Consent

What constitutes consent?

In general, the same principles apply to consent in research and clinical practice although different forms of consent apply in different situations. However, consent should always be:

- **Freely given.**
- **Fully informed** (see below for an outline of the information that should be supplied for consent to be deemed 'informed').

The General Medical Council's guidance to doctors emphasises the role of informed consent within a doctor-patient relationship based on trust. Any potential conflicts of interest must declared before consent can be deemed to have been fully informed. The WMA's (World Medical Association) Declaration of Helsinki highlights the need for sensitivity when seeking consent from potential human research subjects, stating that particular care is needed:

> '*if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship*'[1].

The consent-obtaining procedure must therefore be centred on the person from whom consent is requested, in the sense that it must be a primary objective to find out what they want. This will sometimes places their interests in opposition to the person who is seeking consent, a consideration which is of particular importance within research where the researcher needs to find people willing to participate as research subjects in order to proceed with their programme of investigation. The person seeking consent must therefore be aware of their own behaviour, to ensure that they provide:

- A clear explanation of the scope of consent being sought.
- A honest answer to all questions.

The person from whom consent is sought must be provided with sufficient information to make an informed choice. Information must be offered in an accessible form, for example, by avoiding the use of technical terms. Written information should use short words, sentences and paragraphs. Verbal communication skills will be important for face-to-face interviews, particularly when answering questions. Inter-personal skills will be also be relevant, to ensure that the person from whom consent is sought feels comfortable about asking questions, and does not feel pressured.

Consent should be written where possible. If written consent cannot be obtained, non-written consent must be formally documented and witnessed[2].

[1] http://www.wma.net/e/policy/b3.htm.

[2] http://www.wma.net/e/policy/b3.htm.

What information is needed for informed consent?

For research on human beings the information given should include the following where appropriate:

- Research aims.
- Research methods.
- Sources of funding.
- Possible conflicts of interest.
- Institutional affiliations of the researcher.
- Anticipated benefits of the study.
- Publication and dissemination of results.
- Potential risks of the study. This should include potential risks to the foetus for women who are pregnant or who might become pregnant during the research programme.
- Any discomfort that might be entailed.
- Potential impact on eligibility for life insurance or private medical insurance as a result of the study (including information that might be obtained as part of the study such as identification of a genetic predisposition for a given medical condition).
- Right to abstain from participation.
- Right to withdraw consent to participate at any time.
- Complaint handling procedures.
- Information about the use of placebos; if placebos will be given to some subjects, what chance does each subject have of getting the study drug/treatment.
- Short description of the drug or device under test and the stage of development.
- Where drugs are administered state the dosage of the drug and method of administration.

Within the UK, the Governance arrangements for NHS Research Ethics Committees (GAfREC) section 9.17[3] defines the informed consent process for submissions to Research Ethics Committees (RECs). Applications for approval from a REC must include:

a. *a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent, the time-frame in which it will occur, and the process for ensuring consent has not been withdrawn.*

b. *the adequacy, completeness and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representatives.*

c. *clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.*

d. *assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being).*

[3] http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf.

e. *the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.*

Consent to proceed with a course of medical treatment.

A key principle underlying the notion of informed consent is respect for patient autonomy; it is for the patient, not the doctor, to determine what is in the patient's own best interests.

When requesting consent to treatment, information necessary for decision-making should only be withheld where disclosure would cause the patient serious harm. In this context serious harm does not mean the patient would become upset, or decide to refuse consent. However, there are cultural factors that should be born in mind. For example in some countries it is traditionally the patient's family members who are informed of the diagnosis, prognosis, and treatment plan, and who then make the decision about what information should be given to the patient. Legal obligations will limit the extent to which UK consent procedures can accommodate alternative approaches, but the procedure should be sensitive to cultural differences as far as possible.

Information needed to obtain informed consent might include the following:

- Details of the diagnosis.
- Any uncertainties about the diagnosis including options for further investigation prior to treatment.
- Details of the course of treatment for which consent is sought, including:
    - The purpose of a proposed investigation or treatment.
    - Advice about whether a proposed treatment is experimental.
    - How and when the patient's condition and any side effects will be monitored or re-assessed.
    - The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team.
    - Whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment.
    - A reminder that patients can change their minds about a decision at any time.
    - A reminder that patients have a right to seek a second opinion.
    - Where applicable, details of costs or charges which the patient may have to meet.
- Prognosis with the course of treatment for which consent is sought, including an explanation of:
    - Likely benefits.
    - Probabilities of success.
    - Serious or frequently occurring risks.
    - Lifestyle changes which may be caused by, or necessitated by, the treatment. This might include such things as:
        - The need for long-term care.

