HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

GUIDELINES FOR GOOD PRACTICE
IN THE HEALTH CARE PROFESSIONS

GENERAL ETHICAL GUIDELINES FOR BIOTECHNOLOGY RESEARCH

BOOKLET 7

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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).

PREAMBLE

This guideline booklet was developed by Professor A Dhai, Dr N Msomi and Professor DJ McQuoid-Mason with funding from LIFE*lab* – EcoBio Regional Innovation Centre, Department of Science and Technology.

The Health Professions Council of South Africa adopted the Ethical Guidelines for Biotechnology Research at its meeting in November 2005 as its guideline document on biotechnology research as annexed below.

CODE OF ETHICAL PRACTICE FOR MEDICAL BIOTECHNOLOGY RESEARCH IN SOUTH AFRICA

1. THE IMPORTANCE OF ETHICS

1.1 Introduction

The field of medical science and biotechnology is constantly changing and advancing and new ethical issues emerge regularly. Therefore, this guideline is intended as a live document which is subject to continuous change and amendment in order to address areas of new ethical concerns.

The rapid progress of modern biotechnology has presented a number of new and unique ethical and social challenges within the context of human medical science. Research in medical biotechnology has led to increased knowledge of disease, acceleration of the healing process, improved drug treatment for infectious diseases and hope for the struggle against incurable diseases such as HIV/AIDS, Parkinson's and Alzheimer's. Medical biotechnology promises major advances in human health and therefore, any limitations on the right to freedom of scientific research should be for significant reasons only, and as least restrictive as possible, so as not to impede scientific wisdom and prevent damage to the scientific undertaking.[2] At the same time a duty exists to ensure that research in this area of biotechnology is conducted in ethically acceptable ways. A balance needs to be struck between recognising the potential benefits which biotechnology research offers to individuals and the community as a whole, and the duty to ensure that research in this area is conducted ethically.

South Africa provides a unique research environment due to its sound infrastructure, well equipped research institutions, skilled researchers and surfeit of emerging and re-emerging disease trends.[3] However, a large part of the South African population, consists of vulnerable groups and poor populations with low levels of education, who accept authority without question and who are easily influenced.[4] This poses new ethical dilemmas which have to be addressed. The vulnerability and inequity, coupled with the unique research environment in South Africa, emphasises the need for an ethical guideline governing biotechnology research which ensures that research is conducted ethically and that vulnerable persons and communities are not exploited.[5] For the purposes of this guideline, it is important to define the concept of a 'vulnerable group' and to answer the question of how vulnerability is defined in research.

Vulnerable persons are those who may have 'insufficient power, intelligence, education, resources, strength', or other attributes which make them capable of protecting their own interests.[6] Vulnerable communities can further be defined as those communities which may have some or all of the following characteristics:

- Limited Economic Development;
- Inadequate Protection of Human Rights;
- Discrimination on the basis of health status;
- Inadequate understanding of scientific research;

[2] A Dhai, J Moodley, D J McQuoid-Mason & C Rodeck 'Ethical and Legal Controversies in Cloning for Biomedical Research – A South African Perspective' (2004) *SAMJ* Vol 94, No 11, 909.
[3] Department of Health South Africa *Ethics in Health Research: Principles, Structures and Processes* (2004).
[4] Ibid.
[5] Ibid.
[6] Council for International Organisations of Medical Sciences *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002).

- Limited availability of health care and treatment options;
- Limited availability of individuals in the community to provide informed consent.[7]

The South African Ethics in Health Research Guidelines support these definitions and state:

> Particular caution must be exercised before undertaking research involving participants in such communities.

Since the majority of South African citizens fall within the category of 'vulnerable persons', it is crucial that this ethical guideline should not only protect the rights of individual research participants, but should also ensure that research on potentially vulnerable participants is conducted ethically.

Some aspects of modern biotechnology also gives rise to ethical dilemmas due to the various moral, cultural, religious, family and personal factors involved – these concerns must also be addressed. This ethical guideline recognises the injustices of South Africa in the past and embraces national and international trends and views in the light of the Constitution of South Africa Act 108 of 1996: human dignity, the achievement of equality and the advancement of human rights and freedoms.

1.2 Key texts

The ethical principles and guidelines, contained in the National and International texts and sources set out below, have been combined and extensively utilised in compiling this guideline.

The following South African key texts have directed the development of these guidelines and must be acknowledged:

- The Constitution of the Republic of South Africa;[8]
- The Department of Health – Ethics in Health Research: Principles, Structures and Processes;
- Guidelines on Ethics for Medical Research in South Africa (MRC).

The following key International texts and sources have influenced the development of these guidelines and must be acknowledged:

- The Code of Ethical Practice for Biotechnology in Queensland (issued by the Queensland Government) which became operational on 1 September 2001;
- The Nuffield Council on Bioethics Guidelines;
- Belmont Report, 1973;
- The Cartagena Protocol on Biosafety;
- The Declaration of Helsinki, 2000;
- The Nuremberg Code, 1949;

[7] Joint United Nations Programme on HIV/AIDS (UNAIDS), website available at www.unaids.org cf: Department of Health South Africa *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (2004) 27.

[8] Act 108 of 1996

- The Council for International Organizations of Medical Sciences (CIOMS) Guidelines;
- Commonwealth of Australia, NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (June 1999);
- Commonwealth of Australia, Australian Health Ethics Committee (endorsed by the NHMRC) *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (September 2004);
- Joint United Nations Programme on HIV/AIDS (UNAIDS);
- The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

1.3 Scope of the guidelines

In order to develop a comprehensive ethical framework that would guide researchers in the field of medical biotechnology and human health, it would be important, as a first step, to determine the scope of the subject matter one wishes to set ethical standards for.

This guideline only addresses ethical issues with regard to 'biotechnology research'. The term 'research' covers a broad spectrum of activities and can be defined as the 'systematic search or enquiry for knowledge'.[9] In South Africa, a distinction exists between 'therapeutic' and 'non-therapeutic research'. The Declaration of Helsinki defines therapeutic research as research which is potentially beneficial to the research participant whereas non-therapeutic research is not intended to be beneficial to the actual participant but valuable to the development of health solutions and generalisable medical and scientific knowledge.

Biotechnology is a broad term for a wide range of technologies which use living organisms, biochemistries or synthetic DNA to make or modify products, improve plants or animals, or develop micro-organisms for specific uses. Biotechnologies have many different applications in medicine, agriculture and food production, horticulture, industry and the environment.

The term 'biotechnology' is an ambiguous term and the fact that the field of biotechnology is extensive and diverse, further adds to the complexity and difficulty of setting an ethical standard for research in the field, since it encompasses a multitude of ethical challenges. Researchers in the biotechnology industry face challenges unlike researchers in other sectors. Unlike most other industries, advances and research in the biotechnology industry are often front page news and has to face intense scrutiny by press, academics, government and the public. As biotechnology is a newly emerging field, a further challenge facing the industry is the lack of historical precedence in the sector to provide guidance for the safe and ethical development of the technology.

Some biotechnologies have been around for many years. For instance, the use of yeast and bacteria in the making of bread, wine, beer and cheese by means of conventional fermentation processes is a biotechnology which has been in common practice for centuries. Traditional plant and animal breeding techniques also form part of biotechnology.

[9] Katzenellenbogen, Gear & Tollman (1997) cf: Department of Health South Africa *Ethics in Health Research, Principles, Structures and Processes* (2004).

However, the biotechnologies which are the focus of this ethical code are the more modern kind which take the above techniques a step further and makes use of genetic engineering to adapt the properties of bacteria, plants and animals by directly intervening in the information carrier that is the basis for all properties of each organism: the DNA. These new techniques provide better understanding of, and potentially more control over, living processes at the level of individual cells and genes and offer a variety of new and practical applications in agriculture, medicine and industry. However, these new techniques raise safety issues and important ethical concerns.

Examples of these new controversial techniques are gene mapping, DNA sequencing, diagnostics, genetic modification and cloning. These are briefly discussed below.

1.3.1 Gene Mapping, DNA Sequencing and Diagnostics

As a group these above-mentioned techniques involve identifying and understanding the functions of genetic information and programming, and identifying individual variations in genetic programming for medical or other scientific purposes. Knowledge obtained from these research practices can assist to facilitate better understanding of disease or disease susceptibility, and to design new therapeutic treatments and other processes and products. These techniques include:

- Gene mapping which involves locating the position of genes on a chromosome;
- Gene sequencing which involves the deciphering of the genetic code by finding the ordering of building block molecules within genes;
- Functional genomics which entails searching for changes in DNA sequences (mutations) in inbred experimental animals, such as laboratory mice in order to identify the functions of particular genes; and
- Diagnostics which involves the development and use of test kits and probes to identify particular genetic characteristics in humans, plants and animals. In the health care environment, diagnostic tests are being developed and used to detect an individual's genetic predisposition to particular diseases.

