



GUIDE TO INFORMED CONSENT

Page 1	The Basics
Page 2 – 3	Questions
Page 3	Legal Basis for Informed Consent
Page 3	South African Constitution
Page 3	African Charter on Human and People's Rights
Page 4	The Universal Declaration of Human Rights
Page 4 – 5	Mental Health Act (South Africa)
Page 5 – 6	The Nuremberg Code (1947)

The Basics

Any medical procedure, whether experimental or official, may be tantamount to a crime if carried without the direct or indirect informed consent of the person on whom the procedure is being carried out.

The dictionary definition of informed consent is: “consent to surgery by a patient or to participation in a medical experiment by a subject after achieving an understanding of what is involved.”

<https://www.merriam-webster.com/dictionary/informed%20consent>

In as much as this guide may be applied to any and all medical procedure, including surgical operations, the primary emphasis for the current version is to address concerns related to the covid-19 human experimental research program and the associated injection and the subsequent vaccine, if the vaccine does get manufactured and rolled out.

Before agreeing to being injected or consenting to a loved one being injected, it is important to have the following questions answered. A person may only be said to have given consent when and if the following questions are answered with a **YES**.

If any of the questions is answered with a **NO**, then any procedure being carried out on the person may be illegal and be a crime.

If all of the questions are answered with a **YES**, and the person concerned refuses to have the procedure performed, that person is said to have made an informed refusal.

Questions:

1. Does the person making the decision have the capacity to decide?
2. Has the person's health status been explained to them?
3. Has the condition being treated been explained to the person?
4. Has it been explained that the Minister of Health told Parliament that the current program is a covid-19 human experimental research program and not a vaccine roll out?
5. Has the difference between the experimental covid-19 human experimental research injection and vaccination been explained?
6. Have the available options generally available for preventing infection and maintaining a strong immune system been explained?
7. Have the benefits, risks, costs and consequences generally associated with each option been fully explained?
8. Has the right to refuse to participate in the covid-19 human experimental research program been explained?
9. Have the implications, risks, obligations of such refusal been explained?
10. Has it been explained that the covid-19 human experimental research program is purely voluntary?
11. Has it been explained that there is NO LAW in South Africa that forces anyone to participate in the covid-19 human experimental research program?
12. Has it been explained that the government of South Africa has signed an agreement that says if anything goes wrong with your health or even death, as a result of participating in the covid-19 human experimental research program, you may not sue the pharmaceutical company that manufactured the covid-19 human experimental research injection?
13. Have all the ingredients and the effects or side effects of the covid-19 human experimental research injection been listed and explained?
14. Has it been explained that even if you do participate in the covid-19 human experimental research program and get injected you are still expected to wear a mask?
15. Has it been explained that even if you do participate in the covid-19 human experimental research program and get injected you are still expected to sanitise?

16. Has it been explained that even if you do participate in the covid-19 human experimental research program and get injected you are still expected to maintain physical distancing?
17. Has it been explained that even if you do participate in the covid-19 human experimental research program and get injected the lockdowns will not end?
18. Has it been explained that thousands of people have been injured and some have died from participating in the covid-19 human experimental research program, around the world?
19. Has it been explained that even if you do consent to participate in the covid-19 human experimental research program, because the program is voluntary, you have the right to withdraw your consent any time?
20. Has it been explained to you that the survival rate of covid-19 without any vaccination is more than 99%?
21. Was everything explained to you in a language that you understand?

LEGAL BASIS FOR INFORMED CONSENT

South African Constitution:

Section 12(2): Everyone has the right to bodily and psychological integrity, which includes the right:

- a. to make decisions concerning reproduction;
- b. to security in and control over their body; and
- c. not to be subjected to medical or scientific experiments without their informed consent.

African Charter on Human and People's Rights:

Article 4: Human beings are inviolable. Every human being shall be entitled to respect for his life and the integrity of his person. No one may be arbitrarily deprived of this right.

Article 16 (1): Every individual shall have the right to enjoy the best attainable state of physical and mental health.

The Universal Declaration of Human Rights:

Article 3: Everyone has the right to life, liberty and security of person.

Mental Health Act (South Africa)

Section 6 (1) Every health care provider must inform a user of—

- (a) the user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user;
- (b) the range of diagnostic procedures and treatment options generally available to the user;
- (c) the benefits, risks, costs and consequences generally associated with each option; and
- (d) the user's right to refuse health services and explain the implications, risks, obligations of such refusal.

(2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user's level of literacy.

Section 7(1) Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless—

- (a) the user is unable to give informed consent and such consent is given by a person—
 - (i) mandated by the user in writing to grant consent on his or her behalf; or
 - (ii) authorised to give such consent in terms of any law or court order;
- (b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;
- (c) the provision of a health service without informed consent is authorised in terms of any law or a court order;
- (d) failure to treat the user, or group of people which includes the user, will result in a serious risk to public health; or

(e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service.

(2) A health care provider must take all reasonable steps to obtain the user's informed consent.

(3) For the purposes of this section "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so & who has been informed as contemplated in section 6.

Section 8(1) A user has the right to participate in any decision affecting his or her personal health and treatment.

(2) (a) If the informed consent required by section 7 is given by a person other than the user, such person must, if possible, consult the user before giving the required consent.

(b) A user who is capable of understanding must be informed as contemplated in section 6 even if he or she lacks the legal capacity to give the informed consent required by section 7.

(3) If a user is unable to participate in a decision affecting his or her personal health and treatment, he or she must be informed as contemplated in section 6 after the provision of the health service in question unless the disclosure of such information would be contrary to the user's best interest.

The Nuremberg Code (1947)

Permissible Medical Experiments

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

(Also available: Informed Consent – Liability | request by email info@miric.co.za)