

PART 2

Ethical considerations



5 Ethical principles in health care research

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Chapter topics

- The history of the evolving recognition of the need to regulate research involving human subjects
- Consideration of some key ethical principles relevant to the research process
- Applying ethical understanding in the practice of research

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 recognized that a number of abuses, in terms of research on human subjects, continued into the post-war period in both democratic and Eastern Bloc countries (Mason and McCall Smith 2010). Revelations during the Nuremburg Trials, 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 1932–72 (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 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 have seen a number of countries and organizations highlight issues surrounding the ethics of research on human subjects: for example the Belmont Principles (National Commission 1979) and the Irish Council for Bioethics (2004). In the nursing arena, the International Council of Nurses (ICN 1996), An Bord Altranais (the Irish Nursing Board) (2007), the Royal College of Nursing (RCN 2009) and the Northern Nurses' Federation (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 such international instruments as the Nuremburg Code (1947), the United Nations Declaration on Human Rights (United Nations 1948), especially

articles 1, 3, 5, 12 and 19, the United Nations Convention on the Rights of the Child (1989), the Belmont Report (National Commission 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 (2001), a conceptualization of appropriate ways to treat and protect human beings, both fully functioning adults and vulnerable human beings such as children, older people, the terminally ill, has emerged and continues to be modified over time.

However, as we move into the middle 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 beings 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.

(Irish Council for Bioethics 2004: 6)

Some important considerations

Human beings are deserving of respect and protection as inalienable rights (United Nations 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, 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 of when and in what set of circumstances such concepts are and are not applicable. However, for the purposes of this chapter we will take it that respect is applicable to all human participants in 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

In 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 – that is, 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 that 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 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, it 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 or 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 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: 4), 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, in 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 this would invalidate the study), consent must be sought from the legally authorized 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.

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 as described above. In such circumstances a decision to withhold assent should be acknowledged and respected; thus this individual will 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 tissue 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 the 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 over the past decade in both Ireland and the UK (The Royal Liverpool Children's Inquiry Report 2001; The Dunne 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, health 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 this personal information becoming available publicly, 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 – the **data-collection, handling and storage processes protect 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 health care 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. 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 their 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).

To continue to develop the evidence base for health care 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 making 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, it must be proportionate to the expected gain from the research study – either directly to the participant and/or to society as a whole. In 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 the 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 before introducing human trials. Appropriate oversight of the trial, including close monitoring of participant responses, must be assured (see Chapter 6 for an outline and discussion of research governance). 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 them. (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

In the context of research activity the principle of justice can be conceptualized 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 benefited 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 (given the discussion of the ethical principles providing an appropriate framework for ethically acceptable research activity 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, that 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, in 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 recognized 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 fifth article of the Declaration of Helsinki (WMA 2008) stated the following:

Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are under-represented 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 or their 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 recognized and protected. For detailed discussion of research with vulnerable groups please see Chapter 7.

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 sociocultural, 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 answers to the latter question are crucial in informing the former question. 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 health care 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 (see Chapter 3), 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. 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 a lack of expertise may be positively damaging to the research respondents. Given that health care researchers frequently carry out research with respondents already made vulnerable through illness, this is particularly unacceptable practice from an ethical perspective.

Once the researcher is confident that the design of the study is appropriate and that the data-collection methods or tools will obtain the data required, ethical considerations, we would argue, again concern notions of respect, with a focus on the following issues:

- 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. 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 participants that the researcher is not responsible for the participants' care and that 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.
- The balance of potential inconvenience or risk to participants over potential benefit to participants and/or others.

- Appropriate and sufficient information should 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. 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: 114) 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 in 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 organization in question
- obtaining permission for data collection from the participants (patients, professionals)
- 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 (see, for example, Pranulis 1997; Watts 1997; Sadler et al. 1999; An Bord Altranais 2007).

In line with the principle of respect for persons, participants' anonymity, confidentiality and willingness to participate must be ensured. Risks, benefits and 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. 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. It is also 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 advisers 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 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 in 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: 115) 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 psychosocially focused intervention trials. The 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. (See O'Mathúna 2012 for a wide-ranging and helpful analysis of the importance of researcher integrity throughout the research process.)

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 (for example, 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 signposting 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 evidence-based health care delivery.

Key concepts

- Respect for persons: in the context of research, this 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.
- Beneficence and non-maleficence: literally this means, respectively, do good and do no harm. In the research context, participants should be adequately protected and researchers should avoid exposing participants to unnecessary and undue discomfort, burden or risk.
- Justice: research participants should 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 may require additional protections to be in place.
- Ethical issues permeate the entire research process, from question identification and selection to dissemination of findings.

Key readings

- T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*, 5th edn (New York: Oxford University Press, 2001)
This is a classical text in health care ethics. The authors are the originators of what has become known as the Georgetown principles: respect for autonomy, beneficence, non-maleficence and justice. There are many interesting case applications of the principles, including research-relevant cases.
- J.K. Mason and R.A. McCall Smith, *Law and Medical Ethics*, 8th edn (London: Butterworth, 2010)
This text provides a detailed discussion of ethical principles relevant to the health care context including the health research context.
- D.P. O'Mathúna, Ethical considerations in designing intervention studies, in B. Mazurek Melnyk and D. Morrison-Beedy (eds) *Intervention Research: Designing, Conducting, Analyzing, and Funding: A Practical Guide for Success* (New York: Springer Publishing, 2012), pp. 75–89
O'Mathúna's chapter provides a comprehensive discussion of the research ethics issues involved in the design and implementation of intervention studies. The chapter includes a very useful discussion of the issue of researcher integrity.

Useful articles

- I. Coyne, Research with children and young people: The issue of parental (proxy) consent, *Children and Society*, 24(3) (2010), 227–37
The author explores the implication of blanket requirements for parental consent on the moral agency and respect accorded to children and young people (under 18 years) in the research context.
- N.E. Kass, J. Sugarman, R. Faden and M. Schoch-Spana, Trust: The fragile foundations of contemporary biomedical research, *Hastings Centre Report* (New York: Hastings Centre, September–October 1996)
This article highlights the very specific ethical issues that can underpin patient participation in anti-cancer experimental drug trials.
- J. Leaning, Ethics of research in refugee populations, *Lancet*, 357(9266): (2001), 1432–3
The author explores the delicate balance to be maintained between the desire and the need to involve refugees in relevant research projects with the potential to exploit often very vulnerable individuals.

Useful websites

- Irish Council for Bioethics (2004) *Operational procedures for research ethics committees: Guidance*. Dublin: Irish Council for Bioethics – http://www.drugsandalcohol.ie/5889/1/Bioethics_Ethical_guidelines_for_research.pdf
- The National Institutes of Health (NIH) offers an online tutorial, ‘Human Participants Protections Education for Research Teams’ – <http://phrp.nihtraining.com/users/login.php>
- World Medical Association, *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Subjects* (1964; 1975; 1983; 1989; 1996, 2000, 2002, 2004, 2008) – <http://www.wma.net/en/30publications/10policies/b3/>

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