

# MODULE

# 6

## Legal and human rights

Module 6 looks at the human and legal rights of HIV vaccine trial participants and their communities.

In this module we discuss:

1. What are human rights?
2. What are the different kinds of human rights?
3. What are legal rights?
4. Which rights are important to HIV vaccine trial participants?
5. How does the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights* explain the rights of HIV vaccine trial participants?



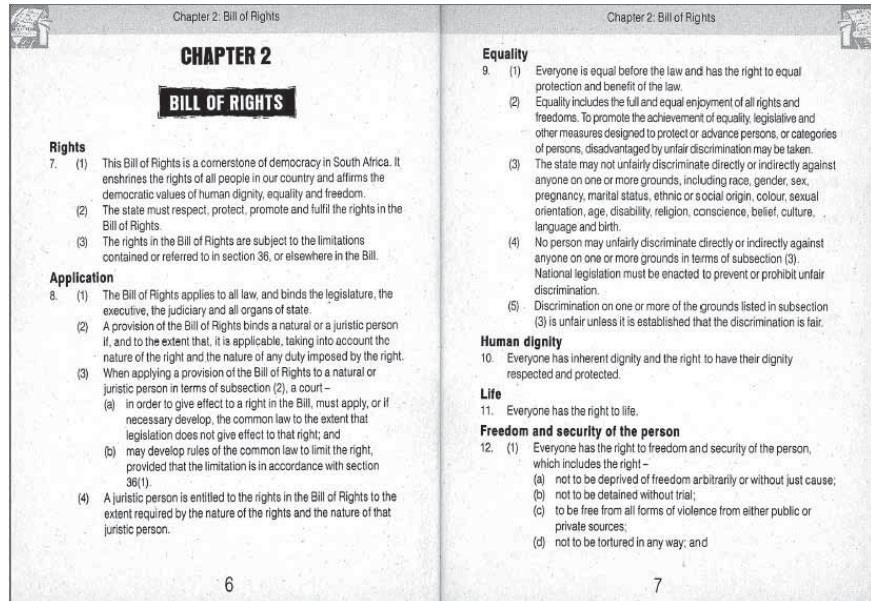
*Justice under a tree:  
the Constitutional  
Court's logo.*



### 1. WHAT ARE HUMAN RIGHTS?

Human rights are rights and freedoms that we all have, just because we are human. For example, every person has the right to life. No one can take these rights from us. In South Africa our human rights are written into the Constitution, in a Bill of Rights. Our human rights are guaranteed, interpreted and given meaning in different ways – one way is by the courts.

**NOTE:**  
*We generally only take a human rights issue to court after trying all other ways of working it out.*



Pages in the Bill of Rights in the South African Constitution.

The idea of human rights comes from different places like religions, **customs** and the law. Human rights can also be seen to have been achieved through the struggle against apartheid. These are now written into our Constitution, in our Bill of Rights.

#### How are our human rights guaranteed?

The state has a duty to respect, protect, promote and fulfil human rights. What does this mean?

- **Respecting human rights:** This is the duty to *not* do anything that takes away a person’s rights; or that stops a person from using and enjoying their rights; or which unfairly **discriminates** against anyone.
- **Protecting human rights:** This is the duty to *do* something (to take action) to protect a person’s rights from being abused by anyone.
- **Promoting and fulfilling human rights:** This is the duty to take reasonable steps to make it possible for people to use and enjoy their rights. An important part of this is to tell people what their rights are and how they can enjoy these rights.

**WORD BOX**  
**Customs:**  
*Fixed practices in a community.*  
**Discriminate:**  
*To treat someone or a group of people unfairly compared to others.*



Individuals, communities and other institutions (e.g. the Human Rights Commission) also have certain duties to ensure human rights. Later we will look at ways to ensure human rights in HIV vaccine clinical trials.

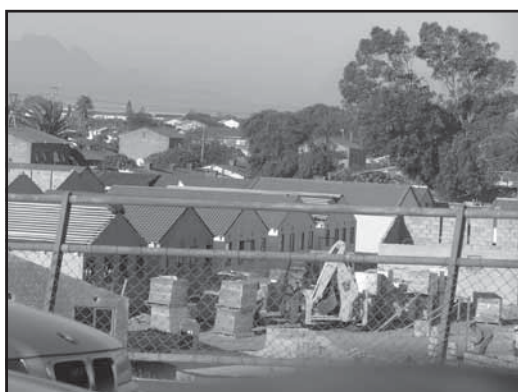
Sometimes human rights can be limited because of other rights, or other people's rights, or because of what is written in the Constitution about a right. For example, the Constitution may say that a right is limited in some way. A person can also give up his or her rights.

**2. WHAT ARE THE DIFFERENT KINDS OF HUMAN RIGHTS?**

The Bill of Rights talks about two main groups of human rights:

- **Civil and political human rights:** These are rights that prevent the state from doing something, for example, the right to life prevents the state from carrying out the death penalty. These rights also require the state to take action so that we can enjoy our human rights. For example, the right to vote means that the state must make sure that we can vote on voting day.
- **Socio-economic human rights:** These are rights to do with people's **social**, economic and cultural security. These rights can only be claimed as a group and not on an individual basis.

