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Indemnity insurance

It is important that all nurses (and other health professionals) have insurance cover for their practice, including research activities. RCN membership includes this indemnity insurance cover. Members should contact RCN Direct on 0845 772 6100 if they have queries or visit www.rcn.org.uk/faqs
Informed consent in health and social care research

RCN guidance for nurses

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Introduction

The purpose of research is to gain knowledge and understanding through original investigation.

(Higher Education Funding Council for England, 2005, p.23)

Nurses are taking an increasingly active role in research in order to develop new knowledge and to create a larger evidence base to inform their practice. This involves them in developing protocols, leading investigations and collaborating with colleagues from other disciplines and institutions.

When they are engaged in research involving human participants, nurses have a responsibility to ensure that the interests of those participants, whether patients or healthy volunteers, are protected. This applies to all research, even when the study is not specifically related to nursing practice, such as trials of new medicines or treatments.

Gaining informed consent from research participants, where this is possible, is a vital part of the research process. When you are involved as a nurse in any research activity, you need to understand the concept and importance of informed consent and how it is gained.

The Royal College of Nursing (RCN) Research Society has developed this guidance for nurses involved in research at any level. It discusses:

- the concept of informed consent
- informed consent in special circumstances
- the ethical and legal framework
- responsibilities in obtaining informed consent
- the participant’s perspective
- the process of gaining informed consent
- working with vulnerable groups
- human tissue samples.

A bibliography of useful reading on the subject of informed consent, further sources consulted in developing this document, and other sources of relevant information are available on the RCN Research Society’s website www.man.ac.uk/rcn/informedconsent

Another RCN document, Research ethics: RCN guidance for nurses (2004), discusses the ethical principles underpinning research in general.
What is informed consent?

Informed consent is an ongoing agreement by a person to receive treatment, undergo procedures or participate in research, after risks, benefits and alternatives have been adequately explained to them.

This section discusses the concept of informed consent and the information potential participants need to receive and understand in order to give informed consent.

Freely given informed consent is central to research involving human participants or the use of human tissues or genetic material. This is because it is essential to ensure that those who participate in research understand exactly what the research involves for them. This applies equally whether they are patients or healthy volunteers. Informed consent helps to ensure that people are not deceived or coerced into participating in research.

In order to give truly informed consent, potential participants need to understand the following:

- the purpose of the research
- the practicalities and procedures involved in participating
- the benefits and risks of participation and, if appropriate, the alternative therapies
- how data about them will be managed and used
- the consent form
- their role if they agree to participate in the research
- how information will be provided to them throughout the study
- that their participation is voluntary
- that they can withdraw from the study at any time, without giving any reason and without compromising their future treatment
- the insurance indemnity arrangements for the conduct of the research where appropriate
- that the research has been approved by a research ethics committee.

They should also be given the following information:

- contact details, should they have further questions or wish to withdraw
- details of the research sponsor and research funding body.

Continued consent

Informed consent is an ongoing requirement, so researchers must ensure that participants:

- continue to understand the information above and any changes in that information
- continue to consent to participate throughout the study.
Informed consent in special circumstances

The principles of informed consent and the process of acquiring it are the same for all potential participants, except in special circumstances. Sometimes it is not possible to obtain participants’ consent before research activity begins. This should not prevent important research from being undertaken, but researchers must take great care to protect the interests of participants and to consult other appropriate people about an individual’s participation. This section discusses informed consent in special circumstances where usual practices may be difficult to apply.

Delayed consent

Delayed consent usually occurs in emergency situations, when obtaining informed consent might make the study impossible. For example, it may be needed for research undertaken:

- at the roadside in the event of an accident
- at a cardiac arrest
- during the early stages of a patient’s emergency admission to an accident and emergency department,

The Mental Capacity Act 2005, to be implemented in 2007, states that urgent or emergency research can be undertaken if ‘it is not reasonably practical’ to meet the requirements for informed consent from a potential participant who lacks the capacity to consent for themselves. The research team will be expected to demonstrate to an ethics committee that this research is necessary and could not have been undertaken in a population where participants were able to provide informed consent in advance. In each instance, the research team should seek informed consent as soon as possible from the participant.

