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Nursing research expands the evidence base and improves clinical practice, and can be a rewarding experience for both nurses and participating patients

Nursing research: ethics, consent and good practice

In this article...

- The process of conducting medical research in the UK
- How to recruit research participants
- Issues of consent, ethics and good clinical practice

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Abstract Bowrey S, Thompson JP (2014) Nursing research: ethics, consent and good practice. *Nursing Times;* 110: 1/3, 20-23.
Nursing practice must be based on reliable evidence and nurse education must equip practitioners with the skills to challenge existing practices, read published research critically and evaluate its role in clinical practice. Health professionals are likely to come into contact with patients taking part in clinical trials, and have a role to play in maintaining a culture of improving care using a strong evidence base.

This article explains the responsibilities of research nurses in clinical trials and how patient safety is maintained. It outlines the role of nurses in clinical research and the regulatory frameworks that underpin it, and explores the consent process and ethical principles.

Clinical trials aim to determine the effectiveness of new treatments in clinical practice. They seek new knowledge and establish how this can be used to benefit patients. They differ from audits, which measure what we are doing and whether this meets accepted standards of practice.

Since nursing practice should always be underpinned by the best available evidence, it is essential that nurses are able to understand the research process and critically review published evidence. The role of research nurses varies between clinical specialties, academic institutions and trusts.

High-quality clinical trials usually involve a rigorous multidisciplinary process of study design, data collection, analysis and publication. Each study is different but good clinical experience, adaptability, flexibility, the ability to use initiative, attention to detail and the ability to work with minimal supervision are all essential.

Types of research

There are many definitions of "clinical trials". However, they are generally accepted to be studies that follow predefined protocols covering interventional and observational methodology.

Interventional methodology involves subjects being given specific treatment or other investigations so outcomes can be measured; in observational studies, subjects are given the treatment they would have received anyway and the investigator observes the outcomes.

The most common types of clinical trial are as follows:

- Clinical trials of investigational medicinal products (CTIMPs), which involve investigating a new drug or using a licensed drug in a new way, for example a new route, dose or for a different condition;
- Clinical trials that do not use any medicinal product (non-CTIMP);
- Questionnaires and surveys;
- Clinical trials of devices.

Research within the NHS

The way clinical research in NHS trusts is organised and funded has changed considerably since the National Institute for Health Research (NIHR) was created by the Department of Health in 2006.

The NIHR's main objectives are to

5 key points

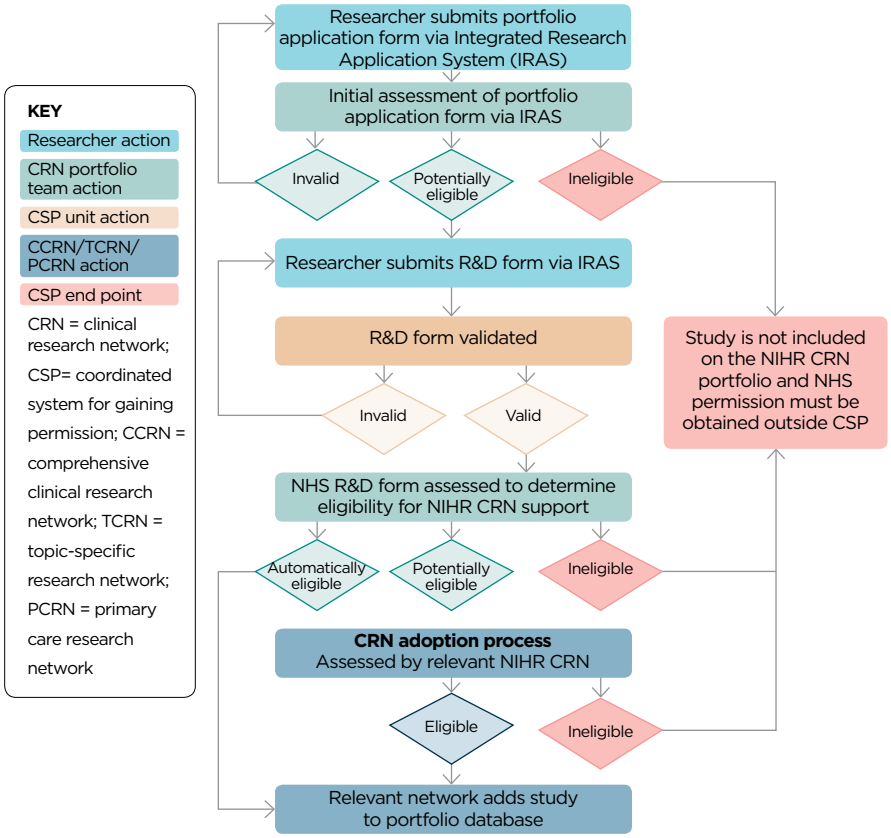
1. **Clinical trials are essential for the development of new knowledge and practice**
2. **Practitioners need to understand the research process in order to critically review evidence**
3. **Adherence to good clinical practice guidelines is compulsory**
4. **Researchers need to gain ethical approval and trust authorisation before they can begin recruiting participants**
5. **Participants must consent to taking part in research, if they are unable to consent, a personal or professional consultee can do so on their behalf**

