatment (case study contributed by Professor Malcolm Molyneux)**

In Malawian villages, many children die of malaria without even reaching hospital. This is due partly to a lack of sophisticated equipment to treat children who are unconscious or unable to drink, and partly to a lack of transport to take patients to a health facility where appropriate treatment could be provided.

A research study was designed to determine whether the use of artesunate suppositories could provide immediate initial treatment for children suspected to have severe malaria, before they were transported to a larger health facility. Artesunate suppositories could be easily stored and administered by unskilled people without sophisticated equipment.

An initial trial was conducted in Blantyre to test whether artesunate was adequately absorbed from the rectum in children with severe malaria. The study, which was conducted in a hospital, involved children admitted with 'moderately severe' malaria. Parental consent was sought for eligible children. Of those enrolled in the trial, four in five received rectal artesunate, and a small control group were given the standard intravenous therapy (quinine).

The process of obtaining consent was not straightforward. The consent form was very complex, with two full pages of text. Researchers found that it was unrealistic to aim to convey this amount of information to a mother with a semi-conscious child. In addition, treatment needed to begin promptly, which meant that the time for explanation, reflection and consultation was limited. Although consent was taken by a nurse in the patient's language, there was also a problem with translation and interpretation of terms such as 'randomisation' and 'drug absorption'.

See Barnes KI, Mwenechanya J, Tembo M, McIlleron H, Folb PI, Ribeiro I, Little F, Gomes M and Molyneux ME (2004) Efficacy of rectal artesunate compared with parenteral quinine in initial treatment of moderately severe malaria in African children and adults: a randomised study *Lancet* **363**:1598-605.

2.8 Other points that were made when considering who should give consent included:

- Particular safeguards may be needed when consent is requested for children (see Boxes 2.2 and 2.3), the mentally incapacitated, and those who are unconscious.
- Obtaining consent in large-scale emergency situations where rapid intervention is required may also be difficult. Examples included situations where research had been conducted on patients with acute disease in refugee camps or during major epidemics. Undertaking a trial of a medicine during a major epidemic of cerebrospinal meningitis was one such case.
- Community randomised trials may raise different issues. For example, in an evaluative study, a new treatment is sometimes made available in health centres in selected communities, and its effects are compared with those in communities not given access to the treatment. In such circumstances it would be important and appropriate to seek the consent of the communities to be included in such a study before decisions are made about which health centres should be included in the trial. While it is clearly appropriate to seek individual informed consent from those offered the new treatment in the communities in which it was introduced (those refusing would be offered the standard treatment), it is unclear whether individuals should be asked to give informed consent in

the communities in which the new treatment was not made available.

- CIOMS 2002 is the only guidance to explicitly allow for the possibility of waiving the process of obtaining consent, when the research carries no more than a minimal risk, and the procedures involved do not usually require signed consent forms.[5] Delegates considered that waiving of consent should only be considered in exceptional circumstances.

Box 2.3: **Consent for children – HIV vaccine trials (case study contributed by Ms Catherine Slack)**

HIV vaccine trials in South Africa (SA) currently involve adults who are able to give consent for participation. However, in some situations there is also a high risk of infection for children. Trials to provide data on safety, immunogenicity and efficacy of preventive HIV vaccines among children are therefore required and issues of consent for children to take part need to be addressed.

Current SA Medical Research Council (MRC) Guidelines allow parents to give consent for their children to participate in research classified as 'non-therapeutic' only where it is observational and of 'negligible' risk.* It is likely that early trials of HIV vaccines will be seen as non-therapeutic but unlikely that HIV vaccine research would fulfil criteria for observational research of negligible risk. Current MRC Guidelines therefore run the risk of excluding children from such trials.

