



MEDICAL AND DENTAL PROFESSIONS BOARD

**GUIDELINES FOR GOOD PRACTICE IN MEDICINE,
DENTISTRY AND THE MEDICAL SCIENCES**

**GENERAL ETHICAL GUIDELINES FOR
DOCTORS, DENTISTS AND
MEDICAL SCIENTISTS**

BOOKLET 1

**PRETORIA
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THE SPIRIT OF PROFESSIONAL GUIDELINES

Medicine, dentistry and the medical sciences are professions based on a relationship of trust with patients. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good doctor, dentist or medical scientist requires a life-long commitment to good professional and ethical practices and an overriding dedication to the good of one's fellow humans and society. In essence, the practice of medicine, dentistry and the medical sciences is a moral enterprise. In this spirit the Medical and Dental Professions Board presents the following ethical guidelines.

¹ Pellegrino, ED. Medical professionalism: Can it, should it survive? *J Am Board Fam Pract* 2000; 13(2):147-149 (quotation on p. 148).

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MESSAGE FROM THE MEDICAL AND DENTAL PROFESSIONS BOARD
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Doctors, dentists and medical scientists live and work in a society that places a high premium on material affluence, economic prosperity, status and related attributes. They are invariably affected by the influences of our age. Advances in science and technology, sophisticated business models and shrinking resources have not simplified the situation. The practice of the professions of medicine, dentistry and the medical sciences is immersed in these modern controversies. The question, however, is how the professions can be safeguarded against a situation where economic, political and social consideration supersede patient welfare? The Medical and Dental Professions Board believes that ethical behaviour defines the very essence and existence of these professions, without which, the nobility with which the professions have hitherto been acclaimed, would be something of the past.

In view of the many ethical dilemmas facing the professions and questions pertaining to ethics arising from the practising of the professions, the Board decided to formulate ethical guidelines that will provide clear guidance on ethical behaviour to their practitioners.

We present these guidelines to you as a professional, in the spirit of the motto of the Health Professions Council of South Africa, namely **“to protect the public and to guide the professions”** and hope that you would be assisted in your ethical reasoning as you resolve the difficult ethical questions encountered in your daily professional practice. We believe that these ethical guidelines will serve as a good, but not necessarily exhaustive basis for championing a course towards optimum patient care.

We trust that you will find inspiration and guidance in these ethical and practice frameworks and indeed continue to find reward in delivering the best service to your patients while maintaining the highest possible standards of ethics.

Prof Len Becker
Chairman

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GENERAL ETHICAL GUIDELINES FOR DOCTORS, DENTISTS AND MEDICAL SCIENTISTS

INTRODUCTION

Being registered as a doctor, dentist or medical scientist with the Health Professions Council of South Africa (HPCSA) confers on us the right and privilege to practise our professions. Correspondingly, practitioners have moral or ethical duties to others and society.

The Medical and Dental Professions Board of the HPCSA has embarked on a project to bring together ethical and professional guidelines for doctors (medical practitioners), dentists, and medical scientists. A series of booklets covering various aspects of professional practice is being prepared for distribution.

This first booklet contains *general ethical guidelines for or general duties* of doctors, dentists and medical scientists. Such guidelines are *aspirational* or *value-oriented*, expressing the most honourable ideals to which members of the profession should aspire.

By contrast, *specific* or *compliance-based ethical guidelines* are more specific *rules* or *duties* derived from those general ethical guidelines or duties. They offer more precise guidance and direction for action in concrete situations. They also make it easier to implement sanctions against transgressors.

It is impossible, however, to develop a complete set of specific ethical prescriptions applicable to all conceivable real-life situations. In concrete cases, doctors, dentists and medical scientists may have to work out for themselves what course of action can best be defended ethically. This requires ethical reasoning.

This booklet has two sections:

- **Section One** lists thirteen core ethical values and standards that underlie professional and ethical practice in medicine, dentistry and medical science, and gives a short explanation of how one makes practical decisions through ethical reasoning.
- **Section Two** explains what a duty is, and catalogues the general ethical duties of doctors, dentists and medical scientists.

In this booklet, the expression “professional” is used to refer to medical, dental and medical science professionals.

