

## Guidance Note 2: The Ethics of Research Related to Healthcare in Developing Countries

Extract from the Nuffield Council on Bioethics website – [www.nuffieldbioethics.org](http://www.nuffieldbioethics.org)

### Introduction

Respect for persons is a fundamental moral duty. In research relating to healthcare, this duty requires that we do not act against a person's wishes. His or her consent to participate in research must thus be obtained. The duty upon those conducting research ordinarily to obtain consent is widely recognised in national and international guidance and in legislation (see Box 6.1). **(1)** The three elements of consent reflected in ethics, national legislation and human rights law are that it must be informed, given voluntarily, and given by a person competent **(2)** to do so. In this chapter we will focus on two elements of consent which are particularly relevant to externally-sponsored research conducted in developing countries: the provision of information to participants in research; and the requirement that consent to research be given voluntarily. Appropriate means of documenting consent to take part in research will then be considered.

When externally-sponsored research is conducted in developing countries, a range of issues arise in seeking consent to take part in research. With regard to informing potential participants, concepts that are common in research, such as the idea of randomisation, or of using placebos, may be unfamiliar to the culture in which the research is being conducted. As regards the voluntariness of consent, in some communities it is common for a spouse or senior member of a family to assent to healthcare (and by extension, to research) on behalf of a woman or adult children. In addition, access to better healthcare and other benefits, which may accrue from taking part in research may act as powerful inducements, casting doubt on the true voluntariness of a participant's consent.

In research, in addition to their responsibilities to individual participants, researchers are seeking to conduct scientifically sound research that will provide generalised information that can improve healthcare. When medical care is combined with research, researchers may make different choices about clinical measures than they would if the participants' best interests were their only concern. For example, during research, healthcare workers may administer placebos or take blood samples for tests that will not benefit participants directly, in order to obtain information. The potential conflict between the dual roles of healthcare providers in such circumstances means that the process for obtaining consent to research must be rigorous and that participants must be made aware of the dual purpose of research before being asked to consent to it. Conversely, when research does not contain any therapeutic component, this fact must also be made clear to prospective participants.

#### Footnotes

1 US Regulations make provision for waiver of consent under four conditions: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation (45 CFR 46.116d). The UK Medical Research Council 1998 guidance entitled 'Guidelines for Good Clinical Practice in Clinical Trials' paragraph 2.9 states that 'freely given informed consent should be obtained from every participant prior to clinical trial participation' though this does acknowledge that situations may exist where this is not possible (e.g. emergency settings) and in such cases, procedures agreed in existing guidelines should be followed provided favourable opinion has been given by the appropriate independent ethics committee. The UNESCO's Universal Declaration states that 'limitations to the principle of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights' (Article 9).

2 A person is considered to be competent if they are able to understand information about the proposed research.

## Recording consent

As regards consent to research, many of the concerns raised by respondents to our public consultation and by those who attended our fact-finding meetings related to the process by which consent was recorded. A common observation was that consent forms often seemed to be designed to protect sponsors of research, pharmaceutical companies and researchers, rather than to provide prospective participants with appropriate information. The most common criticisms were that information and consent forms were too long and contained language that was inappropriate at best, or confusing and misleading at worst (see Box 6.6).

### Box 6.6 Consent forms: criticisms from researchers

The mechanisms of obtaining informed consent in developed countries evolved in communities that are literate and generally aware of modern health practices. Researchers can therefore engage the potential subjects on the basis of pre-existing scientific knowledge and concepts. To use the forms that were designed in such circumstances to obtain informed consent in a non-literate community that operates on different concepts of health and disease, would be an exercise in self deception.' (1)

'Insistence by regulatory authorities on the use of complex consent forms devised for use in litigious Western societies is inappropriate.' (2)

'Consent forms can be too long. Patients don't understand them. It is quality not quantity that is important ...' (3)

'When most of a population was illiterate, participants were very cautious, they [didn't] know what they were signing or whether it could be used against them. Many researchers therefore considered verbal consent to be very important but did not require written consent.' (4)

1 Response by Professor Adetokunbo Lucas to the Working Party's consultation.

2 Response by Professor Brian Greenwood to the Working Party's consultation.

3 Comment made during Working Party's Fact-finding meeting, Chennai, India 21 January 2001.

4 Comment made during Working Party's Fact-finding meeting, Madison Hotel, Washington, USA, 23 March 2001.

As we have made clear, it is the substance of the process for obtaining consent which is important, rather than the procedures used to record or document the process. Wherever research is being conducted, an appropriate and transparent procedure for obtaining genuine consent is required. A written consent form is merely evidence of what was agreed. If a prospective participant in research is given a consent form to sign, without there being an appropriate process for receiving information and then giving consent, a genuine consent to participate in research will not have been given, irrespective of whether or not a form has been signed.