New guidance has therefore been drafted in specific SA MRC Guidelines on HIV vaccine research.† This allows adults to consent to the participation of children in research provided that:

- the research could not be carried out with less vulnerable participants in the trial;
- the purpose is to obtain knowledge relevant to the health needs of children;
- the risks from procedures that do not hold out direct health-related benefit are comparable to those from routine medical or psychological tests;
- the risks from procedures that do hold out direct health-related benefit are justified by the benefit; and
- legal and ethical requirements for consent and assent are met.

* Medical Research Council of South Africa (2002) *Book 1 Guidelines on ethics for medical research: General principles* (SA MRC).

† Medical Research Council of South Africa *Book 5 Guidelines on ethics for medical research: HIV vaccine trials* (SA MRC).

Provision of information

Guidance

2.9 There is unanimous agreement in the guidance that each research participant must be adequately informed about the 'nature, significance, implications and risks' associated with a research trial[6] (Appendix A, Table 1). However, the guidelines vary in the degree of detail that they recommend should be provided to participants. CIOMS 2002 provides the most comprehensive advice. Guideline 5 lists 26 essential features of the research that must be

5 CIOMS 2002, Guideline 4.

6 WMA 2000, paragraph 22; CIOMS 2002, Guideline 4; CoE 2004, Article 14; EU 2001, Article 3, 2(d); EGE 2003, paragraph 2.7; and NCOB 2002, paragraph 6.22.

addressed during the consent process, including the design of the research (e.g. randomisation, double blinding); possible health risks for participants and treatment options; issues relating to data protection; and questions of liability in the case of disability or death resulting from injury related to the research (see also Box 2.4).

2.10 While the provisions of most guidelines focus on issues relating to recording consent, some explanatory notes emphasise the significance of the consent process itself.[7] They stress the importance of developing methods to help participants understand the implications of taking part in research (see Box 2.1).

Workshop discussion

2.11 Several delegates commented that consent forms often appeared to be designed to protect researchers and their sponsors rather than participants. The forms were frequently too long and complex, making them inaccessible to participants. Examples included a consent form for trials of a rotavirus vaccine in India which was nine pages in length. Although the form had been translated into the local language, its content was considered to be too technical for participants to understand. Many potential participants remained confused about both the purpose of the vaccine and the trial. In another example, a consent form for a trial of a meningococcal vaccine in northern Ghana was 14 pages in length. Despite protracted discussion with the sponsors, it had not proved possible to simplify the contents of the form for legal reasons.

2.12 Another problem can arise when consent forms developed for a specific project are adapted without adequate understanding of local knowledge, which may lead to misinterpretation. For example, it was reported that in Kenya a consent form designed in English and translated into the local language was found to have misinterpreted essential information when it was back-translated. Many languages will not have corresponding terms for words such as 'placebo' and particular care is needed if the research is to be explained successfully.

2.13 It was suggested that the essential information for a participant to understand should be identified when a consent form is being drafted. The challenge is to provide clear and concise information which informs the prospective participants without overwhelming or misleading them. Delegates concluded that it was unrealistic to fulfil the 26 requirements for consent set out in the CIOMS guidelines in the consent form itself. Instead, it would be more appropriate to provide a consent form of no more than one page, with essential information contained in a few accessible statements. Additional details could then be provided in an information sheet which would be given to participants to read, or have read to them, at home, before consent was sought. The information in the sheet could also be conveyed to participants in advance of the study through public meetings with the community or by using other methods of explanation, such as illustrations. Some information, relevant only to the ethical review of the study, might be included in the study protocol. A proposal, developed by delegates in the Breakout Groups (see programme, Appendix C) is given in Box 2.4.

7 CIOMS 2002, Commentary on Guideline 4; CoE 2004, Explanatory Report, paragraph 72.

Box 2.4: **Proposal for providing information to prospective research subjects prior to obtaining consent to participate in research**

The 26 CIOMS 2002 requirements for consent are divided below into three groups. They are: those for inclusion in the consent form; those for inclusion in the information sheet, and those for possible inclusion in the research protocol for submission to appropriate research ethics committees (numbers in brackets refer to the list of requirements in CIOMS 2002, Guideline 5 (1-26)).

