



HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

**GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS**

**GENERAL ETHICAL GUIDELINES FOR
HEALTH RESEARCHERS**

BOOKLET 6

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THE SPIRIT OF PROFESSIONAL GUIDELINES

Practice as a health care professional is based upon a relationship of mutual trust between patients and health care practitioners. The term "profession" means "a dedication, promise or commitment publicly made".¹ To be a good health care professional requires a life-long commitment to sound professional and ethical practices and an overriding dedication to the interests of one's fellow human beings and society. In essence, practice as a health care professional is a moral enterprise. In this spirit the Health Professions Council of South Africa presents the following ethical guidelines.

[Note: The term "health care practitioner" in these guidelines refers to persons registered with the HPCSA].

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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GENERAL ETHICAL GUIDELINES FOR HEALTH RESEARCHERS

1. PREAMBLE

Biomedical research has made spectacular strides during the past century. That medical research has increased the well being of humans in much of the world is without doubt but the power to save human lives and ameliorate disease has also raised concerns about how this is achieved and how its fruits will be distributed. South Africa with its scientific expertise, advanced infrastructure, developing country burden of disease and large number of vulnerable populations provides fertile ground for research. Moreover the country is still recovering from its many years under apartheid. Hence the misuse of power in research cannot be ignored. The following guidelines should serve as a reference to research institutions, organisation and researchers registered with the HPCSA

2. INTRODUCTION

- 2.1 Being registered as a health practitioner under the Health Professions Act, 1974 (Act No. 56 of 1974), confers certain rights and privileges. Corresponding to these rights and privileges are the ethical duties a health practitioner owes to individuals and society.
- 2.2 This booklet contains *general ethical guidelines* for health researchers. General ethical guidelines embody the ideals to which members of professions should aspire and subscribe. A failure to do so may result in disciplinary action by the HPCSA and legal consequences.
- 2.3 The ethical guidelines contained herein are drawn from a variety of sources, including the South African Constitution, the Department of Health's Ethics in Health Research: Principles, Structures and Processes, the South African Medical Research Council's Guidelines for Ethics in Medical Research and the Declaration of Helsinki.
- 2.4 The following definitions apply:
- 2.4.1 'Health researcher' refers to all scientific investigators engaged in health research.
- 2.4.2 'Research participant' refers to a person who subjects himself or herself to a process of scientific or health research.
- 2.4.3 'Health research,' as defined in the National Health Act (Act No. 61 of 2003), includes any research that contributes to the knowledge of:
- i The biological, clinical psychological or social processes in human beings;
 - ii Improved methods for the provision of health services;
 - iii Human pathology;
 - iv The causes of diseases;
 - v The effects of the environment on the human body;
 - vi The development or new application of pharmaceuticals, medicines and related substances; and
 - vii The development of new applications of health technology.
- 2.4.4 'Research ethics committee' refers to a multidisciplinary committee charged with the primary objective of protecting research participants through the ethical review, approval and monitoring of research.
- 2.4.5 'Clinical trial' refers to a systematic study involving human participants that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.

- 2.4.6 According to the UNAIDS definition, 'Vulnerable communities' refers to those communities that have some or all of the following characteristics
- i. Limited economic development
 - ii. Inadequate protection of human rights and discrimination on the basis of health status
 - iii. Inadequate community/cultural experience with the understanding of scientific research
 - iv. Limited availability of health care and treatment options
 - v. Limited ability of individuals in the community to provide informed consent
 - vi. Being a junior or subordinate member of a hierarchical group
 - vii. Limited literacy levels

3. ETHICAL GUIDELINES IN HEALTH RESEARCH

- 3.1 Researchers conducting health research involving human participants need to consider the possible adverse impacts of their research on vulnerable groups and thus have a duty to observe the highest possible standards to protect the rights of research participants.
- 3.2 Responsible health research not only makes a *scientific* contribution for the good of humans or animals, but is also conducted in an *ethical* manner.
- 3.3 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 scientifically, ethically and legally sound.
- 3.4 Health research ethics committees use a protocol review procedure to consider all ethical questions regarding human and animal health research proposals and protocols. In terms of the National Health Act (Act No. 61 of 2003), all health research proposals and protocols require approval by an accredited health research ethics committee before the research may commence.

4. BASIC ETHICAL PRINCIPLES IN HEALTH RESEARCH

- 4.1 Some core ethical values and standards have the status of *basic ethical principles*.