1.3.2 Genetic Modification

Genetic modification is the process of allowing genes to be isolated, amplified and transported into new locations, even between species, to obtain desired characteristics in certain target organisms. It is used in a variety of applications including:

- The production of pharmaceuticals (such as human insulin for diabetics) and vaccines (for example, for hepatitis B);
- Gene therapy which involves the treatment or prevention of genetic diseases by changing the expression of a patient's genes through the introduction of DNA or RNA into the patient's cells;

1.3.3 Cloning

Cloning is the process of producing genetically identical organisms through various techniques, including culture of specific cells, artificial division of a single embryo, or cell nuclear transfer where the nucleus of a somatic cell is transferred into an oocyte (the mature female germ cell or egg) from which the nucleus has been removed.

Cloned animals can be used in agriculture to breed animals with improved characteristics. In addition they can be used to model human diseases and to manufacture pharmaceuticals for medical healthcare needs.

In medical research, cloning may also involve the artificial production of particular tissues or organs from embryonic or adult (e.g. bone marrow) cells for the repair of diseased or damaged tissue.

1.4 Ethics approval and Biotechnology Research

In biotechnology research, the usual ethical principles applicable to health research involving animals and human participants must be observed and such research must be scientifically sound.

Any research project should be subject to the review of a South African based Ethics Committee who must review the ethical and scientific rigor of the proposed research. In the context of health research, the National Health Act[10] provides for the establishment of Health Research Ethics committees who must approve any proposed research activity.[11]

The objects of Research Ethics Committees are to:

- Maintain ethical standards of practice in research;
- Protect research participants and investigators from harm or exploitation;
- Preserve the research participant's rights which take preference over society's rights; and
- Provide assurance to the public that research is conducted ethically.

In the context of the genetic modification of organisms, no specific Research Ethics Committee exists, however the Genetically Modified Organisms Act[12] provides for the establishment of an Executive Council to which applications for research involving GMO's must be submitted. The Executive Council is assisted in their decision-making by the Advisory Committee, which consists of scientists and reviewers, as well as information obtained from other countries. No activities involving GMO's[13], including any research, may be commenced until the Executive Council has approved such activity and issued the required permit.

[10] Act 61 of 2003.
[11] Chapter 9.
[12] Act 15 of 1997, sections 3 and 5.
[13] Academic research, use in contained facilities, trials, general commercial use, imports, exports and in-transit consignments.

2. GUIDING PRINCIPLES

This guideline addresses the ethics of research in South Africa to ensure compliance with the basic ethical values of beneficence, non-maleficence, justice and respect for persons. Furthermore, the guideline aims to identify good, desirable and acceptable conduct in research which promotes the welfare and rights of research participants.

Any research, including biotechnology research must conform to the following ethical principles and values:

2.1 Integrity

Researchers must always act with honesty and respect for the truth.

2.2 Autonomy/Respect for persons

Patients, participants and research subjects must be treated with respect for their individual autonomy, freedom of choice, dignity and human rights. Informed consent is a vital element to respecting the right to individual autonomy.

2.3 Beneficence

Researchers must always act in the best interests of the patient/research participant and make efforts to secure their well-being.

2.4 Non-maleficence

The "do no harm" principle applies to biotechnology research and entails refraining from doing harm and attempting to maximise possible benefits and minimising possible harms.

2.5 Justice/Fairness

In research endeavours, researchers must attempt to address past inequities, recognising wider community interests beyond merely the interests of the individual, organisation or corporation, providing redress for the vulnerable and promoting equitable access to resources. This principle can also be described as necessitating an equal distribution of the risks and benefits of research between communities.

2.6 Ethical Duties

2.6.1 Respect for the Law and system of government

There must be compliance with the Constitution of the Republic of South Africa[14] and all relevant South African legislation and standards.

2.6.2 Relevance

[14] Act 108 of 1996.

Biotechnology researchers in South Africa have an ethical responsibility to ensure that their research is relevant. Only biotechnology activities which have the potential, in the South African and African context to improve human health and quality of life, support for the environment and promotion of sustainable agriculture and industry must be pursued. This limits the scope for biotechnology research to areas where the results could have a potential positive impact on human health, the environment and agriculture.

2.6.3 Investigator Competence

Only investigators who are competent and appropriately and suitably qualified in the necessary field of biotechnology should conduct the research. Where delegation of research is necessary, the principal investigator should only delegate to individuals who possess the necessary skills and experience.[15] Researchers must at all times endeavour to achieve the highest level of scientific quality in their research.

When assessing the competence and suitability of the researcher to conduct the specific research the following attributes must be taken into account:

- Technical and research competence;
- Educational background and qualifications;
- Certification;
- Knowledge and experience in the required field;
- Honesty and Integrity;
- Fairness;
- The researcher's sensitivity to identify an ethical issue; and
- The ability to act responsibly and appropriately when faced with an ethically challenging situation.

A technically competent researcher must be empathetic and compassionate and these characteristics will best be maintained in a good clinical and research environment that provides appropriate research mentoring.

Researchers must never misuse their positions or knowledge for personal power or gain.

2.6.4 Informed Consent

It is necessary to obtain the informed consent from the research participant prior to commencing research.[16] This requirement is based on the fundamental moral duty that we do not act against the wishes of a person and that human dignity and integrity should be respected. This is further required in terms of section 12 (2) (c) of the Constitution and section 71 of the National Health Act[17] which states that research or experimentation on a living person may only be conducted with the informed consent of that person. Previously, Research Ethics Committees had to rely on ethical guidelines and to some extent, Constitutional and common law for ethical guidance regarding research on human subjects. The National Health Act can be seen as the first attempt by the

[15] South African Health Info 'Ethics in Health Research' available at www.sahealthinfo.org/ethics/ethicsconduct.htm (site last visited on 03/06/05).
[16] In addition International guidelines on research ethics including the World Medical Association's *Declaration of Helsinki* and the Council for International Organisations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects* stress the importance of obtaining ethically and legally valid consent in research.
[17] Act 61 of 2003.

legislature to address some ethical concerns raised by using human participants, including children, in research and specific emphasis is placed on the issue of informed consent.[18]

The preferred manner of recording consent is in both written and verbal form. Where the participant is not literate, the consent must be obtained in the presence of a literate witness who must confirm in writing that the consent obtained was in fact informed in nature. This means that the research participant was informed of all information relevant to his/her participation, including the risks and benefits of the proposed research and understood all the risks and benefits of such research. Unforeseeable risks obviously cannot be foreseen, but participants must be told the nature and extent of all foreseeable risks or discomfort associated with the research. This includes financial risks attendant on participation. The person must also have been able to give consent voluntarily without any form of coercion or undue influence.

Research Ethics Committees must ensure that informed consent procedures are followed.

The four main requirements for informed consent are:

(a) Disclosure;
(b) Understanding or appreciation;
(c) Voluntariness; and
(d) Capacity to consent.

2.6.4.1 Disclosure

Disclosure relates to information which must be supplied to a research participant prior to obtaining consent to participation in order for such consent to be informed. Participants must be made aware of their right to be informed of relevant new findings, and of the consequences of their withdrawal from research. They should know, too, whether the investigator may terminate participation and be informed of the availability of peer counseling to assist them in making an informed choice.

Disclosures made to prospective participants must be detailed and comprehensive, made in the appropriate language[19] and in a manner that facilitates understanding. The researcher should adopt a non-threatening approach that invites interaction and questions from the participant. Where possible, researchers should make use of an environment where the potential participant feels comfortable and not intimidated.

In the event of significant changes in the conditions or procedures of the research, or if new information comes to light which may impact on participants continuing with the research, new informed consent[20] must be obtained from such participant.

[18] A Strode, C Grant, C Slack & M Mushariwa 'How well does South Africa's Health Act Regulate Research Involving Children' *SAMJ* (2005) Vol 95 No 4 at 265.
[19] In a language in which the participant is fluent and which s/he chooses to converse in.
[20] In obtaining the new informed consent, disclosure must be made of any new conditions, procedures or information.

The following list is a concise summary of essential information that must be disclosed to biotechnology research participants in order to facilitate informed consent. Participants must be informed of all relevant information which may impact on their decision to participate in the research, including the following:

(a) That they are participating in research and that participation is voluntary;

(b) What the aim of the research is and the anticipated time period of his/her involvement in the research;

(c) The research and experimental procedures to which s/he will be subjected;

(d) Any and all responsibilities which s/he will have if they consent to participate in the research;

(e) Any and all risks, dangers and/or complications that may result from, or be inherent in, the research. This includes the possibility of unforeseen risks, dangers and complications that may result from such research;

(f) The benefits to him/herself or others, both during and after the research;

(g) What will happen in the event of him/her being injured in any way during participation in the research, including whether compensation will be given in research related injuries (participants must also be told who to contact in the event of such injury);

(h) That they have a right to be informed of relevant new findings related to the research;

(i) That s/he may at any stage of the project withdraw his or her consent to participate without any disadvantage to him or herself;

(j) The consequences of their withdrawal from research;

(k) Whether the researcher is allowed to terminate participation and the circumstances which may lead to such termination;

(l) That peer counseling is available to assist him/her in making an informed choice;

(m) The extent to which confidentiality will be maintained and that the sponsors of the study and regulatory bodies[21] will be permitted to inspect research records;

(n) Where during the course of research, information comes to light which the participant may have a legal duty to disclose to a third party[22], the researcher may have a duty to disclose such information to the third party, should the participant refuse/fail to do so;

[21] Such as the Medical Control Council (MCC) and applicable Research Ethics Committees (REC's).
[22] For example where disclosure is required in terms of a life insurance policy or where withholding the information may endanger a third party.