        - Mobility
        - Capacity to drive a car.
        - Fitness for employment
        - Impact on personal/sexual relationships.
        - Capacity to engage in sport/exercise.
        - Changes to diet.
        - Will the patient be able to drink alcohol?
        - Can the patient continue to take their regular medication?
        - Should the patient refrain from giving blood?
        - What happens if the patient becomes pregnant?
- Other options for treatment or management of the condition, including the option not to treat.
- Prognosis with these other options, including the option not to treat, including details of:
    - Likely benefits
    - Probabilities of success
    - Serious or frequently occurring risks.
    - Lifestyle changes which may be caused by, or necessitated by, the treatment. This might include such things as:
        - The need long- term care.
        - Mobility
        - Capacity to drive a car.
        - Fitness for employment
        - Impact on personal/ sexual relationships.
        - Capacity to engage in sport/exercise.
        - Changes to diet.
        - Will the patient be able to drink alcohol?
        - Can the patient continue to take their regular medication?
        - Should the patient refrain from giving blood?
        - What happens if the patient becomes pregnant?
- Details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief.
- How the patient should prepare for the procedure.

- Details of what the patient might experience during or after the procedure including common and serious side effects.
- If the patient is unable to work, or will be rendered unfit for work as a result of treatment, details of when they might expect to return to employment.

Patients may also ask for details of the success rates regarding the options presented to them, expressed in terms of nationwide performance, performance for a specific unit, or performance of the individual doctor/healthcare worker/researcher.

Procedure for people who cannot give consent

The WMA (World Medical Association)'s Declaration of Helsinki[4] states that people who are legally incompetent (whether minors or adults) or physically or mentally incapable of giving consent should not be used in research at all unless the following conditions are met:

- The research is necessary to promote the health of the population represented.
- This research cannot instead be performed on legally competent persons.

If these conditions are met then the researcher must obtain consent from their legally authorised representative in accordance with applicable law. Consent from this legally authorised representative must meet all the normal conditions for informed consent. It should be noted that not all legally incompetent subjects are deemed incapable of giving assent:

> *'If a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative'*[5].

Sources of Information

The UK Clinical Ethics Network provides information and support to both developing and existing clinical ethics committees within the health service. It has a very useful online resource on consent.
See: http://www.ethics-network.org.uk/Ethics/econsent.htm.

The Department of Health (DOH) has web pages which cover the issue of consent in detail with sections devoted to clinicians, adults, children & young people, people with learning disabilities, parents, and relatives & carers. A range of downloadable forms is also provided. See:
http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/fs/en.

The **British Medical Association** (**BMA**)publishes the Report of the consent working party (March 2001)
(http://www.bma.org.uk/ap.nsf/Content/Reportoftheconsentworkingparty) plus an accompanying tool kit (http://www.bma.org.uk/ap.nsf/Content/consenttk2) designed to help doctors work through the practical problems, ethical dilemmas and legal pitfalls of gaining patient consent. They also publish *The older person - consent and care* (1995) and *Consent, rights & choices in health care for children & young people*, available from their

[4] http://www.wma.net/e/policy/b3.htm.
[5] *Ibid.*

bookshop (extracts from the latter can be viewed via their web pages (http://www.bmjpg.com/consent/)). Their book on *Assessment of mental capacity* (1995) has a section devoted to capacity to consent to and to refuse medical treatment which is available online at http://www.bma.org.uk/ap.nsf/Content/Capacity+to+consent+to+and+refuse+medical+treatment.

The **General Medical Council** (GMC) provides detailed guidance on the ethical considerations relating to seeking patients' consent (http://www.gmc-uk.org/standards/default.htm).

British Medical Journal: The BMJ's Collected Resources includes an 'Informed Consent' category. See http://bmj.bmjjournals.com/cgi/collection/informed_consent.

GAfREC (Governance arrangements for NHS Research Ethics Committees) provides guidance on the information required in relation to informed consent for human research subjects. See: http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf.

COREC (Central Office for Research Ethics Committees): Provides a sample Patient Information Sheet and Consent form downloadable from: http://www.corec.org.uk/wordDocs/pis.doc.

CERES (http://www.ceres.org.uk/) is an independent charity set up 1989 to promote informed debate about research and help users of health services to develop and publicise their views on health research and on new treatments. It produces a number of downloadable documents on good practice, covering general guidance and specific topics such as:

- Involving people who speak little to no English
- Writing information for people asked to take part in health research.

The Science & Development Network aims to enhance the provision of reliable and authoritative information on science- and technology-related issues that impact on the economic and social development of developing countries. It has a webpage on informed consent. See: http://www.scidev.net/dossiers/index.cfm?fuseaction=specifictopics&dossier=5&topic=9&CFID=1154067&CFTOKEN=57257435.

AIMS (Association for Improvements in Maternity Services) (http://www.aims.org.uk/. Produces a Charter for Ethical Research in Maternity Care, co-written by AIMS and the National Childbirth Trust, which sets out professional guidelines to help women make informed choices about participating in medical research.

Involve, formerly Consumers in NHS Research, (http://www.invo.org.uk/) believes that members of the public should be involved at all stages of the R&D process, including deciding what research should take place; commissioning and undertaking research; and disseminating the findings. Involve provides a range of downloadable documents on involving the public in research.

Alliance for Human Research Protection: (http://www.ahrp.org/) is a US oriented network of lay people and professionals dedicated to advancing responsible and ethical medical research practices. It is currently running a campaign for Informed Consent, with useful information on their views regarding what is required before informed consent can be given. Parental consent for research involving children is given separate consideration.

The **University of Minnesota** has an online guide to the informed consent process, including a tool to assist in the creation of a consent document: http://www.research.umn.edu/consent/orientation.html.