Information in consent form	Information in additional information sheet	Information in research protocol
that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled; (2)	for controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken; (4)	that the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary; (1)
the purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care; (3)	whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount; (6)	whether the investigator is serving only as an investigator or as both investigator and the subject's physician; (21)
any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner; (9)	the expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it; (5)	the limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality; (15)
the provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified; (14)	that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status; (7)	
	that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure); (8)	
	any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in	

Continued

Box 2.4: *(Continued)*

Information in consent form	Information in additional information sheet	Information in research protocol
the possible research uses, direct or secondary, of the subject's medical records and of biological specimens taken in the course of clinical care, and details about their storage and possible future use if relevant; (18 and 19)	the research, including risks to the health or well-being of a subject's spouse or partner; (9) (see also *Information in Consent Form*)	
	the direct benefits, if any, expected to result to subjects from participating in the research; (10)	
	the expected benefits of the research to the community or to society at large, or contributions to scientific knowledge; (11)	
that treatment will be provided free of charge for specified types of research-related injury or for complications associated with the research, and details about the provision of such treatment; (23)	whether, when and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them; (12)	
	any currently available alternative interventions or courses of treatment; (13)	
If relevant: policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject; (16)	the sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research; (17)	
	whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products; (20)	
	the extent of the investigator's responsibility to provide medical services to the participant; (22)	
	in what way, and by what organization, the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation); (24)	

Continued

Box 2.4: *(Continued)*

Information in consent form	Information in additional information sheet	Information in research protocol
	whether or not, in the country in which the prospective subject is invited to participate in research, the right to compensation is legally guaranteed; (25) that an ethical review committee has approved or cleared the research protocol. (26)	

Summary

A consent form should contain the following information:

I consent to take part in … .

I understand that I am free to withdraw from the research at any time without penalty (2)

It has been explained to me that the purpose of the research is… (3)

And that the risks involved are…. (9)

I understand that the confidentiality of my records will be maintained by … (14)

It has been explained to me what will happen in the event of injury or complications (23)

I have had the opportunity to ask questions

If appropriate: The policy with regard to the use of genetic tests has been explained to me (16)

I understand that x, y and z will happen to any biological samples collected during the course of the research (18, 19, and 20).

2.14 Creative and cost-effective methods of communication may also be required. Communities could be made aware in advance, by using the press, radio and television, by making 'information packs' available, or by holding community seminars. Other examples cited included the use of dance troupes and school plays to convey information (see also Box 2.5). The process of informing participants should continue after enrolment, allowing time for further explanation, reflection and consultation. It might also be helpful for participants to have the opportunity to discuss the trial on more than one occasion, before making a decision on whether to take part.[8]

2.15 Community leaders and representatives, and individual participants, must be able to trust the process of consent. It was suggested that members of the community, rather than just the principal investigator, could also be involved in the process of obtaining consent. However, other delegates were concerned that this step might lead to community leaders having undue influence over recruitment. Delegates agreed that field workers and assistants needed to be trained so they could respond to questions about the research that may be posed by participants.

2.16 Methods to assess whether participants have properly understood the nature of the research

8 This option would not apply to trials of treatment for acute life-threatening illness.

Box 2.5: **Obtaining informed consent – Kenya AIDS Vaccine Initiative (KAVI) (case study contributed by Dr Job Bwayo)**

Trials to evaluate the safety and immunogenicity of a candidate HIV vaccine were held for the first time in Kenya in 2000. The recruitment rate was initially slow and so measures were put in place to improve awareness of the trials in the community. They included:

- Community representatives were given training to enable them to initiate discussions about the purpose, benefits and risks of the research.
- A range of informal community seminars were held. Scientists were invited to 'talk science' to the community in a language that was well understood.
- Interested individuals were invited to attend formal seminars at an evaluation unit, which included the opportunity to participate in question and answer sessions with the researchers.