(o) Whether the research has been approved by an accredited research ethics committee and that the contact details of such research ethics committee representatives must be made available to the participant;

(p) The investigator's qualifications which make him/her suitable and competent to conduct the research;

(q) The investigator's contact details should the participant require additional information or suffer an adverse event;

(r) The possible research uses, direct or secondary, of the participants medical records and of biological specimens taken during the course of the research;

(s) Whether biological specimens collected during the research will be destroyed, stored[23], possible future use. Participants must be made aware that they have the right to decide about the future use of such specimens and that the specimens may not be used in any other or subsequent research unless the participant's informed consent has been obtained in writing for that specific research project;

(t) That the researcher may have a legal duty to breach confidentiality if, during the course of research, it is discovered that the participant has a notifiable disease.

2.6.4.2 Understanding or appreciation

Obtaining informed consent must be done in a manner which recognises the individuality of the specific participant by considering factors such as his/her age, maturity, intelligence, education and belief system. Merely reading out the contents of the consent form in a mechanical way will not suffice as satisfactory disclosure. The researcher must be completely certain and confident that all information disclosed to the participant was understood and that s/he appreciates all risks and benefits associated with the proposed research. The researcher must allow the participant to ask questions freely and must ensure that all questions are answered honestly and appropriately. In addition, the researcher must ensure that the participant is provided with sufficient opportunity to consider all the information prior to consenting.

In the South African context, researchers must pay particular attention to the vulnerability of potential research participants. Many vulnerable South African populations do not have access to primary, secondary or tertiary education, nor to adequate health care services which makes them particularly vulnerable to exploitation by researchers and research establishments. For this reason, details of the proposed research must be supplied to the participant in a manner which is easily understandable and which takes cognizance of the cultural background, language, customs and beliefs of the participant.

2.6.4.3 Voluntariness

[23] Where such specimens will be stored, the participant must be informed of whether the stored specimen will be marked in an identifiable or anonymous form and what the implications for storage will be for the participant.

Informed consent is only valid when it is obtained without dishonesty or misrepresentation. Any compulsion or undue influence on the part of the researcher will negate the consent given by the participant.

2.6.4.4 Capacity to consent

Consent must be given by someone who is legally and factually capable of consenting. In relation to competence to consent and proxy consent, two broad categories of research participants must be recognised: Adults and Minors.

2.6.4.4.1 Adults

The general rule is that sane and sober adults have the capacity to give valid consent to participation in research. However, the following categories of adults are exceptions to the general rule since consent obtained from these categories may be compromised. In some instances the consent given may be invalid or special or additional considerations must be addressed for such consent to become valid.

The Mentally ill or handicapped

Section 60 A of the Mental Health Act[24] provides for consent to clinical interventions, including research of a therapeutic nature, on mentally ill patients which are institutionalised.

In the case of therapeutic research on a mentally ill or defective person who is incapable of consenting, it is permissible to obtain proxy consent. However, proxy consent is only permissible where the proposed research is directly or indirectly relevant to the patient's mental illness or defect. In addition, the assent of the mentally ill person must be obtained, provided that such patient is able to comprehend the issues involved.

As a general rule, participation of a mentally ill or handicapped person in non-therapeutic research is not allowed. However, certain exceptions exist where non-therapeutic research is permitted, provided that proxy consent is obtained. The exceptions are:

- Observational research of a non-invasive nature since the incapacitated person is not placed at risk and there is no interference with his/her integrity. The research must entail no more than minimal risk or discomfort;
- Observational research of a non-invasive nature provided that no more than minimal risk is foreseeable or known from routine medical practice and distress and discomfort must be minimal.

With regard to non-therapeutic research, the following requirements must be met in addition to the above:

- The research must pertain directly or indirectly to the mental illness or defect from which the person suffers;
- The assent of the participant must be sought and adequate consideration given to his or her wishes expressed in any advanced directives. Any objection by the incapacitated person would be decisive and the research will not be permitted;
- The research involved must significantly benefit persons of the same category as the research participant;
- The research will not be permitted if the same scientific results can be obtained by other methods or by research on persons who do not belong to the same category as the proposed mentally ill or incapacitated participant.

[24] Act 18 of 1973.

Elderly

The general rule is that, in the absence of any indication to the contrary, elderly persons are assumed to be competent to consent to research. Consideration should however be given to the likelihood of factors such as:

- Possible mental deterioration;
- The ability to comprehend; and
- Their dependence and vulnerability.

Pregnant Women

It is generally assumed that pregnant women are competent to consent to research. However, certain circumstances e.g. active labour, may compromise their decision. As a general rule, the father of the unborn child should be included in the decision making process where possible.

Unconscious Patients

Unconscious patients are incapable of consenting to research. Therapeutic research on unconscious patients would however be legally permissible where:

- there are no indications to the contrary;
- informed consent of a competent relative has been obtained.

The Dying

When determining the capacity of a dying person to consent to research, each situation will be assessed independently and on its own merit. The vulnerability and dependency of such participant must always be taken into account in any attempt to obtain their consent for research.

2.6.4.4.2 Minors and Children

Minors may participate in research only where their participation is indispensable to the research.[25] Furthermore, the research must never be contrary to the minor's best

[25] Department of Health South Africa *Ethics in Health Research: Principles, Structures and Processes* (2004) 21.

interests[26] and the aim of the research should investigate and focus on issues which are relevant specifically to children. It is important that the circumstances in which the research involving children is conducted must provide for the physical, emotional and psychological safety of the minor involved.[27]

The Constitution[28] and the Child Care Act[29], defines a child as a person under the age of 18 years. In terms of the Age of Majority Act[30], a person under the age of 21 years is a minor. Where a person on account of age is not capable of consenting to the proposed research procedure, proxy consent[31] must be procured.

Special guidelines must be followed for research on minors. The following terms are defined in the South African Department of Health Research Ethics Guidelines 2004 and are important definitions to review for determining proper research protocol on minors:[32]

- *Therapeutic Research* includes 'interventions that may hold out the prospect of direct health-related benefits for the participant'.
- *Non-therapeutic research* includes 'interventions that will not hold out the prospect of direct health-related benefits for the participants, but results may be produced that significantly contribute to generalisable knowledge about the participant's condition'.

The Child Care Act outlines that:

- Minors 14 years or older are 'legally capable of consenting to medical treatment on themselves and their children'.
- Minors who are 18 years or older are 'legally capable of consenting to surgical operations upon themselves'.

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[26] The Children's Bill (available at www.childrenfirst.org.za/pdf/27January2004Bill.pdf) outlines key factors that must be considered when determining the "best interests of the child". These factors include:

- The child's age;
- Needs;
- Gender
- Background;
- Maturity and stage of development;
- Needs to protect the child from physical and psychological harm; and
- The opinion of the child.

[27] Commonwealth of Australia NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (1999) 25.

[28] Section 28 (3).

[29] Act 74 of 1983.

[30] Act 57 of 1972.

[31] Consent by a person who is legally authorised to act on behalf of the incompetent person.

[32] Department of Health South Africa *Ethics in Health Research: Principles, Structures and Processes* (2004) 21.

Those minors who do not fit into these age criteria, must have the consent of a parent or legal guardian grant approval for medical treatment or surgical operations.

Considerable confusion exists regarding whether provisions in the Child Care Act (to be repealed by the Children's Bill (B70 – 2003 Reintroduced)) extend to consent to participation in medical research.

The National Health Act regulates consent in research. Section 71, while regulating on minors does not distinguish them into age categories. Rather, it looks at minors as one group and outlines requirements for 'therapeutic' and 'non-therapeutic' research.

According to the National Health Act:[33]

Therapeutic research on minors may only be conducted:

- If it is in the best interest of the minor;
- With the consent of the parent or guardian of the minor;
- If the minor is capable of understanding, with the consent of the minor.

Non-therapeutic research on minors can only be conducted:

- With the consent of the Minister of Health;
- With the consent of the parent or guardian of the minor;
- If the minor is capable of understanding, with the consent of the minor.

2.6.5 Privacy and Confidentiality

Privacy and confidentiality in the context of genetic research is discussed in chapter 13.2.2 and supplements the basic principles of privacy and confidentiality in research as discussed in this chapter. Please refer to this chapter.

The right to privacy is protected in section 14 of the Constitution and includes protection against the disclosure of private facts which were obtained during a relationship where confidentiality applied.[34] This right includes protection against the unwanted publication or disclosure of intimate personal information. Information regarding a research participant obtained during the course of research must be treated as confidential,

[33] Act 61 of 2003, section 71 (2).
[34] J de Waal, I Currie & G Erasmus *The Bill of Rights Handbook* 4ed (2001) 268.

irrespective the origin of such information.[35] The right to confidentiality is also recognised in section 14 of the National Health Act[36] which states that:

> (1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.
>
> (2) Subject to section 15[37], no person may disclose any information contemplated in subsection (1) unless –
>
> (a) The user consents to that disclosure in writing;
>
> (b) A court order or any law requires that disclosure; or
>
> (c) Non-disclosure of the information represents a serious threat to public health.