So, you cannot claim the right to access to housing on an individual basis. But, in certain circumstances, a community can claim their right to access to housing, when for example, a municipality evicts people unfairly from land without giving them another place to live.



*Progressive realisation of the socio-economic right to housing.*

A civil and political right that applies to HIV vaccine research is the right not to be subjected to medical or scientific experiments without informed consent (Constitution, Section 12 (2) (c)).

A socio-economic right that applies is the right of **access** to health care services (Constitution, Section 9).

**WORD BOX**

**Civil rights:**

*The personal rights of any citizen of a country.*

**Political rights:**

*The right to make political choices, the right to free and fair elections, and the right to vote.*

**Socio-economic:**

*The social and economic aspects of something.*

**Social:**

*Refers to people or society as a whole.*

**Economic:**

*Relating to the economy, which is the organisation of money and resources within a nation or a community.*



The table below shows which rights from the Bill of Rights fit into each of the two groups of human rights:

| <b>Civil and political human rights:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Socio-economic human rights:</b>                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• Right to equality</li><li>• Right to human dignity</li><li>• Right to life</li><li>• Freedom of security of the person</li><li>• Freedom from slavery, servitude and forced labour</li><li>• Right to privacy</li><li>• Freedom of religion, belief and opinion</li><li>• Freedom of expression</li><li>• Freedom of assembly, demonstration, picket and petition</li><li>• Freedom of association</li><li>• Political rights</li><li>• Right to citizenship</li><li>• Freedom of movement and residence</li><li>• Freedom of trade, occupation and profession</li><li>• Labour rights</li><li>• Right of access to information</li><li>• Right to just administrative action</li><li>• Right to access the courts</li></ul> | <ul style="list-style-type: none"><li>• Environmental rights</li><li>• Property rights</li><li>• Right to housing</li><li>• Right to access to health care, food, water and social security</li><li>• Children's rights</li><li>• Right to education</li><li>• Right to use the language and to participate in the cultural life of choice</li><li>• Rights of cultural, religious and linguistic communities</li></ul> |

We will look at how these rights apply in the section on the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights* further on.

So far we have looked at human rights, but what is a legal right?

### **3. WHAT ARE LEGAL RIGHTS?**

Legal rights are found in the laws of a country. These can be applied by the courts.



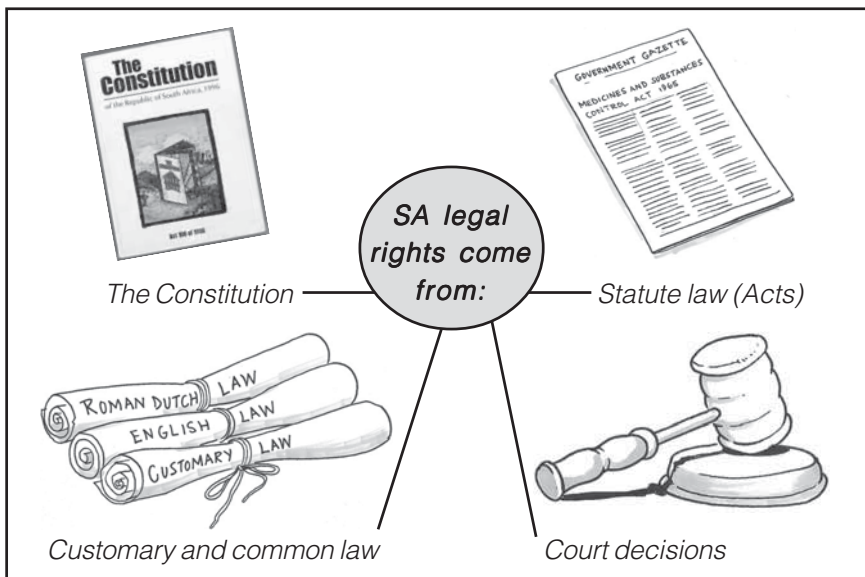
#### **DID YOU KNOW?**

The law is made up of rules that govern the way we behave – what we must do; what we can do; and what we must not do.

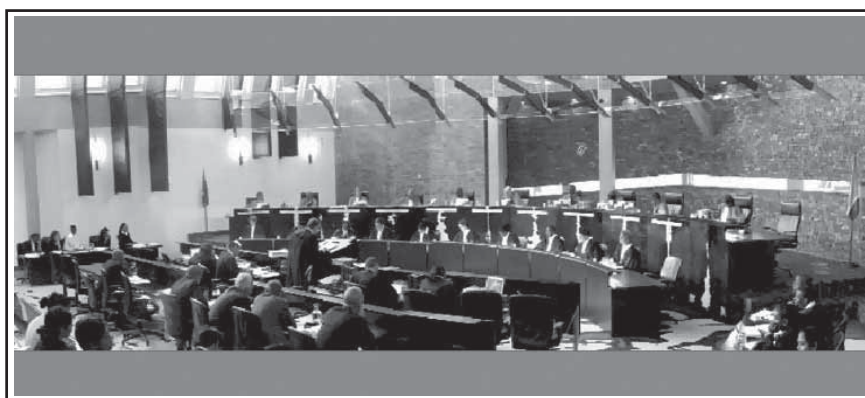
In South Africa, our democratic government gives us ways to contribute to the making of our laws. For example, during the elections, we can vote for people to represent our interests in government.



