Informed consent: things to keep in mind when using this template

1. Obtaining informed consent is a process in terms of which you provide information sufficient to enable the patient to make an informed decision. Although the signature of a consent form often constitutes completion of the consent process, a signature on a consent form without a balanced discussion does not constitute informed consent. Therefore, this process is best described as "informed decision-making".

2. This template has been drafted in compliance with section 6 of the National Health Act[1], which requires users of healthcare services to have full knowledge of: their health status; the range of diagnostic procedures and treatment options generally available; the benefits, risks, costs and consequences generally associated with each option, and; the user's right to refuse health services and the implications, risks, and obligations of such refusal.

3. In South Africa, the manner in which information for consent is conveyed by a practitioner to a patient is of cardinal importance, all the more so because of the diversity in this country of cultural, racial, socio-economic, language and educational differences and divides. The onus is on the practitioner to ensure not only that enough information has been imparted but also that the patient has fully understood all the relevant implications and risks. It is therefore preferable and advisable for the practitioner, without being condescending or paternalistic, to underestimate, rather than overestimate, the patient's intelligence and comprehension of what is being imparted. That is, when a patient has difficulty understanding information being imparted, the practitioner must have the patience and care to repeat, perhaps in another form, the necessary facts to ensure that they are properly understood, and this information must

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preferably be supplied in an unambiguous manner, with as little medical jargon as possible, and in non-technical terms. In the final analysis therefore, the practitioner is obliged to explain the procedure or treatment until he or she is satisfied that the patient (or his or her family) understands the procedure and its possible consequences and outcomes.

4. The four steps to obtaining informed decision-making are as follows:

Step one: Introduction

- In explaining the patient's condition use simple language
- Avoid technical medical terminology

Step two: Explain the procedure and material risks

- Discuss options for treatment, including nonoperative care and no treatment, together with the potential benefits and risks of each
- Make use of anatomical drawings
- Discuss recognised complications
- Discuss potential follow-up treatment
- Allow an opportunity for questions and answers
- Provide further sources of patient information (e.g., Surgicom patient educationleaflets)

- Invite the patient to contact you if additional questions arise prior to the planned procedure

Step three: Explain the costs involved in the procedure

Step four: Obtain written consent[2]

- The description of the patient's condition to be entered in paragraph 1
- The surgical procedure to be performed to be inserted in paragraph 2
- Ensure the patient initials the document
- Ensure the patient signs with the correct date
- Provide the relevant patient information sheet to the patient during the consultation with the patient initialing the relevant block under paragraph 3
- Sign the declaration at the end of the form
- Attach the relevant patient information sheet to the informed consent form
- Allow the patient to take a copy and keep one copy for the practice.

[2] In addition to completing the consent form, record the details of the consent discussion with your patient in the patient's note.