Furthermore, researchers have a duty to take precautions to preserve confidentiality by for example using codes in research records as a means to identify participants instead of using their real names.

Examples of measures aimed at protecting the privacy of research participants include:[38]

- **Potentially identifiable (coded) storage methods**

  Data may have identifiers removed and substituted with a code. However, the process is reversible since the code could be used to re-identify the person to whom the data relates.

- **De-identified storage method**

  This method ensures the utmost protection of confidential information. Normally the identifiers are removed permanently or the data has been de-identified permanently. The de-identified information cannot be retrieved and remains anonymous, ensuring confidentiality.

The general rule is that information about research participants may only be released to a third party if the participant, or someone legally capable of consenting on his or her behalf, consents thereto. However, there are exceptions to this general rule which are discussed in chapter 2.6.5.1 and 2.

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[35] The origin could be from the medical or other records of the participant or from the research activity itself.

[36] Act 61 of 2003.

[37] Section 15 provides that personal information regarding a user may be disclosed as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties and where such disclosure is in the interest of the user.

[38] Department of Health *Ethics in Health Research: Principles, Structures and Processes* 34 – 35.

The duty to respect and maintain privacy and confidentiality does not end at the conclusion of the specific research project. It extends to any subsequent use of the confidential information.[39]

2.6.5.1 Endangered third parties

Where, during the course of research, facts regarding a condition or factor affecting the participant comes to light, which poses a serious risk to a third party, the researcher may have a duty to disclose the existence of such fact to the third party. This is in accordance with the principle of beneficence. However, the researcher should only disclose in the event that the participant/patient refuses to do so. In the same vein the Health Profession's Council of South Africa has imposed an ethical duty on medical practitioners to make a disclosure to the sexual partner or spouse of their HIV positive patient, if the patient refuses to do so themselves.[40] Medical practitioners may be held legally liable for failing to disclose this information to the relevant third party.[41]

2.6.5.2 Notifiable diseases

Confidentiality may also be broken where legal exceptions apply and disclosure is required by law as it is an ethical duty to respect the law and system of government. This is the case where clinicians or researchers have a duty to disclose if it comes to light that the participant has a notifiable disease. Researchers must note that they have to inform the participant of this duty when obtaining informed consent.

[39] It must be borne in mind that for any subsequent use, new informed consent must be obtained from the research participant.
[40] South African Medical and Dental Council (SAMDC) *Bulletin* (September 1989) 6 2.
[41] MA Dada & DJ McQuoid-Mason *Introduction to Medico-Legal Practice* (2001) 21.

3. THE ETHICS OF RESEARCH RELATED TO HEALTHCARE IN SOUTH AFRICA AS A DEVELOPING COUNTRY

3.1 Ethical Duties

At all times the four ethical duties which are crucial when research is carried out in developing countries must be adhered to. These are:

(a) The duty to show respect for persons;
(b) The duty to alleviate suffering;
(c) The duty to be sensitive to cultural differences and different cultural perspectives which individuals might bring to questions of health and healthcare;
(d) The duty not to exploit the vulnerable or weaker for own advantage.[42]

3.2 Informed Consent

Refer to chapter 2.6.4 of this guideline where the usual requirements for informed consent are discussed in full.

In South Africa, as a developing and multi-cultural country, the issue of informed consent is pertinent. Many people in different cultures are unfamiliar with or do not readily understand scientific concepts such as 'biotechnology'. The potential for abuse is great and regard must be had to the language, culture, traditions and education of the specific individual in order to ensure that the person fully understands all implications of the proposed treatment or research and that the consent obtained from such person is truly informed and voluntary.

In order to protect the vulnerability of many of the research populations, researchers should develop culturally appropriate ways to communicate information that is essential for observance of the usual standards required in the informed consent process.

3.3 Recognition and respect for different cultures, values and beliefs

When planning and conducting research there exists a duty to recognise and respect the importance of national and local cultures, social systems, values and beliefs of the people and communities that may be affected by such research.

3.4 Allocation of resources

As a developing country, South Africa has limited national resources to be allocated to biotechnology research. Subsequently, research must, as a first priority, be aimed at those technologies which have the potential to directly benefit South African health care and agriculture and address the needs of the South African population and sustainability of the environment. The pertinent issues of HIV/AIDS, Tuberculosis (TB), tropical

[42] Nuffield Council on Bioethics 'The Ethics of Research Related to Healthcare in Developing Countries' (2002).

diseases[43], malnutrition and other poverty related illnesses are examples of areas which biotechnology research and development should prioritise and address.

Furthermore, section 70 of the National Health Act[44] sets out certain health research priorities which the National Health Research Committee must consider when identifying areas where the Minister should prioritise allocating resources to. These considerations are:

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

[43] Such as malaria, African sleeping sickness, dengue fever, river blindness, elephantiasis, leishmaniasis, Chagas disease, schistosomiasis etc.
[44] Act 61 of 2003.

4. INTEGRITY OF RESEARCH AND PRODUCT TESTING

The Constitutional Right to freedom of research set out in section 16 (1) (d) of the Constitution must be exercised in a manner that will protect the scientific, intellectual and professional integrity of researchers and research establishments.

All research and product testing must be performed by appropriately qualified persons to optimal scientific standards with full regard to the relevant facts and data.

Accurate and comprehensive records of research and product testing must be kept and must comply with the appropriate regulatory authorities. Negative as well as positive results must be reported.

Conflicts of interest which may call into question the integrity of research, product trials, or other biotechnology activities must be avoided. Systems must be established to ensure that all conflicts, or potential conflicts of interest, are disclosed and that reasonable steps are taken to address and resolve the conflict.

5. CARE AND PROTECTION OF RESEARCH STAFF

Adequate safety measures must be employed within biotechnology organisations to ensure the health and safety of staff engaged in biotechnology activities and research. All staff must be properly trained in safety procedures.

Furthermore the Occupational Health and Safety Act[45] places a duty on employers to ensure the health and safety of their employees and to take measures to protect them against the hazards to health and safety arising out of, or in connection with, the activities such employees are involved in. The appropriate Research Ethics Committee should stress the importance of protecting the safety and welfare of research staff.

The primary investigator in the research should devise guidelines and apply safety rules for the proper handling of all hazardous materials.[46] In this regard, the Hazardous Substances Act[47] must be consulted.

Employers have a duty to comply with the relevant requirements of the Basic Conditions of Employment Act[48], Labour Relations Act[49], Compensation for Occupational Injuries and Diseases Act[50] and the Occupational Health and Safety Act[51]. All relevant South African and institutional standards governing laboratory safety must be adhered to in order to ensure the welfare of researchers and laboratory personnel.

[45] Act 85 of 1993.
[46] South African Health Info 'Ethics in Health Research' available at www.sahealthinfo.org/ethics/ethicsconduct.htm (site last visited on 06/06/2005).
[47] Act 15 of 1973.
[48] Act 75 of 1997.
[49] Act 66 of 1995.
[50] Act 130 of 1993.
[51] Act 85 of 1993.

6. CARE AND PROTECTION OF ANIMALS

Animal testing raises many contentious issues. Researchers must at all times ask the question: 'How valuable is the knowledge sought and how necessary is the use of animals to obtain the knowledge?'

Sentient animals must not be used in research, nor research conducted on such animals, unless the potential benefit of the technology being researched outweighs the moral and ethical concerns raised by utilising such animals as a means to an end.

6.1 Medical Research Council Guidelines on the use of animals in research and training

The guidelines laid down by the Medical Research Council (MRC) in 'Guidelines of Ethics for Medical Research: Use of Animals in Research and Training' must be observed. This is only an extract and the full text should be consulted and is available at www.mrc.ac.za.

6.1.1 General Policy

The following are the main ethical points recognised by the MRC which must be adhered to:

- It is preferable to only subscribe to studies which promise to contribute to the understanding of biology and environmental principles and to the acquisition of knowledge that can reasonably be expected to benefit humans, animals or the environment.
- All vertebrate animals are protected by law in South Africa[52] and it may be an offence to kill or interfere with the well-being of an animal for scientific or educational purposes without justification which is ratified by a formal process of ethical review.
- Animals may only be used when the researcher's best effort to find a non-sentient alternative has been unsuccessful.
- Optimal standards of animal health and care must be observed to provide good quality results which enhance credibility and reproducibility.
- The three "R" principles of replacement, reduction and refinement[53] must be adhered to when conducting and planning animal studies. These uphold the principles and practice of utilising the most humane methods on the smallest number of animals that will permit valid scientific information to be required.
- The use of animals in science depends on maintaining public confidence in the mechanisms and processes used to ensure that animal experiments are justified and humane.
- Laboratory animals are protected by law in South Africa and accordingly their use in education, testing and research purposes must be justified.

6.1.2 Ethical Principles

6.1.2.1 Moral philosophy

[52] Animal Protection Act 71 of 1962.
[53] As discussed in chapter 6.1.2.4 of this guideline.

It is accepted that sentient, non-human animals have the capacity to experience a range of physical sensations and emotions and are therefore subjects of moral concern.

