Ethical Principles in Healthcare Research

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Abstract

Ethical issues permeate the entire research process from the identification of the research question and selection of research participants, to dissemination of findings. This chapter identifies some of the historical influences informing the development of research ethics frameworks internationally. The author then moves to highlight some of the key ethical issues that need to be considered throughout the various elements of the research process. Some of the important principles underlying research ethics frameworks are identified and interpreted within the context of the research process.

Keywords

Nursing research • Research ethics • Respect for persons • Autonomy Beneficence • Informed consent

Introduction

Recognition of the need to regulate research on human beings can be traced back to reactions against the abuses associated with German and Japanese research during World War II. However as the twentieth century rolled out it was increasingly recognised that a number of abuses, in terms of research on human subjects,

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continued into the post-war period in both democratic and communist countries (Mason and McCall Smith 2010). Revelations during the Nuremburg Trails, for example, of the atrocities committed in the name of medical experimentation during World War II, combined with other twentieth century medical research scandals such as the Tuskegee Syphilis Study 1932–1927 (Adams 1996), the Willowbrook hepatitis studies (Krugman 1986) and the New Zealand cervical cancer inquiry (Cartwright 1988; Paterson 2010) has helped develop widespread resolve regarding the need to protect participants in human research projects and the need to continue to monitor the conduct of such research internationally. The first internationally accepted set of ethical guidelines with regard to these issues was the Nuremburg Code published in 1947 (for further comment see Annas and Grodin 1992). The World Medical Association (WMA) publicly endorsed the principles expressed in the Nuremburg Code by drawing up the Declaration of Helsinki in 1964 (WMA 1964). This Declaration has been revised a number of times since its first publication.

The past 30 years has seen a number of countries and organisations highlight issues surrounding the ethics of research on human subjects: for example the Belmont Principles (The Belmont Report 1979), the Irish Council for Bioethics (2004). In the nursing arena NMBI (the Nursing and Midwifery Board of Ireland) (2015) the Royal College of Nurses (RCN 2011) the International Council of Nurses (ICN 1996) and the Nordic Nurses Association (1995) all published new or revised guidelines for nursing research. Issues regarding the human rights of research participants have also been underlined by the Council of Europe (Council of Europe 1997).

Guided by international instruments (such as the Nuremberg Code, the United Nations Declaration on Human Rights (1948) the United Nations Convention on the Rights of the Child (1989), the Belmont Report (1979), and the Declaration of Helsinki (WMA 2008)), in addition to various ethical theories that have become influential in health care ethics in general, such as Kantian ethics and the principle-based framework of Beauchamp and Childress (2013), a conceptualisation of appropriate ways to treat and protect human beings, both the fully functioning adult and vulnerable human beings such as children, the older person, the terminally ill, has emerged and continues to be modified over time.

However as we move towards the end of the second decade of the twenty first century there are certain ethical principles that are seen as fundamental to the framework of ethics that guides decisions regarding the morally appropriate consideration and treatment of human being during research activities. For example the Irish Council of Bioethics in 2004 commented as follows:

> Research involving human participants should be based on a fundamental moral commitment to the individuals concerned and to advancing human welfare, knowledge and understanding. A number of guiding moral principles govern the ethical review of research proposals. These principles aim to protect the well-being and rights of research participants/volunteers. (p. 6).

Some Important Considerations

Human beings are deserving of respect and protection as inalienable rights (UNDHR 1948). This is equally the case during research activities as it is in any other circumstances. Based on the work of the philosopher Immanuel Kant[1] such values are expressed in the principle of respect for persons, sometimes translated as respect for autonomy. Such expressions of course raise questions of the definition of person and autonomy and when and in what set of circumstances such concepts are and are not applicable.[2] However for the purposes of this chapter we will take it that respect is applicable to all human participants in nursing and health care research. The question then arises regarding what this actually means in the case of individual participants in a particular research project. At a minimum, the considerations explored below are relevant.

Respect for the Human Person

Within the context of research activity the principle of respect for persons is frequently articulated in terms of rights – both rights to autonomous participation and welfare rights (welfare rights refer to the right to have one's support and protection needs respected). Some such rights are the following:

- The right not to be injured or mistreated.
- The right to give informed, un-coerced consent to participate in the particular piece of research.
- The right to privacy, confidentiality and/or anonymity.