Measures were also put in place to help ensure that those who were interested in participating had understood the nature of the research:

- Those who wanted to join the trial attended at least three one-to-one counselling sessions before being considered for entry.
- Before potential volunteers were entered into the trial, they took a test to assess their understanding. A minimum score of 80% was required before an individual could be invited to consent to participate.
- Eligible volunteers were given the option to proceed to enrolment or to withdraw their consent, either at this stage or at any other time during the research.

The involvement of the community improved the recruitment of volunteers and the rate of retention. It also enhanced community ownership of the process of vaccine development.

Wakasiaka S, Bwayo JJ, Ndinya JA, Jaoko WG, Omu A, Omosa G M, Ogutu HA and Nyange J (2004) Enhanced volunteer recruitment in HIV vaccine trials in Kenya *XV International AIDS Conference 11-16 July 2004 Bangkok, Thailand Conference* Abstract number: ThPeA6999. Available: http://www.iasociety.org/ejias/show.asp?abstract_id=2170240 Accessed on: 25 Feb 2005.

in which they are participating were also considered. It was suggested that a separate team, again appropriately trained, may be required to monitor consent. Monitoring should aim to assess the participants' general understanding of the implications of the trial rather than test their retention of information with a check list of facts. It was noted that monitoring would be a valuable addition to many trials conducted in developed countries, where participants may have an incomplete understanding of the implications of their participation.

Recording consent

Guidance

2.17 The guidance differs with respect to the acceptability of different methods of documenting consent to participate in research (Appendix A, Table 1). EGE 2003 does not indicate how consent should be recorded, while WMA 2000, CIOMS 2002, CoE 2004 and NCOB 2002 recommend that researchers should obtain written consent when appropriate. When written consent is not feasible, WMA 2000, CIOMS 2002, CoE 2004, EU 2001 and NCOB 2002 state that verbal consent is acceptable, provided that it is formally documented and witnessed.[9] EU 2001 specifies illiteracy as a necessary condition for permitting verbal consent.

9 WMA 2000, paragraph 22; CIOMS 2002, Commentary on Guideline 4; CoE 2004, Explanatory Report, paragraph 79; EU 2001, Article 3.2 d; NCOB 2002, paragraphs 6.37–6.40.

Workshop discussion

2.18 It was suggested that there is too much emphasis on 'written' consent in the guidance. For example, in Mexico, national regulations specify that 'valid informed consent' must be obtained before research begins and that the consent form must be signed by the participant and two witnesses.[10] Researchers have found that this requirement creates some difficulties. The presence of additional people during the consent process may cause discomfort for the participant and limit confidentiality. One of the witnesses will often be the study co-ordinator, but providing a second witness may be more difficult. Investigators will often ask participants to attend with a relative, who can act as a witness and support the participant during the research. However, when the accompanying relative is a man, he may be very influential and inhibit a woman from deciding for herself whether or not to participate. An additional complication is that some sponsors will not accept family members as witnesses.

2.19 There was general agreement that proper monitoring and documentation of the consent process was more important than whether or not a participant provided written consent. If consent is recorded with a tape recorder, it would be important to ensure that the tape was safely stored and would not deteriorate. Delegates agreed that in many situations, having the consent process witnessed would be more acceptable to participants than providing a signature. For example, in Malawi, trial participants were often concerned that signing may entail unforeseen obligations, such as tax liabilities or trouble with the police.