6.1.2.2 Utilitarian ethic

The use of laboratory animals as research subjects in bio-medical science must be justified by the assurance that the potential benefit to either humans, animals and/or the environment outweighs the potential harm to the animal subjects. Each proposed experiment must therefore be supported by an ethical analysis stating the harm to animals/benefit to humans, animals or the environment. This ethical analysis must determine that more utility (good) than disutility (harm) will probably result from the proposed experiment. The end result should therefore be that the overall likely benefit will outweigh the potential harm to the animals.

6.1.2.3 Human obligations towards laboratory animals

Laboratory animals should be able to live, grow, reproduce and interact under conditions and circumstances in which their species' specific needs are met, as far as possible. Special consideration should be given to the needs of social animals in this regard and to animals which have adapted to special circumstances or environments e.g. nocturnal animals and marine animals.

6.1.2.4 Humaneness and the principles of humane experimental techniques

Experimental procedures which may expose animals or cause conditions such as hunger, thirst, injury, disease, discomfort, fear, distress, deprivation or pain must be kept to a minimum. The definition of humaneness is the practice to reduce the sum total of these conditions to a minimum or, preferably, to eliminate them altogether, by applying the 'three R' principles of Russell and Burch as follows:

- **Replacement**

Replacement of sentient animals with non-sentient research models or systems in order to eliminate the use of animals that can experience unpleasant sensations.

- **Reduction**

Reduction of the numbers of animals in experiments by design strategies that facilitate the use of the smallest number that will allow valid information to be obtained from the study.

- **Refinement**

Refinement of animal sourcing, animal care practices and experimental procedures to minimise or remove physical and psychological distress, within the limitations imposed by the requirements of the research.

Researchers should guard against any tendency to under-rate or ignore the potential discomfort or suffering of animal subjects, and may not try to achieve cost savings by compromising the quality of care afforded to them.

6.1.2.5 The Ethical Review Process

Every experiment in which sentient animals are used for research, testing or educational purposes must first undergo a formal process of ethical review by the appropriate Ethics Committee.

6.1.3 Other important guidelines regarding the use of animals in research

All relevant South African legislation[54] and the National Code for the Handling and Use of Animals in Research Education, Diagnosis and Testing of Drugs and Related Substances in South Africa and applicable international treaties such as the Convention on International Trade in Endangered Species (CITES) must be adhered to.

[54] The Animal Protection Act 71 of 1962, The Animal Diseases Act 35 of 1984, The National Parks Act 57 of 1976, The Nature Conservation Ordinances of the former four provinces (Cape Province ordinance 19 of 1974, Orange Free State ordinance 8 of 1969, Natal Ordinance 15 of 1974 and Transvaal Ordinance 12 of 1983).

7. RISK ASSESSMENT AND RISK MANAGEMENT

Biotechnology products and other biotechnology activities must be fully assessed for adverse impacts on human or animal safety or the environment. Long-term as well as short-term impacts, including impacts that may not be immediately apparent must be addressed. Risk assessments must be conducted in accordance with accepted scientific principles. Any identified risks must be acknowledged through open and accountable processes.

Where biotechnology applications are developed, risk management strategies must be established to ensure that any risks are effectively managed. Any risk or adverse consequence associated with research or product development must be reported to the relevant authority responsible for product oversight, regulation, risk assessment or risk management. If, after product approval, risks or adverse consequences associated with the product, and not previously apparent at the time of approval, become known, the relevant authority must be informed as soon as possible.

7. WASTE DISPOSAL

Any waste associated with biotechnology activities must be managed and disposed of in such a manner that there is no negative impact on the environment and human health.

In the management of waste, researchers and research institutions, have a duty to comply and familiarise themselves with all national, provincial and local authority legislation dealing with the disposal of waste in his or her possession or under his or her control. As biotechnology activities may involve the work with, or production of substances or organisms which may be hazardous or potentially hazardous to the environment or human health, researchers and research facilities must comply with the provisions of the Hazardous Substances Act[55] where this act is applicable.

In respect of health care waste, the Health Professions Council of South Africa has issued comprehensive guidelines entitled 'Guidelines for the Management of Healthcare Waste'[56]. Health care waste is defined as:

> [H]azardous waste which refers to any material or substance that, if handled improperly, has the potential to harm people, property or the environment. In this regard, all human and anatomical waste, blood and body fluids are considered to be potentially hazardous. The unsafe disposal of such waste could have detrimental effects for people who might come into contact with health care waste.[57]

For guidance in relation to the disposal of health care waste, reference must be made to the Health Professions Council's Guidelines mentioned above which are available at www.hpsca.co.za.

[55] Act 15 of 1973.
[56] Guidelines for Good Practice in Medicine, Dentistry and the Medical Sciences, Booklet 6, issued October 2002.
[57] In terms of the Code of Practice of the South African Bureau of Standards on the Handling and Disposal of Waste Materials within Health Care Facilities (SABS 0248:1993).

8. BIOLOGICAL WEAPONS

Biotechnology must not be used to develop biological weapons for use in human warfare or terrorism, and no assistance may be given to any other organisations, persons or countries to develop, produce, duplicate, stockpile or utilise such weapons. In this regard the Biological and Toxin Weapons Convention of 1972 which South Africa signed on 10 April 1972 and ratified on 3 November 1975 is affirmed.

9. INTELLECTUAL PROPERTY AND COMMERCIALISATION

The provisions of the Patents Act[58] and the National Environmental Management: Biodiversity Act[59], with regard to benefit sharing with indigenous communities, must be respected and adhered to in all instances where application for registration of a patent is made.

Biopiracy may not be practiced in any form. "Biopiracy" refers to the appropriation of developments or discoveries in the area of biological resources, by another party without consent. In this context, discoveries by indigenous communities must be respected and appropriately acknowledged.

When application is made for a patent, the following must be observed:[60]

- The applicant must disclose the origin of genetic or biological resource or knowledge used in the invention in the application, and non-disclosure or wrongful non-disclosure of prior knowledge, traditional knowledge oral or otherwise is unethical (and may have legal consequences in that the application is refused or the patent revoked);
- The informed consent of the owners or holders of traditional knowledge must be obtained, prior to applying for the right to obtain patent protection for any element of indigenous knowledge or heritage, for the sharing of ownership, control, use and benefits. Such consent must be adequately documented and submitted with the application to the Registrar of Patents.

New discoveries by South African researchers must be developed in ways that provide appropriate returns to the State and as far as practical, control must be maintained over the intellectual property within South Africa. Where, despite best endeavours, it is not possible to develop such discoveries within South Africa, the aim should be to license rather than sell the intellectual property.

It must be recognised that other developing countries are also seeking to improve their biotechnology capacity and the exchange of technology between countries must be supported for broader global social development and benefit of the world economy.

Not all biotechnology research may attract significant commercial interest. Research may be pure or strategic, or may be undertaken solely for community service or public benefit reasons. This type of research has much value and importance and is encouraged. A duty exists to pursue research and development which may benefit the South African population, especially the poor and disadvantaged communities, even where such research does not result in commercial returns to the organisation or to the state.

The transactional costs associated with intellectual property should not obstruct access by the poor and disadvantaged populations to new biotechnology discoveries that may benefit them.

[58] Act 57 of 1978.
[59] Act 107 of 1998.
[60] These ethical principles are based on the proposed amendments to the Patents Act.

10. INTERNATIONAL OBLIGATIONS

Any conduct which may violate South Africa's obligations as a good International citizen must be avoided. All relevant laws and standards applicable to other countries in which South Africa conducts biotechnology activities, or to which South Africa exports biotechnology research or products, must be observed.

11. FACILITATION OF DISCUSSION ABOUT ETHICAL ISSUES

Consideration and discussion of ethical issues associated with the specific biotechnology research projects, undertaken by organisations or individual research projects, must be encouraged within research organisations.

Where possible, having regard to the organisation's size and resources, the involvement of qualified ethics advisors to assist in addressing ethical issues and concerns must be considered and implemented where possible.

The rights of all persons to contribute to public debate and discussion about the ethical challenges created by biotechnology must be upheld. Many ethical issues cannot be resolved purely by the organisation or relevant profession engaged in the research and consequently broader perspectives need to be engaged. These broader perspectives must be included in any consideration of ethical challenges.

12. MEDICAL RESEARCH AND HEALTH CARE

13.1 Review by Research Ethics Committees

Research involving humans must be conducted with the highest standards of safety, integrity and respect for human dignity, and must comply with all relevant South African Ethical Guidelines, in particular the Department of Health Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa, 2000.

The National Health Act[61] provides for research involving humans and requires that such research must be reviewed and approved by the appropriate accredited Research Ethics Committee established by the institution or in terms of any applicable legislation for the purpose of providing ethical oversight of research proposals and ensuring that research is conducted ethically.

13.2 Human Genetic Research

Genetic research improves our understanding of how human genes and environmental factors interact with each other to impact on our individual health and the health of the population. In addition to the usual ethical concerns that govern research involving humans, supplementary ethical issues exist which are unique to genetic research. These issues arise from the nature of genes and genetic information which, although personal to the actual participant, are shared with family members and unrelated members of the population. The potential for harm to participants, through the use of genetic information discovered during research, includes stigmatisation and the potential for discrimination by, for example, insurance companies and current or potential employers. Subsequently it is important that care be taken to ensure that participants in genetic research are not at risk, due to their participation in genetic research, of being denied the benefits available to other members of the community.