Implied consent

A straightforward example of when a participant implies their consent is when they return a completed anonymous questionnaire. In other situations, potential participants with severe disabilities or multiple injuries may be unable to communicate their consent verbally or in writing. In these cases, researchers can gain implied consent, in which a person indicates consent by their actions after they have received information about the study. In such circumstances a protocol should require that a witness is present who also signs the consent form. A researcher or a witness can infer that a patient has given implied consent when each of these criteria are met:

- the patient can reasonably be expected to be aware of the sharing of their data and to understand the need for it to be shared
- the benefits to the patient or the public outweigh the risks to the patient
- the patient is offered a clear procedure for withholding consent, but does not do so.

Best interests

In England, Northern Ireland and Wales currently (before The Mental Capacity Act 2005 is implemented in 2007), nobody can legally give consent for another adult for treatment or for participation in a research study (Department of Health, 2001). If a person is unable to consent, treatment can be given without their consent providing the intervention is considered in the ‘best interests’ of the individual. The individual’s own wishes and values should be taken into account if known – for example, through an advance statement/directive.

In Scotland, the Adults with Incapacity Act 2000 permits another person to provide informed consent on behalf of an incapacitated adult for treatment or for participation in a research study. In 2007 when The Mental Capacity Act 2005 has been implemented, this will also be the case in England and Wales.
**Consent by proxy**

In cases where potential participants are unable to consent for themselves, it has been common practice for another appropriate person to be asked to give ‘proxy consent’, however, as noted, this has no legal standing outside Scotland. Traditionally, researchers have relied on proxy consent when the potential research subject is deemed not to be legally competent. This can apply to a number of groups including:

- children
- people with dementia or other cognitive impairment
- people with learning disabilities
- people with mental illnesses.

In these situations, researchers must assess a potential participant’s level of competence to make decisions, and assure themselves that it is appropriate to obtain proxy consent and not directly from the participant. Researchers will also be required to demonstrate this to their research ethics committee.

A family member, next of kin or carer most often provides proxy consent. It is sometimes given by a professional carer such as a nursing or medical professional who is not involved in the research study. A recognised advocate can also give consent.

Researchers must ensure that the individual providing consent is able to give informed proxy consent. This means they must be given and understand all the information which would normally be given to potential participants themselves. Researchers should consider whether the person giving proxy consent is acting in the best interests of the potential participant and, where appropriate, does so with due regard either to the participant’s last known wishes or to their lifelong value system.
The ethical and legal framework

Informed consent is bound by ethical and legal frameworks, and the processes for gaining it must be independently scrutinised and approved. This section discusses the ethical and legal requirements regarding informed consent, and the bodies responsible for ensuring that the processes for gaining consent are adequate.

The ethical framework

Informed consent is at the heart of ethical research, and the national research governance frameworks state that researchers must make appropriate arrangements to obtain informed consent from their participants (DH, 2005).

The core ethical principle in research is respect for every individual (RCN, 2004). Researchers must therefore respect diversity when gaining informed consent (DH, 2001 & 2005; Scottish Executive Health Department, 2001; Wales Office of Research and Development, 2001; DHSSPSNI, 2002). Researchers must take into account factors such as:

- ethnicity
- gender
- disability
- religious beliefs
- culture
- language
- level of understanding.

Since researchers cannot know how any or all of these factors might affect a potential participant, they must be sensitive when going through the process of gaining consent.

The legal framework

Gaining informed consent in research which involves invasive procedures is considered to be a legal requirement. If a research activity proceeds without an individual's informed consent legal action could be taken against the chief investigator or researcher for battery.

Case law on consent in the UK has established three requirements to be satisfied before a potential research participant can give informed consent:

- the consent should be given by someone with the mental ability to do so
- sufficient information should be given to and understood by the participant
- the consent must be freely given.