**In South Africa our legal rights come from:**



**The Constitution:** This is the highest law of South Africa and all other laws must be in line with it. The Constitution tells us how the state must be organised and includes the Bill of Rights. We can challenge laws that go against the Constitution in the Constitutional Court. This court can **strike down** these laws if they do not agree with the Constitution. When the courts interpret the Bill of Rights, they must also look at international law and even the law in other countries to help guide their decisions.



*The South African Constitutional Court at work.*

**WORD BOX**

**Strike down:**  
Cancel.



**Statute law:** These are written laws that are called statutes or Acts. They are made or changed by Parliament - the highest law-making body in the country. They can also be made or changed by provincial and local governments. The following are some Acts that apply to HIV vaccine research:

- *The Medicines and Substances Control Act of 1965.* One thing it says is that research must go for regulatory and ethical review.
- *The National Health Act of 2003,* which, for example, deals with some of the rights of children involved in research.

A statute can give a person (e.g. a Minister) power to make more laws that complement or give further detail to a statute. These are called regulations. The Constitution is also a statute.

**Common law:** This is law that comes from Roman-Dutch and English law, which was brought to South Africa long ago by Dutch and English **settlers**. When statute law does not cover a legal problem, then we can look to the common law for guidance. If common law is used it must be in line or in agreement with the Constitution. The following areas of common law are important for HIV vaccine research and development:

- The Law of **Contract:** This law rules agreements between parties, for example, between trial participants and institutions running the trials.
- The Law of **Delict:** This law rules actions that harm others or their property, for example, this law could cover the right to confidentiality, and compensation for research-related injury .

Many of the general principles of our law come from common law, for example, the general principles about informed consent. The courts can develop common law, or they can replace the common law with statute law so that it is in line with the Constitution.

**Customary law:** These are written and unwritten laws that develop from the customs of a community. Customs become law when they are known and generally followed by most people in the community, and they are **enforced** in some way.

**Court decisions:** When people are involved in a conflict about the law, or when someone has broken the law, they can take the conflict or person who has broken the law to the courts for a decision.

Let's now see which human rights are important to HIV vaccine research and development.

**WORD BOX**

**Settlers:**

*People who settle in a new colony or move into a new country.*

**Contract:**

*A legal agreement between two or more people that can be enforced by the law.*

**Delict:**

*An act committed by a person which harms another person or his/her property.*

**Enforced:**

*Put into force, or to cause to be carried out.*



#### 4. WHICH RIGHTS ARE IMPORTANT TO HIV VACCINE TRIAL PARTICIPANTS?

The table below shows which human rights are most important to People Living with HIV or AIDS (PLWHAs). Many of these rights are also important to HIV vaccine trial participants.

| Section in Bill of Rights | Right                                                                                                                                                                                                                                                                                                                                                            | What this means for People with HIV or AIDS (PLWHAs), or for HIV vaccine trial participants                                                                                                                                                                  |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9                         | <p><b>EQUALITY</b><br/>Everyone has the right to equality and non-discrimination:</p> <ul style="list-style-type: none"> <li>• Everyone is equal before the law and has the same right to protection from the law.</li> <li>• No one may be unfairly discriminated against on grounds such as race, gender, sex, sexual orientation, disability, etc.</li> </ul> | No one may be unfairly discriminated against.                                                                                                                                                                                                                |
| 10                        | <p><b>HUMAN DIGNITY</b><br/>Everyone has the right to have their dignity respected and protected.</p>                                                                                                                                                                                                                                                            | No one may insult or damage a person's dignity by their words or actions.                                                                                                                                                                                    |
| 12 (2)                    | <p><b>FREEDOM AND SECURITY OF THE PERSON</b><br/>Everyone has the right to:</p> <ul style="list-style-type: none"> <li>• make decisions about pregnancy;</li> <li>• security and control over their body; and</li> <li>• not be subjected to medical or scientific experiments without informed consent.</li> </ul>                                              | <p>People have the right to make their own decisions about medical treatment and pregnancy, for example, you cannot be forced to test for HIV.</p> <p>HIV vaccine trial participants have a right to decide whether or not to participate in the trials.</p> |
| 14                        | <p><b>PRIVACY</b><br/>Everyone has the right to privacy.</p>                                                                                                                                                                                                                                                                                                     | PLWHAs and trial participants have the right to keep their information private. No one can force them to disclose their HIV status or any other information about themselves.                                                                                |
| 16                        | <p><b>FREEDOM OF EXPRESSION</b><br/>Everyone has the right to freedom of expression. This includes freedom to receive or give out information or ideas.</p>                                                                                                                                                                                                      | Everyone should get proper information about how to prevent HIV – even people in schools or prisons.                                                                                                                                                         |