The principle set out in the *Universal Declaration on the Human Genome and Human Rights* (1997) that "everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics and that dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity," must be observed.

Genetic research which involves children requires special ethical responsibilities and protection.[62] Knowledge gained through genetic studies may place children at risk of stigmatization within and beyond the family.[63] It is therefore recommended that genetic research involving children should not be carried out unless an effective intervention is available.[64] In all instances, the information to be gained must outweigh the risk of harm.[65] [66]

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[61] Section 73.
[62] Medical Research Council of Canada *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* available at www.ncehr-cnerh.org/english/code_2/ (site last visited on 11/02/2005).
[63] Ibid.
[64] Ibid.
[65] Ibid.
[66] The testing of a child for an early onset condition such as polyposis coli, may be appropriate since the knowledge of this disease will affect the treatment options of the child. It would however be inappropriate to test a child for an adult onset disease such as Huntington Disease for which there are at present no effective prevention.

13.2.1 Informed consent and genetic research

Refer to chapter 2.6.4 of this guideline where the basic principles of informed consent are discussed. However, in genetic research, there are additional requirements for informed consent which are discussed in this chapter.

When obtaining consent from the research participant for collection of genetic material and information, the following must be disclosed to the participant to enable him/her to make an informed decision:

(a) The participant is free to refuse consent to participation and s/he does not have to furnish any reasons for such refusal;
(b) Arrangements and protocols will be put in place to protect the privacy and confidentiality of the participant's genetic information with regard to persons who are family members, and individuals who are not family members of the participant;
(c) The manner in which the genetic material and information collected will be used – whether it will be in an identified, potentially identifiable or de-identified form. In the case where the information will be used in a de-identified form, the participant must be informed that it will not be possible to provide him/her with personal research results;
(d) The reliability of the research result i.e. the typical rate of false positives and false negatives and the probability of the development of a serious genetic disease;
(e) That full information of the disorders which may come to light during the research, including the ways in which the disorders are transmitted[67], the seriousness, how variable it is in its effects, and what therapeutic options are available, will be disclosed;
(f) Whether the research may reveal information which could be potentially important to the participant's offspring, family members or another identified or potentially identifiable research participant;
(g) Whether researchers will endeavour to provide information regarding the research outcome. It is important that the participant be made aware if researchers are not intending to provide feedback;
(h) Where feedback will be provided, the participant may choose whether s/he wants to be informed of the results which have an impact on him/her as an individual. S/he must be informed that should s/he choose to know the results, which could include knowledge of a predisposition to a genetic disorder, s/he has a duty to relay this genetic information to the insurance carrier to which s/he belongs and also in any future application for insurance cover.
(i) The participant must know that counseling is available to help him/her understand the implications of receiving the feedback. If the participant does not want to be notified of research results, their decision must be respected;
(j) Should the participant choose to be informed of the genetic research results which impacts on him/her as an individual, s/he must know the following:
    a. That s/he must disclose such genetic information to any third parties that have a legal or contractual right to receive such information i.e. insurance companies. The researcher must

[67] Whether it is dominant, recessive and sex-linked mechanisms and the significance of carrier status.

stress the fact that the participant, if informed of genetic research results which may impact on his or her health, must disclose this new information to the insurance company to which s/he presently belongs;

b. In addition, the participant must know that s/he has a duty to disclose the results of genetic research, where the results may have an impact on the participant's future health, in any subsequent application for insurance.

(k) Should the research generate information about the research participant which may be relevant to the health of family members, no disclosure to family will be made without the participant's consent unless required by rule of law;

(l) Whether information about the participant's family members may be required during the course of the research;

(m) Where researchers may want to approach relatives of the participant, the prior consent of the participant will be obtained. Furthermore, researchers must, when deciding whether or not to recruit relatives, consider the privacy and any sensitivities of the relatives of which they have been made aware, the ways of communication within the family and the balance of potential benefits and harms which may result from their participation in the research;

(n) Whether the research could potentially detect non-paternity or non-maternity;

(o) That the genetic material and information obtained from the research may have uses unrelated to the present research. However, it must be made clear that no material and information will be used unless the prior consent of the participant is obtained for such further use;

(p) Whether the researcher/s have any intention to store the genetic material and information of the participant for future research. Furthermore, participants must know that they should receive counseling with regard to the possible consequences of the future use of their genetic material. If consent for unspecified future use is given by the participant the duration of storage must be disclosed to the participant. Where the participant refuses to future use, his/her genetic material and information must be disposed of at the end of the current research, once the sample storage and record keeping requirements of good practice have been met by researchers;

(q) Should the participants be sensitive to the manner in which their genetic material is disposed of after completion of the research, these sensitivities should be established and recorded at the outset of the research and observed at the time of disposal;

(r) Participants must know that they are free to terminate their participation at any stage of the research. Participants may decide whether or not their genetic material or information may be disposed of where the samples can be identified. The wishes of participants must be respected;

(s) Participants must be informed that disposal on request will not be possible where their stored samples are de-identified;

(t) Occasionally during genetic research, completely unanticipated and unexpected genetic information may be discovered which directly impacts on the participant and his or her family. Where this occurs, genetic counseling is mandatory. However, the participant is still

entitled to make the decision whether or not s/he wants to know the information;

(u) Participants must be informed that genetic counselors will be made available to them throughout the research process and that participants may consult them on a confidential basis at any stage.

The interests of patients who are unable to give proper informed consent (such as minors or the mentally ill) and who require special safeguards must be protected throughout the entire research process.

Refer to chapter 2.6.4.4.1 and 2 where informed consent in relation to persons who are unable to give proper informed consent is discussed.

13.2.2 Genetic Research and Confidentiality

Researchers must ensure that they comply with the basic principles regarding privacy and confidentiality in research, as discussed in chapter 2.6.5 of this guideline. However, the nature of genetic research raises additional ethical issues in relation to privacy and confidentiality which are discussed in this chapter.

The results of human genetic research that become available must be kept confidential by the researcher. The genetic research protocol must ensure effective arrangements for the preservation of confidentiality in relation to genetic information, genetic material and any information derived from studying the genetic material. The preferred methods of storage for protection of privacy of participants are potentially identifiable or de-identified storage methods, which have been discussed in chapter 2.6.5.

Any information the participant shares about his/her family members must be treated as confidential. Individuals should be fully informed of the results of the genetic research and in particular what the implications of the results would be for the family. When genetic research reveals information that may have serious implications for relatives, it should be explained to the participant why the information should be communicated to other family members. It is recommended that in such an instance researchers should seek to persuade individuals, if persuasion is necessary, to allow the disclosure of relevant genetic information to other family members. The researcher should also seek to ensure that treatment, counseling and support are made available to those family members who receive the unsought information.

Where the researchers are unable to persuade the research participant to consent to disclosure of the relevant genetic information to family members who may be affected by this information, the law and ethics[68] provide for exceptional circumstances where confidentiality may be breached. In such exceptional circumstances, the individual's desire for confidentiality may be overridden. The deciding issue regarding whether or not to breach confidentiality is the following: Should the interests of the third party, in terms of the prevention of harms, take precedence over the interests of the individual participant concerned?

[68] Specifically the principle of beneficence.

EXAMPLE:

Where a research participant was diagnosed with a serious genetic disorder or with a predisposition thereto, it would be in the interests of other family members for the researcher to breach confidentiality, if the family could benefit effectively from immediate medical treatment or preventative measures. The knowledge of a serious genetic disorder, or a predisposition thereto, could provide the family member with the opportunity to take preventative actions such as dietary improvements, therapy, surgery or diagnostic measures. Since preventative measure may be effective in averting the manifestation of the genetic disorder, it may be vital and indeed ethically correct in terms of the principle of beneficence, to inform the relevant family member.

Each individual case should be treated on its own merits when making the decision whether or not to breach confidentiality and inform the interested family members. The following principle should be observed in coming to a decision:

- Access by third parties to the personal genetic information of a research participant should be granted only when, on balance, the interests of the third party (family members), in terms of prevention of harms, outweighs the participant's right to privacy and confidentiality.[69] [70]
- The risk posed to the third party must be a real and serious risk and there must be no other means of preventing the harm from occurring, save breaching the confidentiality of the participant.[71]

13.2.3 Genetic Counseling in the context of research

Only health professionals who have appropriate training, skills and expertise may provide counseling to research participants about the implications of genetic research results and any other issues related to such research and results.

Genetic counseling must be made available to participants throughout the research process and all counseling sessions are confidential.

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[69] In terms of section 36 of the Constitution, any right in the Bill of Rights, which includes the right to privacy, may be limited in certain circumstances. In the context of genetic research, this would involve a 'balancing' between the right to privacy of medical information and the interests of a third party in preventing harm to such third party e.g. family members who may have an interest in knowing the genetic status of a close family member.
Factors that will be taken into account to determine whether or not limitation of any right in the Constitution (in this context the right to privacy) is justifiable are set out in section 36 (a) – (e) as follows:
the nature of the right;
the importance and the purpose of the limitation;
the nature and extent of the limitation;
the relation between the limitation and its purpose; and
less restrictive means to achieve the purpose.