The first principle of data protection (Data Protection Act, 1998) is that information must be used fairly and lawfully. It is legally established that personal information should not be used for research without the explicit consent of the individual. This means they must have been asked specifically for their permission to disclose the information, been given an explanation of how the information will be used, and have given their permission in writing for the information to be used. The exception to this rule occurs in situations which are deemed by the State to be in the interest of patients and the wider public good.
Independent scrutiny

All research proposals should be subject to independent scrutiny to ensure they are ethically acceptable. The application for ethical approval will include details of the proposed processes for gaining informed consent. Research teams may seek ethical approval from a number of relevant bodies, including:

✦ university and NHS research ethics committees – many institutions have their own committees to consider the ethical implications of research proposals

✦ local research ethics committee (LREC) – research involving human participants requires approval from an LREC, normally established by the ‘health authority’ in the area where the research will be undertaken

✦ multi-centre research ethics committees (MREC) – if research is to be undertaken in more than one site, researchers need ethical approval from a MREC. In most instances, site-specific approval will also be required in each research location

✦ Gene Therapy Advisory Committee (GTAC) – all proposals to conduct gene therapy research must be approved by the GTAC as well as from an LREC or MREC.
Individual responsibilities

This section examines the responsibilities of different practitioners and groups in the process of seeking informed consent.

Nurses

Even when you are not leading research studies, as a nurse you may often be involved in delivering the intervention concerned. The NMC code of professional conduct states that you are accountable for your own practice (NMC, 2004). Whatever the level of your involvement, you must be satisfied that participants have given informed consent to take part in the research study before you act.

Lead researcher

Overall responsibility for all elements of research activity, including gaining informed consent, rests with the lead researcher, although each individual member of the research team is responsible for their own specific actions. If you are the lead researcher you may delegate the task of obtaining informed consent to another appropriately qualified member of the research team, but this delegation must be clearly documented, and the person gaining informed consent must sign the consent form when required. To sign a consent form when you have not personally been involved is fraudulent.

Sponsors and funding bodies

The sponsor and funding body of a research study are often the same entity (such as a pharmaceutical company). However, they have slightly different roles:

- the funding body provides financial support through contracts with the researchers and/or their institutions
- the sponsor has primary responsibility for ensuring that the design, conduct and reporting of the study meet appropriate standards.

Both will have a view on how informed consent is gained. For example, some protocols specify the qualifications of the person required to obtain consent.

Research participants

Potential participants should understand that if they agree to take part in research they have a duty to the researchers. In giving informed consent they are agreeing to comply with the requirements of the research. If at any time they are unable or unwilling to do this they should consider withdrawing from the research. It is important to emphasise that withdrawal from a clinical study will not compromise the quality of care they receive, although their treatment may change. For example, if the study is examining a new treatment, they may go back to receiving standard treatment.
The participant’s perspective

Deciding whether or not to take part in a research project involves considering a number of factors including personal and financial costs. Some research projects provide travel expenses to attend appointments, child care costs and remuneration for time off work. This section examines how the benefits involved, or health professionals’ views, may influence an individual’s decision to participate in research.

Benefits

Participating in research can have a number of perceived benefits for patients including:

- access to experimental treatments that might give better outcomes than standard treatments
- closer monitoring
- increased access to members of the multidisciplinary team
- extra investigations
- the satisfaction of benefiting future patients.

These incentives may be available to both patients and healthy volunteers. However, volunteers may also receive payment for participating.

Potential participants should be informed of the possible benefits of taking part. However, researchers must take care that these benefits, particularly the financial ones, do not lead individuals to be persuaded to participate in research for the wrong reasons. If the proposed study is a randomised controlled trial, it should be made clear that potential participants might not receive the experimental treatment or an intervention but may receive standard care or a placebo.

Professionals’ views

When discussing a research study with potential participants, it is important that you as a researcher do not allow your personal views to influence whether or not an individual consents to take part. You must give them adequate information and then allow them to decide for themselves.