SECTION ONE

ETHICS IN MEDICINE, DENTISTRY AND THE MEDICAL SCIENCES

1. CORE ETHICAL VALUES AND STANDARDS FOR GOOD PRACTICE

- 1.1 Everything ethically required of a professional to maintain good professional practice is grounded in core ethical and professional values (in boldface below) and standards (the directives following the core values). Although these core values and standards may be presented as a hierarchy (for example, autonomy and confidentiality may be classified under respect for persons), we present them as a linear list for the sake of simplicity.
- 1.2 In concrete cases, the demands of these core values and standards may clash, thus making competing demands on us. The only way to address such clashes is through ethical reasoning.
- **Respect for persons:** Respect patients as persons, and acknowledge their intrinsic worth, dignity, and sense of value.
 - **Best interest or well-being: Non-maleficence:** Do not harm or act against the best interests of patients, even when they conflict with your own self-interest.
 - **Best interest or well-being: Beneficence:** Act in the best interests of patients even when there are conflicts with your own personal self-interest.
 - **Human rights:** Recognise that some interests of individuals may be so important that they acquire the status of human rights in the form of either claims or freedoms to be respected by all.
 - **Autonomy:** Honour patients' right to self-determination or to make their own informed choices, living their lives by their own beliefs, values and preferences.
 - **Integrity:** Incorporate core ethical values and standards as the foundation for good character and responsible practice.
 - **Truthfulness:** In professional relationships with patients, regard the truth and truthfulness as the basis of trust.
 - **Confidentiality:** In professional relationships with patients, treat personal or private information as confidential, unless overriding reasons confer a moral right to disclosure. (For examples of such reasons, see "Duties to our patients", item 24 in **Section Two**. See also the *Booklet on Confidentiality* (in preparation).
 - **Compassion:** Be sensitive to and empathise with individual and social needs for comfort and support, and seek and create opportunities to translate emotions, such as feelings of sympathy or empathy, into action.
 - **Tolerance:** Respect the rights of people to have different ethical beliefs as these may arise from deeply held personal, religious or cultural convictions.
 - **Justice:** Treat all individuals and groups in an impartial, fair and just manner.
 - **Professional competence and self-improvement:** Continually endeavour to attain the highest level of knowledge and skills required within your area of practice (see the *Booklet on Professional Self-development*).

- **Community:** Consistent with your professional abilities and standing in the community, strive to contribute to the betterment of society.

2. ETHICAL REASONING

- 2.2 The core values and standards referred to above are the foundation that grounds the (mostly) general or aspirational ethical guidelines in this booklet. Being general, such guidelines can be applied to many different concrete cases.
- 2.3 But how does one proceed from these guidelines to making practical decisions or choices? How does a guideline apply in a specific case? And how do we handle difficult cases where two (or more) guidelines prescribe contradictory solutions?
- 2.4 Briefly, what is needed is *ethical reasoning*. Roughly speaking, such practical reasoning proceeds in four steps:
- **The problem:** Formulate the problem. Is there a better way of understanding it?
 - **Information:** Gather all the relevant (clinical, personal, social, etc.) data.
 - **Options:** Consider all reasonable options, choices or actions in the circumstances.
 - **Moral assessment:** Weigh the ethical content of each option by asking -
 - ◆ What are the likely *consequences* of each option?
 - ◆ What are the most important *values, duties, and rights*? Which weighs the heaviest?
 - ◆ What are the *weaknesses* of your view?
 - ◆ How would *you* want to be treated in the circumstances of the case? That is, apply the *Golden Rule*.
- 2.5 For a more detailed discussion of ethical reasoning, see the *Booklet on Ethics Resources for Doctors, Dentists and Medical Scientists*, which will be made available on request by the Medical and Dental Professions Board upon completion.

SECTION TWO

GENERAL ETHICAL DUTIES OF DOCTORS, DENTISTS AND MEDICAL SCIENTISTS

1. WHAT IT MEANS TO HAVE A DUTY
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- 1.1 Ethical guidelines express duties. A duty is an obligation to do or refrain from doing something.
- 1.2 If we have a duty to another person, it means we are bound to that person in some respect and for some reason. We owe that person something. In addition, he or she may hold a corresponding right or claim against us.
- 1.3 For example, I reach an agreement with a colleague that she would *locum* for me while I am away on family business. We then have corresponding duties and rights-claims – she has a duty to do the *locum* for me, and I have a right to her professional services; she has a right to fair remuneration, and I have a duty to compensate her.
- 1.4 To have a duty is to face the question “What do I owe others?” To have a right is to face the question “What do others owe me?”
- 1.5 Duties may be ethical, legal, or both at once. And duties operate in the personal, social, professional or political spheres of our lives.
- 1.6 Concurrently, doctors, dentists and medical scientists are human beings, professionals and fulfil institutional roles. Accordingly, we have *different kinds or types of duties*:
- ***As human beings we have “natural duties”***, namely *unacquired general* duties simply because we are members of the human community - for example the natural duties to refrain from doing harm, to promote the good, or to be fair and just. As is the case with everyone, doctors, dentists and medical scientists owe these duties to all other people, whether patients or not, and quite independently of our professional qualifications.
 - ***As professionals we have “moral obligations”***, namely *general* duties we *acquire* by being qualified and licensed as professionals, that is, *professionals* entering into contractual relationships with patients - for example the professional duties to provide medical care, relieve pain, gain informed consent, respect confidentiality, and be truthful.
 - ***As professionals working in specific institutions or settings we have “duties”***, namely *acquired* duties specific to our particular *institutionalised* role or position - for example the duties of a doctor or medical scientists employed by a hospital, a dentist in the employ of a prison, or a single-practice general practitioner or specialist. These duties are circumscribed in employment contracts, job descriptions, conventional expectations, and the like.
- 1.7 Duties listed in this booklet fall broadly in the second category – the *general*, but *acquired* duties of a doctor, dentist or scientist *as a professional*.
- 1.8 No duty is absolute or holds without exception irrespective of time, place or circumstance. This is not surprising, since different duties may prescribe quite opposite decisions and actions in a specific concrete or real-life situation.