[70] The NHMRC of the Commonwealth of Australia, in their document entitled 'Guidelines under Section 95 of the Privacy Act 1988' at 7, also take the view that the right to privacy is not an absolute right. They state that in some circumstances, the right to privacy must be weighed against the equally justified rights of others and against matters that benefit society as a whole.

[71] British Medical Journal 'Results of Genetic Testing: When Confidentiality Conflicts with a Duty to Warn Relatives' available at www.bmj.bmjjournals.com (site last visited on 21/06/2005).

13.2.4 Genetic research and Insurance

Policy holders have an ethical and contractual duty to disclose any information relevant to his/her health risks and any changes or new information which impacts on their health status to their insurance carrier as soon as such information becomes known to them. Failure to do so would amount to non-disclosure and breach of contract and the insurance company could legitimately refuse to pay the insurance benefits to such policy holder.

In the context of genetic information and applications for insurance cover, one can distinguish three situations:

- Where a patient has previously undergone genetic testing or screening, the predisposition to a genetic disorder is discovered and the results conveyed to the participant. The patient then applies for insurance. In these circumstances, the patient clearly has a duty to disclose such information to the insurance company.
- The patient has a genetic disorder of which he is aware and the symptoms are already apparent and present when application for insurance is made. The patient has a duty to disclose such information to the insurance company.
- A predisposition to a certain genetic disorder becomes apparent through a participant's involvement during medical research.

The third scenario would be relevant in the context of biotechnology research.[72] The participant has a legal duty to disclose this information to the insurance company, irrespective of the fact that it was obtained during participation in research and s/he must be informed of this during the informed consent process.[73] The participant must know that if s/he fails to disclose such information, the insurance company may legitimately refuse to honour the policy. The researcher has no duty to inform the insurance company of the genetic information since the contract is binding between the insurance company and the participant only.

The Nuffield Council on Bioethics states the following with regard to genetic results which indicate the predisposition to develop a certain genetic disease:

> [A] genetic predisposition to disease is not always an indication of future ill health. The probability that a disease will develop can vary greatly. It may also be very difficult to predict for any given individual the age at which a disease is likely to become manifest. Any prediction is further complicated by the fact that environmental factors often play a major role in many late-onset diseases. Thus, in some cases, it will be particularly difficult, if not impossible, for insurance companies to calculate the chance of an individual developing a disease… Huntington's disease, for example, lies at the extreme end of a spectrum. It is a dominantly inherited disease where there is a high level of probability that those having the defective gene will develop the disease. On the other hand, infamilial hypercholesterolaemia

[72] Refer to chapter 16.4.1 where informed consent and genetic research is discussed.

[73] Should the participant choose to be informed whether or not s/he is predisposed to developing a genetic disorder, s/he, once aware of such medical status, must disclose such predisposition in any future insurance application.

> another dominantly inherited disease by no means all of those with a gene will develop coronary heart disease at an early stage and environmental factors such as diet, smoking and exercise may play a major part.[74]

It is recommended that South African Insurance Companies should adhere to their current policy of not requiring any genetic tests as a prerequisite of obtaining insurance because the following dangers are recognised:

- The difficulty of assessing what may be slender evidence on the genetic susceptibility of individuals to develop polygenic and multifactorial diseases (e.g. some cancers and some heart diseases);
- An awareness that ordinary commercial practice will lead companies to be overcautious in their assessment of the risks derived from medical data; and
- The potential for abuse i.e. discrimination.

13.2.5 Genetic Research and employment

Where during genetic research, genetic screening of employees for occupational risks is contemplated, it may only be done in the following circumstances:

- Where there is strong evidence of a clear connection between the working environment and the development of the condition for which genetic screening can be conducted;
- Where the condition in question is one which seriously endangers the health of the employee or is one in which an affected employee is likely to present a serious danger to third parties;
- Where the condition is one for which the dangers cannot be eliminated or significantly reduced by reasonable measures taken by the employer to modify or respond to the environmental risks.

Although it may be appropriate to introduce a genetic screening programme on these limited grounds, it should be done only if accompanied by safeguards for the employee, and after consultation with the appropriate Institutional Ethics Committee.

It is important that when obtaining informed consent from a research participant for genetic screening, it must be disclosed to the participant that if, during the screening process, it is discovered that the participant has a condition which may endanger third parties in the workplace, the researcher may have a duty to disclose this condition to the employer, should the participant refuse to do so.

13.3 Gene Therapy Research

Gene therapy involves the modification of the genetic material of living cells.[75] The practice of gene therapy relates to two groups of cells – somatic cells and germ-line cells. A germ-line cell is a cell which, during the first few weeks after conception, is set aside in the embryonic sex organs to provide, possibly decades later, ova or sperm.[76] A somatic cell is any body cell except a germ-line cell.

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[74] Nuffield Council on Bioethics 'Genetic Screening: Ethical Issues' (1993) 66.

[75] U.S. Department of Health and Human Services Center for Biologics Evaluation and Research – Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy (March 1998).

[76] Germ-line cells may also be defined as the specialised cells that come together during fertilisation (conception) in organisms that reproduce sexually.

The genes carried by each of these two kinds of cells have distinct roles and the distinction is very important. Genes carried by germ-line cells may be transmitted to offspring and successive generations. Genes which are carried by somatic cells have their role in the corporate life of those cells within the tissues and organs of the individual whom they endow.

All research in relation to gene therapy must be directed to alleviating diseases in the individual patients and no attempts should be made through the use of gene modification, to change human traits not associated with disease.

13.3.1 Somatic Cell gene therapy research

Somatic cell gene therapy is similar to current routine therapies. It is seen as a form of medical treatment and is not subject to the ethical principles governing research. Somatic cell gene therapy is allowed under the National Health Act and therefore, by inference, research into somatic cell gene therapy is permissible.

All research into somatic cell gene therapy must comply with the stringent ethical guidelines applicable to human genetic research.

13.3.2 Germ line gene therapy research

Germ line gene therapy involves the insertion of genes into eggs already fertilized or very early embryos. The inserted genes would be transferred to subsequent generations as it has the effect of modifying the human germ line. Research relating to germ line gene therapy is therefore not acceptable.

13.4 Reproductive Biotechnology Research

The highest regard to the dignity, equality and rights of all persons must be had in the application of research and treatment into assisted reproductive technology.

While bio-medicine may offer increasing ability to diagnose, prevent and treat disabilities and birth abnormalities, the fullest respect and support must be given to those with disabilities, those with disabilities who cannot be cured or remedied by biotechnology and those who decline genetic treatment options for ethical reasons.

Reproductive procedures that attempt to fuse human cells with those of animals or other species may not be undertaken.

13.4.1 Genetic Screening and reproductive biology

While pre-natal diagnosis and genetic screening (including pre-implantation screening in the case of in vitro fertilisation) offer expanding tools for assessing and addressing potential genetic disease and birth abnormalities, such technologies may not be employed for non-medical reasons. For example, such technologies may not be employed in order to assist couples wishing to have a child with particular characteristics (such as particular gender, hair colour, intelligence, or physical strength) if these characteristics have no significant bearing on the health of the child.

13.5Human cloning research

13.5.1 Introduction

Stem Cells

Stem cells are tissue precursor cells that have the ability to self-renew and differentiate into more specific adult cells which are required in the human body.[77] Because of their unique capacities stem cells can be made to grow into different types of tissue, for example blood, nerve cells, organs or heart muscle.[78] Stem cells are found in most tissues and at all stages of development.[79] There are three types of stem cells namely totipotent, pluripotent and multipotent.

Totipotent cells can develop into complete human beings. They are found in the embryo in up to the 16 cell stage and are genetically identical.[80] At present, research involving totipotent stem cells is strictly prohibited.

The early human embryo (5-6 day-old blastocyst) consists of an outer cell layer which develops into the placenta, and an inner cell mass, consisting of approximately 200 pluripotent cells which develop into the fetus.[81] This inner cell mass is the source of embryonic stem cells.[82] Research on embryonic stem cells is allowed up to 14 days of development of the zygote.[83] This may only be done with the permission of the Minister of Health.[84]

Somatic stem cells (adult stem cells) are more committed or multipotent. Their differentiation is limited to one or a few tissue lineages.[85] Despite the ability of somatic cells to differentiate indefinitely, self-renewal is especially low in mature organs and in general their frequency and versatility decline with differentiation.[86]

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[77] A Dhai, J Moodley, D J McQuoid-Mason & C Rodeck 'Ethical and Legal Controversies in Cloning for Biomedical Research – A South African Perspective' (2004) *SAMJ* Vol 94 No 11, 906.

Potential sources of embryonic stem cells are:

- Fetal tissue that becomes available after an abortion;
- Excess embryos from assisted reproductive technologies;
- Embryos created through in vitro fertilisation (IVF) specifically for research purposes;
- Embryos created asexually as a result of the transfer of a human somatic cell nucleus to a denucleated ovum.