4.1.1. *The principle of best interest or well-being*

The principle of non-maleficence: risks and harms of research to participants must be minimised.

The principle of beneficence: The benefits of health research must outweigh the risks to the research participants.

4.1.2. *The principle of respect for persons:*

The principle of autonomy: participants that are capable of deliberation about personal choices should be treated with respect for their capacity of self determination and be afforded the opportunity to make informed decisions with regard to their participation in research. Therefore there must be special protections for those with diminished or impaired autonomy i.e. dependant and or vulnerable participants need to be afforded safeguards against harm or abuse.

The principle of confidentiality: A participant's right to both privacy and confidentiality must be protected. The researcher must ensure that where personal information about

research participants or a community is collected, stored, used or destroyed, this is done in ways that respect the privacy or confidentiality of participants or the community and any agreements made with the participants or the community

4.1.3. *The principle of justice*

Justice imposes an ethical obligation to treat each person in accordance with what is right and proper. In research this is primarily distributive justice whereby there should be equitable distribution of both burdens and benefits of research participation. It is an ethical imperative that the study should leave the participant and or community better off or no worse off. Researchers have an obligation to justify their choice of research questions and to ensure that such questions are neither gratuitous nor result in the exploitation of study participants. The selection, recruitment, exclusion and inclusion of research participants must be just and fair, based on sound scientific and ethical principles. No persons may be inappropriately or unjustly excluded on the basis of race, age, sex, sexual orientation, disability, education, religious beliefs, pregnancy, marital status, ethnic or social origin, conscience, belief or language.

Where research involves participants from vulnerable communities, added protections will be necessary to safeguard their vulnerabilities. There needs to be justification for doing research in vulnerable communities. Moreover, the research should be responsive to their particular vulnerabilities. Enhanced or added consent procedures would be necessary where appropriate. Vulnerable communities should not be targeted for research just because of administrative and logistical ease of availability.

5. THE SOCIAL VALUE OF RESEARCH

5.1 Research in South Africa should be responsive to the health needs of our communities and in line with our national health research priorities as outlined in section 70 of the National Health Act. The following factors should be taken into consideration:

- 5.1.1 The burden of disease;
- 5.1.2 The cost-effectiveness of interventions aimed at reducing the burden of disease;
- 5.1.3 The availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities;
- 5.1.4 The health needs of vulnerable groups such as women, older persons, children and people with disabilities; and
- 5.1.5 The health needs of communities.

6. DUTIES TO RESEARCH PARTICIPANTS

6.1 ACTING IN THE BEST INTERESTS OF RESEARCH PARTICIPANTS

In order to always act in the best interests of research participants, health researchers should always:

- 6.1.1 Place the life, well being, health, privacy and dignity of their research participants before all other interests.
- 6.1.2 Honour the trust that research participants place in them.
- 6.1.3 Recognise that they are in a position of power over research participants and should avoid abusing their position.

- 6.1.4 Abstain from engaging in research projects involving human research participants unless they are in no doubt that the risks involved have been adequately assessed and can be satisfactorily managed throughout the duration of the project.
- 6.1.5 Stop the involvement of research participants if continuation of the research may be harmful to them or where it becomes obvious that the risks are outweighing the benefits.
- 6.1.6 Be accessible to research participants in the course of their investigations.
- 6.1.7 Ensure that their personal beliefs do not influence their choice of research participants. Such beliefs may prejudice choices regarding the lifestyle, culture, beliefs, race, colour, gender, sexual orientation, age, social status, or perceived economic worth of research participants, and will be unethical.
- 6.1.8 Respond to criticism and complaints promptly and constructively.
- 6.1.9 Report violations and seek redress, if possible, in circumstances where they believe that violations of the rights of research participants are taking place.
- 6.1.10 Ensure that research participants are compensated for all reasonable expenses or loss of income incurred as a result of their participation in research and such compensation should be specified in the relevant research protocol or proposal.
- 6.1.11 Ensure that all research participants are compensated for trial related injuries and that there is adequate insurance cover for research participants. .
- 6.1.12 Ensure that no undue inducements are offered to participants to encourage them to participate in the research by exploiting their unfavourable socio – economic status.
- 6.1.13 Ensure at the end of a drug trial that on-going treatment where needed/necessary is available to research participants.

