Royal College of Nursing

Informed consent in health and social care research

RCN guidance for nurses

Second edition

Date for review: January 2015

Royal College of Nursing

An introductory note on indemnity and insurance cover

It is important that all nurses (and other health professionals) have either indemnity or insurance cover for their practice, which will include their research activities.

If you are a health professional working under a contract of employment, then your employing organisation is liable for your actions as an employee and will have appropriate indemnity or insurance arrangements in place. In the NHS, for example, all staff will be covered by the NHS Indemnity arrangement.

RCN indemnity cover is also available for RCN members involved in the consent process for research purposes.

Members should be aware of their indemnity or insurance arrangements and, if they have any queries, should speak to their employer or contact RCN Direct on 0345 772 6100.

Acknowledgements

The RCN Research Society would like to thank all those who contributed to the preparation of the first and second editions of this guidance document.

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Published by the Royal College of Nursing, 20 Cavendish Square, London, W1G 0RN

Informed consent in health and social care research

RCN guidance for nurses

Contents

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Introduction

Research is:

"The attempt to produce generalisable new knowledge by addressing clearly defined questions with rigorous and systematic methods."

(Gerrish and Lacey, 2010)

Nurses are taking an increasingly active role in research, developing new knowledge and creating a stronger evidence base to inform their practice. This can involve working, leading and collaborating in all stages of the research process.

When engaged in research involving human participants, nurses have a responsibility to ensure that the interests of participants, whether patients or healthy volunteers, are protected. This applies to all research – including studies not specifically related to nursing, such as clinical trials of investigational medicinal products (CTIMPs) or other clinical trials.

Gaining informed consent from research participants, whenever possible, is central to the research process. It is therefore important that nurses understand the principles associated with informed consent and the process of obtaining informed consent before they embark on, or become involved in, any research activity.

The Royal College of Nursing (RCN) Research Society has developed this guidance for nurses involved in research, regardless of what form that may take or where that research takes place. This document provides an overview of:

- the concept of informed consent for research
- the ethical and legal framework
- informed consent in special circumstances
- the responsibilities of those involved in undertaking research
- the process of gaining informed consent
- the participant's perspective
- obtaining informed consent from vulnerable groups.

A bibliography of useful reading on the subject of informed consent, together with a list of the sources consulted in the development of this guidance and other useful sources of relevant information, can be found at the end of this document.

This second edition of RCN guidance on informed consent incorporates a number of amendments and additions that reflect significant changes in both UK law and ethical review processes. Another RCN document – *Research ethics: RCN guidance for nurses* (RCN, 2009) – considers the ethical principles underpinning research in general, and should be read alongside this document.

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What is informed consent?

Informed consent is:

"The process of agreeing to take part in a study based on access to all relevant and easily digestible information about what participation means, in particular, in terms of harms and benefits."

(Parahoo, 2006)

In this section we discuss 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. It is essential that those who participate in research understand exactly what the research involves for them, and freely agree to participate in it; this applies equally whether they are patients or healthy volunteers.

Obtaining informed consent helps to ensure that people are not deceived or coerced into participating in research. When potential participants may lack the capacity to understand information or make a decision, great care should be taken in obtaining meaningful informed consent.

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

- the purpose of the research
- how long their participation will last
- who is involved in the research
- the practicalities and procedures involved in participating
- the possible benefits and risks of participation and, when appropriate, the alternative therapies
- how data about them will be managed and used
- how long and where the data will be stored
- the purpose of the consent form
- what is expected of them if they agree to participate in the research
- how information will be provided to them throughout the research
- 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.

Participants should also be given the following information:

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

In addition, a participant information sheet should be prepared which:

- invites the reader to participate in the research
- uses language appropriate to the potential participant group, avoiding the use of technical language
- includes diagrams, pictures, tables and flowcharts if these contribute to explaining the research.

It is also important to remember that written information is only one way to share information with potential participants. There may be circumstances when video, podcasts, recordings or other means of sharing information might be more appropriate.

Ongoing consent as a process

Informed consent is an ongoing process and consequently researchers must ensure that participants:

- continue to understand what the research is about and what their participation involves
- are provided with any new information which might influence their decision to continue their participation in the research
- continue to consent to participate throughout the research.

Revisiting informed consent is often done informally, but on occasion it might be appropriate to formally reconsent research participants. For example, during longitudinal research projects it might be wise to ask

informally if participants are happy to continue their participation before commencing research activities.

Reconsenting is also appropriate if there is a significant change to a research project, or if there is new information which might alter an individual's willing to participate in a research project. In these scenarios it would usually be expected that a new information sheet is provided and informed consent is revisited in a more formal manner.

