Research ethics application: a guide for the novice researcher

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Abstract

The aim of this paper is to assist the novice researcher in the research ethics application process. The novice researcher in this context refers to any researcher negotiating a research ethics application for the first time. This may be a student or a more experienced registered nurse engaged in research activity. The paper applies ethical principles to the varied elements of a research ethics application form to explain the theoretical basis of the application criteria. The impetus for this paper arose following an internal audit of the decisions made by the research ethics committee of the nursing department at the Institute of Technology in Tralee, Ireland. The audit revealed the common reasons why full approval was not granted following initial review. This information prompted the development of a paper which would assist novice researchers in avoiding common errors and omissions in the research ethics application process. Despite the specific requirements of individual research ethics committees in different jurisdictions, the fundamental elements of research ethics approval remain unchanged. While the paper has local origins, its relevance holds a wider appeal. The paper takes a structured approach using the three ethical principles of respect for persons, beneficence, and justice, as outlined by the Belmont Report (1979) to provide a framework for discussion. Despite the advent of other frequently used frameworks for research ethics, the principles of the Belmont report remain constant as guidance for good practice in the research ethics context.

Key words: Research ethics application ■ Novice researcher ■ Ethical principles ■ Belmont report ■ Nursing

International regulatory boards of nursing have provided guidance for nurses on the ethical conduct of research and the necessary measures to protect all those involved in the research process (American Nurses' Association, 1985; Australian Nursing Federation, 1997; An Bord Altranais, 2007; Royal College of Nursing, 2009). Since the Declaration of Helsinki (World Medical Association, 2008), it is established that the welfare of any participant within a research study should take precedence over the advancement of science. To ensure the protection of participants, research ethics guidelines for nurses and other health professionals have incorporated broad ethical principles to guide the conduct of research. These principles, articulated within the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979) included three key principles; respect for persons, beneficence and justice.

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The Belmont Report was commissioned by the USA's Department of Health, Education and Welfare in response to unethical research practices, particularly the Tuskegee syphilis experiment (1932–1972). Within the Tuskegee syphilis experiment, 399 African American males were enrolled in a study investigating the effects of tertiary syphilis. The true nature of the experiment was not explained to them, and they were not allowed treatment once it became available (Jones, 1993). While acknowledging that other ethical principles exist, it is proposed that the principles articulated in the Belmont Report are sufficiently comprehensive and generalizable to assist all stakeholders in the research process to understand the inherent ethical issues. In this paper, the authors explain the three ethical principles of respect for persons, beneficence and justice and use the principles to guide novice researchers through the research ethics application process.

Ethics application: criteria and ethical principles

The researcher's initial task is to become familiar with the individual elements of the ethics application form and the supplementary documentation required. This documentation may include information leaflets and consent forms for the research participants, a summary of the research protocol, and details regarding how access to participants will be sought. Generally, research ethics committees provide a contact person who can address the nurse researcher's application queries in advance of submission. The novice researcher's goal, when completing an ethics application form, is to provide sufficient information to the research ethics committee to enable members to fulfil their obligations to safeguard the interests of human participants.

The research ethics committee will review the research design, recruitment strategy, informed consent process, protection afforded to research subjects, and the manner in which their rights are respected. The membership of committees varies, but most include educational and healthcare representatives, a legal expert, an ethicist and

one or more members of the public. Others may be co-opted depending on the context of the study or research methodology employed. The committee will review the application in light of their established criteria and may decline to consider the application pending the receipt of additional information. Similar to other jurisdictions, the criteria adhered to by the committee at the Department of Nursing and Health Care Studies (Institute of Technology, Tralee), which are listed within a Research Ethics Validation Checklist (2010), are aligned to the Belmont principles (*Table 1*). The criteria will be referred to in the context of the associated ethical principles as the paper proceeds, and will explain how application seeks to ascertain adherence to the these principles.

Table 1. Principles of the Belmont Report

Principles of Belmont Report	Research ethics validation checklist
Respect for persons	Access to participants Informed consent Confidentiality Methodology
Beneficence/non-maleficence	Risk assessment Methodology
Justice	Intervention Access to participants Methodology

The Belmont principles

Respect for persons

Respect for persons identifies two moral considerations in accordance with the Belmont Report (1979). Participants ought to be treated as autonomous agents, and those who are unable to act autonomously must be sufficiently protected. This ethical principle involves issues regarding access to participants, informed consent and confidentiality. Essentially, the principle of respect for persons serves to prevent the exploitation of participants. It is not acceptable that participants are seen merely as a means to new knowledge, but that they are respected as individuals in their own right. As articulated by the Belmont Report, respect for persons is intrinsically linked with the principle of autonomy. Beauchamp and Childress (2009) acknowledged the multifaceted nature of the concept, but defined autonomy as:

> **'Self-rule that is free from both controlling interference by others and from certain limitations such as an inadequate understanding that prevent meaningful choice.'**

Central to the notion of respect for persons and autonomy is the manner in which participants are recruited to a research study. The research ethics committee will need to be informed of researchers' plans to gain access to participants and relevant sites. It is essential that researchers provide clear evidence of how participants will be recruited. Researchers should clarify their own positions with regard to the research to eliminate the risk of bias, or the potential to exert undue influence on participants. This may refer to situations where the researcher as a nurse, or nurse educator, could influence participant behaviour (Polit and Beck, 2006). In the interests of transparency, any conflict of interest should be outlined.

The requirement to obtain informed consent from all human participants taking part in a research study has been central to research ethics since the Nuremburg Code (US Department of Health and Human Services, 2005). The Nuremburg Code was formulated to protect participants in research following the Nuremberg Medical Trial of 1946–1947, where the unethical practices of human experimentation in Nazi concentration camps were exposed. Informed consent is fundamental to respect for persons and autonomy. It is a central feature of an ethical review.

> **'Informed consent takes place when a competent and informed person understands the risks and benefits at stake and authorizes a health care professional to treat them.' (Dooley and McCarthy, 2005)**

Capacity and authorization

In a research context, the patient becomes a participant and authorizes the researcher to undertake whatever intervention or activity is required in the study. The researcher must ensure that the participant has the capacity and authorization, under law, to give consent. If not, alternative means of acquiring consent should be explored. The researcher is

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required to demonstrate why and how any third party consent was required and obtained. Most ethics applications list a number of vulnerable populations where particular vigilance is required within the consent process. These can include infants, children, the elderly, mentally ill and prisoners (An Bord Altranais, 2007). It is important to be familiar with the specific laws relating to consent in the country where approval is being sought. This includes legislation relating to parental consent in the context of a minor, and the means to acquire consent by proxy in adults with diminished capacity. It is important to note that, while minors may have the capacity to give consent, they do not have the necessary authority in law. In this instance, the parent or guardian is required to give consent; however, good research practice has suggested that the assent or agreement of the child should be gained prior to commencement of the study (Conroy and Harcourt, 2009). The Department of Health (DH) (2001) has provided some useful guidance regarding the consent process in a number of client groups, including children.

Nature of the research

The obligation to inform within the consent process requires that participants receive information regarding the purpose and nature of the research. Best practice has indicated that the researcher should produce an information leaflet or letter that clearly outlines the aims of the study and the exact detail of what is required of participants for the duration of the research. It should also include any possible risks or benefits, including relevant support mechanisms, to enable prospective participants to make an informed judgement. In the context of a qualitative study, where interviews are the main data collection tool, the researcher needs to explain the frequency and duration of the interviews to participants. For example, the National Patient Safety Agency in the UK, in association with The National Research Ethics Service (2009), has provided clear guidance to researchers regarding the structure of information sheets and consent forms for patients. The research ethics committee to which the researcher is applying may have specific templates available.

Recruitment and withdrawal

It is important that potential participants are given adequate time to review material and make an informed choice. In addition, the methods of recruitment must be clearly outlined within the research protocol to ensure that no coercion is employed. In circumstances where potential participants are approached in the hospital setting, it is essential that the information sheet indicates that declining to participate will have no effect on current relationships, or therapies, within the healthcare environment. Another key component in research studies is that participants are made aware of their right to withdraw from the study at any time. Furthermore, the researcher must demonstrate the traceability of each participant so that the correct participant will be withdrawn from the study. The research ethics committee will require clarification of the above in the researcher's application. The committee will also expect that potential participants are actively made aware of any future uses of the research data in publication, or further study, and of the mechanism for registering complaints regarding the research.

Privacy

The requirement to protect participants' privacy is also an integral component of respect for persons in the ethics application process. Discussion of confidentiality forms part of the informed consent process (Oliver, 2003). Researchers need to demonstrate clearly how confidentiality and anonymity will be maintained throughout the study in light of the specific methodology employed. A researcher who is engaging in focus groups will need to be aware that anonymity is not achievable, as participants will be in the company of fellow participants and may therefore be identifiable. This should be explained to prospective participants. If using a quantitative questionnaire, the researcher needs to make explicit why and how any coding is applied to the tool and the subsequent implications. The duration and methods of data storage and mechanisms for disposal of material should also be clearly outlined within the application.