In terms of protecting the participant's right not to be injured or mistreated, it is normally the duty of the research team not to expose the research participant to significantly burdensome, unreasonable, known or predictable risk. On occasion however, when significant burden or predictable material risk is unavoidable, it is the duty of the research team to provide appropriate information on the likely burden and /or risk involved, so that the participant can determine if they fully understand and accept such burden or risk. Thus, for example, in drug trials and trials involving medical devices, the trials are phased and normally commence with non-human (laboratory and animal) trials. Such measures help to provide insight into likely effects of the particular drug or device – at least on non-human subjects. Thus by the time clinical trials (trials using human participants) commence, previous phases give insight into the actions of the agent (drug or device for example). This provides a certain level of confidence that the agent will either not cause

[1] For an introduction to Kantian ethics please see Chap. 2.

[2] For discussion of conceptions of personhood in nursing and ethics please see Chap. 6. For a discussion of the concept of autonomy please see Chap. 7.

significant physical risk to the trial participants or that any such risks, which will be explained to the participant prior to participation, can and will be managed and /or mitigated by the research team. Where discomfort, burden and/or risk cannot be avoided such discomfort, burden and/or risk must be proportionate to the anticipated gain, either directly to the individual participant and/or to humanity or society. Such considerations are directly linked to the discussion of the principles of beneficence and non-maleficence below.

Informed Consent

Respect for the individual's right to make decisions about themselves and their life (respect for autonomy) requires that research participants are adequately and properly informed regarding the nature of the research project. For example, potential participants must be informed with regards to what will be required of the individual participant, including the approximate time requirement, any procedures that will be performed on him/her, any known or predictable risks or side effects, the nature of the trial (where a clinical trial is part of the research design), whether a placebo is being used, whether the trial is blinded and so forth. Such information enables the potential research participant to give *informed consent* to participate in the particular research activity or project.

There are two other crucial elements that must be in play in order to ensure that consent is not only informed but also voluntary – and thus autonomously exercised. These elements are:

- The participant must have the capacity to both understand the information being provided regarding the particular piece of research, including the implications of participation for the individual, and the (cognitive) ability to exercise consent.
- The participant must be free from coercion. Thus the participant must be assured and accept, for example, that refusal to consent will not affect her/his current care and treatment if the individual is being cared for by any member of a health care team; either in hospital or in the community. The individual should also be free from any other form of duress related to the research in question - from the research or health care team or from relatives or significant others (see Doyal and Tobias (2001) for a detailed discussion of the principal requirements of informed consent).

In instances where the potential research participant is a patient, practitioners should be aware of the profound influence that they may have on patients to whom they suggest participating in research. For example Kass et al. (1996), in a study on participant consent to involvement in cancer clinical trials, express it thus:

> Clinicians should be mindful of the tremendous influence they have over their patients, given that the mere suggestion of enrolment in research by a patient's personal physician was interpreted by many patients to be endorsement.

Some research, within the context of health and developing the appropriate evidence base for health care provision, will require the participation of individuals who are incompetent or temporarily not competent to give consent to participate in the research activity. Such people should only be involved in research under very clearly articulated and strictly monitored conditions. If it is impossible to carry out the particular research project with competent participants (or for example to wait for the unconscious person to regain consciousness, or where such would invalidate the study) consent must be sought from the legally authorised guardian of the individual involved. As a general rule of thumb incompetent individuals, or members of other vulnerable groups, should only be involved in research when it is reasonable to expect that the individual, or the group of which she /he is a member, will ultimately benefit from the research in question; and where the potential participant is exposed to minimal risk and burden. This is part of protecting the welfare of such individuals. However it is also important, from an ethics point of view, that people with these kind of disabilities are involved in high quality research that is relevant to their care and treatment – in order to develop a relevant evidence base for this care and treatment.

Should the potential participant, identified as incompetent to consent, be able to give assent to participation in research, such assent should be sought - in addition to the consent of the legal guardian described above. In such circumstances a decision to withhold assent should be acknowledged and respected; thus this individual should not be included in the research project in question.

A corollary of informed consent is that the individual should be assured that her/his participation, responses, tissue samples and so forth are being used for the purposes of the identified research project only. Personal information and/or donated material, such as tissues samples, will then be destroyed under properly regulated mechanisms that are fully protective of the autonomy and privacy of the participant. If this is not the case the potential participant should be made aware, explicitly, that it is intended to use such material for another, future study or studies. This enables the potential participant to knowingly consent, or withhold consent, to any potential future study. It clearly protects against a recurrence of cases, such as those reported in the past in both Ireland and the UK (The Royal Liverpool Children's Inquiry Report 2001; The Dunn Inquiry 2005; Government of Ireland 2006), where human organs were retained, post mortem, for potential use in current or future research projects.