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The ethical and legal framework

"The aim [of the Mental Capacity Act 2005] is to balance the importance of properly conducted research into the treatment or care of people who lack capacity with the need to protect their interests and respect their current and previously expressed wishes and feelings."

(Piffaretti, 2007)

Informed consent is bound by ethical and legal frameworks, and the processes for obtaining it must be independently scrutinised and approved. In this section we take a look at the ethical and legal requirements regarding informed consent, and the bodies responsible for ensuring the processes for gaining consent are adequate and appropriate.

The ethical framework

Freely given informed consent is at the heart of ethical research, and the national and international governance frameworks – including the World Health Organisation's *Declaration of Helsinki* – state that researchers must make appropriate arrangements to obtain informed consent from research participants.

The key ethical principle relating to informed consent in research is the belief that everyone should be treated with respect (RCN, 2009). Researchers must respect diversity when gaining informed consent and 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 informed consent.

Once an individual has made a decision relating to participation in a research project, the researcher must respect that autonomous decision – even if they disagree with it. This respect for autonomous and informed decision-making also requires that potential participants are never coerced into participating in research. It is important to remember that all research participants are potentially vulnerable to such coercion, by virtue of the very nature of their relationship with the researcher.

The legal framework

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

UK case law on consent has established three requirements that need to be satisfied before a potential research participant can give informed consent:

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

If any of these requirements is lacking then the consent is invalidated.

In recent years it has become increasingly important for researchers to consider the law when planning their research and the manner in which they will seek to obtain informed consent. Researchers should consider the following when considering issues related to informed consent:

- Mental Capacity Act (2005)
- Adults with Incapacity (Scotland) Act (2000)
- EU Clinical Trials Directive 2004/20/EC
- Medicines for Human Use (Clinical Trials) Regulations (2004)
- Data Protection Act (1998)
- Human Tissue Act (2004).

You can find detailed information on these items and their application to research ethics and informed consent on the National Research Ethics Service (NRES) website at www.nres.nhs.uk

Independent scrutiny

All research should be subject to independent scrutiny to ensure it is ethically acceptable; this includes consideration of the proposed processes for gaining informed consent.

Researchers must gain approval from the relevant research ethics committee before beginning their research. Depending on the nature of the research, this ethical approval should be sought and obtained from one of the following sources:

- NHS/NRES research ethics committee
- university or faculty research ethics committee
- other independent research ethics committee (for example, a local authority social care research ethics committee).

The research ethics committee (REC) will want to be reassured that **all** participants freely give informed consent, and will therefore scrutinise carefully the participant information sheet and the proposed process relating to obtaining informed consent.

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Informed consent in special circumstances

"Failure to include any patient group in research could be described as discrimination because its members will not benefit from the potential advances in knowledge and understanding of their condition."

(Gelling, 2004)

The principles and processes for obtaining informed consent are the same for all potential research participants, except in a small number of special circumstances. Sometimes it is not possible to obtain a participant's informed 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 the individual's participation. This section briefly 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) 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 NHS REC that this research is necessary, and could not have been undertaken in a population able to provide informed consent in advance of any research activities. In each instance, the research team should seek informed consent as soon as possible from the participant or seek the opinion of a consultee.

The *Mental Capacity Act* (2005) is relevant only to research involving adults aged 16 years or older, applies only in England and Wales, and is not relevant to CTIMPs; the *Adults with Incapacity (Scotland) Act* (2000) and the *Age of Legal Capacity (Scotland) Act* (1991) apply in Scotland. While there are no equivalent statutes in Northern Ireland, similar common law principles relating to capacity and consent apply.

Implied informed consent

Implied consent may arise when express written and/or verbal consent is not given; for example, when a participant implies their informed consent by returning a completed anonymised questionnaire. In these circumstances the REC will want to be reassured that there is no way that the researcher will be able to identify the participant from their responses.

Consent by proxy

Before the enactment of the *Mental Capacity Act* (2005) and the *Adults with Incapacity (Scotland) Act* (2000) there was a lack of clarity around the inclusion of those unable to give their own informed consent to participate in research, and the term 'proxy consent' was used to describe the process of seeking consent/assent from a family member or other person to include another individual in research. The law has now been clarified on this issue, and it would be unusual to use the term 'proxy consent' in a research situation.

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Individual responsibilities

"Informed consent is at the heart of ethical research."

(Department of Health, 2005)

In this section we examine the responsibilities of practitioners and groups involved in the process of obtaining informed consent.