You should answer any questions potential participants may have, or ask a colleague to do so if you do not know the answer. If the patient wants someone to help them make their decision, recommend they discuss it with a relative or friend – or a health care professional who is not involved in the research – as they may be better able to give an objective view. However, you should emphasise that ultimately, potential participants should only consent to participate if they are certain that they wish to.
The process of gaining informed consent

This section looks at factors you need to consider when going through the process of gaining informed consent.

The discussion

It is important to make potential participants as comfortable as possible about discussing the research, so that they are able to concentrate and feel confident to ask questions. You should plan ahead to meet in relaxed surroundings, where there will be no interruptions, and to allow the potential participant to have a relative or close friend present if they wish to do so. While giving the information you can ensure they are able to give informed consent by:

- repeating, explaining and reinforcing information
- asking questions to check their understanding of the information.

You should also think about the timing of the discussion. For example, patients who may have just been given news of a life-threatening illness are unlikely to be able to make an informed decision about participating in a research project when still struggling to come to terms with their situation.

Acknowledging diversity

It is important to acknowledge diversity when gaining informed consent, including factors such as a potential participant's ethnicity, gender, sexuality, disability, religious or cultural beliefs and language. You cannot be expected to know how these might affect individuals, and should not make assumptions based on stereotypes. Asking questions can help you to understand what might influence potential participants, so that you can deal with these issues sensitively.

Reinforcing the discussion

It is not enough to give potential participants a verbal explanation of the research project and what their involvement would entail. You should also give them further information, such as a written information sheet to take away, to help them to make their decision. Researchers may also be able to direct potential research participants to other sources of information, including books and websites. You may need to prepare materials in various formats, depending on the particular needs of the potential participants (see section eight on Vulnerable People). For example, information for people with a visual impairment should be written in large, clear print. Alternatives to written information can include audiotape, videotape and pictures as an aid for discussion on the proposed research. Materials used should explain the main points of the research to remind potential participants of your discussion, and act as a point of reference when they discuss participation with their family and others.

The consent form

The signing of a form has become standard practice in confirming that an individual has freely given their informed consent to participate in a research study. However, while a signed consent form provides good evidence that a discussion has taken place, it does not prove that consent is truly informed.

Potential participants should not be asked to sign the consent form until they have been given full information about the study and have had time to consider their decision. When you ask for their decision, you must explain verbally all aspects of the study again and check their understanding. In certain circumstances, a protocol may require that a witness is present who also signs the consent form, for example where a potential participant can neither read nor write.
This section discusses the special needs of individuals and groups who may be considered vulnerable and the factors to take into account when gaining informed consent for their participation in research.

“Every recipient of health care is in some way vulnerable, but those with more limited ability to act autonomously can also be more vulnerable to the impact of research activity”

( RCN, 2004)

Assessing potential participants’ capacity to give their informed consent autonomously is an essential part of the informed consent process.

Recognising special needs

People can have a range of special needs that you need to take into account, and these are not always obvious, or may be concealed by some people. For example, someone with reading or writing difficulties may conceal this because they are embarrassed (‘I’ve forgotten my glasses, I’ll read it later’). Others may have visual or hearing impairments, illness or emotional difficulties. It is vital to explore your potential participant’s abilities sensitively.

Where the researcher and the potential participants do not speak the same language or their command of the same language is not good enough to enable effective communication, written information should be translated into the first language of the participant. To be sure that the participant freely gives consent on the basis of proper understanding, a professional interpreter (rather than family members or friends) should be available for your discussions with them.

Older people are more likely to suffer from sensory deficits, so you should check they are able to read written information and hear verbal information.

The ability to process information can slow with age, so older people should be given plenty of time and opportunity to ask questions and think about whether to participate.

Capacity to decide

People can only give consent if they are capable of choosing between alternative courses of action. This means they must be able to understand the information given by researchers.

Including participants who have impaired capacity to decide in a study is more acceptable where research is necessary to promote the health of that particular group, and cannot be performed on legally competent people instead (for example, in testing drug dosages for children or interventions for Alzheimer’s disease). Researchers must be particularly sensitive to participants’ needs and vulnerabilities.