In some, perhaps many, nursing research projects private, intimate information may be sought from the research participant during data collection; for example, information on previous medical history, information on personal behaviours and habits or information on the participant's children, siblings and so forth. Intimate, personally significant information may also be discovered as a result of interventions designed into the particular research initiative –i.e. genetic screening, chromosome studies, screening for risk of cancer and cardiac disease, alcohol use, sexual activity, patient satisfaction surveys and so forth. Research participants, in order to be properly protected from unwarranted risk of such personal information becoming available publically, and thus potentially being used to the detriment of the

research participant, (and to enable the participant to feel safe to participate in the particular study) should be assured that such *personal information will be kept private and confidential*. Where strict confidentiality cannot be assured appropriate mechanisms should be designed into the study to protect participants. Participants can thus be assured that their identity will not be divulged – i.e. the *data collection, handling and storage processes protects anonymity*. In this latter case, for example, participants are normally not asked to divulge their names on self-completed questionnaires– such as when completing patient satisfaction questionnaires or when a staff member completes a staff survey.

Beneficence and Non-maleficence

Two of the internationally accepted, fundamental core principles underpinning both nursing practice and research are the principle of beneficence (do good) and the mirror principle of non-maleficence (do not harm). Thus one should do good to and should not harm one's patients, clients or research participants. Clearly some interventions (for diagnostic, therapeutic and/or research purposes) may be uncomfortable, burdensome or painful. Some may cause a degree of harm - for example surgical intervention, dressing of wounds and burns and so forth. However, the basic stance is that the core function of the health care professional is to work for the benefit of the patient or client from a health perspective. Thus the practitioner or the researcher must not cause unnecessary or avoidable harm or distress to one's patients, clients or research participants. Article 6 of the Declaration of Helsinki states this position with particular clarity: *"In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests"* (WMA 2008).

In order to continue to develop the evidence base for health care and nursing practice, relevant, well-designed research is both important and essential. Conversely, the results of poorly designed research may, at worst, seriously harm participants or, at best, waste their time, while at the same time make misleading or detrimental contributions to the evidence base. This means that significant time and effort should be invested into research training and research oversight and governance.

At the level of the individual participant the duty to do good, and prevent harm, warrants equal vigilance. In instances where the participant is likely to experience discomfort, burden and/or risk, such discomfort, burden and/or risk must be proportionate to the expected gain from the research study – either directly to the participant and/or to society as a whole. Within the context of clinical trials, particularly drug trials for example, this gives rise to a number of issues. In the first instance in order to warrant the use of a clinical trial there must be genuine doubt with regards to the efficacy of the drug, or treatment intervention being considered. This is often referred to as a state of *equipoise*. Such conditions exist when either the evidence is not available from which to make a judgement regarding the impact

of a particular intervention, or in situations where that evidence that does exist is inconclusive and/or contradictory. (For a useful discussion of this concept in particular, and ethical issues underlying intervention studies in general, see O'Mathúna 2012).

As indicated above when moving to set up clinical trials the relevant groundwork must be completed and verified, prior to introducing human trials. Appropriate oversight of the trial including close monitoring of participant responses must be assured. Furthermore, when patients are participating in experimental drug trials they must be fully aware of this, including being made aware of the very high chance of the experimental intervention not "working". From the perspective of the ethical conduct of the clinical trial it is good ethical practice for the research team to have a protocol in place to help determine when participation in the trial should be terminated. Such a protocol is particularly pertinent in experimental trials of new anti-cancer agents. The lack of such a protocol can lead to unnecessary hardship for very ill, vulnerable patients and for the staff who care for such patients (for a detailed description and discussion of these and related issues see Hobson 2003).

A corollary of the principles of beneficence and non-maleficence, in terms of clinical trials, is that a study must be stopped immediately, when the risks are found to outweigh the potential benefits. A similar imperative exists when there is conclusive evidence of positive and beneficial results from one of the agents under investigation.