Nurses

Even when they are not leading research studies, nurses are often involved in delivering the intervention or investigation concerned. The Nursing and Midwifery Council's code states that nurses should:

> **"...make the care of people your first concern, treating them as individuals and respecting their dignity."**
>
> *(Nursing and Midwifery Council, 2008)*

Every nurse is accountable for their own practice, so every nurse must be satisfied that participants have given informed consent to take part in a research study before being involved in any research activities.

Furthermore, nurses and other health care professionals need to consider their professional responsibilities alongside their responsibilities as a researcher.

Lead researcher

While each individual member of the research team is responsible for their own specific actions, overall responsibility for all elements of research activity – including gaining informed consent – rests with the lead researcher who is sometimes described as the chief or principal investigator.

The lead researcher may delegate the task of obtaining informed consent to another appropriately qualified and trained 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. While entirely irrelevant to the consenting process itself, signing a consent form when you have not been personally involved is poor professional practice (in other words, the signature carries no weight in the assessment of whether the patient did lawfully consent to the proposed intervention).

Sponsors and funding bodies

It is not unusual for the sponsor and funding body of a research study to be the same entity (such as a pharmaceutical company). However, both 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. The sponsor is responsible for ensuring that the individual obtaining informed consent is trained to do so.

Research participants

Potential participants should understand that, if they consent to take part in research, there is an expectation that they will comply with the requirements of the research as detailed in the participant information sheet and consent form. If the participant does not do what is expected of them, this can have implications for the quality of the research.

If at any time they are unable or unwilling to do this, the participant should consider withdrawing from the research. It is important to emphasise that withdrawal from a clinical study will not compromise the quality of care an individual receives, although this treatment may change. For example, if the study relates to examining a new treatment, the individual may go back to receiving a standard treatment.

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The process of gaining informed consent

"A fundamental principle underlying ethical practice is 'informed consent'."

(Dobson, 2008)

In this section we review the factors to be considered when going through the process of obtaining 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 enough to ask questions. A location should be used where there are unlikely to be any interruptions, and the potential participant should be encouraged to have a relative or close friend present if this makes them feel more comfortable.

When giving information about the research, it is important to ensure potential participants are in a position to give informed consent by:

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

It is also important to 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 while struggling to come to terms with their situation. Many of these issues will need to be considered when preparing the initial application for ethical approval.

Acknowledging diversity

It is important to acknowledge diversity, alongside all other factors listed in section 3 of this document, when gaining informed consent. Researchers are not expected to know how these factors might affect individuals, and should not make assumptions based on stereotypes. Asking questions can help the researcher to understand what might influence potential participants, so that they 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 will entail. They must also be given a permanent record of information about the research – such as a written participant information sheet – to take away to support them in their decision-making.

It may be necessary to prepare information materials in various formats, depending on the particular needs of the potential participants (see the section 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 recordings and pictures as an aid for discussion on the proposed research.

The materials used should explain the main points of the research, acting as a prompt to remind potential participants of your discussion and as a point of reference when individuals discuss their participation with their family and others.

The consent form

The signing of a form has become standard practice in confirming 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 and therefore legally valid.

Potential participants should not be asked to sign the consent form until they have been given adequate information about the study and have had time to consider their decision. When asking for their decision, it is important to 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.

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The participant's perspective

"Many research ethics committee members start their review by reading the participant information sheet for a concise understanding of the purpose of the research and what it will entail. If the information provided does not convey this understanding, it will cause delays in obtaining approval, however good the rest of the application may be."

(Smajdor et al., 2009)

Deciding whether or not to participate in a research project involves considering a number of issues. These can often be complicated, so it is essential that the researcher presents them as clearly as possible. In this section we examine how consideration of the benefits and the risks might impact on an individual's decision to participate, and briefly consider how a health care professional's views may influence decision-making.

Benefits

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

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

Potential participants must be informed of the potential benefits of taking part. However, care should be taken to ensure that these benefits do not lead to people being persuaded to participate in research for the wrong reasons. If the proposed research 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.

Participants might be offered a financial incentive to participate in a research project. When this happens the research ethics committee will want to be reassured that the sum offered is commensurate with the burden of participation, and is not so much that it will alter the potential participant's decision. This can be difficult to judge, because what might seem like a small sum for one person could seem like a considerable sum to someone else.

Risks

Potential participants should also be informed of the possible risks or burdens associated with participating in the research project; for CTIMPs this might be a long list of possible physical side-effects. Researchers should also consider the possible emotional and psychological risks which might arise, particularly in the context of qualitative research, but can often be overlooked.