- 1.9 For example, our duties to our patients may compete with our duties to our employer. Or our duty to respect a patient's confidentiality may clash with our duty to protect innocent third parties from harm. (HIV/AIDS examples are particularly perplexing.) These are instances of conflicts of interest or dual loyalties.
- 1.10 Still, it does not follow that we are free to take duties lightly. Some duties are indeed more stringent than others, but all duties need to be taken very seriously, and should only be overridden by an even more stringent competing duty in the concrete circumstances of a specific case. This entails weighing or balancing duties against one another in a process of ethical reasoning.
- 1.11 No list of such duties is ever complete, but the catalogue of duties below presents a fairly comprehensive picture of what it is, in general, that binds any doctor, dentist or medical scientist as a professional to his or her patients, as well as to others. However, it should be noted that these duties, if not honoured without justification, may constitute the basis for sanctions being imposed on professionals by the Medical and Dental Professions Board.
- 1.12 To some extent, any classification of duties is arbitrary, since a specific duty may be owed to different parties simultaneously. The classification system or convention used below should therefore be viewed as no more than a rough compass.
- 1.13 Bear in mind that underlying and giving rise to these duties are the core ethical values and standards for good practice identified in **Section One**.

2. DUTIES TO PATIENTS

2.1 PATIENTS' WELL-BEING OR BEST INTERESTS

1. Always regard concern for the best interests or well-being of your patients as your primary professional duty.
2. Honour the trust of your patients.
3. Be mindful that a medical, dental or medical science practitioner is in a position of power over a patient and avoid abusing your position.
4. Within the normal constraints of your practice, be accessible to patients when you are on duty, and make arrangements for access when you are not on duty.
5. Make sure your personal beliefs do not prejudice your patients' care. Beliefs that might prejudice care relate to patients' race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
6. If you feel your beliefs might affect the treatment you provide, explain this to your patients, and inform them of their right to see another professional.
7. Do not refuse or delay treatment because you believe that patients' actions have contributed to their condition, or because you may be putting your health at risk.
8. Apply your mind when making diagnoses and considering appropriate treatment.
9. Act quickly to protect patients from risk if you believe yourself to be impaired.

10. Respond to criticism and complaints promptly and constructively.
11. Do not employ any intern, doctor or dentist in community service, or medical practitioner with restricted registration with the HPCSA, as a *locum tenens* or otherwise in your or any associated health care practice.
12. Inform your patients if you are in the employ of, in association with, linked to, or have an interest in any organisation or facility that could be interpreted by an average person as potentially creating a conflict of interest or dual loyalty in respect of your patient care.
13. Provide health care in emergency situations within the limits of your practice, experience and competency. If unable to do so, refer the patient to a colleague who can provide the required care.

2.2 RESPECT FOR PATIENTS

14. Respect patients' privacy and dignity.
15. Treat patients politely and with consideration.
16. Listen to your patients and respect their opinions.
17. Avoid improper relationships (for example sexual relationships or exploitative financial arrangements) with your patients, their friends or family members.
18. Guard against human rights violations of patients, and do not allow or participate in any actions that lead to the violations of the rights of patients.

2.3 INFORMED CONSENT

19. Give your patients the information they ask for or need about their condition, its treatment and prognosis.
20. Give information to your patients in the way they can best understand it.
21. Refrain from withholding from your patients any information, investigation, treatment or procedure you know would be in their best interest.
22. Apply the principle of informed consent as an on-going process.
23. Allow patients access to their medical records (see Booklet on keeping of medical records (in preparation)).

2.4 PATIENT CONFIDENTIALITY

24. Recognise the right of patients to expect that you will not pass on any personal and confidential information you acquire in the course of your professional duties, unless they agree to disclosure, or unless you have good and overriding reason for doing so. (Examples of such reasons may be any probable and serious harm to an identifiable third party, a public health emergency, or any overriding and ethically justified legal requirements.)
25. Do not breach confidentiality without sound reason and without the knowledge of your patient.

26. Ask your patients' permission before sharing information with their spouses, partners or relatives.

2.5 PATIENT PARTICIPATION IN THEIR OWN HEALTH CARE

27. Respect the right of patients to be fully involved in decisions about their treatment and care.
28. Respect the right of patients to refuse treatment or to take part in teaching or research.
29. Inform your patients that they have a right to seek a second opinion without prejudicing their future treatment.

2.6 IMPARTIALITY AND JUSTICE

30. Be aware of the rights and laws concerning unfair discrimination in the management of patients or their families on the basis of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability such as contained in health rights legislation (see *Booklet on the National Patients' Rights Charter*).

2.7 ACCESS TO CARE

31. Promote access to health care. If you are unable to provide a service, refer the patient to another health-care professional who or to a health-care facility which can provide the required service.

2.8 POTENTIAL CONFLICTS OF INTEREST

32. Always seek to give priority to the investigation and treatment of patients solely on the basis of clinical need.
33. Avoid over-servicing. Recommend or refer your patients for necessary investigations and treatment only. Prescribe only treatment, drugs or appliances that serve patients' needs.
34. Declare to your patients – verbally and by notice displayed – any financial interest you may have in institutions, diagnostic equipment, or the like to which you make referrals (see *Booklet on Ethical and Professional Rules* and the *Booklet on Policy Statement on Perverse Incentives*).
35. Refrain from placing pressure on patients or their family to give you gifts or any other undue benefit.