The purpose of a consent form is to record what has been agreed between the researcher and participant. Consequently, a consent form will not protect participants in research from possible harm, except to the extent that it discloses information which may lead to a prospective participant choosing whether to take part in the research and run a certain risk. Likewise, a consent form is neither an appropriate nor effective medium for seeking to limit legal liability for any possible harmful consequences of research. Questions about liability for harm arising from participation in research should be agreed by the parties involved in designing, sponsoring and conducting the research before the research begins (these questions will be governed by law in some jurisdictions). Participants in research in developing countries will need to be made aware of who will be responsible for looking after them should they suffer any harm as a result of research participation, and, unless informed, may be less likely than participants in developed countries to realise that they have avenues of redress.

Participant Information Sheets which are long, complex and inappropriate for the cultural context in which they are being used, are likely to confuse, rather than inform, participants in research, and should not be approved by ethics research committees. Some ethics research committees, such as, for example, the committee in The Gambia prefer that all consent forms be no more than one page in length, and that appropriate language be used. Information sheets, which can be taken home and read, shared, translated and re-read, may be longer but still need to be written clearly.

## Situations where consent forms are inappropriate

There are circumstances in which, while genuine consent to research can be obtained, it may be inappropriate to ask participants in research to sign consent forms, no matter how well designed. One obvious example is when research is being conducted in an illiterate population and it is not consistent with the duty of respect for persons to require a prospective participants to 'sign' a written consent form that they are unable to read. However, in such populations participants may find it useful to take written information sheets away with them for discussion with literate family members or colleagues, and for future reference.

Some forms of guidance explicitly recognise that written guidance will not be appropriate in all circumstances and set out appropriate safeguards. For example, the Declaration of Helsinki (2000) (paragraph 22) states that where written consent cannot be obtained, verbal consent must be fully documented and witnessed. **The Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa** (2000) in referring to vulnerable communities state that where a person is illiterate "verbal consent ... should be obtained in the presence of and countersigned by a literate witness" (paragraph 3.5).

In other societies, literate participants may fear that signing forms may link them to particular organisations and leave them open to retribution from repressive regimes.

The 'Guidelines for the Conduct of Health Research involving Human Subjects in Uganda' note that a research participant's wish not to execute a written informed consent form should be honoured but the investigator must obtain oral informed consent and document such. NBAC (2001) recognises that this rejection stems from Uganda's past experience of torture and persecution of individuals found to be associated with particular enterprises and that individuals may consequently be reluctant to sign a form which associates them with certain activities.

In some cultures, participants' only experience of signing forms may be in relation to tax documents or court proceedings. Thus, signing a consent form is likely to have negative connotations, making otherwise willing participants less likely to take part. In one research trial examining the consequences of domestic violence, it was considered inappropriate to ask female participants to sign a consent form before enrolling them in the research because of their concerns that signing a form would mean that a record of victims of domestic violence would be kept and this might lead to them suffering more harm.

If requesting that participants sign consent forms is inappropriate, other means of recording their genuine consent to participation in research is required to protect them from being enrolled in research that they have not consented to. In many circumstances, the research worker who is informing the participant will sign a form stating that the appropriate information was given and verbal consent received. An alternative is to record consent on audio-tape. As an additional safeguard, it is desirable for an independent witness to observe the verbal consent. In some circumstances it may be more appropriate to have an independent witness to observe the process of providing information to the community and individuals, rather than observing the verbal consent to participate in research (see Box 6.7).

### **Box 6.7 Witnessing verbal consent**

Some forms of large-scale research in developing countries, such as research into vaccines, may involve many thousands of participants. In such circumstances information may be provided in a number of ways, including by television, radio and articles in newspapers. In addition, regional, local and community meetings may be held to discuss the research. If participants wish to take part in research, they will then attend one of a number of sites where the vaccine is to be administered. In such circumstances, where there is a limit to the resources and appropriately trained staff available, it may be more appropriate for the provision of information to be witnessed, rather than to attempt to provide witnesses at the field sites to confirm that each individual who attends wishes to participate in the research.