Justice (Including Case Study)

Within the context of research activity the principle of justice can be conceptualised as fairness (Rawls 1985). In Rawlsian terms fairness is achieved if the principles guiding distribution of capabilities and resources, for example, are applied so as to ensure that the "least advantaged" are benefitted and not harmed or forgotten. Thus research participants should be treated fairly. For example, if participants are being put at considerable discomfort, inconvenience or risk (it is assumed that participants are fully aware of the demands being made of them), then it may be completely reasonable to compensate a participant for such inconvenience and any expenses they may incur due to their participation in the particular research project. However such compensation should not be such as to induce financially vulnerable individuals to place themselves at significant risk for financial gain.

Another issue that emerges during discussion of the principle of justice, within the context of research activity, is who should participate in research activity? Should certain groups be excluded on grounds such as vulnerability? Over the past number of years it has been recognised that all patient /client groups, including those identified as especially vulnerable, have the right to participate in, indeed may be necessary participants in, investigations to improve health care and to generate a

sound evidence base for such care. For example the 5th article of the Declaration of Helsinki (WMA 2008) states the following:

> Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

However article 17 qualifies this in the following manner:

> Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

Groups that come to mind are children, the terminally ill, those who are physically disabled or cognitively impaired. It is a matter of justice that such individuals are enabled to participate in relevant research as fully as possible. Such participation assists in developing our understanding of the health and illness experience of certain vulnerable groups. It helps gain insight into their perceptions of, responses to, and requirements of, interventions provided by health care practitioners (and the health service they encounter) over the course of their lives/illness trajectory.

However special considerations need to come into play to ensure appropriate support and protection of such individuals. In particular specific mechanisms must be put in place to ensure that the welfare rights of vulnerable groups are recognised and protected.

A relevant case example concerns emerging research interest in the use of a micro camera (SenseCam), to record daily life of individuals (life-logging) with early-stage dementia (Piasek 2015). *The research focuses on an in-depth analysis of the experiences of three people in early-stage dementia whilst using, over a 7 week period, an automatic camera taking photographs of the person's day-to-day life. Each participant had 14 contacts with the researcher over the 7 week period. The study is unusual in terms of the depth of analysis, and the opportunity it provides for the person with dementia, and in two of the cases a family care-giver, to voice their experience of taking part in a trial of a new, potentially therapeutic, intervention. The intervention is placed in the context of how a person with dementia might maintain his/her identity in a situation where cognitive impairment may make this increasingly difficult.*

This study is enabling much needed research on a potential treatment of a vulnerable group of people – those with early stage dementia. However in addition to key ethical issues regarding respect for persons and information giving to enable informed consent in this study, the study also generates a requirement to acknowledge that the intervention used may generate distress in either the person with early stage dementia or the carer - thus causing potential harm. This highlights the need to identify and put in place measures to be taken should distress occur. There are also potential ethical issues related to privacy – not only those of the participant and

carer, but also issues of photographing unsuspecting members of the public, should the participant have the camera on and rolling, while entertaining guests in the participant's home or while out in public places.

Working It through: Ethical Issues and the Stages of the Research Process

As indicated above, ethical issues and considerations permeate the entire research process. This begins with the research questions that are asked (and that receive research grant funding as against those questions which do not get asked and those projects which, through lack of funding, do not proceed) and continues right through to reporting of research findings and terminating the researcher/ respondent contact.

Researchers need to be sensitive to the nature of particular research agendas and the motivations, personal, political, institutional and socio-cultural, that drive them. For example, the current drivers of evidence-based practice in health care are at least tripartite - political, economic and professional. As practitioners we are becoming more convinced that our practice must be evidence-based - and there are numerous clinical studies going on attempting to develop our evidence-base. However, it is interesting to note that we are a lot less clear on what we mean by evidence, or what should count as evidence in health care practice (Scott 2006).

It seems reasonably clear that what counts as evidence for X (health care practice for example) largely determines the type of evidence we should be seeking and the studies that should be funded. Despite this, little work is currently being carried out, or being funded, in relation to questions regarding the nature of the evidence base appropriate for healthcare and nursing practice. This problem has philosophical, moral and professional implications. One of the most serious is the potential impact that our lack of knowledge and understanding, regarding the nature of an appropriate evidence base, will have on patient care.

However, once the researcher has decided on the appropriate research question, it is a moral and professional requirement to ensure that the selected piece of research is necessary. Thus the researcher needs to be sure that the knowledge is required, and does not already exist in a sufficiently comprehensive state. This indicates the need for the researcher to be equipped to do the required literature searching and reviewing. To do otherwise is likely to lead not only to a poorly refined research question and consequent poor research design; it is also wasteful of resources and shows a lack of respect for the study respondents and those who provide support for the researcher.