3. DUTIES TO COLLEAGUES AND OTHER PROFESSIONALS

3.1 REFERRALS TO COLLEAGUES AND POTENTIAL CONFLICTS OF INTEREST

1. Act in your patients' best interest when making referrals and providing or arranging treatment or care. Do not ask for or accept any inducement, gift, or hospitality because it may affect or be seen to affect your judgement. Do not offer such inducements to colleagues.

2. Treat patients referred to you in the same manner in which you treat your own patients.

3.2 WORKING WITH COLLEAGUES

3. Work with and respect other health-care professionals in pursuit of the best health care possible for all patients.
4. Do not discriminate against colleagues, including professionals applying for posts, because of your views of their race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
5. Refrain from speaking ill of colleagues or other health-care professionals.
6. Do not make a patient doubt colleagues' knowledge or skills by making comments about them that cannot be fully justified.
7. Support colleagues who uphold the core values and standards embodied in these guidelines.

4. DUTIES TO OTHER PROFESSIONALS' PATIENTS

Risk of harm to others' patients

1. Act quickly to protect patients from risk if you believe a colleague to be impaired.
2. Report violations and seek redress in circumstances where you have good or persuasive reason to believe that the rights of patients are being violated.

5. DUTIES TO YOURSELF

5.1 KNOWLEDGE AND SKILLS

1. Maintain and improve the standard of your performance by keeping your professional knowledge and skills up to date throughout your working life. In particular, regularly take part in educational activities that relate to your branch or discipline of medicine, dentistry or medical sciences.
2. Acknowledge the limits of your professional knowledge and competence. Do not pretend to know everything.
3. Since there are laws that govern aspects of professional health care practice, observe and keep up to date with those that affect your practice.

5.2 MAINTAINING A PROFESSIONAL PRACTICE

4. Keep your medical equipment in good working order.
5. Maintain proper hygiene in your working environment.
6. Keep accurate and up-to-date patient records (see *Booklet on Keeping of Patient Records*).

7. Refrain from engaging in activities that may affect your health and lead to impairment.

6. DUTIES TO SOCIETY

6.1 ACCESS TO SCARCE RESOURCES

1. Deal responsibly with scarce health-care resources. Refrain from providing a service that is not needed, whether it provides financial gain or not. Refrain from unnecessary wastage, and from participating in improper financial arrangements, especially those that escalate costs and disadvantage individuals or institutions unfairly.

6.2 HEALTH-CARE POLICY DEVELOPMENT

2. Include ethical considerations and human rights in the development of health care policies.

7. DUTIES TO YOUR PROFESSION

7.1 REPORTING MISCONDUCT

1. Report violations and seek redress in circumstances where you have good or persuasive reason to believe that the rights of patients are being violated.
2. Where it is in your power, protect someone who reports misconduct from victimisation or intimidation.

7.2 ACCESS TO APPROPRIATE HEALTH CARE

3. Promote access to health care. If you are unable to provide a service, refer the patient to another professional or health-care facility.

8. DUTIES TO THE ENVIRONMENT

8.1 CONSERVATION OF NATURAL RESOURCES

1. Recognise that natural resources are limited and guard against their exploitation.

8.2 DISPOSAL OF HEALTH CARE WASTE

2. Protect the environment and the public by assuring that health care waste is disposed of legally and in an environmentally friendly manner (see *Booklet on the Management of Health Care Waste*).

Ethical guidelines for good practice in medicine, dentistry and the medical sciences

The Medical and Dental Professions Board of the Health Professions Council of South Africa has embarked on a project to bring together ethical and professional guidelines for doctors (medical practitioners), dentists, and medical scientists. The following Booklets are separately available:

- Booklet 1:** *General ethical guidelines for doctors, dentists and medical scientists*
- Booklet 2:** *General ethical guidelines for health researchers*
- Booklet 3:** *Ethical and professional rules of the Medical and Dental Professions Board*
- Booklet 4:** *Professional self-development*
- Booklet 5:** *Guidelines for making professional services known*
- Booklet 6:** *Guidelines for the management of health care waste*
- Booklet 7:** *Policy statement on perverse incentives*
- Booklet 8:** *Guidelines for the management of patients with HIV infection or AIDS*
- Booklet 9:** *Guidelines on research and clinical trials involving human subjects*
- Booklet 10** *Research, development and use of the chemical, biological and nuclear capabilities of the State*
- Booklet 11** *Guidelines on keeping of patient records*
- Booklet 12** *Canvassing of patients abroad*
- Booklet 13** *National Patients' Rights Charter*
- Booklet 14:** *Confidentiality: Protecting and providing information*
- Booklet 15:** *Seeking patients' consent: The ethical considerations*



MEDICAL AND DENTAL PROFESSIONS BOARD

**GUIDELINES FOR GOOD PRACTICE IN MEDICINE,
DENTISTRY AND THE MEDICAL SCIENCES**

**GENERAL ETHICAL GUIDELINES FOR
HEALTH RESEARCHERS**

BOOKLET 2

**PRETORIA
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THE SPIRIT OF PROFESSIONAL GUIDELINES

Medicine, dentistry and the medical sciences are professions based on a relationship of trust with patients. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good doctor, dentist or medical scientist requires a life-long commitment to good professional and ethical practices and an overriding dedication to the good of one's fellow humans and society. In essence, the practice of medicine, dentistry and the medical sciences is a moral enterprise. In this spirit the Medical and Dental Professions Board presents the following ethical guidelines.