| Section in Bill of Rights | Right                                                                                                                                                                                                                                                                                                                       | What this means for People with HIV or AIDS (PLWHAs), or for HIV vaccine trial participants                                                                                                                                                                                                                                                                                     |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 18                        | <b>FREEDOM OF ASSOCIATION</b><br>Everyone has the right to freedom of association.                                                                                                                                                                                                                                          | Anyone can join any organisation they choose.                                                                                                                                                                                                                                                                                                                                   |
| 21                        | <b>FREEDOM OF MOVEMENT AND RESIDENCE</b><br>Everyone has a right to freedom of movement and to leave the country. All citizens have the right to enter, to remain in, and to live anywhere in the country.                                                                                                                  | PLWHAs cannot be forced to live in a separate place, away from the rest of society. They are free to move around the country.                                                                                                                                                                                                                                                   |
| 22                        | <b>FREEDOM OF TRADE, OCCUPATION AND PROFESSION</b><br>Citizens have the right to choose their trade, occupation or profession freely.                                                                                                                                                                                       | PLWHAs can choose what kind of work they want to do. They cannot be told that they cannot be a doctor, a teacher or a health care worker.                                                                                                                                                                                                                                       |
| 23                        | <b>LABOUR RELATIONS</b><br>Everyone has the right to fair labour practices.                                                                                                                                                                                                                                                 | No one may be unfairly discriminated against at work.                                                                                                                                                                                                                                                                                                                           |
| 24                        | <b>ENVIRONMENT</b><br>Everyone has the right to an environment that is not harmful to their health or well-being.                                                                                                                                                                                                           | Like everyone else, PLWHAs have the right to a healthy environment, even if they are living in a prison or hospital.                                                                                                                                                                                                                                                            |
| 26                        | <b>HOUSING</b><br>Everyone has the right to have access to adequate housing. No person may be evicted from their home, or have their home demolished, without an order of court made after considering all the relevant circumstances.                                                                                      | PLWHAs may not be refused a subsidy or loan to buy a house because of their HIV status. They may not be evicted from a house or flat because of their health.                                                                                                                                                                                                                   |
| 27                        | <b>HEALTH CARE, FOOD, WATER AND SOCIAL SECURITY</b><br>Everyone has the right to have access to: <ul style="list-style-type: none"> <li>• health care services, including reproductive care; and</li> <li>• social security, including social assistance if they cannot support themselves and their dependants.</li> </ul> | <ul style="list-style-type: none"> <li>• No person may be refused emergency medical treatment.</li> <li>• Hospitals or doctors cannot refuse to treat a person with HIV or AIDS or someone who is participating in an HIV vaccine clinical trial.</li> <li>• PLHWAs have the right to disability grants if they are too ill to support themselves or their families.</li> </ul> |



| Section in Bill of Rights | Right                                                                                                                                                                               | What this means for People with HIV or AIDS (PLWHAs), or for HIV vaccine trial participants                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 29                        | <b>EDUCATION</b><br>Everyone has the right to a basic education, including adult basic education.                                                                                   | PLWHAs have the same right as all people to education. A school cannot refuse to educate them or their children because they have HIV or AIDS.                                                                                                                                                                                                                                                                                                                                                         |
| 32                        | <b>ACCESS TO INFORMATION</b><br>Everyone has the right to have access to any information that is held by another person and that is needed to carry out or protect their rights.    | <ul style="list-style-type: none"> <li>• If anyone believes they are being discriminated against because of a policy, then they can demand to see that policy and they can challenge it in a court. The same right applies to private institutions (e.g. companies), and information that may be kept about a person (e.g. their medical records).</li> <li>• People who are held in state institutions have the right to education and lifeskills training on issues such as HIV and AIDS.</li> </ul> |
| 33                        | <b>JUST ADMINISTRATIVE ACTION</b><br>Everyone whose rights have been negatively affected by administrative actions, has the right to be given written reasons.                      | If anyone feels that they are being refused a social service (e.g. a house or education) for unjust administrative reasons, then they can demand to see these reasons in writing.                                                                                                                                                                                                                                                                                                                      |
| 35                        | <b>ARRESTED, DETAINED AND ACCUSED PERSONS</b><br>Everyone who is detained, including every sentenced prisoner, has the right to conditions of detention that protect their dignity. | Prisoners cannot be treated in a discriminatory or undignified way just because of their HIV status.                                                                                                                                                                                                                                                                                                                                                                                                   |

(Adapted from *HIV/AIDS and the Law* (3<sup>rd</sup> edition).



We will now look at which of these human rights are particularly important to HIV vaccine trial participants.