6.2 RESPECT FOR RESEARCH PARTICIPANTS

In order to demonstrate respect for their research participants, health researchers should always:

- 6.2.1 Respect the privacy and dignity of research participants.
- 6.2.2 Treat research participants politely and with consideration.
- 6.2.3 Listen to the research participants and respect their opinions.
- 6.2.4 Respect the right of research participants to safeguard their integrity.
- 6.2.5 Avoid improper relations with research participants, their friends or family members.
- 6.2.6 Remember that contemporary societal reactions to particular diseases may place research participants at risk and this must be taken into account when selecting research participants.
- 6.2.7 Guard against human-rights violations and avoid participating in any actions that violate the rights of others.

6.3	INFORMED CONSENT
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Health researchers should always:

- 6.3.1 Give research participants sufficient information about the nature and effect of the research - in particular the effect of the research on the participants including its consequences, risks and benefits - to enable them to make an informed choice about their participation.
- 6.3.2 Give research participants the information they ask for and need about their research participation.
- 6.3.4 Remember that responsibility for the well-being of research participants always rests with the health researcher - not the research participants - even though the latter have given consent.
- 6.3.5 Give information to research participants in a language that the participant understands and in a manner that takes into account the participant's level of literacy, understanding, values and personal belief systems. Participation at all times should be voluntary and not coerced.
- 6.3.6 Use caution when obtaining informed consent where the research participant is in a dependent relationship with the health researcher or is in a situation where he or she may consent under duress. In such cases, informed consent should be obtained by a well-informed health care practitioner who is not engaged in the research and who is completely independent of this relationship.
- 6.3.7 Refrain from purposefully withholding from research participants any information, investigation or procedure that health care practitioners know is in the best interests of the participants.
- 6.3.8 Obtain the consent of legally authorised representatives in cases of research participants who cannot consent for themselves, e.g. children, mentally challenged, elderly and the unconscious. 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.
- 6.3.9 Remember that the principle of informed consent should be viewed as an on-going process in that research participants are entitled to change their minds. Moreover, the consent process should be reinforced during the trial.
- 6.3.10 Inform research participants of their right to abstain from participating in the study, or to withdraw from participating in the study - by revoking their consent - at any time, without suffering prejudice or reprisal.
- 6.3.11 Allow competent research participants unimpeded access throughout the research period to information concerning the research.
- 6.3.12 Inform participants of the limits to the confidentiality of the information about them gathered during the research - e.g. bodies such as the National Health Research Ethics Council, the HPCSA, and the Medicines Control Council may review or inspect data.

- 6.3.13 Adhere to the principle of informed consent by keeping proper documentation. After ensuring that the research participant understands the information, the health researcher should obtain the participant's freely given informed consent in writing. If the consent cannot be obtained in writing, the non-written consent must be fully documented and witnessed. Both verbal and written informed consent must be obtained unless there are good reasons for not doing so. Where the research participant is not literate verbal consent should be obtained in the presence of an independent literate witness who should verify this in writing. Where the independent witness is not literate, the consent process should be audio-visually recorded.

6.4	RESEARCH PARTICIPANT CONFIDENTIALITY
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Health researchers should always:

- 6.4.1 Recognise the right of research participants to expect that health researchers will not pass on any personal and confidential information that the latter learn in the course of their professional duties, unless the research participants agree.
- 6.4.2 Not breach confidentiality without sound reason and without the knowledge and consent of the research participants.
- 6.4.3 Protect the confidentiality of research data or other disclosures made by research participants.

6.5	IMPARTIALITY AND JUSTICE
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Health researchers must always:

- 6.5.1 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.
- 6.5.2 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.
- 6.5.3 Design research projects so that the selection, recruitment, exclusion or inclusion of research participants is fair and equitable.
- 6.5.4 Balance the burdens and benefits of research within different population groups.
- 6.5.5 Avoid imposing an unfair burden of research participation on particular groups and communities, who are likely to be subject to over-researching.

6.6	HEALTH RESEARCH AND MEDICAL HEALTH CARE
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Health care should not be assumed to refer to drug treatments only. It extends to considerations of all other aspects of health care under the control of the investigator.