improve the quality, relevance and focus of research by distributing funds openly following competition and peer review. The UK Clinical Research Network (UKCRN) is part of this organisation and is made up of a primary care research network, a comprehensive clinical research network and six "topic" research networks:

- Cancer;
- Dementia and neurodegenerative diseases;
- Diabetes;
- Medicines for children;
- Mental health;
- Stroke.

These local networks aim to increase the number of people involved in research and provide advice and support to the research community. At the core of the UKCRN is the "study portfolio", a collection of high-quality clinical studies that receive financial and practical support from the network. To receive this assistance, studies must be formally adopted onto the UKCRN portfolio by meeting a range of criteria (Fig 1).

FIG 1. **CRITERIA FOR ACCEPTANCE ON THE NATIONAL INSTITUTE FOR HEALTH RESEARCH STUDY PORTFOLIO**



Source: National Institute for Health Research (2013)

The role of research nurses

Clinical research nurses have become an essential part of the research team due to an increasing focus on recruiting participants into clinical trials.

There are advantages to keeping a part-time clinical role in addition to being a research nurse but, in practice, this can be difficult to coordinate. A clinical role helps nurses to keep their practice up to date. However, many studies need more than a part-time commitment to run effectively, and nurses in combined roles may find difficulties with continuity of research or clinical care, problems planning rotas and conflict between clinical and research duties.

Research nurses are responsible for coordinating many aspects of clinical trials. Responsibilities can include:

- Liaising with other health professionals, including principal investigators, trust research and development staff, research ethics committees, clinical staff, clinical trials pharmacists, external funding bodies, departmental research staff, accountants, commercial companies, university collaborators and external regulatory authorities;
- Identifying, screening, gaining consent from and recruiting potential participants;
- Administering study drugs;
- Collecting and sometimes processing blood and other samples;
- Collecting data and completing report forms;
- Identifying and reporting adverse events;
- Completing annual reports and submitting data;
- Maintaining site files and external audit systems;
- Supporting clinical colleagues;
- Ensuring all aspects of the trial comply with the principles of good clinical practice;
- Promoting a culture of research awareness among colleagues.

Challenges of research nursing

Research nurses have long been seen as data collectors and often worked office hours. However, successful research often needs more input.

The demands of a study may mean working unsociable hours (often at short notice), alone or as part of a small group away from clinical colleagues. National and international legislation, such as the *Research Governance Framework for Health and Social Care* (Department of Health, 2005) and *Guideline for Good Clinical Practice* (International Conference on Harmonisation of Good Clinical Practice, 1996), can make recruitment to clinical trials difficult. Most studies only run for a specified length of time, which adds to the pressure of recruiting the most appropriate participants quickly.

Research is highly competitive. Ideas, grant applications, research and development applications, data analysis and papers written for publication are all evaluated and scrutinised by other professionals.

If a clinical study is perceived as interfering with or being different from routine practice, this can attract criticism from nursing and medical colleagues. Studies will be more successful if they have the support of the whole clinical team; colleagues are much more likely to suggest potential recruits if they are interested in the study and feel involved.