Other sources of stem cells are:

- Umbilical cord blood;
- Fetal blood and fetal tissue;
- Bone marrow;
- Blood;
- Liver; and
- Brain.

[78] Ibid.
[79] Ibid.
[80] Ibid.
[81] A Dhai, J Moodley, D J McQuoid-Mason & C Rodeck 'Ethical and Legal Controversies in Cloning for Biomedical Research – A South African Perspective' (2004) *SAMJ* Vol 94 No 11, 906.
[82] Ibid.
[83] The National Health Act 61 of 2003, section 57.
[84] Ibid.
[85] A Dhai, J Moodley, D J McQuoid-Mason & C Rodeck 'Ethical and Legal Controversies in Cloning for Biomedical Research – A South African Perspective' (November 2004) Vol 94 No 11 *SAMJ* 907.
[86] Ibid.

The use of stem cells is controversial mainly because much of the current research is focused on deriving these cells from human embryos and cadaveric fetal tissue.

Since the use of embryos is one of the main controversies in stem cell research, the embryo must be treated with respect since it is genetically unique and a potential human life.

Cloning

The term 'clone', in its strictest sense, means a precise genetic copy of a life form.[87] At a molecular level, cloning involves the copying of DNA fragments containing genes and amplifying these in a host cell.[88] Cellular cloning involves the copying of somatic cells and growing them in culture.[89] The utility of these types of cloning would be for the testing and production of new medical products.

Reproductive Cloning

The National Health Act defines reproductive cloning as 'the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose'.[90] Research into the cloning of entire human beings, is not ethically or legally permissible and is prohibited by the National Health Act.[91]

Therapeutic Cloning

Therapeutic Cloning involves the process of somatic cell nuclear transfer where the nucleus from an adult cell is injected into a human ovum of which the nucleus has been removed. The National Health Act defines therapeutic cloning as the 'manipulation of genetic material from adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues'.[92]

Where allowed by the National Health Act, research may continue into cloning of genes and cells for specific medical purposes, where such research has been approved by the Minister of Health and the relevant Health Research Ethics Committee.

13.5.2 Prohibited and unethical practices in relation to cloning

In addition to the principles discussed above, the following practices are not allowed and clinicians and researchers must not engage in any of the following: [93]

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[87] Medical Research Council of South Africa Guidelines: *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research* (Book 2) paragraph 3.4.2

[88] A Dhai, J Moodley, D J McQuoid-Mason & C Rodeck 'Ethical and Legal Controversies in Cloning for Biomedical Research – A South African Perspective' (November 2004) Vol 94 No 11 *SAMJ* 907.

[89] Ibid.

[90] Section 57 (6) (a).

[91] Section 57 (1).

[92] Section 57 (6) (b).

[93] These ethical principles were extracted from the following sources:
Commonwealth of Australia NHMRC *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (1999) 10; Prohibition of Human Cloning Act 2002 No. 144, 2002; Medical Research Council of South Africa *Guidelines on Ethics for Medical Research: Reproductive Biology and Genetic Research* Book 2 paragraph 3.4.3.2; The National Health Act 61 of 2003.

- Research on embryonic stem cells exceeding 14 days of the development of the embryo;[94]
- The manipulation of any genetic material, including genetic material of human gametes, zygotes or embryos for the purpose of the reproductive cloning of a human being;[95]
- Any activity, including nuclear transfer or embryo splitting for the purpose of reproductive cloning of a human being;[96]
- Import or export of human zygotes or embryos without the prior written approval of the Minister of Health;[97]
- Placing a cloned human embryo into the body of a human or animal;
- Creating or developing a human embryo which contains the genetic material of more than two persons;
- The intentional alteration of the genome of a human cell in a manner that makes the alteration heritable by descendants of the human whose cell was altered;
- Collecting a viable human embryo from the body of a woman;
- Creating a chimeric or hybrid embryo;
- Placing an animal embryo into the body of a human for any period of gestation;
- Placing a cloned human embryo into the body of a woman;
- Commercial trading in eggs, sperm or embryos of humans; and
- Research involving totipotent stem cells.

13.5.3 Surplus embryos derived from IVF treatment

When creating embryos for IVF treatment, in order to respect the potential life of an embryo, clinicians should take care to limit the number of embryos created to those that will likely be needed by the patient during the course of treatment. In so doing, the unnecessary creation of surplus embryos will be limited and the potential for abuse[98] minimised. Ways of achieving this are to:

- minimise ovarian stimulation;
- limit the number of ova fertilized and embryos stored; and
- not start new treatment cycles for patients when clinically suitable embryos are in storage.

Prior to initiating IVF treatment, the written, voluntary and informed consent of the IVF patient must be obtained, as required by law,[99] concerning the ulitisation of excess embryos. All relevant information regarding the proposed use of such embryos must be disclosed to the patient, so that the patient can make a proper informed judgement as to whether or not she would allow the embryos to be used for such research.

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[94] The National Health Act 61 of 2003, section 57 – Research on embryonic stem cells may only be conducted up to the 14 day stage with the consent of the Minister.
[95] The National Health Act 61 of 2003, section 57 (1) (a).
[96] Ibid, section 57 (1) (b).
[97] Ibid, section 57 (3).
[98] It would be ethically unacceptable to purposely create 'extra' embryos during IVF treatment solely to have 'spares' for research purposes.
[99] Section 57 (4) of the National Health Act requires consent from the donor of zygotes before such zygotes may be used for research.

Information must be disclosed to the patient in a way that facilitates understanding and research many not proceed unless it is certain that the patient fully understands the implications and consequences of her consent.

Explicit consent for all permissible purposes must be obtained on all occasions from both the mother and father who must be legally competent to give consent. However, the consent of the father is not necessary where:[100]

- The father's identity cannot reasonably be ascertained;
- The father's whereabouts are unknown and cannot reasonably be ascertained; or
- The father is not reasonably available.

Where a dispute arises regarding consent to use of surplus embryos in research, or where the mother or father[101] dies without leaving clear instructions with regard to the use of such surplus embryos, the embryos may not be used in research.[102]

13.5.4 Use of Cadaveric fetal tissue

Cadaveric fetal tissue may be useful as a source of stem cells in medical biotechnology research. Fetal cells are capable of proliferating faster and more often than fully developed adult stem cells. Their usefulness lies in the fact that they are able to rapidly reverse the lost function of the host.[103]

The use of cadaveric fetal tissue in research is a sensitive issue. Clinicians and researchers must treat the fetus and the parents of the deceased fetus with the utmost respect and consideration. The use of human fetal tissue is in itself not objectionable.[104] Although fetal tissue has distinct biological properties, it raises the same ethical issues as raised by the use of tissue obtained from a deceased adult or child.[105] Care must be taken to ensure that women do not seek abortions with an altruistic view to provide fetal tissue for therapy.

The informed consent of both the father and mother of the fetus must be obtained prior to utilising cadaveric fetal tissue. The consent of the father need not be obtained where:[106]

- The father's identity cannot reasonably be ascertained;
- The father's whereabouts are unknown and cannot reasonably be ascertained;
- The father is not reasonably available; or
- The pregnancy resulted from rape.

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[100] Department of Health *Ethics in Health Research: Principles, Structures and Processes'* 25
[101] Subject to the exception set out in (a) – (c) above.
[102] Commonwealth of Australia NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (June 1999) 52.
[103] P Schrock 'Fetal Tissue Transplantation' (1997) available at www.hsc.missouri.edu (site last visited on 23/06.2005).
[104] Ibid
[105] Ibid.
[106] Department of Health *Ethics in Health Research: Principles, Structures and Processes'* 25

In obtaining informed consent from the parent/s for the use of the cadaveric fetal tissue it must be disclosed that:[107]

- The fetal tissue is to be used in research;
- The research is not intended to provide medical benefit to the donor of the tissue;
- The research is voluntary and the patient may refuse without having to give any reasons why. In addition, refusal will not in any way affect the quality of clinical care;
- Whether or not the results of the research could have commercial interest;
- The donor will receive no financial or other benefits for the donation or from the research or from any commercial products;
- Where the research will derive cell lines, whether or not the information could be used to identify the tissue donor, or whether the identifiers will be removed prior to the use or derivation of the cell lines;
- Where the fetal tissue or derived cell lines may be used in clinical transplantation, that such research will be carried out altruistically and the donor may not direct into whom the tissue or cell lines will be transplanted;
- Where the tissue or derived cell lines will be used in clinical transplantation, whether the identity of the donor will be disclosed to the recipient;
- Derived cell lines or cell lines may be stored for many years and shared with multiple researchers at various research institutions.

13.5.5 Payment for donated tissue, embryos and fetal tissue

Payment for any human tissue is unethical and unlawful due to the potential for abuse. In terms of the National Health Act[108] it is an offence for a person who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her.[109] It is also an offence to sell or trade in tissue, gametes, blood or blood products.[110]

[107] Juvenile Diabetes Research Foundation International *Policy Statement/Guidelines for the Use of Human Fetal Tissue in Research* February 2003 available at www.jdrf.org (site last visited on 23/06/2005).
[108] Act 61 of 2003
[109] Ibid Section 60 (4) (a).
[110] Ibid Section 60 (4) (b).

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*