GUIDELINES: INFORMED CONSENT

It has long been part of South African law that a patient must provide informed consent for all medical treatment (diagnostic or therapeutic) on him/her (*Stoffberg v Elliot*, 1912). Basically, informed consent means that sufficient information is provided to the patient to make an informed decision and that the patient actually understands the information and the implications of acting on that information. Informed consent relates to a person's right to human dignity and autonomy. The medical practitioner has the duty to obtain the consent, as s/he is in a position to answer questions and provide further details.

According to the HPCSA Guidelines for Good Practice in the Health care professions, there are general and ethical guidelines which must be adhered to for a practitioner to be practicing within the ethical and legal boundaries which is required not only by law, but also by moral code.

The following Guideline Booklets are worthy to note:-

Booklet 9 in its entirety discusses Seeking a Patiens' Informed Consent and what the ethical considerations are.

Extracts from other Booklets regarding Informed Consent:

Booklet 1 : General Ethical Guidelines for the Health Care Professions

Health care practitioners should:

- Give their patients the information they ask for or need about their condition, its treatment and prognosis.
- Give information to their patients in the way they can best understand it. The information must be given in a language that the patient understands and in a manner that takes into account the patient's level of literacy, understanding, values and belief systems.
- Refrain from withholding from their patients any information, investigation, treatment of procedure the health care practitioner knows would be in the patient's best interest.
- Apply the principle of informed consent as an on-going process
- Allow patients access to their medical records

Booklet 2: National Patient's Rights Charter

Informed Consent:

Everyone has a right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and risks associated therewith and the costs involved.

Booklet 6: General Ethical Guidelines for Health Researchers

Informed Consent:

Health researchers should always:

- Give research participants sufficient information about the nature and effect of the research – in particular the effect of the research on the participants including its consequences, risks and benefits – to enable them to make an informed choice about their participation.
- Give research participants the information they ask for and need about their research participation
- Remember that responsibility for the well-being of research participants always rests with the health researcher – not the research participant – even thought the latter have given consent
- Give information to research participants in a language that the participant understands and in a manner that takes into account the participant's level of literacy, understanding, values and personal belief systems. Participation at all times should be voluntary and not coerced.
- Use caution when obtaining informed consent where the research participant is in a dependent relationship with the health researcher or is in a situation where he or she may consent under duress. In such cases, informed consent should be obtained by a well-informed health care practitioner who is not engaged in the research and who is completely independent of this relationship
- Refrain from purposefully withholding from research participants any information, investigation or procedure that health care practitioners know is in the best interests of the participants
- Obtain the consent of legally authorized representatives in cases of research participants who cannot consent for themselves, e.g. children, mentally challenged, elderly and the unconscious. These groups should not be included in research unless the research is

necessary to promote the health of the population represented and unless this research cannot instead be performed on legally competent persons

- Remember that the principle of informed consent should be viewed as an ongoing process in that research participants are entitled to change their minds. Moreover, the consent process should be reinforced during the trial
- Inform research participants of their right to abstain from participating in the study, or to withdraw from participating in the study – by revoking their consent – at any time, without suffering prejudice or reprisal
- Allow competent research participants unimpeded access throughout the research period to information concerning the research
- Inform participants of the limits to the confidentiality of the information about them gathered during the research – e.g. bodies such as the National Health Research Ethics Council, the HPCSA, and the Medicines Control Council may review or inspect data.
- Adhere to the principle of informed consent by keeping proper documentation. After ensuring that the research participant understand the information, the health researcher should obtain the participant's freely given informed consent in writing. If the consent cannot be obtained in writing, the non-written consent must be fully documented and witnessed. Both verbal and written informed consent must be obtained unless there are good reasons for not doing so. Where the research participant is not literate verbal consent should be obtained in the presence of an independent literate witness who should verify this in writing. Where the independent witness is not literate, the consent process should be audio-visually recorded.

<u>The following are elements of informed consent:</u>

- Consent must be voluntary and without constraint;
- In the case of a HIV test, consent should preferably be written, although consent may be implied;
- Consent must not conflict with good morals or the Constitution;
- The patient must be capable of consenting;
- The patient must give the consent personally, unless proxy consent is applicable (see below);
- The patient should know why the medical practitioner needs the results of the test;
- There should be sufficient information on the diagnosis, proposed treatment, expected benefits, risks, alternative treatment, probable results, etc;

- The patient must actually understand, i.e. there is likely to be a need for an interpreter or at least sensitivity that the patient may not actually understand everything and arrangements should be made so as to assist the process of understanding.