### **The right to human dignity**

The right to human dignity is at the heart of the South African Constitution. This right is guaranteed in Section 10 of the Constitution. It is the foundation of many other rights, such as the right to equality and the right to informed consent. It is based on the idea that we must recognise that every person has worth and value, and must be treated with dignity. The right to dignity also plays an important role in clinical trials. This is because trial participants have inborn worth as human beings – they are not ‘guinea pigs’ or only there to help us find medical or scientific answers. This right is also at the heart of the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights*.

### **The right to equality and non-discrimination**

Equality and non-discrimination are dealt with in Section 9 of the Constitution and in *The Promotion of Equality and Prevention of Unfair Discrimination Act 2000* (also called the *Equality Act*). These laws say that you cannot discriminate against anyone because of the following – race, gender, sex, pregnancy, marital status, ethnic origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.

This right is built on the idea that no one may discriminate against anyone who is living with HIV and/or AIDS. An HIV vaccine trial participant can also not be discriminated against because they are participating in an HIV vaccine trial or if they have a false-positive HIV test result. Discrimination that is related to a person’s participation in a trial is called ‘trial-related’ discrimination.

#### **WORD BOX**

**Violated:**  
*Broken or disregarded.*



#### **DID YOU KNOW?**

Not all discrimination is unlawful or unfair. For example, in HIV vaccine trials, it would not be unfair or unlawful to include healthy people but to exclude unhealthy people as it may worsen their health to go through the trial. For example their high blood pressure could increase due to the stress of regular HIV tests during the trial. However, it would be unfair to exclude women from the trials but to include men.

In a society as unequal as ours, some people, for example, those who are vulnerable or at risk, or come from disadvantaged conditions, may need to be treated differently or special measures may need to be put in place to ensure that their right to equality can be achieved. The courts look at the social, economic and political conditions of a person or a group to see if their right to equality is being **violated**.



### The right not to be subjected to medical or scientific experiments without informed consent

We have said that this right means that each person has a right to agree to participate, or to refuse to participate, in medical or scientific experiments – this includes HIV vaccine research. This right is found in international law, in Section 12 (2) (c) of our Constitution under the right to bodily and psychological integrity, and in our common law.



*A volunteer has a right not to be part of a medical experiment if he or she does not go through the process of informed consent.*

### The right to privacy and confidentiality

The right to privacy is found in Section 14 of the Constitution. The common law also describes a right to privacy and a right to confidentiality. In HIV vaccine trials, we must protect a trial participant's right to privacy and confidentiality because:

- they may fear discrimination and **stigmatisation** if people find out that they are part of the HIV vaccine trials; and
- they may fear discrimination if they become HIV infected while they are participating in the trial.

Sometimes the right to privacy and confidentiality can be limited:

- someone may decide to make certain information public, for example, they might give an interview to a newspaper;
- there may be other laws that say that in certain cases some information must be reported to the authorities, for example, if someone is being abused; and
- there may be a situation where someone is at risk and the harm can be stopped if the person is given information that is usually confidential. For example, an HIV vaccine trial participant becomes HIV infected during the trial and tells a counsellor that he or she will not tell or practice safer sex with his or her partner. The counsellor must first try different ways to encourage the person to tell their partner. If the trial participant continues to refuse, the counsellor may finally decide to tell the trial participant's partner because their partner is at risk of becoming infected with HIV.

#### NOTE:

*Go back to page 89 to read more about informed consent.*

#### WORD BOX

##### **Stigmatisation:**

*To be treated as if you should be ashamed of who you are or what your situation is.*



It is not likely that a court would say that the counsellor violated the trial participant's right to privacy if the counsellor shows that she first tried to work out the problem in other ways before telling the participant's partner. For example, that she had counselled the trial participant on risk-reduction behaviour and offered to help disclose the participant's HIV status to their partner.

*What if the researchers say that only people who give up their right to confidentiality can participate in the trial?*



*This is breaking the right to privacy. No one may force people to give up their right to confidentiality unless they freely agree to do so.*

Let's see how the right to confidentiality applied in the following true case.

#### WORD BOX

##### **Civil claim:**

*In a civil claim, you bring a case against a person or a company or another organisation. You can claim for money that is owed to you. Or you can claim compensation in the form of money for harm that was done to you or injuries that you suffered.*

##### **Compensation:**

*Payment for damages done.*

#### THE RIGHT TO CONFIDENTIALITY

Mr McGeary wanted to apply for a life assurance policy. The insurance company told him to first have an HIV test. So he went to his doctor, Dr Kruger, and asked him to do the test. When Dr Kruger got the test results he told McGeary that he had tested HIV positive.

The next day Dr Kruger played golf with another doctor and a dentist. During the game the men discussed AIDS and Dr Kruger mentioned that Gary had tested positive for HIV. Within days the news of Gary McGeary's HIV status spread throughout the small community in which he lived.

McGeary began a **civil claim** against Dr Kruger to receive compensation from him for violating his right to confidentiality. The court said that a doctor cannot reveal the HIV status of a patient to other doctors without the permission of the patient, unless there was a clear legal duty to do so. The court ruled in Mr McGeary's favour and said that Dr Kruger must pay him R5 000 in **compensation**.