Assuming that the research question is a legitimate and useful one, the researcher must draw on personal or outside expertise in designing an appropriate study, that will provide a real possibility of gaining answers to the research question posed; or which will provide a firm basis for further work. This is not only a methodological issue. Sound study design is required in order to ensure that the study is ethically sound. Lack of appropriate expertise in study design is again, at a minimum,

wasteful of time and other resources and indicates a lack of respect for respondents and those supporting the work of the researcher. At worst such lack of expertise may be positively damaging to the research respondents. Given that nursing researchers frequently carry out research with respondents already made vulnerable through illness, as indicated in the short case example above on the potential therapeutic use of SenseCam, lack of appropriate expertise is particularly unacceptable from an ethical perspective.

Once the researcher is confident that the design of the study is appropriate and that the data collection methods/tools will obtain the data required, ethical considerations broadly focus on ensuring respect for the participants and include the following elements:

- The role of the practitioner-researcher and the implications of the researcher identifying him or herself as a nurse, doctor, physiotherapist, clinical psychologist and so forth. The implications are potentially both positive and negative. Such self-identification may make recruitment to a study much easier – both because it may provide easier access to a participant pool and /or because a health practitioner such as a nurse is automatically seen as trustworthy by a patient or member of the public. However, it may also confuse or set up false expectations in patient-participants. Conflicts of interest are likely to arise where a practitioner is using his/her own patient group in research. Such confusion of roles should normally be avoided. Where a self-identified, qualified practitioner is carrying out a piece of research (for postgraduate work for example), it should be made clear to a participant that the researcher is not responsible for the participant's care and refusal to participate in the research will not have any impact on care provision. This should also be expressed, clearly, on either the written information participants receive regarding the research study and /or on the consent form. In the case of vulnerable group – such as those cited in the case example above – the fact that the researcher is not responsible for the participant's health care, should be repeated on each visit to /contact with the participant.
- The balance of potential inconvenience or risk to participants over potential benefit to participants and/or others. For example with the life logging example described above, the potential to come up with what ultimately may prove a beneficial intervention for some people with dementia must be balanced against the potential to cause distress and anxiety to study participants in current, very early stage exploratory studies.
- Appropriate and sufficient information must be given regarding the nature of the study to enable the potential participant to make an informed choice, and to give or withhold informed, voluntary consent. Taking the example of the individual with dementia the researcher needs to think through, very carefully, what types of information should be provided to the participant (and perhaps also the main carer) and in what form(s) this information should be provided. People experiencing cognitive decline and memory impairment pose particular challenges to the meaning of "being informed" and "giving informed consent". In

the moment of engaging with the researcher, these individuals may understand clearly what the study is about and what is being asked of them as participants. They may also agree to participate very willingly in the proposed study. However this understanding and willingness to continue to participate will need to be reconfirmed on each occasion the researcher interacts with the participant.

In instances where the participants are unable to receive the information or to make informed decisions, for whatever reason, clear transparent processes which aim to ascertain and protect participants' interests, throughout the period of their participation, must be instituted. The continued right of competent participants to withdraw from the study, without any negative consequences to the participant, must be made clear at the commencement of the study and thereafter, as the study unfolds, as required.

- Issues of anonymity and confidentiality must be given careful consideration, and detailed information on these notions given to participants. As de Raeve (1996) points out this may be particularly pertinent for health practitioner/researchers who may, for example, be used to the rather broader notion of confidentiality which is used within the health care team.

In empirical studies, data collection is a crucial area for research ethics. Ethical issues can be identified in the following areas:

- Obtaining permission for data collection from the organisation in question.
- Obtaining permission for data collection from the participants (patients, professionals).
- Consideration of who else may need to be approached in term of permission – in the case example above visitors, friends or even members of the public exposed to the SenseCam camera should be informed of the study and be given the option not to be recorded when in the vicinity of the study participant.
- Guaranteeing appropriate ethical behaviour from researchers during the data collection period.

As discussed above, in obtaining permission from individual participants, the issue of informed consent is central. It should be noted that normally practitioners directly involved in care giving do not obtain participants' consent to participate in research, as clear conflict of interest issues may arise. However clinical nurses, in particular, may have a significant role in supporting patient–participants in making informed decisions regarding participation in a particular piece of research (NMBI 2015).