Participants should also be informed of the economic consequences of taking part in the research. For example, it is important to inform potential participants if expenses are to be reimbursed – or not. While this may not be a factor in preventing an individual's participation in research, this knowledge is important to them making an informed decision.

When it comes to creating a meaningful and useful participant information sheet, it can be helpful if patients and/or representatives from groups likely to be recruited to the research are involved in the development of this information.

Professionals' views

When discussing a research study with potential participants, it is important that nurses and health care professionals do not allow their own opinions to influence whether or not the individual consents to take part in the research.

It is the responsibility of the nurse or health care professional to ensure the individual is given sufficient information, and then allowed to decide for themselves.

8

Vulnerable participants

"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, 2009)

This section examines the special needs of individuals and groups who may be considered vulnerable, and reviews the factors to take into account when gaining informed consent for their participation in research.

Assessing a potential participant's capacity to give informed consent autonomously is an essential part of the informed consent process. This, however, can prove challenging so it is important to involve practitioners and others who know the individual in making such decisions.

It is important to remember that the *Mental Capacity Act* (2005) begins with the presumption of competence, and that capacity can fluctuate and be affected by the manner in which information is provided. The provision of accurate and meaningful information is at the very heart of the process of acquiring informed consent.

Recognising special needs

People can have a range of special needs that need to be taken into account and which are not always obvious; some people may conceal them. For example, some people with reading or writing difficulties may conceal their limitations due to embarrassment -"I've forgotten my glasses, I'll read it later" – while others may have visual or hearing impairments, illness or emotional difficulties. It is vital, therefore, to explore the potential participant's abilities sensitively.

Where the researcher and the potential participant do not speak the same language or their command of the same language is not good enough to enable effective communication, information should be translated into the first language of the participant; to ensure the participant can freely give consent on the basis of proper understanding, a professional interpreter should be available. Research ethics committees seldom permit the involvement of families at this stage in the consenting process because the quality of the translation cannot be guaranteed.

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 they wish to participate. Consideration also needs to be given to problems that might arise as a result of memory problems. It is important, however, that older people are involved in research and not excluded for this reason.

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 with impaired capacity to decide 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 individuals diagnosed with Alzheimer's disease. Researchers must be particularly sensitive to the needs and vulnerabilities of participants.

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, and they may need extra time to do so; 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 have the capacity to do so. This means they are able to understand the nature and consequences of their participation in the research.

Young people aged 16 years and older are generally capable of giving their own consent, while many under

16 years of age are also able to give informed consent or be involved in the decision making process. It is necessary to assess the individual child's capacity, depending on their maturity and understanding. On many occasions this is best achieved with support from parents or guardians.

Gaining a child's views and desires can require the use of creative ways of providing information and alternative means for them to express their thoughts.

Children should not receive monetary rewards for participation in research, although you can give non-monetary gifts, such as toys, providing their value is not excessive. Any rewards for participating should benefit the child, not the parents. In addition, travel costs should be reimbursed for the child and those travelling with them.

Long-term care residents

Older people and others in hospitals or living in long-term care facilities may find it more difficult to refuse to participate in a study if approached by staff involved in their day-to-day care. If the research involves such a population, it is important to take particular care that potential participants do not feel pressured or coerced into taking part and to ensure that every effort is made to facilitate the consenting process in a way that meets the needs of the older person.

People with learning disabilities

Individuals with learning disabilities must be given the same respect as anyone else and be protected from harm if they take part in the 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.

Care should be taken in evaluating each individual's comprehension; use plain language, supported if necessary by other material such as pictures. If a potential participant finds it difficult to understand the nature of research it may be necessary to present the information in different formats or over a longer period of time.

Every effort should be made to seek informed consent and researchers should record evidence that the individual consented to participate after weighing up potential risks and benefits. It may be necessary to involve a range of people who understand the individual's situation and can contribute to an assessment of 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 a CTIMP 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 require that:

- the 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 is 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 are specially defined and constantly monitored
- the interests of the patient will always prevail over those of science and society.

In Scotland the *Adults with Incapacity (Scotland) Act* (2000) permits another (defined) person to give consent on behalf of an incapacitated adult. It is argued that the exclusion of unresponsive patients from non-medicinal research is a form of discrimination as the evidence base for their care will not develop without it (Gelling, 2004).

If the patient regains consciousness and capacity, informed consent should be sought 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.

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. In addition to the usual approval procedures, approval must be sought from the head of health care within the appropriate statutory bodies. A prisoner's participation will be subject to their informed consent in the normal way, but particular attention should be paid to the need to avoid coercion.