Children and young people

Children and their parents or guardians should be involved in the research consent process in proportion to the child or young person’s competence to weigh the risks and benefits. Children may need extra time to process information. If the child’s parent or guardian is giving consent, the child must also indicate that they do not object to the research activity. Children can give consent to participate in research themselves provided they are ‘Gillick competent’. This means they are able to understand the nature and consequences of their participation in the research. Gaining a child’s views and desires can require you to use of creative ways of providing information and alternative means for them to express their thoughts.

Young people aged 16 years and older are generally capable of giving their own consent, while many who are under 16 are also able to give informed consent, or be involved in the decision making process. You will need to assess the individual child’s capacity, depending on their maturity and understanding.
Children are not allowed to receive monetary rewards for participation in research, although you can give non-monetary gifts such as toys, providing their value is not excessive. Any inducements to participation offered should benefit the child, not the parents (although items like travel costs are allowed).

The Nursing and Midwifery Council (2002) states that: ‘if the child is under 16 in England and Wales, 12 in Scotland and 17 in Northern Ireland, you must be aware of legislation and local protocols relating to consent’. This is set out in the Children Act 1989 and in section 2(4) of the Age of Legal Capacity (Scotland) Act 1991.

Long-term care residents

Older people and others living in long-term care facilities may find it more difficult to refuse to participate in a research study if approached by staff involved in their day-to-day care, because they don’t want to disappoint their carers. If your research involves such a population, you must take particular care that potential participants do not feel pressured or coerced into taking part.

People with learning disabilities

People with a learning disability must be given the same respect as anyone else and be protected from harm if they take part in research. Some may not be able to exercise fully their right to self-determination but they should be offered choices within their capabilities. These potential participants can choose or refuse to participate.

Take care in evaluating each individual’s comprehension; use plain language, supported if necessary by other material such as pictures. If a potential participant cannot reasonably understand the nature of research, your emphasis should be less on information and more on evidence that they consent to participate, and on weighing up potential risks and benefits. You may need to involve a range of people who understand the individual’s situation and can act in their best interests.

Unresponsive patients

Unresponsive patients, as a result of injuries or sedation, can only be included in research for very specific reasons. For individuals recruited to pharmaceutical research, The Medicines for Human Use (Clinical Trials) Regulations 2004, enacted as a result of the EU Directive 2001/20/EC, allows for written informed consent to be obtained from a legal representative. The principles in the regulations state:

- informed consent given by a legal representative for an incapacitated adult in a clinical trial should represent that adult’s presumed will
- the clinical trial should be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the cognitive abilities of the patient
- the risk threshold and the degree of distress should be specially defined and constantly monitored
- the interests of the patient always prevail over those of science and society.

When a potential research participant is being recruited to research (other than that covered by The Medicines for Human Use (Clinical Trials) Regulations 2004), The Mental Capacity Act 2005 and Scotland’s Adults with Incapacity Act 2000 permit another person to provide informed consent on behalf of an incapacitated adult if the following criteria are met:

- the research should be about the participant’s condition or their treatment
- it should not be possible to undertake the research with individuals able to consent for themselves
- the possible benefits to the individual should not be disproportionate to the expected burden
- informed consent should be gained from a person who is involved in the care of the individual, usually a family member, and who is able to reflect on what that individual might have decided to do.
If the patient regains consciousness, you must seek informed consent as soon as is practical. If the individual refuses consent, all documentation and data relating them to the study should be destroyed. However, in the case of a clinical therapeutic trial, all documentation must be retained for audit purposes, but it should not be used as part of the research.

*The Mental Capacity Act 2005* also describes the actions researchers must take if a participant who was deemed competent to consent loses that competence during the course of the research. Under such circumstances, the participant can remain in the research as long as:

- approval was previously given for the research to continue if this competence should be lost
- the researcher continues to protect the participant’s rights
- the participant does not appear to object to their ongoing involvement in the research.

**Prisoners**

Prisoners should not be used as research participants unless there is a valid reason — for example, if the study is looking at conditions associated with violent and criminal behaviour. As well as the usual approval procedures, approval must be sought from the head of health care at the appropriate statutory bodies, and prisoners’ participation is subject to their informed consent.