(Jansen van Vuuren versus Kruger, 1993)





## 5. HOW DOES THE DRAFT SAAVI PREVENTATIVE HIV VACCINE TRIAL PARTICIPANT CHARTER OF RIGHTS EXPLAIN THE HUMAN RIGHTS OF TRIAL PARTICIPANTS?

The draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights* was written for preventative HIV vaccine trials, but most of it can also be applied to therapeutic HIV vaccine trials. For a full copy of the draft Charter see page 112.

The Charter is made up of a few different sections. These include:

- The Preamble;
- Section 1: Informed consent;
- Section 2: Non-discrimination and human dignity;
- Section 3: The right to have access to health care services;
- Section 4: The right to privacy; and
- Section 5: The responsibilities of trial participants.

Here is a brief summary of each section of the Charter:

The **Preamble**: This is the introduction to the Charter. It says what the **subscribers** agree to, recognise and commit themselves to.

### **Section 1: Informed consent to participate in trials**

Section 1 talks about every volunteer or trial participant's right not to be subjected to the trials without their independent informed consent. It lists the information that they must get so that they can make a free and informed decision about whether to participate in the trial or not.

### **Section 2: Non-discrimination and human dignity**

This section deals with the right of trial participants to be treated with dignity and respect and not to be discriminated against on any grounds.

### **Section 3: The right to have access to health care services**

This section deals with every trial participant's right to have continued free access to different health care services throughout the trial, for example, counselling, testing and treatment.

### **Section 4: The right to privacy**

Section 4 deals with the trial participant's right to privacy and confidentiality. This includes the right to have their information kept confidential and it explains situations when this right may be limited.

### **Section 5: Responsibilities of trial participants**

With rights come responsibilities. This section deals with the responsibilities of trial participants in the HIV vaccine trials.

#### WORD BOX

**Preamble:**

*Introduction.*

**Subscribers:**

*People to whom the Charter applies.*



## TO SUM UP

- Human rights are rights and freedoms that everyone has, just because they are human. The state has a duty to respect, protect, promote and fulfil human rights. Individuals, communities and other institutions also have certain duties to ensure human rights.
- In our Constitution, the human rights that are written into our Bill of Rights include civil and political, and socio-economic human rights. Socio-economic rights can only be claimed as a group and not on an individual basis.
- Sometimes human rights are limited because of other rights, other people's rights, or situations in which a person gives up his or her rights. The Constitution also says how certain rights are limited.
- Legal rights are rights that are found in the laws of a particular country. In South Africa, our legal rights come from the Constitution, statutes, common law, customary law and court decisions.
- The following rights are particularly important to HIV vaccine trial participants:
  - the right to human dignity;
  - the right to equality and non-discrimination;
  - the right not to be subjected to medical or scientific experiments without informed consent (from the person involved);
  - the right to privacy and confidentiality; and
  - the right to have access to health care services.
- The rights and responsibilities of preventative HIV vaccine clinical trial participants are written into the draft *SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights*.
- Much of the Charter can also be used to address therapeutic HIV vaccine trials and clinical trials in general.



## Patients Rights Charter

For many decades the vast majority of the South African population has experienced either a denial or violation of fundamental human rights, including rights to health care services.

To ensure the realisation of the right of access to health care services as guaranteed in the Constitution of the Republic of South Africa (Act No. 108 of 1996), the Department of Health is committed to upholding, promoting and protecting this right and therefore proclaims this PATIENTS RIGHTS CHARTER as a common standard for achieving the realisation of this right.

### **PATIENTS RIGHTS**

#### **1. Healthy and safe environment**

Everyone has the right to a healthy and safe environment that will ensure their physical and mental health or well-being, including adequate water supply, sanitation and waste disposal as well as protection from all forms of environmental danger, such as pollution, ecological degradation or infection.

#### **2. Participation in decision-making**

Every citizen has the right to participate in the development of health policies and everyone has the right to participate in decision-making on matters affecting one's health.

#### **3. Access to health care**

Everyone has the right of access to health care services that include:

- i. **receiving timely emergency care** at any health care facility that is open regardless of one's ability to pay;
- ii. **treatment and rehabilitation** that must be made known to the patient to enable the patient to understand such treatment or rehabilitation and the consequences thereof;
- iii. **provision for special needs** in the case of newborn infants, children, pregnant women, the aged, disabled persons, patients in pain, persons living with HIV or AIDS patients;
- iv. **counselling without discrimination**, coercion or violence on matters such as reproductive health, cancer or HIV/AIDS;
- v. **palliative care** that is affordable and effective in cases of incurable or terminal illness;
- vi. **a positive disposition** displayed by health care workers that demonstrates courtesy, human dignity, patience, empathy and tolerance; and
- vii. **health information** that includes the availability of health services and how best to use such services and such information shall be in the language understood by the patient.