While the number of research nursing posts has increased, many research nurses still work in small teams or independently under the supervision of a lead clinician. This can feel isolating, especially as most nurses are used to working as part of a large clinical team. This is especially relevant to small specialist units such as critical care, which may have only one research nurse per department. Networks between local units or individual research nurses

BOX 1. ADVICE ON ACCURATE DOCUMENTATION

- Keep copies of everything. Make a file note to record events that have occurred and may be relevant in the future. File notes act as a good aide memoire, especially if the study runs for a long time.
- Ensure consent procedures are followed meticulously and original consent forms are filed with a copy of the patient information leaflet. Issue a GP letter on the date the patient is recruited.
- Maintain comprehensive calibration, temperature, study drug storage, delegation, screening and recruitment logs. Document every study-related visit in the care report form and medical notes so you can reconstruct the study and account for your actions.
- Keep a note of when investigators' good clinical practice certificates expire and when annual reports are due.
- Demonstrate completeness in all aspects of the study. Ensure standards of written documentation reflects your high standards of clinical practice.

working in different areas are a good source of professional support and advice for these nurses, and are particularly valuable for those undertaking multi-centre studies.

Regulations and good clinical practice

All research involving human participants is strictly governed by the principles of good clinical practice. This provides a framework of laws, guidelines and regulations that instruct how clinical research is set up and conducted.

"Good clinical practice is a set of internationally recognised, ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects" (HM Government, 2004). The associated ethical and safety standards are closely governed at local, national and international levels and the ethical standards of clinical trials are legally binding.

Complying with good clinical practice protects the rights, safety and wellbeing of participants, and helps to ensure results are credible and accurate. All clinical researchers need to undertake good clinical practice training and follow local guidelines on training updates.

Clinical studies may be checked to ensure they meet good clinical practice standards; this depends on the intervention, any risk associated with the study, and local research and development policies. All studies have the potential to be audited, including internal NHS trust audits and external NHS trust inspections by agencies such as the Medicines and Healthcare products Regulatory Agency and pharmaceutical companies.

Funding

Attracting funding for research projects is competitive and challenging, but financial support is essential. Investigator time and consumables can be expensive and NHS departments may want to be reimbursed for time spent on research projects. Pharmaceutical and other healthcare companies may assist, and research grants can be applied for via the NIHR (www.nihr.ac.uk), and from charities and other organisations.

Local researchers can apply for funds from the UKCRN for staff to participate in portfolio-registered, multicentre trials. This has been successful in many centres in increasing research activity and the number of research nurses.

Maintaining a site file

Auditors use site files and documentation to check compliance with clinical trial regulations, so documentation needs to be completed to a high standard and with enough detail so a person who is not involved in the research can use it to reconstruct the entire study (Box 1).

The site files should contain all trial-related documentation, including copies of all paperwork used, all relevant correspondence, applications and approvals as well as study supplies, finance, equipment information and reports.

Participant consent – ethical issues

The ethical and legal codes that govern medical practice also apply to clinical trials.

Research involving patients is well regulated to protect them. Approval from the trust itself and a research ethics committee, usually comprised of a panel of clinical and non-clinical professionals and lay people, is mandatory before a study can begin.

All trial procedures follow a study plan detailing what researchers will do in the study.

What is informed consent?

Informed consent does not mean simply completing and signing a consent form. It is the process of participants learning the facts about a clinical trial before deciding whether to take part.

When people are invited to take part, they should be given a verbal explanation of the study, including details such as its purpose and duration, the required procedures and an explanation of the risks, burdens and potential benefits. They should then be given a written information sheet and have a set period in which to consider whether they want to participate before written consent can be given.

Potential participants should be advised that consent is not a contract, and consent must be given without any undue influence. They should also be made aware that inclusion is voluntary, they are free to withdraw at any time without affecting their medical care, and their confidentiality and anonymity will be respected at all times. Throughout the duration of the study, participants must be provided with ongoing information.

The process of gaining consent

Written informed consent must be given for participation in most clinical trials. This is governed by important ethical principles; whether consent is valid is decided by local trust policy and any commercial organisation initiating the study.

The process for obtaining consent varies from study to study (Box 2); it is particularly problematic in emergency medicine and critical care studies because the severity of patients' clinical condition can affect their capacity to give informed consent. In these cases, next of kin are sometimes allowed to give consent but it can be difficult to have this conversation while their loved one is in a critical condition. In certain emergency studies, which have a short therapeutic time frame, retrospective consent can be given.

These trials usually involve treatment protocols being started immediately on admission, such as studies into thrombolysis or major trauma. The Mental Capacity Act (HM Government, 2005a) provides a framework for obtaining consent for research in circumstances where patients are incapacitated and cannot give consent.