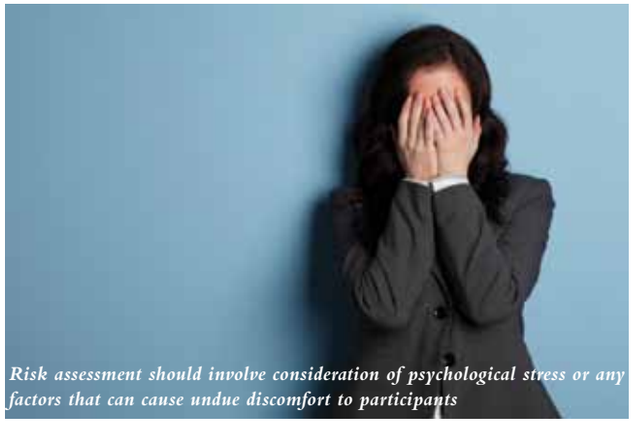
At-risk patients

It is important to note that, while the participant's right to privacy exists both as a moral and legal right, this right is not absolute if they, or another, is deemed to be at risk. This must be made explicit within the consent process. The disclosure of sensitive information may occur within an interview and raise ethical issues for the researcher (Oliver, 2003), and the researcher may be morally and legally obliged to share that information with a third party. In this context, participants should be made aware of the researcher's professional accountability and when disclosure is required the researcher should inform the participant(s) and discuss the reason for this disclosure. In this respect, the principles of beneficence and non-maleficence may take precedence over the principle of autonomy. While the researcher respects the participant's right to privacy, in accordance with the principle of autonomy, concern for their welfare takes precedence in accordance with the principles of beneficence and non-maleficence. This is a feature of ethical decision making and is not confined to the research ethics environment.

Beneficence

In accordance with the Belmont Report (1979), the principle of beneficence requires that researchers ensure the wellbeing of participants. However, it also incorporates the principle of non-maleficence which refers to the duty to protect participants from harm. The principle of beneficence therefore demands that the researcher maximises any possible benefits of the research and minimises any harms. The researcher is required to provide the research ethics committee with sufficient detail regarding the benefits and risks involved in the study to enable the committee to determine the ethical suitability of the project. This includes detail regarding the type of intervention to be carried out where an intervention is planned.

A risk-benefit assessment considers if the potential risks in a study, whether financial, physical, psychological or social, outweigh the benefits of the research (Polit and Beck, 2010).



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Risk assessment should involve consideration of psychological stress or any factors that can cause undue discomfort to participants

Ethics committees may have different review procedures if a project is deemed to represent only minimal risk, in accordance with pre-specified criteria. Polit and Beck (2010) defined minimal risk as 'that expected to be no greater than ordinarily encountered in daily life'.

Psychological distress

Findings from the authors' internal audit of decisions made by the local research ethics committee are noteworthy. These revealed that, while researchers often considered the possible physical risks associated with an intervention, the social or psychological risks were often not sufficiently outlined or emphasized. Risk assessment should involve consideration of psychological stress or any factors that can cause undue discomfort to participants. This may arise in the interview situation as noted above when sensitive data can be disclosed and raise uncomfortable feelings for the participant (Oliver, 2003).

Where there are risks of this nature, the researcher needs to identify the support mechanisms in place for participants such as debriefing sessions to answer questions or air complaints (Polit and Beck, 2010). Even the most innocuous of topics can unexpectedly trigger distress for the participant in a healthcare context where personal health-related issues are explored. If a research participant becomes very distressed during an interview, the researcher may need to suspend the process bearing in mind the researcher's primary responsibility to the research participant. It is acknowledged that this is particularly an issue for nurse researchers who must balance their role as researcher with the caring responsibilities inherent in their profession (Eide and Kahn, 2008). The rigour of the research may occasionally need to be compromised to meet the demands of beneficence. When this occurs researchers should discuss the protocol with their supervisors.

Therapeutic misconception

Participants may experience a sense of false hope by taking part in research. This is akin to the 'therapeutic misconception' associated with interventions in clinical trials. Therapeutic misconception occurs when patients interpret a clinical trial as therapeutic as opposed to a means towards new knowledge (Kimmelman and Palmour, 2005). The researcher should inform participants of the nature of the study and their role in the research context.

Justice

In accordance with the principle of justice, the Belmont Report (1979) asks the researcher to consider who receives the benefits and who bears the burden of research. It is essential to defend the requirement to include and exclude certain groups from the research study. While this requirement is of significance with regard to respect for persons it is also closely linked to the principle of justice. In a research ethics context, this principle demands that those who are unable to protect their own interests are not exploited to advance new knowledge (Polit and Beck, 2010). Recent Irish social history acts as an example of this practice where children in mother and baby homes and orphanages were recruited to carry out clinical trials on the polio vaccine. At least 211 children were given investigative vaccines during three separate drug trials in 1960/1961, 1970 and in 1973 (Gartland, 2010).