#### **4. Knowledge of one's health insurance/medical aid scheme**

A member of a health insurance or medical aid scheme is entitled to information about that health insurance or medical aid scheme and to challenge, where necessary, the decisions of such health insurance or medical aid scheme relating to the member.

#### **5. Choice of health services**

Everyone has a right to choose a particular health care provider for services or a particular health facility for treatment provided that such choice shall not be contrary to the ethical standards applicable to such health care providers or facilities and the choice of facility is in line with prescribed service delivery guidelines.



## **6. Treated by a named health care provider**

Everyone has a right to know the person that is providing health care and therefore must be attended to by only clearly identified health providers.

## **7. Confidentiality and privacy**

Information concerning one's health, including information concerning treatment may only be disclosed with informed consent, except when required in terms of any law or an order of court.

## **8. Informed consent**

Everyone has the right to be given full and accurate information about the nature of one's illnesses, diagnostic procedures, the proposed treatment and the costs involved for one to make a decision that affects any one of these elements.

## **9. Refusal of treatment**

A person may refuse treatment and such refusal shall be verbal or in writing provided that such refusal does not endanger the health of others.

## **10. A second opinion**

Everyone has the right to be referred for a second opinion on request to a health provider of one's choice.

## **11. Continuity of care**

No one shall be abandoned by a health care professional worker or a health facility which initially took responsibility for one's health.

## **12. Complaints about health services**

Everyone has the right to complain about the health care and to have such complaints investigated and receive a full response on such investigation.

## **RESPONSIBILITIES OF THE PATIENT**

Every patient or client has the following responsibilities:

1. To take care of his or her health.
2. To care for and protect the environment.
3. To respect the rights of other patients, health workers and health care providers.
4. To utilise the health care system optimally and not to abuse it.
5. To know his or her local health services and what they offer.
6. To provide health workers with relevant and accurate information for diagnostic, treatment, rehabilitation or counselling purposes.
7. To advise the health providers of his or her wishes with regard to his or her death.
8. To comply with the prescribed treatment and/or rehabilitation procedures.
9. To enquire about the related costs of the treatment and/or rehabilitation and to arrange for the payment.
10. To take care of health records in his or her possession.

Source: This Patients Rights Charter can be found at:  
[www.doh.gov.za/docs/legislation/patientsright/chartere.html](http://www.doh.gov.za/docs/legislation/patientsright/chartere.html)



## **SAAVI Preventative HIV Vaccine Trial Participant Charter of Rights (4th draft – 11/03/2004)**

### **PREAMBLE**

We, the subscribers to this Charter of Rights – volunteers, trial participants, affected families and communities, sponsors, principal investigators, researchers, and other relevant trial site staff:

- Believe that appropriate medical research is of value to society and that we need an affordable, effective, and relevant HIV vaccine.
- Respect the fact that individuals in our society are willing to participate in clinical trials – even where no protective benefit from the test vaccine is guaranteed.
- Recognise that medical and/or scientific experimentations have on occasion in the past resulted in exploitation of individuals.
- Recognise, further, that medical and/or scientific experimentation in South Africa must comply not only with the highest attainable standards of ethics, but also with the provisions of the South African Bill of Rights.
- Recognise, further, that the South African Bill of Rights places legal obligations on the state and, where applicable, on private institutions and individuals.
- Therefore, require that prior approval for clinical trials be obtained through independent scientific and ethical review, and any other approval required by law.
- Undertake to minimise risks and reduce harm to trial participants.

We therefore, subscribe to this Trial Participant Charter of Rights, so as to –

- Demonstrate our commitment and adherence to the values of equality, freedom and dignity underlying the South African Constitution during the conduct of trials.

### **SECTION 1: INFORMED CONSENT TO PARTICIPATE IN TRIALS**

- 1.1 Every volunteer/trial participant in an HIV preventative vaccine trial has the right not to be subjected to medical or scientific experimentation without his or her (or, where appropriate, his or her parent's or guardian's) independent and informed consent.
- 1.2 In the case of a minor volunteer/trial participant, both the parent or guardian and the minor must provide informed consent unless the minor is incapable of understanding what he or she is consenting to.
- 1.3 Informed consent can only be given if a volunteer/trial participant is provided with a full disclosure of all relevant information relating to the trial. This information includes but is not limited to:
  - a. information about the nature, scope, duration, research methodologies (including whether placebos are involved), the objectives and the relative importance of objectives of the trial;
  - b. information about the nature, duration, and extent of the medical intervention;
  - c. information on the actual and foreseeable risks and information on the possibility of as yet unknown risk;
  - d. information on the role of the principal investigator, trial organisers, and trial administration, and information on who and how to contact them in appropriate circumstances;
  - e. information on actual and expected benefits to participants and society;
  - f. information on possible resources or referral points to assist in dealing with social harm and trial-related stigma and discrimination;
  - g. information about the need to submit to regular HIV tests for the duration of the trial; and,
  - h. information about the voluntary nature of participation, no guarantee of protective benefit, and the right of the participant not to take part in the trials after being provided with the information above.