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GENERAL ETHICAL GUIDELINES FOR HEALTH RESEARCHERS

INTRODUCTION

Being registered as a doctor, dentist or medical scientist under the Health Professions Act, 1974 (Act No. 56 of 1974), confers certain rights and privileges. Corresponding to these rights and privileges are ethical duties a doctor, dentist or medical scientist owes to individuals and society.

The Medical and Dental Professions Board has embarked on a project to bring together ethical guidelines that spell out these duties of registered practitioners and health researchers. In the series *Ethical guidelines for good practice in medicine, dentistry and medical sciences*, this is the second booklet.

This booklet contains *general ethical guidelines* for health researchers. General ethical guidelines are *aspirational guidelines* because they formulate the most honourable ideals to which members of the professions should aspire. Put differently, general ethical guidelines formulate the *general ethical duties* of members of the professions.

More *specific ethical guidelines* and *rules* are derived from these general ethical guidelines. They formulate more *specific ethical duties* and give more precise guidance and direction for action in concrete situations. They also make it possible to implement sanctions against transgressors.

Although the ethical guidelines contained herein are drawn from a variety of sources, the Board supports the principles of good health research set out in the Declaration of Helsinki.

The following terminology needs to be clarified:

- a. "health researcher" to refer to all scientific investigators engaged in health research; and
- b. "research participant" instead of "research subject".

This booklet has two sections. Section One provides a brief background discussion of the ethics in health research.

Section Two catalogues the general ethical duties which health researchers owe to other individuals, society and themselves.

SECTION ONE

ETHICS IN HEALTH RESEARCH

1. ETHICAL GUIDELINES IN HEALTH RESEARCH

- 1.1 Responsible health research achieves two objectives. First, it makes a *scientific* contribution for the good of humans or animals. Second, it is conducted in an *ethical* manner.
- 1.2 For research to be ethical, guidelines need to be followed. Such guidelines flow from underlying ethical values, standards, and principles. Effective guidelines contribute to achieving health research that is both scientifically and ethically sound.
- 1.3 The ethical guidelines for health research catalogued in this booklet are general or aspirational ones. They are the foundation of all specific ethical guidelines or rules governing health research found in various codes of health research ethics. Given their generality, they can be applied to many different research proposals.

2. CODES OF HEALTH RESEARCH ETHICS

- 2.1 Nazi atrocities during the Second World War extended to the health research community. Health researchers were, therefore, also put on trial at Nuremberg and, following these trials, the *Nuremberg Code* came into being. This code sets forth the ethical obligations of a doctor or health researcher to his or her research participant(s). The *Nuremberg Code* was the first historical document to identify the need for the protection of human research participants in health research.
- 2.2 The World Medical Association (WMA), in its 1964 Assembly, developed the *Declaration of Helsinki*. This document has been revised six times reflecting biomedical and technological advances and greater awareness of the ethical complexities imbedded in health research.
- 2.3 Other well-known international documents addressing the use of human participants in health research include the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation (WHO) (revised in 1982 and 1983), and the Belmont Report written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.
- 2.4 In South Africa, specific ethical guidelines for health research are issued by -
 - a. the Medical Research Council of South Africa (MRC), and
 - b. the Department of Health (DOH).
- 2.5 Research ethics committees, for both human and animal research, are designed to consider all ethical questions regarding specific health research through the practice of research protocol review.

3. CORE ETHICAL VALUES AND STANDARDS FOR GOOD PRACTICE IN HEALTH RESEARCH
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3.1 Everything ethically required of a health researcher to practise good professional research is grounded in the following core ethical values and standards. (Values are in boldface, followed by their corresponding standards.)

- **Respect for persons:** Respect research participants as persons or centres of value and acknowledge their intrinsic worth and dignity.
- **Best interest or well-being: Non-maleficence:** Do not harm or act against the best interests of research participants or society, even when there are conflicts with your own personal self-interest.
- **Best interest or well-being: Beneficence:** Act in the best interests of research participants and society, even when there are conflicts with your own self-interest.
- **Human rights:** Recognise that some interests of research participants may be so important that they acquire the status of human rights in the form of either claims or freedoms to be respected by all.
- **Autonomy:** Honour research participants' right to self-determination or to make their own informed choices, living their lives by their own beliefs, values and preferences.
- **Integrity:** Incorporate core ethical values and standards as the foundation for good character and responsible research practice.
- **Truthfulness:** In all professional research relationships, regard the truth and truthfulness as the basis of trust. Record research results meticulously and honestly. Published results must not include unjustified claims of authorship.
- **Confidentiality:** In professional relationships with research participants, treat personal or private information as confidential, unless special circumstances confer a right to disclosure.
- **Compassion:** Be sensitive to and empathise with a research participant's individual and social needs for comfort and support, and seek and create opportunities to translate feelings into action.
- **Tolerance:** Respect the rights of people to have different ethical beliefs as these may arise from deeply held personal, religious or cultural convictions.
- **Justice:** Treat all individuals and groups in an impartial, fair and just manner.
- **Professional competence and self-improvement:** Continually endeavour to attain the highest level of knowledge and skills within your capability.
- **Community:** Consistent with your professional abilities and standing in the community, strive to contribute to the betterment of society, but let the well-being of research participants take precedence over the interests of science and society.