In all instances, health researchers should:

- 6.6.1 Combine health research with medical care only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value.
- 6.6.2 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.
- 6.6.3 At the conclusion of their study, ensure that research participants have access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
- 6.6.4 Fully inform research participants about which aspects of medical care, if any, are related to health research, and clearly distinguish between therapeutic interventions and health research processes.
- 6.6.5 Ensure that research participants understand that the health researcher's role as a researcher differs from their role as health care practitioners.
- 6.6.6 Promote access to health care. Should health researchers be unable to provide the required research related health care for research participants they should refer the research participants to another health care practitioner or healthcare facility. The costs of this care should be the responsibility of the researcher and sponsor.
- 6.6.7 Ensure that in multi-centre and multi-national studies, equal standards of care are applied across countries to all research participants

6.7	POTENTIAL CONFLICTS OF INTEREST
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All health researchers should:

- 6.7.1 Declare to all research participants any conflicts of interest they may have in institutions, equipment, research sponsors etc. This includes the need to declare whether the research is being conducted for academic purposes.
- 6.7.2 Disclose any potential conflicts of interest to their research ethics committee before the research commences.
- 6.7.3 Design their research to exclude any potential conflicts of interest with sponsors or collaborators.

7. DUTIES TO RESEARCH COLLEAGUES AND OTHER PROFESSIONALS

Health researchers should always:

- 7.1 Work with and respect other health care practitioners in pursuit of the best health care possible for all research participants.
- 7.2 Not discriminate against colleagues because 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.
- 7.3 Not allow research participants to doubt the knowledge or skills of colleagues by making unnecessary or unsubstantiated comments about them.
- 7.4 Refrain from unjustifiably hindering other colleagues who wish to conduct research in similar fields.

8. DUTIES TO HEALTH RESEARCHERS THEMSELVES

8.1 KNOWLEDGE AND SKILLS

- 8.1.1 Health researchers who are suitably qualified should conduct health research studies. In all cases including multi-national collaborative research the local primary investigator must be a South African based researcher (i.e. a person who is permanently based in South Africa). The Principal Investigator must be registered with the HPCSA and must be responsible for the ethical management of study.
- 8.1.2 All health researchers should always:
 - 8.1.2.1 Maintain and improve the standard of their performance by keeping their professional knowledge and skills up to date throughout their working life. In particular, they should regularly take part in educational activities that enhance their scientific and research ethics knowledge.
 - 8.1.2.2 Acknowledge the limits of their professional knowledge and competence.
 - 8.1.2.3 Observe and keep up to date with the ethical and regulatory frameworks that affect health research.
- 8.1.3 In all cases there should be skills development for researchers from the previously disadvantaged backgrounds. This is the duty of the Principle Investigator. Institutions accredited by the HPCSA must have clear development plans in accordance with the relevant prescripts.

8.2 EQUIPMENT, HYGIENE, AND RECORD KEEPING

Health researchers should always:

- 8.2.1 Keep their research equipment in good working order.
- 8.2.2 Maintain proper hygiene in their working environment.
- 8.2.3 Keep accurate and up-to-date records about research participants.

9. DUTIES TO SOCIETY

9.1. RESPECT FOR LIFE

- 9.1.1 Health researchers should treat all living objects - humans, animals and plants - with the necessary and appropriate respect.
- 9.1.2 Animals should not be used in research requiring them to be harmed or sacrificed where alternative methods such as computer-generated models can be used to achieve the same results.

9.2 REPORTING SCIENTIFIC MISCONDUCT

Health researchers should report evidence of fraud and other crimes or scientific misconduct in research to the HPCSA.

- 9.2.1 Scientific misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- 9.2.2 Fabrication is making up data or results and recording or reporting them
- 9.2.3 Falsification is manipulating research material, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- 9.2.4 Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit
- 9.2.5 Scientific misconduct does not include honest error or honest difference of opinion
Definition available at http://www.ostp.gov/html/001207_3.htm
- 9.2.6 Scientific misconduct also includes but is not limited to:
- Failure of obtaining informed consent
 - Inappropriate disclosure of research participant data
 - Deviation from approved protocol
 - Falsification of credentials
 - Deception in the research proposal

9.3 ACCESS TO SCARCE RESOURCES

Health researchers should always:

- 9.3.1 Deal responsibly with scarce health care resources, and should refrain from research that duplicates other research unnecessarily.
- 9.3.2 Refrain from any form of resource wastage in carrying out their research.
- 9.3.3 Refrain from participating in improper financial arrangements that escalate costs or disadvantage research participants, patients or institutions unfairly.
- 9.3.4 Design and conduct research to include or provide the use of appropriate facilities, in order to manage any rising contingencies.
- 9.3.5 Avoid research that impacts adversely on public health facilities.