- 1.4 Every volunteer/trial participant has the right to be presented with all relevant information in a way that he or she will be able to understand. This includes access to trained staff capable of explaining the information in a manner and in a language that a volunteer/trial participant can understand.
- 1.5 After being provided with all the relevant information, every volunteer/trial participant has the right to choose or to refuse to take part in the trial and to choose whether to involve family, friends, partners, or others in such a decision.
- 1.6 Every volunteer/trial participant has the right to be presented with a comprehensive written informed consent document and, if he/she decides not to take part in the trial, the right to refuse to sign such a document.
- 1.7 Every volunteer/trial participant has a right not to be pressured or unduly influenced to provide informed consent. In particular, every volunteer/trial participant has the right to consider all relevant information for a reasonable time before deciding to provide informed consent.
- 1.8 Every trial participant has a right to leave the trial at any time without losing any of the rights set out in this Charter of Rights. In order to enable participants to exercise this right in a responsible and independent manner, every trial participant has a right to be provided with:
  - a. all relevant new information about the nature and scope of the trial and the nature and scope of the risks associated with the trial as this information becomes available;
  - b. all relevant information about the progress of the trial as well as information about when the results may become available and how these results could be accessed; and,
  - c. all relevant information about the risks, if any, associated with leaving the trial.

## **SECTION 2: NON-DISCRIMINATION AND HUMAN DIGNITY**

- 2.1 Every trial participant has the right to be treated with dignity and respect.
- 2.2 Every trial participant has the right not to be subjected to unfair discrimination on any ground, including race, sex, gender, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language, birth, HIV status and economic status.
- 2.3 In order to prevent unfair discrimination against trial participants from all vulnerable groups, including women, children and sex workers, trial organisers/administrators have a duty, where appropriate, to take special measures to ensure their full and equal enjoyment of the rights set out in this Charter.
- 2.4 In order to protect every trial participant against unfair discrimination, trial participants have the right to:
  - a. appropriate counselling and other assistance aimed at empowering participants to deal with trial-related social harm, such as stigma and discrimination; and,
  - b. re-imburement for agreed-upon expenses incurred as a result of participating in the trial.
- 2.5 All trial participants maintain their legal rights and do not waive any of their legal rights by consenting to take part in the trial.

## **SECTION 3: THE RIGHT TO HAVE ACCESS TO HEALTH CARE SERVICES**

- 3.1 Every trial participant has the right to have continued free access throughout the trial to the optimal standard of preventive counselling about the risks of HIV infection available in the country.
- 3.2 Every trial participant has the right to have access to free and accurate testing for HIV infection throughout the trial. This right includes a right to have access to voluntary pre-test and post-test counselling.
- 3.3 Every trial participant has the right to have access to free follow-up testing after completion of the trial in the event of an antibody-positive HIV test until the test shows a negative result.
- 3.4 Every trial participant has the right to free access to treatment for any injury or illness caused by the study vaccine or trial-related procedure.



- 3.5 Every trial participant who becomes infected with HIV during the trial, at a minimum, has the right to free access to the highest standard of health care available in the public health sector, or such higher standard negotiated at a national level.
- 3.6 In order to safeguard the continued health of trial participants, every trial participant has the right to be informed whether they have received a placebo or the study vaccine when the study ends or when medically required.
- 3.7 Every trial participant who had received a placebo has a right to free access to any effective vaccine tested during the trial.
- 3.8 The rights in this section can be enforced against the state and/or relevant state institutions and/or trial sponsors in accordance with pre-trial agreements concluded between the state, state institutions and trial sponsors.

#### **SECTION 4: THE RIGHT TO PRIVACY**

- 4.1 Every participant has the right to privacy and confidentiality which includes:
  - a. the right of every individual participant to have all information about his or her participation in the trial kept confidential; and,
  - b. the right not to have any data gathered about him or her which is not directly related to the trial.
- 4.2 Despite the right to confidentiality guaranteed in 4.1, a trial participant's name and record may be released to institutions or bodies evaluating the study, or for emergency health reasons. Individuals may also explicitly waive their general right to confidentiality.
- 4.3 Every trial participant has the right to be offered study identification, confirming participation in the study. This optional identification will include a phone number, and/or address, or the name of a person who can provide additional information about trial participation in general but not confidential information about a participant's personal participation, without his or her informed consent.

#### **SECTION 5: RESPONSIBILITIES OF TRIAL PARTICIPANTS**

- 5.1 Every trial participant has a duty to:
  - a. inform trial site staff as soon as possible about any negative consequences to themselves, their family or community, resulting from association with the trial;
  - b. not to attempt to donate blood during the trial;
  - c. not to attempt to determine whether they have received the vaccine or the placebo by getting an HIV test done outside of the study site before the end of the study;
  - d. treat trial organisers and trial site staff with respect and dignity;
  - e. keep confidential others' participation in the study should they get access to this information;
  - f. comply with trial study requirements to the best of their ability and provide complete and accurate information; and,
  - g. inform trial site staff as soon as possible if they are unable to continue or decide to discontinue their study participation.

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