4. BASIC ETHICAL PRINCIPLES IN HEALTH RESEARCH

4.1 Some of these core ethical values and standards have the status of *basic ethical principles*. The following principles are the most basic action-guides in responsible health research:

4.1.1 For human and animal research:

- *The principle of best interest or well-being*
 - The principle of non-maleficence
 - The principle of beneficence

4.1.2 For human research:

- *The principle of respect for persons*
 - The principle of autonomy
 - The principle of informed consent
 - The principle of confidentiality
- *The principles of justice*
 - The principle of formal justice (impartiality)
 - The principles of substantive justice (fair distribution)

4.2 These principles are discussed in greater detail in the *Booklet on Ethics resources for doctors, dentists and medical scientists* (in preparation).

SECTION TWO

GENERAL ETHICAL DUTIES OF HEALTH RESEARCHERS

1. WHAT IT MEANS TO HAVE A DUTY

- 1.1 Ethical guidelines express duties. A duty is an obligation to do or refrain from doing something.
- 1.2 If you have a duty to another person, it means you are bound to that person in some respect and for some reason. You owe that person something, while he or she holds a corresponding right or claim against you.
- 1.3 Suppose you promise your neighbour that you would feed his dog while he's away. You then owe it to your neighbour to keep your promise, while your neighbour has a right to hold you to your promise.
- 1.4 To have a duty is to face the question "What do I owe others?" To have a right is to face the question "What do others owe me?"
- 1.5 Duties may be ethical, legal or both at once. And duties operate in the personal, social, professional or political spheres of our lives.
- 1.6 Health researchers fulfil different roles. Accordingly, they have different kinds of duties:
- 1.6.1 **As human beings you have "natural duties"**, namely unacquired general duties simply because you are members of the human community, for example the natural duties to do good, to refrain from causing harm, or to be fair and just. Like all other persons, health researchers owe these duties to all other people, whether research participants or not and irrespective of your special professional qualifications.
- 1.6.2 **As professionals you have "moral obligations"**, namely general duties you acquire voluntarily by being qualified and licensed as a health researcher in your capacity as a doctor, dentist or medical scientist, for example the duties not to harm research participants, to obtain informed consent from them or to treat them fairly and justly.
- 1.6.3 **As professionals working in specific institutions or settings you have "duties"**, namely acquired duties specific to your particular institutionalised role, for example the duties of a health researcher employed by a pharmaceutical company, a health researcher in the employ of a governmental research agency, or a doctor engaged in personal clinical research. These duties are circumscribed in employment contracts, job descriptions, conventional expectations and the like.
- 1.7 Duties listed in these general guidelines mostly fall in the second category – the *general* but *acquired* duties of a health researcher *as a professional*.
- 1.8 No duty holds without exception or without the potential to be outweighed by another duty, not even the most basic duties not to kill or to save life. Thus no duty is absolute. This is not surprising, since different duties may prescribe quite opposing courses of action in a concrete situation.
- 1.9 In short, all duties are *prima facie*, which means that they are not absolute, but need to be taken very seriously and weighed against one another, in the concrete circumstances of every case and in a balancing process of ethical reasoning.

- 1.10 No list of such duties is ever complete, but the catalogue of duties below presents a fairly comprehensive picture of what it is, in general, that binds any health researcher as a professional to his or her research participants, as well as to others. However, it should be noted that these duties, if broken, may constitute the basis of sanctions being imposed on health researchers by the Medical and Dental Professions Board.
- 1.11 To some extent, any classification of duties is arbitrary, since a specific duty may be owed to different parties simultaneously. The classification system or convention used below should, therefore, be viewed as no more than a rough compass.
- 1.12 Bear in mind that underlying and giving rise to these duties is a set of core ethical values and standards for good practice in health research (see “Core ethical values and standards for good practice in health research” in Section One hereof).

2. DUTIES TO RESEARCH PARTICIPANTS

2.1 WELL-BEING OR BEST INTERESTS OF RESEARCH PARTICIPANTS
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1. Overriding all other interests, place the care of and concern for the life, health, privacy and dignity of your research participant first.
2. Honour the trust a research participant has in you.
3. Recognise that a health researcher is in a position of power over a research participant and avoid abusing your position.
4. Abstain from engaging in research projects involving human research participants unless you are in no doubt that the risks involved have been adequately assessed and can be satisfactorily managed throughout the project's duration.
5. Stop the involvement of any participant if continuation of the research may be harmful to that person.
6. Be accessible to research participants in the course of your investigations.
7. Make sure your personal beliefs do not prejudice your choice of research participants. Beliefs might prejudice choices relating to research participants' lifestyle, culture, beliefs, race, colour, gender, sexual orientation, age, social status, or perceived economic worth.
8. Cease any research if the risks are found to outweigh potential benefits or if positive and beneficial results appear remote or unlikely.
9. Act quickly to protect research participants from risk if you believe you are in any way impaired.
10. Respond to criticism and complaints promptly and constructively.
11. Inform your research participants if you are in the employ, in association with or linked to any organisation that could be interpreted by an average person as one that causes harm to or compromises the rights of research participants.
12. Remember that it is your duty to ensure that all research participants must be informed volunteers.