9.4 LEGAL REGULATIONS

Health researchers should always:

- 9.4.1 Conform to relevant legal requirements and ensure that their research is lawful.
- 9.4.2 Adhere to ethical guidelines. Where the ethical guidelines prescribe a higher standard than the law, health researchers should conform to the higher standard.
- 9.4.3 Ensure that at all times research is conducted or supervised by experienced, qualified, competent and ethical health researchers who are approved by all the legally required bodies.

10. DUTIES TO THE HEALTH CARE PROFESSION

10.1 REVIEW PROCESSES

The following research guidelines are applicable to all health care practitioners registered with the HPCSA irrespective of where they conduct their research.

Health researchers should:

- 10.1.1 Receive approval for their research projects from all the relevant committees before beginning the project. This includes bodies like the MCC, Provincial and hospital authorities and the National Department of Health where applicable.
- 10.1.2 Notify all relevant reviewing bodies if the risks to research participants are found to be disproportionate to the benefits during the course of the trial.
- 10.1.3 Inform relevant reviewing bodies and institutions of any changes to their research protocol.
- 10.1.4 Ensure that the health research institutions with which they work are accredited by the National Health Research Ethics Council (NHREC) and have established or provided access to an accredited health research ethics committee which is registered with the NHREC.
- 10.1.5 Report inadequate or inappropriate reviews of research protocols to the HPCSA.
- 10.1.6 Prematurely terminate a study where:
 - the research question has been answered;
 - the research proves harmful to participants

11. DUTIES TO ANIMALS

Health researchers should:

- 11.1 Accept responsibility for the care of animals used in health research and respect their welfare.
- 11.2 Demonstrate that their research is justifiable and scientifically based on literature reviews, prior observations, approved studies and, when applicable, laboratory and animal studies.
- 11.3 Follow the ethical and regulatory guidelines established at institutional level regarding the use of animals by professional associations, and by governmental authorities.
- 11.4 Use, when appropriate, inanimate materials and processes instead of animals.
- 11.5 When 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.
- 11.6 When designing the research protocol, use the minimum number of animals necessary to yield valid answers to the research hypothesis.
- 11.7 Take active measures to use procedures that minimise both the incidence and severity of the pain and suffering experienced by animals.

12. DUTIES TO THE ENVIRONMENT

Health researchers should:

- 12.1.1 Ensure that the research does not impact on the environment in a manner that is harmful to the health and well-being of the population, nature and the environment. In all instances health researchers must ensure that the environment is protected for the benefit of present and future generations as is required by the South African Constitution.
- 12.1.2 Recognise that natural resources are limited and guard against their exploitation.
- 12.1.3 Health researchers should protect the environment and the public by assuring that health care waste is disposed off legally and in an environmentally friendly manner

13. DATA AND SPECIMEN STORAGE

- 13.1 Data and specimens obtained as a result of research activity should be securely stored.
- 13.2 Data, including tape recordings should be stored for a minimum of 2 years after publication or 6 years in the absence of publication.
- 13.3 There must be justifiable reasons which should be provided to Research Ethics Committees for data and specimens to leave the country. This should only be done after a Material Transfer Agreement has been signed and submitted to the local Research Ethics Committee.

Ethical guidelines for good practice in the health care professions

The following Booklets are separately available:

- Booklet 1:** *General ethical guidelines for health care professions*
- Booklet 2:** *Ethical and professional rules of the Health Professions Council of South Africa as promulgated in government gazette R717/2006*
- Booklet 3:** *National Patients' Rights Charter*
- Booklet 4:** *Professional self-development*
- Booklet 5:** *Guidelines on over servicing, perverse incentives and related matters*
- Booklet 6:** *General ethical guidelines for health researchers*
- Booklet 7:** *Ethical Guidelines for Biotechnology Research in South Africa*
- Booklet 8:** *Research, development and the use of the chemical, biological and nuclear capabilities of the State*
- Booklet 9:** *Seeking patients' informed consent: The ethical considerations*
- Booklet 10:** *Confidentiality: Protecting and providing information*
- Booklet 11:** *Guidelines for the management of patients with HIV infection or AIDS*
- Booklet 12:** *Guidelines withholding and withdrawing treatment*
- Booklet 13:** *Guidelines on Reproductive Health management*
- Booklet 14:** *Guideline on Patient Records*
- Booklet 15:** *Canvassing of patients abroad*
- Booklet 16:** *Guidelines for the management of health care waste*