

CARD 10

Research

1 Is separate consent required for research procedures?

Yes. Doctors must take care to ensure that patients asked to consider taking part in research are given the fullest possible information presented in terms and a form that they can understand. Patients must be aware that they are being asked to participate in a research project and that the results are not predictable. Adequate time must be given for reflection prior to the patient giving consent. Where patients do not wish to receive full information about the research, this may affect the doctor's decision to involve them. (See also Card 1 list: 'Research', 'Consent', 'DoH', 'MET', 'MDU', 'MPS', 'GCP'.)

The storage and use of identifiable human tissue removed from living individuals and the storage and use of identifiable and anonymised human tissue removed after death for research requires consent from the donor, a person with parental responsibility, a 'qualifying relative' or 'nearest relative'. Consent should be documented. Consent is not required for the storage and use of material from living individuals for research where the material has been anonymised, such that the person carrying out the research does not know the identity of the donor, and the research has been approved by a research ethics committee unless this is a requirement of the research ethics committee. (See also Card 1 list: 'HTL').

2 What information should be provided?

Information should preferably be provided in writing and should include: the purpose of the research; the probability of random allocation to treatment; information about trial-related procedures, particularly invasive procedures; arrangements for covering expenses of patients and compensation in the event of trial-related injury. Information should also be provided about confidentiality and the possibility of access to confidential notes by third parties such as regulatory authorities, auditors or ethics committees. Patients must also be aware that they can withdraw at any time without penalty. All written information should be approved in advance by a research ethics committee. (See also Card 1 list: 'GCP'.)

3 Is there a relevant distinction between 'therapeutic' and 'non therapeutic' research?

Research is often divided into two categories of 'therapeutic' and 'non-therapeutic' although this distinction is increasingly challenged. All research that involves particularly vulnerable people (such as children or incompetent adults) must have special safeguards. Whether or not the participant is likely to benefit personally (so-called 'therapeutic research') is one of a number of relevant factors for research ethics committees to consider.

4 Can patients who lack capacity participate in research?

In England, Wales and Scotland it is lawful under the relevant mental capacity legislation to involve adults who lack capacity in research provided it is related to the condition from which they are suffering. The research must be approved by a research ethics committee and it must not be possible to conduct the research involving individuals who retain capacity to consent. Where the research is 'therapeutic' the risks must not be excessive in relation to the anticipated benefits. Where the research is 'non-therapeutic' the risk to the individual must be negligible and any intrusion kept to a minimum.

In Northern Ireland, such research is not covered by statute but it is the generally accepted view that it is lawful under the common law provided it is 'therapeutic' in nature. Advice should, however, be sought from the appropriate research ethics committee. (See also Card 1 list: 'Capacity', 'Scotland', 'MCA'.)

5 Can research take place in an emergency situation where the patient is unable to give consent?

Yes, if the research has approval by a research ethics committee. In December 2006, an amendment to the UK's Medicines for Human Use (Clinical Trials) Regulations 2004 came into force to allow unconscious patients to be enrolled in clinical trials of pharmaceutical products without prior consent in emergency situations.

6 Can a competent minor give consent to participate in 'therapeutic' research?

Current guidance emphasises that, even where the minor is competent to make this decision for him or herself, it would be inadvisable to proceed without the approval of someone with parental responsibility. Researchers should seek the views of the appropriate research ethics committee. (See also Card 1 list: '0-18 years', 'Children', 'Capacity'.)

7 Can children who lack capacity to consent participate in 'non-therapeutic' research?

There is general agreement that participation by immature minors in 'non-therapeutic' research is not necessarily unethical provided that: the research carries no more than minimal risk; it does not entail any suffering for the child; parental agreement is obtained; there is approval from an appropriate research ethics committee; and the child does not appear to object. Nonetheless, researchers should be aware that the law is unclear and therefore legal advice should be sought. (See also Card 1 list: '0-18 years', 'Children', 'Capacity'.)