In line with the principle of respect for persons, participants' anonymity, confidentiality and willingness to participate must be ensured. Risks/benefits/burdens to respondents must be explored. The risk or burden to the participant must be weighed against the potential benefits of the research findings to the general population or

specific patient populations. In the case example above this translates into the need to balance any potential for distress to be caused to the study participants and/or their carers' with the potential to identify a useful new therapy for certain individuals with dementia. Participants in clinical trials must be as fully informed as possible regarding the nature and objectives of the trial. It should be made clear to the participants the nature of any specific risks or benefits that may accrue to trial participants. As highlighted above in relation to individuals with some element of cognitive impairment, it is important to bear in mind that informed consent is an ongoing process. Research participants may have questions that arise during the data collection process, in particular, that should be addressed. Participants must also be informed and assured that they may withdraw their consent and cease participation at any point during the research process, without this negatively impacting on them or their care.

Ethics and Data Analysis

Analysis of data is an interesting issue from an ethical perspective. At a minimum the researcher and /or his or her research advisors need to have a good grasp of both the strengths and limitations of the method of analysis or any analytical tools used. This is important from an ethical perspective in order to ensure that no inappropriate claims are made, based on the analysis. The relevance of this point in terms of clinical practice and patient care is clear. A significant reason for carrying out empirical research, within health care, is to improve patient care and develop sound policy and practices. Inappropriate analysis is likely to lead to inaccurate results and thus potentially to poor policy and practice.

Ethics and the Relationship with Research Participants

de Raeve (1996) highlights the lack of attention to ethical issues surrounding 'leaving the field' or termination of the relationship between researcher and participant. This is likely to be a particularly complex issue for researchers involved in some forms of qualitative research and in some psycho/socially focused intervention trials. It was an issue in the SenseCam intervention study (Piasek 2015) described above. Study participants and the two carers involved had come to rely on the researcher for social interaction, the hope of effective treatment and, for one of the carers, the ability to get some time to themselves while the researcher was with the participant. A researcher needs to be aware of the potential problems in this type of researcher-participant relationship. Steps should be taken to ensure that the participant does not confuse the research relationship with a therapeutic, counselling-type relationship or a friendship. Insight and personal integrity is actively required from the researcher throughout the data collection period to guard against misuse or abuse of the researcher-participant relationship (O'Mathúna 2012).

Ethics and Dissemination of Research

From an ethics perspective, if the researcher is to value and respect the contributions made by participants, funding bodies and others supportive of the research effort, it is incumbent on the researcher to report and disseminate the findings of the particular study - positive and negative - in the most effective ways available to the researcher.

In reporting the study results, the ethical issues include continued protection of the rights of, and honouring promises made to, participants (e.g. confidentiality, protection of privacy, anonymity), reporting findings truthfully, accurately and completely, citing appropriately the work of others and ensuring the authorship credits and acknowledgements are stated accurately. To do otherwise once again indicates lack of respect for the various actors in the research process. It is also wasteful of valuable resources, including those of future researchers who might have gained from the sign-posting of "blind alleys" and from insights into the findings, strengths and weaknesses of the unreported study.

Conclusion

A number of the key ethical principles relevant to research with human participants are explored in this chapter. The ethical understanding thus gained is then applied to the component elements of the research process. High quality, ethically sound research is important in developing the evidence base for health care practice and in the provision of effective, humane patient care. Understanding the principles guiding ethically sound research activity is thus a key component in the education and practice of health care professionals.

Key Learning Points

- The need to ensure a strong ethical framework to scrutinise and regulate research in health care has been informed, in particular, by the abuses of World War II and a number of notorious research scandals uncovered in the twentieth century.
- Within the context of research the principle of respect for persons refers to ensuring, for example, that participants are adequately informed about the research project. Such information should enable participants to give informed consent to participate in the piece of research in question. Respect for persons also requires that participants are assured of confidentiality or anonymity and that their privacy is protected.
- Two other important ethical principles underlying ethical research practices are the principles of beneficence and non-maleficence: Literally this means, respectively, do good and do no harm. Within the research context participants should be adequately protected and researchers should avoid exposing participants to unnecessary and undue discomfort, burden or risk.

- The principle of justice demands that research participants should also be treated fairly. All sectors of the population including, where relevant, vulnerable groups and individuals, should be enabled to participate in research initiatives. Such participation requires additional protections to be in place.
- Ethical issues permeate the entire research process from question identification and selection to dissemination of findings.

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