Armed forces

Research carried out on members of the armed forces is subject to the *Official Secrets Act*, which has repercussions in relation to confidentiality, honesty and publishing results. The armed 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, paying particular attention to the need to avoid coercion.

Health care staff

Health care staff are sometimes invited 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. It is important not to assume that because they understand the need for research, they are any more predisposed to participate than other people.

Students

Students should receive the same level of care and protection as all other research participants. When recruiting students to research being undertaken by lecturers, fellow students or others investigators should give due consideration to possible power relationships and the risk of coercion. Like participants in all other forms of research, student should be able to make an autonomous and informed decision about their participation in a research project. Students should never be obliged to participate in research.

Human tissue samples

Not all research involves the active participation of volunteer living participants. In some instances the research involves studying tissue samples from living or deceased donors. In undertaking this form of research it is necessary to comply with the requirements of the *Human Tissue Act* (2004). As with all other forms of research samples cannot be collected, stored or analysed unless informed consent has been obtained from the individual or their next of kin. The principles and processes described above also apply to research of this kind.

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Conclusion

Nurses are accountable for their professional practice and should always act in the best interests of patients, clients and research participants.

The key principle in obtaining informed consent to research is to put the potential participant's needs first.

To participate effectively in informed consent processes, the researcher should have the knowledge, expertise and capability to give sufficient information and be able to answer any questions raised by a potential research participant.

The researcher should also have knowledge of the relevant law and, when necessary, be able to assess a potential participant's capacity to give informed consent. If the researcher is open and honest, and ensures the participant understands all they need to about the study, then truly informed consent will be obtained.

In this guidance document it has only been possible to offer the briefest of insights into informed consent in health and social care research. The following section will highlight some additional sources of information.

10

References

Department of Health (2005) *Research governance framework for health and social care* (2nd edition), London: DH. Available from www.dhgov/uk/en

Dobson C (2008) *Conducting research with people not having the capacity to consent to their participation: a practical guide for researchers*, Leicester: British Psychological Society. Available from www.bps.org.uk

Gelling L (2004) Research patients in the vegetative state: difficulties of studying this patient group, *Nursing Times Research*, 9(1), pp.7-17.

Gerrish K and Lacey A (2010) *The research process in nursing* (6th edition), Oxford: Wiley and Sons.

Nursing and Midwifery Council (2008) *The code: standards of conduct, performance and ethics for nurses and midwives*, London: NMC. Available from www.nmc-uk.org

Parahoo K (2006) *Nursing research: principles, process and issues* (2nd edition), Basingstoke: Palgrave Macmillan.

Piffaretti E (2007) Capacity to make decisions? Changes in the law – are you prepared? Clinical Discovery, Jun/Jul, pp.20-21.

RCN (2009) *Research ethics: RCN guidance for nurses*, London: RCN. Available from www.rcn.org.uk/publications Publication code: 003 138

Smajdor A, Sydes MR, Gelling L and Wilkinson M (2009) Applying for ethical approval for research in the United Kingdom, *British Medical Journal*, 339, pp.968-972.

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Additional information and legislation

Further information

WMA Declaration of Helsinki – ethical principles for medical research involving human subjects. Available from the World Medical Association's website **www.wma.net** (Internet).

The Integrated Research Application System (IRAS) can be accessed via **www.myresearchproject.org.uk** (Internet).

The National Institute for Health Research (NIHR) provides extensive resources on informed consent on its website **www.nihr.ac.uk** (Internet).

Full information on the NHS National Research Ethics Service (NRES) can be found at **www.nres.npsa.nhs.uk** (Internet).

Information on the RCN Research Society, and the RCN Research and Development Coordinating Centre, can be found at **www.rcn.org.uk** (Internet).

Legislation

The following UK legislation can be viewed at **www.legislation.gov.uk** (Internet):

- Adults with Incapacity (Scotland) Act (2000)
- Data Protection Act (1998)
- Human Tissue Act (2004)
- Medicines for Human Use (Clinical Trials) Regulations (2004)
- Mental Capacity Act (2005)
- The EU Clinical Trials Directive 2004/20/EC can be viewed at www.eur-lex.europa.eu (Internet).

The RCN represents nurses and nursing, promotes excellence in practice and shapes health policies

First edition, December 2005,
Second edition, **June 2011**

RCN Online
www.rcn.org.uk

RCN Direct
www.rcn.org.uk/direct
0345 772 6100

Published by the Royal College of Nursing
20 Cavendish Square
London
W1G 0RN

020 7409 6100

Publication code 002 267

ISBN 978-1-906633-70-7