In a number of cases a patient may not be able or capable of giving informed consent. In terms of the Child Care Act a child that is older than 14 years may independently consent to medical treatment.

This means that such a child can consent to a HIV test without his/her parents/guardian knowing.

A person who is older than 18 years may consent to any operations. Schools, whether they are public or private, may not test learners without the consent as required by the Child Care Act and it is likely that, even if consent is obtained in the school setting, such tests may be found to violate the human rights of the learners concerned.

A teacher will also not be able to provide consent on behalf of a learner. Where research with, for example, HIV drugs is concerned, it is suggested that both parental and children's consent is obtained. In the case of mentally ill persons the curator, spouse, parent, major child or brother or sister, or the superintendent
must consent on their behalf. If a person is temporarily incapable of providing consent, the general principle is that such a person should first be restored to a state where s/he can consent. In the case of a lengthy operation there may be a need to test the person.

The consent requirement could be dispensed with if the defense of necessity (need to commence PEP treatment for a health care worker) and the requirements of the constitutional limitation clause (see above) are met.

The HPCSA suggest that vicarious or proxy consent should be obtained from such a patient's closest relative. Prisoners (i.e. arrested, detained, awaiting trial and sentenced prisoners), like any other person, have to consent to HIV tests and should be given pre- and post-test counseling (*C v Minister of Correctional Services*, 1996). HIV and Prisoners are discussed in more detail below.

The issue of informed consent becomes pertinent in the multi-cultural setting.

Language and cultural barriers may prevent patients from expressing their concerns or from asking questions on HIV tests. Medical practitioners should ensure that a patient has actually consented, as these barriers may result in the consent actually not being provided freely and voluntarily.

According to a report by the South African Human Rights Commission, Australian guidelines provide that a patient should be told if an interpreter is available. In
emergency cases where an interpreter is not available, a telephone interpreter service should be utilised and that all staff members that act as (non-professional) interpreters should receive appropriate training.

As the South African Constitution provides for equality of languages, the South African Medical Association believes that there is a duty on the state to provide for (policies on) interpreting or at least for proper training for staff acting as interpreters.

A general poster in a ward or consultation room that "all patients will be tested for HIV" does not constitute informed consent. It is also not recommended that a patient be merely provided with a leaflet or just referred to another institution to explain to him/her what the HIV test is about.

It is often argued that in emergencies, one may dispose of the requirement of informed consent if it is necessary to save a patient's life. This is, however an unlikely situation and the circumstances may be too vague for a practitioner to defend him/herself against claims against not obtaining informed consent.

If there is a needle-stick injury and the patient is not willing or not capable to consent, it is possible to, to test an existing blood sample. This should however not be the general policy or first line of reaction. Refer to the section below on occupational injuries as well. It should however be stressed that this will not prevent any patient from taking (legal) action against a medical practitioner in these circumstances.

If the South African Law Commission's proposals go through, the law will allow for rape suspects to be tested for HIV without their consent. This duty is likely to be performed by the District Surgeons or medical staff servicing prisons or places of detention, which has to verify that the detainee is in fact a rape suspect.

Example of a consent form:

I, …….. (full name), an adult male/female from …….. (address) hereby confirm that I have been informed by Dr …… about the nature, conduct, benefits, risks and implications involved in undertaking a HIV test (or treatment). I have also received and understood all the relevant information concerning the proposed test (or treatment). I have had sufficient opportunity to ask questions and to consider whether I want to proceed with the test (or treatment).

I therefore freely and voluntarily agree to the HIV test being performed, which includes the drawing of a blood sample and a test on that sample. I agree that Dr ……. will inform me of the results of the test in person.I hereby agree that the results of the test (or treatment) may be anonymously used for purposes of research and/or data-collection purposes, provided that such information is de-identified with sufficient safeguards. I know that I am, at any stage, free to withdraw my consent to undergo this test (or treatment).

Signed:

…….. ……

Patient (full name, signature and date) Witness 1

…….. ……

Doctor (full name, signature and date) Witness 2

A proxy consent form should include references to the capacity of the person who is consenting on behalf of the patient, the reason why s/he is consenting on behalf of the patient (e.g. in terms of Mental Health Act or Child Care Act), etc.