13. Act quickly to protect research participants from risk if you believe a colleague to be impaired.
14. Report violations and seek redress, if possible, in circumstances where you believe violations of the rights of research participants are taking place.

2.2 RESPECT FOR RESEARCH PARTICIPANTS

15. Respect research participants' privacy and dignity.
16. Treat research participants politely and with consideration.
17. Listen to your research participants and respect their opinions.
18. Always respect the right of research participants to safeguard their integrity.
19. Avoid improper relations with your research participants, their friends or family members.
20. Remember that contemporary societal reactions to particular diseases may place research participants at risk and consider this risk in the selection of research participants.
21. Guard against human-rights violations and do not allow or participate in any actions that lead to violations of the rights of others.

2.3 INFORMED CONSENT

22. Give your research participants the information they ask for or need about their research participation, its foreseeable risks and potential benefits.
23. Remember that responsibility for the well-being of a human research participant must always rest with the health researcher and never with the research participant, even though he or she has given consent.
24. Give information to your research participants in the way they can best understand it.
25. Use caution when obtaining informed consent if the research participant is in a dependent relationship with you as health researcher or may consent under duress. In such cases, informed consent should be obtained by a well-informed medical practitioner who is not engaged in the research and who is completely independent of this relationship.
26. Refrain from purposefully withholding from your research participants any information, investigation or procedure you know would be in their best interest.
27. Obtain the consent of legally authorised representatives in cases where a research participant, such as a minor child, is unable to give consent for decisions about research participation.
28. Consider the legal implications of informed consent. For a research participant who is legally incompetent, physically or mentally incapable of giving consent, or is a legally incompetent minor, the researcher must obtain informed consent from the legally authorised representative in accordance with applicable law. These

groups should not be included in research unless the research is necessary to promote the health of the population represented and unless this research cannot instead be performed on legally competent persons.

29. Remember that the principle of informed consent should be viewed as an on-going process.
30. Inform the research participant of his or her right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal.
31. Allow competent research participants unimpeded access throughout the research period to information concerning the research.
32. Remember that in any research on human beings, each potential research participant must be adequately informed of the aims, methods, sources of funding, potential conflicts of interests, institutional affiliations of the researcher, anticipated benefits and risks of the study, and any discomfort it might entail.
33. Adhere to the principle of informed consent by keeping proper documentation. After ensuring that the research participant understands the information, the health researcher should then obtain the participant's freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be fully documented and witnessed.

2.4 RESEARCH PARTICIPANT CONFIDENTIALITY

34. Recognise the right of research participants to expect that you will not pass on any personal and confidential information you learn in the course of your professional duties, unless they agree.
35. Do not breach confidentiality without sound reason and without the knowledge of your research participant.
36. Protect the confidentiality of research data or other disclosures.

2.5 PARTICIPATION BY RESEARCH PARTICIPANTS

37. Respect the right of research participants to be involved in decisions about their research participation.
38. Respect the right of research participants to withdraw from a research project at any time without providing any reason.

2.6 IMPARTIALITY AND JUSTICE

39. Be aware of the rights and laws concerning unfair discrimination in the management of research participants or their families on the basis of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability such as contained in health-rights legislation.

40. Do not discriminate in the selection and recruitment of participants by including or excluding them on the grounds of race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability, except where the exclusion or inclusion of particular groups is critical to the research purpose and scientific design.
41. Design research projects so that the selection, recruitment, exclusion or inclusion of research participants is fair and equitable.
42. Balance the burdens and benefits of research within populations.
43. Avoid imposing on particular groups, who are likely to be subject to over-researching, an unfair burden of participation.

2.7 HEALTH RESEARCH AND MEDICAL CARE

44. Combine health research with medical care only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value.
45. Test the benefits and burdens, risks and effectiveness of new methods against those of the best current prophylactic, diagnostic and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic and therapeutic method exists.
46. At the conclusion of your study, assure research participants access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
47. Fully inform your research participants which aspects of medical care, if any, are related to the research.
48. Promote access to health care. In the course of your research, should you be unable to provide required care, refer the research participant to another doctor, specialist, or health-care facility.

2.8 POTENTIAL CONFLICTS OF INTEREST

49. Declare to your research participants any financial interest you may have in institutions, equipment, research sponsors and the like.
50. Refrain from placing pressure on a research participant or his or her family to give you gifts or any other undue benefit.
51. Disclose any potential conflict of interests to your research ethics committee before the research commences.
52. Design your research to exclude any potential conflict of interests with sponsors or collaborators.

3. DUTIES TO RESEARCH COLLEAGUES AND OTHER PROFESSIONALS

1. Work with and respect other health-care professionals in pursuit of the best health care possible for all research participants.

2. Do not discriminate against colleagues because of your views of their race, culture, ethnicity, social status, lifestyle, perceived economic worth, age, gender, disability, communicable disease status, sexual orientation, religious or spiritual beliefs, or any condition of vulnerability.
3. Refrain from speaking ill of colleagues or other health-care professionals.
4. Do not make a research participant doubt another colleague's knowledge or skills by making unnecessary or unsustainable comments about them.