Inducements to take part in research

Guidance

2.20 CIOMS 2002 recommends that payments to research participants, either in money or in kind, 'should not be so large as to persuade them to take undue risks or volunteer against their better judgment'[11] (Appendix A, Table 1). NCOB 2002 comments that inducements to take part in research must be appropriate to the local context and, along with CoE 2004, recommends that they are considered by the local research ethics committee.[12]

Workshop discussion

2.21 Where healthcare facilities are lacking, participants may decide to take part in research in order to have access to better care. The availability of treatment during and after a trial might also count as an inducement. Delegates emphasised that while researchers should aim to ensure that participants are not placed in a worse position by participating in research, a decision to participate must be made voluntarily. Care should be taken to ensure that any payment did not become an inappropriate inducement to accept risks that would not otherwise be considered acceptable. It was suggested that guidance should be clearer on the question of payments, including when they should be made and which costs should be covered. The point at which inducements become excessive was not always clear. In many developing countries, $5 for loss of earnings or for travel costs could be a substantial incentive for individuals to participate. Delegates suggested that, where possible, improvements to healthcare were more appropriate inducements than financial payments (see Box 2.6).

10 Ley General de Salud (General Law of Health) (Articles 100 and 103) *Rules for research in human beings*.

11 CIOMS 2002, Commentary on Guidelines 3 and 7.

12 NCOB 2002, paragraph 6.32; CoE 2004, Articles 11 and 12 and Appendix xvi.

Box 2.6: **Inducements – the International HapMap project (case study contributed by Professor Charles Rotimi)**

An international project, HapMap, was established in 2002 to create a haplotype map of the human genome. The project will describe the common patterns of human DNA sequence variation and may be used to identify genes linked to susceptibilities to disease. Researchers from Canada, China, Japan, Nigeria, the UK and US expect to complete the map by 2005. Participants are asked to donate blood samples so that their DNA can be studied.

Participants in the International HapMap project in Nigeria were each given an equivalent of approximately US $8.00 and multivitamins worth about US $4.00 to compensate them for their time and travel. This amount was comparable to the sum given for the donation of blood (for use in the blood transfusion service) in the same region. Prospective donors were only told that they would be compensated after they had arrived to donate blood. This approach was adopted to guard against the possibility that they would be induced to participate by the prospect of material benefit. However, they might have learned of the payment by word-of-mouth.

One community requested assistance to establish a hospital in return for their contribution to the HapMap project. This request raised concerns that community leaders would place undue pressure on people to participate in the research because of the promise of a new hospital. Even if a hospital was provided for the community, it might not be sustainable in the long term. An alternative healthcare benefit for the local community was therefore under consideration.

See The International HapMap Consortium (2003) The International HapMap Project *Nature* **426**: 789–96; The International HapMap Consortium (2004) Integrating ethics and science in the International HapMap Project *Nature Reviews Genetics* **5**: 467–75.

Summary of discussion on consent

2.22 Several themes emerged during the Workshop. These were:

- The primary purpose of the consent process should be to inform and protect the participant and ensure that he or she understands the reasons for the research and the consequences of taking part.
- This may mean adapting the guidance to fit the local context and will certainly require simple consent forms, supplemented by more detailed information for participants, using appropriate language and explanations.
- It will often be necessary to seek innovative ways of providing information to participants and the process may need to be continued after consent has been given.
- Proper monitoring and documentation of the process is more important than whether the participant provides written consent.
- The trust of the participants in the process is crucial.

2.23 Additional points that are not currently addressed by most guidance included:

- There was some debate as to whether health services and operational research[13] were adequately covered in the guidance. It was suggested that both individual and

[13] Health services and operational research are concerned with the study of methods of delivery of healthcare, access to treatment and quality of care, with the aim of finding improved methods that lead to better care. Such studies often include an evaluation of the cost of providing the intervention and the benefit it provides.

community consent should be sought for this type of research. However, this approach is not currently followed in practice and may be difficult to organise.

- Difficult consent issues had arisen when research was conducted primarily for the benefit of the community rather than for individual participants. For example, a trial might be conducted to find out which treatment would be most appropriately supplied through the local health authority, rather than whether one is better than another.
- Particular difficulties had been experienced when obtaining consent from patients with acute disease in hospitals or in emergency situations.
- The guidance tended to be biased towards clinical trials and did not address issues raised in other areas of research such as genetics.