Minority and vulnerable groups

The principle of distributive justice also requires that minority or vulnerable groups are not excluded from research (Polit and Beck, 2010). For example, a study which excludes non-English speaking members of a population can be ethically problematic if they represent a section of the individuals experiencing the phenomena under investigation. Where specific groups are excluded within the research protocol a rationale should be provided for this decision. There is also a debate as to the extent to which certain vulnerable client groups, for example, children, or those who have an acute psychosis, are excluded from research owing to the difficulty in obtaining informed consent. Hem et al (2007) suggested an alternative approach to obtaining consent in a specific mental health context where the standard method proved unsuccessful. The researchers in this observational study found it impossible to obtain informed consent at all times from individuals admitted to a secure psychiatric unit. Instead, they adopted the 'non-compliant' approach where general information on the project was provided, respect was afforded to any patient with reservations about being observed, and consent was continually negotiated. This is a contentious issue, but one that merits some consideration within the research community to ensure that certain populations are not excluded from investigation and subsequent knowledge and practice development. In this context, consent is continually negotiated in a climate of trust and is not a 'one off' process.

Methodology and the research ethics process

There is debate regarding the extent to which methodology is the concern of the research ethics committee (Goodyear-Smith et al, 2002). The authors concur with Dawson and Yentis (2007) that poor science has ethical consequences, as methodologically unsound studies will fail to yield reliable results. In this context, methodological issues have reference for the principle of beneficence, but also respect for persons and justice. Normally, research ethics committees will ask the researcher to provide a summary of the research proposal and any data collection tools involved to enable them to make a judgement regarding the scientific merit of the study. The

study population and sample size should be clearly identified with suitable justification for the sampling strategy applied. There needs to be congruence between the research title, literature review, aim, question, data collection methods and analysis (Polit and Beck, 2010). It is also important that the feasibility of a study is considered in the context of the time frame available for completion prior to submission of the proposal for ethical approval. Discipline in relation to these criteria should improve the rigour both of the research proposal and, ultimately, that of the research study.

Submitting the form and receiving feedback

Researchers should treat ethics application forms as academic assignments. Proofreading for content, spelling and grammatical errors prior to submission is essential. It is the researcher's responsibility to ensure all the required documentation is included and all elements of the form have been accurately completed. Failure to do so can delay the approval procedure. The application may require signatures from a number of parties involved in the research process, and the researcher should ensure that a realistic time frame is allowed to complete this process. Generally, ethics committees provide a checklist which the researcher should review before submission. Some ethics committees invite the researcher to attend the meeting to answer queries as the review proceeds.

Once the committee has reviewed the application, a decision will be made. The committee may grant full or conditional approval subject to adherence to specific conditions. If the latter is the case, the chairperson may judge adherence to the conditions outlined, therefore not necessitating full ethical reconsideration by the committee. If the committee does not grant approval, it may invite the researcher to resubmit in the light of recommendations. The committee may also reject the proposal entirely if it is believed to be ethically problematic. In this case, the researcher will not be invited to resubmit. The novice researcher should review the decision of the committee carefully and refer to the chairperson or secretary for clarification, if required. Any resubmission should only take place following adherence to the recommendations of the committee and discussion with the researcher's supervisor.

As a final note, practical ethical judgements for the researcher begin once the study commences. It is the researcher's responsibility to ensure the welfare of the participants and inform the research ethics committee of any adverse events. Many committees require the researcher to submit an interim report or summary sheet on completion of the study. In addition, notification of amendments may be required if there is a change in protocol before or during the study. The researcher should comply with these requirements to fully meet their responsibilities as an ethical researcher.

Conclusion

Applying for ethical approval can be a daunting experience for novice researchers who may be negotiating short time lines, and challenging study and work schedules. Exploration of the theoretical basis of the research ethics application process, and understanding the principles of respect for persons, beneficence and justice are essential for researchers to sufficiently demonstrate that they have met the requirements for ethical approval. BJN

KEY POINTS

- Applying for ethical approval can be a daunting process for the novice researcher
- The Belmont Report (1979) outlines a number of ethical principles as central to research ethics; respect for persons, beneficence and justice
- Understanding the theoretical basis of these principles can assist novice researchers to demonstrate that they have met the requirements for ethical approval
- This article assists novice researchers by applying the Belmont principles to the varied elements of the research ethics application process

Conflict of interest: none

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