4. DUTIES TO YOURSELF

4.1 KNOWLEDGE AND SKILLS

1. Maintain and improve the standard of your performance by keeping your professional knowledge and skills up to date throughout your working life. In particular, regularly take part in educational activities that relate to your branch of medicine, dentistry or medical science, as well as health research.
2. Acknowledge the limits of your professional knowledge and competence. Do not pretend to know everything.
3. Observe and keep up to date with the laws that affect health research.

4.2 EQUIPMENT, HYGIENE, AND RECORD KEEPING

4. Keep your research equipment in good working order.
5. Maintain proper hygiene in your working environment.
6. Keep accurate and up-to-date research participant records.

5. DUTIES TO SOCIETY

5.1 RESPECT FOR LIFE

1. Treat living objects - humans, animals and plants - with the necessary and appropriate respect.

5.2 REPORTING SCIENTIFIC MISCONDUCT

2. Report evidence of fraud and other crimes or scientific misconduct in research to an appropriate person or authority.

5.3 ACCESS TO SCARCE RESOURCES

3. Deal responsibly with scarce health-care resources. Refrain from research that duplicates other research unnecessarily.

4. Refrain from any form of resource wastage in carrying out your research.
5. Refrain from participating in improper financial arrangements that escalate costs or disadvantage research participants, patients or institutions unfairly.
6. Design and conduct research to include or provide the use of appropriate facilities, in order to manage any rising contingencies.

5.4 LEGAL REGULATIONS

7. Conform to relevant legal requirements and ensure that your research is lawful.
8. Should both a legal requirement and an ethical guideline apply to research, the legal requirement will take precedence although they will normally be consistent.
9. Adhere to ethical guidelines. Where ethical guidelines prescribe a higher standard than the law, conform to that higher standard.
10. Conduct or supervise research performed only by experienced, qualified, competent and ethical health researchers who are approved by all relevant bodies.

6. DUTIES TO YOUR PROFESSION

6.1 REPORTING MISCONDUCT

1. Report violations and seek redress, if possible, in circumstances where you believe violations of the rights of others are taking place.
2. Report evidence of fraud or misconduct in research to an appropriate person or authority.

6.2 REVIEW PROCESSES

3. Receive approval for your research project from all relevant committees before beginning the project.
4. Notify all relevant reviewing bodies if the risks to participants are found to be disproportionate to the benefits.
5. Stop the involvement of any participant if continuation of the research may be harmful to that person.
6. Inform relevant reviewing bodies and institutions of any changes to your research protocol.

7. DUTIES TO ANIMALS

1. Accept stewardship for animals used in health research and respect their welfare.

2. Demonstrate that your research is justifiable and based on documentation of literature reviews, prior observations, approved studies and, when applicable, laboratory and animal studies.
3. In the use of animals, follow the ethical and regulatory guidelines established at institutional level, by professional associations, and by governmental authorities.
4. Utilise, when appropriate, inanimate materials and processes instead of animals.
5. If the use of an animal species is scientifically necessary, use lower animal species that may be less susceptible to pain and suffering, without compromising the integrity of the research.
6. When designing the research protocol, the numbers of animals used should reflect the minimum necessary to yield valid answers to the research hypothesis.
7. Take active measures to use procedures that minimise both the incidence and severity of the pain and suffering experienced by animals.
8. In non-survival research or surgery, do not allow the animal to regain consciousness or experience any pain prior to euthanasia.
9. In non-survival research or surgery, use a species-appropriate and effective method of euthanasia.

8. DUTIES TO THE ENVIRONMENT

8.1 CONSERVATION OF NATURAL RESOURCES
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1. Recognise that natural resources are limited and guard against their exploitation.

8.2 DISPOSAL OF HEALTH CARE WASTE
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2. Protect the environment and the public by assuring that health care waste is disposed of legally and in an environmentally friendly manner (see *Booklet 6 on the Management of Health Care Waste*).

Ethical guidelines for good practice in medicine, dentistry and the medical sciences

The Medical and Dental Professions Board of the Health Professions Council of South Africa has embarked on a project to bring together ethical and professional guidelines for doctors (medical practitioners), dentists, and medical scientists. The following Booklets are separately available:

- Booklet 1:** *General ethical guidelines for doctors, dentists and medical scientists*
- Booklet 2:** *General ethical guidelines for health researchers*
- Booklet 3:** *Ethical and professional rules of the Medical and Dental Professions Board*
- Booklet 4:** *Professional self-development*
- Booklet 5:** *Guidelines for making professional services known*
- Booklet 6:** *Guidelines for the management of health care waste*
- Booklet 7:** *Policy statement on perverse incentives*
- Booklet 8:** *Guidelines for the management of patients with HIV infection or AIDS*
- Booklet 9:** *Guidelines on research and clinical trials involving human subjects*
- Booklet 10** *Research, development and use of the chemical, biological and nuclear capabilities of the State*
- Booklet 11** *Guidelines on keeping of patient records*
- Booklet 12** *Canvassing of patients abroad*
- Booklet 13** *National Patients' Rights Charter*
- Booklet 14:** *Confidentiality: Protecting and providing information*
- Booklet 15:** *Seeking patients' consent: The ethical considerations*