**Armed forces**

Research carried out on members of the armed forces is subject to the Official Secrets Act, causing problems with confidentiality, honesty and publishing results. The forces rarely give consent for studies on their personnel, unless it relates to issues specific to them. However, if research is undertaken on forces personnel, the principles of informed consent apply.

**Health care staff**

Health care staff are sometimes asked to become research participants. Their knowledge may be no greater than other participants, so they must receive the same detailed information. They must also be given encouragement to ask questions, as they may be reluctant to display gaps in their knowledge. You should not assume that because they understand the need for research, they are any more predisposed to participate than other people.
Human tissue samples

Not all research involves living participants. In some cases it involves studying tissue samples from living or deceased donors. The principles of informed consent apply equally in these situations. The Human Tissue Act 2004, which will come into force in 2006, states that when the person concerned is living, informed consent should be obtained in the normal way. When post-mortem tissues are to be collected, informed consent must be gained from the individual before their death, or from a relative. This section examines issues relating to tissue samples, organs and post mortem examinations.

Tissue sampling

The same general principles of informed consent apply to tissue sampling for research from living patients. But where tissue sampling is included as part of another procedure, a patient may request that samples are not used for research purposes. If using separate consent forms for each procedure, the researcher and the participant will both need to be sure about what they are consenting to.

Genetics

Informed consent for genetics research is complicated by the sensitivity of the subject matter and the social context in which it is undertaken. Nurses involved in acquiring informed consent for genetics research need to ensure that participants are fully aware of the potential implications of genetic information, in particular that:

- data gathered from family history and/or from genetic tests for a particular inherited condition may also reveal information about other genetic conditions that may not be the subject of the research enquiry
- genetic information has the potential to predict the likelihood of illness at some stage in the future.

Before seeking consent from potential participants for this type of research, the research team must have discussed and decided how to handle these issues if they arise.

Unlike other forms of research, the potential for harm to participants and to others is significant primarily with regard to the use of and access to information gathered about participants (Chadwick, 2001). Therefore, when you are seeking informed consent for genetics research, it is important to pay particular attention to confidentiality and privacy issues. It is also important that you retain contact details so that you can contact participants should this become necessary.

Consent to post mortem

Hospitals and trusts have procedures for gaining consent from relatives to perform a post mortem where it is not a legal requirement. A bereavement officer may help in this process. Again, the process of obtaining consent should involve giving clear, written and verbal information about what is involved and about the research study. If you are seeking permission to store tissue samples or organs, you must also clearly explain this. People should be given time to ask questions and consider the options.
Conclusion

As a professional nurse, you are accountable for your practice and should always act in the best interest of your patients/clients. The key principle in obtaining informed consent in research is to put the potential participant’s needs first. To participate effectively in informed consent processes, you should have the knowledge, expertise and capability to give sufficient information and be able to answer any questions raised by a potential research participant. If you are open and honest, and ensure the participant understands all they need to about the study, you will gain truly informed consent.
References


Department of Health Social Services and Public Safety (2002) Research governance framework for health and social care, Belfast: DHSSPSNI.


Websites

Central Office for Research Ethics Committees (COREC)
www.corec.org.uk

Consumers for Ethics in Research (CERES)
www.ceres.org.uk

Data Protection Act (1998)

Gene Therapy Advisory Committee
www.advisorybodies.doh.gov.uk/genetics/gtac/

Guidance Notes, Section 60 of the Health and Social Care Act 2001
www.dh.gov.uk/assetRoot/04/06/63/84/04066384.pdf

Human Tissue Act 2004

Medical Research Council standardised consent form
www.mrc.ac.uk/pdf-tissue_guide_fin.pdf

Nursing and Midwifery Council (NMC)
www.nmc-uk.org

Royal College of Nursing Research Society
www.man.ac.uk/rcn/rs

Royal College of Nursing
www.rcn.org.uk

A bibliography listing additional sources consulted in the preparation of this booklet and useful websites is available online at:
www.man.ac.uk/rcn/informedconsent
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