Research involving participants who lack capacity

A participant is assumed to have the capacity to make a decision unless it is evident they have some difficulty understanding information and making choices. Researchers must consider whether potential participants have the capacity to make judgements about what might be asked of

them (HM Government, 2005b). According to the Medical Research Council's ethics guide (2007): "Mental capacity is considered to be lacking if a person is unable to make a decision for him or herself because of an impairment or a disturbance in the functioning of their mind or brain."

People are deemed unable to consent to a research study if they are unable to understand the relevant information, retain the information for long enough to make the decision, understand the consequences of taking or not taking part, or communicate their decision (HM Government, 2005a).

Research involving adults who lack mental capacity to consent can lead to innovations and can potentially improve the health and quality of life of participants, as well as those of future patients. It is therefore important that these adults are given the opportunity to participate in research and it would be discriminatory to exclude them. Exclusion could also bias the results of some studies if patients without capacity were not included.

Special safeguards are needed to protect this vulnerable group when participating in research.

The MRC Ethics Guide (2007) provides principles on the participation of adults who lack capacity in research:

- The interests of the person must always outweigh those of science and society;
- The research must relate to a condition or impairment that affects the person or the treatment of their condition;
- It must not be possible to conduct equally effective research with adults who have the capacity to consent;
- The potential benefits of the project should outweigh the risks;
- Views of those close to the participant should always be sought, unless this is not possible due to the circumstances;
- Participant who lacks capacity should only be included in a study when there are no indications they object to this.

Giving consent on behalf of an adult who lacks capacity

In the UK, consent of adults who lack capacity can be given on their behalf by a legal representative or relative; these are often referred to as a personal or professional consultee. The clinical trials regulations (HM Government, 2004) specify that this form of consent represents the presumed wishes of the participant rather than using the "best interest" test.

The laws and regulations of involving adults who lack capacity to consent in research give criteria that must be met for the research to be legal and allow for varying degrees of consent by others.

There are two types of consultee:

- Personal consultee: this could be a next of kin, an unpaid carer or someone who has an interest in the welfare of the potential participant.
- Professional consultee: if a personal consultee is not available, and if this has been approved by the research ethics committee, researchers can approach a nominated or professional consultee, who may be a medical consultant, senior nurse or allied health professional but must not be connected to the study in any way.

Both types of consultees must be satisfied that the risk:benefit balance is significantly in the patient's favour, and that the patient is likely to have agreed had they been able to give consent. If a participant regains capacity after being recruited to a study, they must be given the option of continuing or withdrawing from it.

Consultees: information requirements

When consultees are approached, they should be told why they are being approached, given a detailed explanation of what the role involves, told that it is voluntary and given information about the research study.

Researchers should ensure that consultees are in a position to give an opinion on what the participant's view on inclusion would be likely to be. If a consultee gives the opinion that the participant would not have wanted to continue in the study after being recruited, the participant must be withdrawn.

BOX 2. CONSENT PROCESS

Patient consent whenever possible

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Trial enrolment after consultation and written consent with relative or friend (personal consultee)

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Trial enrolment after consultation and written consent with an independent person nominated by the researcher (professional consultee)

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Trial enrolment after a procedure agreed by the research ethics committee, which may include gaining retrospective consent

Source: Mental Capacity Act (2005b)

Recruitment

Recruiting patients to clinical trials can be challenging and researchers often underestimate how long it takes. Many factors can affect recruitment, including patients or consultees withholding consent, logistical problems and insufficient time to gain valid consent.

This is a particular problem with emergency admission or critical care studies, which aim to recruit participants within a set time following admission to hospital. In emergencies, finding a personal consultee can be difficult and it is useful to have access to a professional consultee. Approaching distressed relatives to provide consultee consent for studies in emergency or critical care settings can be challenging and must be done sensitively.

It is a good idea to seek advice from experienced research colleagues on how to maximise recruitment in the study design phase.

Conclusion

The main goal of clinical research is to produce outcomes and knowledge that assist with the development and approval of new treatments.

The research nurse role can be rewarding and provides opportunities to develop new skills and enhance knowledge. To ensure nursing practice is evidence based, we need to explore different ways of delivering care and challenge existing systems. We must encourage the process of incorporating proven research results and best practices into everyday practice and encourage continuous learning.

Conducting research is competitive and challenging, but competition helps researchers to produce methodologically sound and credible research that will hopefully shape the future of practice. **NT**

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